

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD 9931]

Office of the Secretary**31 CFR Part 33**

RIN 1545-BP97

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB98

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 410, 411, 414, 417, 433, and 510****Office of the Secretary****45 CFR Parts 147, 155, and 182**

[CMS-9912-IFC]

RIN 0938-AU35

Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule with request for comments (IFC) discusses CMS's implementation of section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which established Medicare Part B coverage and payment for Coronavirus Disease 2019 (COVID-19) vaccine and its administration. This IFC implements requirements in the CARES Act that providers of COVID-19 diagnostic tests make public their cash prices for those tests and establishes an enforcement scheme to enforce those requirements. This rule also establishes an add-on payment for cases involving the use of new COVID-19 treatments under the Medicare Inpatient Prospective Payment

System (IPPS). This IFC provides for separate payment for new COVID-19 treatments under the Outpatient Prospective Payment System (OPPS) for the remainder of the PHE for COVID-19 when these treatments are provided at the same time as a Comprehensive Ambulatory Payment Classification (C-APC) service. This rule also interprets and implements the requirement to maintain Medicaid beneficiary enrollment in order to receive the temporary increase in Federal funding in the Families First Coronavirus Response Act (FFCRA). This IFC modifies policies of the Comprehensive Care for Joint Replacement (CJR) model and adds technical changes to accommodate these policy changes. Specifically, we are extending Performance Year (PY) 5 by adding 6 months, creating an episode-based extreme and uncontrollable circumstances COVID-19 policy, providing two reconciliation periods for PY 5, and adding DRGs 521 and 522 for hip and knee procedures. This rule also amends regulations regarding coverage of preventive health services to implement section 3203 of the CARES Act, which shortens the timeframe within which non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must begin to cover without cost sharing qualifying coronavirus preventive services, including recommended COVID-19 immunizations. This IFC also revises regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for State Innovation Waivers under section 1332 of the Patient Protection and Affordable Care Act (PPACA) during the public health emergency for COVID-19.

DATES: *Effective date:* These regulations are effective on November 2, 2020, except for amendatory instructions 36 and 37, which are effective on January 1, 2021.

Applicability date: Except as otherwise specified in this paragraph, these regulations are applicable from November 2, 2020, until the end of the public health emergency for COVID-19 as determined by the HHS Secretary. The regulations at 42 CFR 410.57, 410.152, 410.160, 411.15, 414.701, 414.707, 414.900, and 414.904 and at 42 CFR part 510 (other than 42 CFR 510.300(a)(1)(i) and (iii)) are applicable November 2, 2020. Because the requirement at section 6008(b)(3) of the Families First Coronavirus Response Act (FFCRA) is not limited to the

duration of the public health emergency for COVID-19, regulations at 42 CFR part 433, subpart G, apply from November 2, 2020, through the end of the last month of the public health emergency for COVID-19 in accordance with section 6008(b)(3) of the Families First Coronavirus Response Act. Regulations at 42 CFR 510.300(a)(1)(i) and (a)(1)(iii) are applicable October 1, 2020.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 4, 2021.

ADDRESSES: In commenting, please refer to file code CMS-9912-IFC.

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-9912-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-9912-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: Laura Kennedy, (410) 786-3377, for discussion related to COVID-19 vaccine and administration payment provided under Medicare Part B.

Lina Rashid, (443) 902-2823, or Michelle Koltov, (301) 492-4225, Centers for Medicare & Medicaid Services, Department of Health and Human Services, Services, Kimberly Koch, (202) 622-0854, Department of the Treasury, for issues related to State Innovation Waivers Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency.

Dr. Terri Postma or Rhonda Sheppard, (410) 786-8465, or via email at COVID19CashPrice@cms.hhs.gov, for provisions related to Price Transparency for COVID-19 Diagnostic Testing.

Cristina Nigro, (410) 786-7763, for issues related to the Medicare Inpatient Prospective Payment System (IPPS) New COVID-19 Treatments Add-on Payment (NCTAP) for the remainder of the public health emergency.

David Mlawsky, (410) 786-1565, Centers for Medicare & Medicaid Services, Department of Health and Human Services, Elizabeth Schumacher, (202) 693-8335, Employee Benefits Security Administration, Department of Labor, Dara Alderman, (202) 317-5500, Internal Revenue Service, Department of the Treasury, for issues related to Rapid Coverage of Preventive Services for Coronavirus.

Stephanie Bell, (410) 786-0617, for issues related to the temporary increase in Federal Medicaid funding.

Bobbie Knickman, (410) 786-4161; Heather Holsey, (410) 786-0028; Sarah Mioduski, (410) 786-2014 or email CJR@cms.hhs.gov for the Comprehensive Care for Joint Replacement Model.

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.

Background

The United States is responding to an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China and has now been detected in more than 190 countries internationally, and all 50 States, the District of Columbia, and U.S. territories. The virus has been named “severe acute respiratory syndrome coronavirus 2” (“SARS-CoV-2”) and the disease it causes has been named “coronavirus disease 2019” (“COVID-19”).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a “Public Health Emergency of International Concern.” On January 31, 2020, pursuant to section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d), the Health and Human Services Secretary (the Secretary) determined that a public health emergency (PHE) exists for the United States to aid the nation’s health care

community in responding to COVID-19 (hereafter referred to as the PHE for COVID-19). On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, President Donald J. Trump (the President) declared the COVID-19 pandemic a national emergency. Effective October 23, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020 and July 23, 2020 that a PHE exists and has existed since January 27, 2020.

The Administration is committed to ensuring that Americans have access to a COVID-19 vaccine through Operation Warp Speed, a partnership among components of the HHS, including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA). Operation Warp Speed engages with private firms and other Federal agencies, including the Department of Defense (DoD), Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. Through the work of the Federal Government and the private sector, Operation Warp Speed seeks to accelerate the development, manufacture, and distribution of a COVID-19 vaccine to the American people.

The CDC has reported that some people are at higher risk of severe illness from COVID-19.¹ These higher-risk categories include:

- Older adults, with risk increasing by age.
- People who have serious chronic medical conditions such as:
 - ++ Obesity.
 - ++ Cardiovascular disease.
 - ++ Diabetes mellitus.
 - ++ Hypertension.
 - ++ Chronic lung disease.
 - ++ Neurologic/Neurodevelopmental disability.²
 - ++ Immunocompromised individuals.
- Residents of Long Term Care (LTC) facilities, including nursing homes, Intermediate Care Facilities for Individuals with Intellectual and Developmental Disabilities (ICF/IIDs), inpatient psychiatric and substance abuse treatment facilities including Institutions for Mental Disease (IMDs) & Psychiatric Residential Treatment Facilities (PRTFs), assisted living facilities, group homes for individuals

with developmental disabilities and board-and-care facilities.³

As the health care community implements and updates recommended prevention and control practices, regulatory agencies operating under appropriate waiver authority granted by the PHE for COVID-19 are also working to revise and implement regulations that support these health care community infection prevention and treatment practices. Based on the current and projected increases in the incidence rate of COVID-19 in the US, observed fatalities in the older adult population, and the impact on health care workers at increased risk due to treating special populations, CMS⁴ is reviewing and revising regulations, as appropriate, to offer states, providers, suppliers, and group health plans and health insurance issuers additional flexibilities in furnishing and providing services to combat the PHE for COVID-19 and to address and minimize the unique impact of the PHE for COVID-19 on other regulatory provisions.

CMS addressed additional policies in three previous interim final rules with comment period (IFCs). The “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” IFC appeared in the April 6, 2020 **Federal Register** (85 FR 19230) with an effective date of March 31, 2020, and the “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” IFC appeared in the May 8, 2020 **Federal Register** (85 FR 27550) with an effective date of May 8, 2020. The “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments, and Patient Protection and Affordable Care Act: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” IFC appeared in the September 2, 2020 **Federal Register** (85 FR 54820) with an effective date of September 2, 2020.

This IFC implements a number of measures intended to further the Administration’s commitment to ensure every American has timely access to a COVID-19 vaccine without any out-of-pocket expenses, no matter their source of coverage, or whether they are covered at all.

¹ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm>.

² https://www.cdc.gov/mmwr/volumes/69/wr/mm6924e2.htm?s_cid=mm6924e2_w.

³ <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>.

⁴ Throughout this IFC, unless otherwise specified, “we” and “our” refer to CMS only.

In this IFC, CMS discusses Section 3713 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act which added the COVID-19 vaccine and its administration to section 1861(s)(10)(A) of the Social Security Act (the Act) in the same subparagraph as the flu and pneumococcal vaccines and their administration. It also specified that under Medicare Part B, beneficiaries can receive a COVID-19 vaccination (vaccine and administration) with no cost sharing (deductible or copayment).

In this IFC, HHS and the Departments of Labor and the Treasury (referred to collectively as “the Departments”) clarify certain aspects of coverage of preventive services without cost sharing under the current regulations implementing section 2713 of the Public Health Service (PHS) Act, as added by PPACA and incorporated into the Employee Retirement Income Security Act of 1974 (ERISA) by section 715 of ERISA and into the Internal Revenue Code (the Code) by section 9815 of the Code. The Departments also amend those regulations to implement the unique requirements related to rapid coverage of qualifying coronavirus preventive services under section 3203 of the CARES Act. Specifically, this IFC clarifies that plans and issuers subject to section 2713 of the PHS Act must cover without cost sharing recommended immunizations as well as the administration of such immunizations, regardless of how the administration is billed. This IFC also defines qualifying coronavirus preventive services consistent with the definition provided in section 3203 of the CARES Act and clarifies that plans and issuers subject to section 2713 of the PHS Act must cover recommended immunizations for COVID-19 that are qualifying coronavirus preventive services, even if not listed for routine use on the Immunization Schedules of the CDC. Due to the urgent need to ensure coverage of and access to qualifying coronavirus preventive services, and to ensure that participants, beneficiaries, and enrollees can access qualifying coronavirus preventive services on the expedited basis specified by statute, this IFC also provides that during the PHE for COVID-19, plans and issuers must cover, without cost sharing, qualifying coronavirus preventive services, regardless of whether such services are delivered by an in-network or out-of-network provider. This coverage is required to be provided within 15 business days after the date the United States Preventive Services Task Force (USPSTF) or the Advisory Committee on Immunization Practices of the CDC

(ACIP) makes an applicable recommendation relating to a qualifying coronavirus preventive service.

Section 3202(b) of the CARES Act establishes a requirement to publicize cash prices for COVID-19 diagnostic testing during the PHE. For purposes of implementing section 3202(b) of the CARES Act, this IFC adds a new 45 CFR part 182, including (1) definitions of “provider of a diagnostic test for COVID-19” (or “provider”), “COVID-19 diagnostic test,” and “cash price,” and (2) requirements for posting cash price information on the internet, or upon request and through signage (if applicable) if the provider does not have its own website. This IFC gives CMS discretion to take any of the following actions, which generally, but not necessarily, will occur in the following order if CMS determines the provider is noncompliant with section 3202(b)(1) of the CARES Act and the requirements of § 182.40:

- Provide a written warning notice to the provider of the specific violation(s).
- Request that a provider submit and comply with a corrective action plan (CAP) under § 182.60 if its noncompliance is not corrected after a warning notice.
- Impose a civil monetary penalty (CMP) on the provider if the provider fails to respond to CMS’ request to submit a CAP or to comply with the requirements of a CAP approved by CMS.

This IFC creates a New COVID-19 Treatments Add-on Payment (NCTAP) under the Inpatient Prospective Payment System (IPPS) for COVID-19 cases that meet certain criteria. We believe that as drugs and biological products become available and are authorized or approved by FDA for the treatment of COVID-19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE. Therefore, effective for discharges occurring on or after the effective date of this rule and until the end of the PHE for COVID-19, this IFC establishes the NCTAP to pay hospitals the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the CARES Act, for certain cases that include the use of a drug or biological product currently authorized or approved for treating COVID-19. The NCTAP will not be included as part of the calculation of the operating outlier payments.

This IFC provides for separate payment for New COVID-19 Treatments under the Outpatient Prospective Payment System (OPPS) for the remainder of the PHE for COVID-19 when these treatments are provided at the same time as a Comprehensive Ambulatory Payment Classification (C-APC) service. Although we do not expect that many beneficiaries would both receive a primary C-APC service and a drug or biological for treating COVID-19 on the same claim, we nonetheless believe that as drugs or biologicals become available and are authorized or approved for the treatment of COVID-19 in the outpatient setting, it would be appropriate to mitigate any potential financial disincentives for hospitals to provide these new treatments during the PHE for COVID-19. Therefore, effective for services furnished on or after the effective date of this rule and until the end of the PHE, CMS is creating an exception to its OPPS C-APC policy to ensure separate payment for new COVID-19 treatments that meet certain criteria.

This IFC adds a new subpart G, Temporary FMAP Increase During the Public Health Emergency for COVID-19, to 42 CFR part 433, including a new § 433.400. This new provision interprets and implements section 6008(b)(3) of the FFCRA to require states, as a condition for receiving the temporary FMAP increase described at section 6008(a) of the FFCRA, to maintain beneficiary enrollment with specified protections. The terms of new § 433.400 are effective immediately upon display of this rule. CMS’ previous interpretation, described in this preamble and in the FAQs cited therein, continues to apply up to the date this rule is effective.

This IFC modifies policies of the Comprehensive Care for Joint Replacement (CJR) model and adds technical changes to accommodate these policy changes. Specifically, we are extending Performance Year (PY) 5 an additional 6 months, creating an episode-based extreme and uncontrollable circumstances COVID-19 policy, providing two reconciliation periods for PY 5, and adding DRGs 521 and 522 for hip and knee procedures.

This IFC provides for flexibilities in the public notice requirements for a State Innovation Waiver (also referred to as a section 1332 waiver) described in section 1332 of PPACA that apply during the PHE for COVID-19. Specifically, this IFC gives the Secretary of HHS and the Secretary of the Treasury the authority to modify, in part, the public notice procedures to

expedite a decision on a proposed waiver request that is submitted or would otherwise become due during the PHE for COVID-19. This IFC also gives these Secretaries the authority to modify, in part, the post-award public notice requirements for an approved waiver request that would otherwise take place or become due during the PHE for COVID-19.

II. Provisions of the Interim Final Rule—Department of Health and Human Services

A. Medicare Coding and Payment for COVID-19 Vaccine

1. Summary

This section of this IFC discusses CMS's implementation of section 3713 of the CARES Act, which established Medicare Part B coverage and payment for a COVID-19 vaccine and its administration. While section 3713(e) of the CARES Act authorizes CMS to implement section 3713 via "program instruction or otherwise," we believe it is important to clarify in this IFC our interpretation of Section 3713 and ensure the public is aware of our plans to ensure timely Medicare Part B coverage and payment for COVID-19 vaccine and its administration.

2. Background on Medicare Part B Coverage, Payment, Coding and Billing for Vaccines

As required under section 1842(o)(1)(A)(iv) of the Act, the Medicare Part B payment allowance limits for influenza, pneumococcal, and hepatitis B virus (HBV) vaccines are 95 percent of the Average Wholesale Price (AWP) as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department, Rural Health Clinic (RHC), or Federally Qualified Health Center (FQHC), skilled nursing facility, and home health. Where the vaccine is furnished in these settings, payment for the vaccine is based on reasonable cost.

For preventive vaccines described in section 1861(s)(10) of the Act, Medicare pays for both the vaccine and its administration. Under sections 1833(a)(1)(B), annual Part B deductible and coinsurance amounts do not apply for these vaccinations. In 2020, payment for vaccines is based on the 95 percent of the AWP for a particular vaccine product except where furnished in the settings for which payment is based on reasonable cost. For example, for the 2020-2021 influenza season, payment

limits for adult flu vaccines range from about \$19 to \$61 per adult dose.⁵

We note that in the Calendar Year 2021 Physician Fee Schedule Proposed Rule (85 FR 50162-50163), CMS proposed to increase the Medicare payment rate for administration of the flu, pneumococcal or HBV vaccine furnished by a physician, non-physician practitioner, or other supplier. CMS will address public comments on the proposal and establish payment rates for administration of these vaccines by a physician, non-physician practitioner, or other supplier in the Calendar Year 2021 Physician Fee Schedule Final Rule, which will be issued later this year. Note that the payment rates for administration of these preventive vaccines established in the CY 2021 Physician Fee Schedule final rule do not apply when the vaccine is furnished by the providers and suppliers paid for administration under reasonable cost. Under the CY 2021 OPPTS proposed rule, CMS proposed to assign the HCPCS codes for administration of the influenza, pneumococcal, and hepatitis B vaccines to APC 5691, Level 1 Drug Administration. See Addendum C to the CY 2021 OPPTS/ASC proposed rule. Payment amounts for these preventive vaccines and their administration are not adjusted based on product-specific factors.

Generally, providers and suppliers bill for the vaccine and the vaccine administration separately using different codes. For example, many vaccine products are identified by AMA CPT codes in the 90000 series, while others are identified by Level II HCPCS codes, usually beginning with the letter Q. Vaccine administration services are described by the types of codes used to describe professional and/or hospital outpatient services, and are typically identified by a G code for Medicare billing, or by a different AMA CPT code in the 90000 series.

Many providers, professionals, and other suppliers can bill Medicare for the preventive vaccines and vaccine administration they furnish using claims rules similar to those that apply to the other Medicare covered items and services. Additionally, certain entities can enroll under Medicare as mass immunizers to offer and bill Medicare for flu vaccinations, pneumococcal vaccinations, or both to large groups of Medicare beneficiaries under roster billing. A mass immunizer may be enrolled in Medicare as another type of

⁵ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing>, accessed September 29, 2020.

provider or supplier such as a physician, non-physician practitioner, hospital outpatient department, home health agency or skilled nursing facility. An entity or individual that does not otherwise qualify as a Medicare provider or supplier but wishes to furnish mass immunization services may be eligible to enroll in Medicare as a "Mass Immunization Roster Biller" via the Form CMS-855 enrollment application (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB Control No.: 0938-0685; Expires 12/21). Aside from meeting all applicable enrollment requirements in 42 CFR part 424, subpart P (and as outlined in CMS Pub. 100-08 (Program Integrity Manual), chapter 10, section 10.2.4), a party enrolled only as a mass immunization roster biller must comply with the following: (1) May not bill Medicare for any services other than pneumococcal pneumonia vaccines (PPVs), influenza virus vaccines, and their administration; (2) must submit claims through the roster biller or centralized biller process; and (3) the enrolled entity or individual must meet all applicable state and local licensure or certification requirements. In other words, an enrolled mass immunizer roster biller may only roster bill Medicare for the services described in the previous sentence. (For more information on the enrollment process for mass immunization roster billers, see <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Become-a-Medicare-Provider-or-Supplier> and/or contact your local Part A/B Medicare Administrative Contractor.)

For entities that are already enrolled Medicare providers and suppliers, these entities would contact their MAC if they plan to submit claims as a mass immunizer. Mass immunizers may submit claims for immunizations (vaccine and administration) on roster bills that include a limited set of information on each beneficiary and the vaccine(s) they were given. We note that HBV vaccinations require an assessment of a patient's risk of contracting hepatitis B; they require a physician's order and cannot be roster billed by mass immunizers.

3. Provisions of the CARES Act

Section 3713 of the CARES Act provides for coverage of the COVID-19 vaccine under Part B of the Medicare program without any beneficiary cost sharing. Specifically, section 3713 amended section 1861(s)(10)(A) of the Act to include COVID-19 vaccine and its administration. The amendments made are effective on the date of

enactment and apply to a COVID-19 vaccine beginning on the date that such vaccine is licensed under section 351 of the PHS Act (42 U.S.C. 262). Section 3713(e) of the CARES Act further states that the Secretary may implement the provisions of, and the amendments made by, this section by program instruction or otherwise.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Commissioner of Food and Drugs, as delegated authority by the Secretary, may authorize, during the effective period of a declaration of emergency or threat justifying emergency authorized use, the introduction into interstate commerce of unapproved medical products or unapproved uses of approved medical products to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological and nuclear defense (CBRN) threat agents when there are no adequate, approved, and available alternatives. On March 27, 2020, on the basis of his determination of a PHE that has a significant potential to affect national security or the health and security of United States citizens living abroad involving COVID-19, the Secretary declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic (85 FR 18250). Pursuant to this declaration, the Commissioner of Food and Drugs, as delegated authority by the Secretary, may issue an emergency use authorization (EUA) for a drug or biological product if, after consultation with officials such as the Director of the CDC and the Director of the NIH, to the extent feasible and appropriate, the Commissioner reasonably concludes that, among other criteria, based on the totality of available scientific evidence, the product may be effective in diagnosing, treating or preventing such disease or condition, and the product's known and potential benefits when used to diagnose, prevent, or treat such disease or condition, outweigh its known and potential risks.

FDA's June 2020 guidance to industry titled "Development and Licensure of Vaccines to Prevent COVID-19"⁶ and October 2020 guidance to industry titled "Emergency Use Authorization for Vaccines to Prevent COVID-19"⁷ state

⁶ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>, accessed September 30, 2020.

⁷ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/>

that issuance of an EUA may be appropriate for a COVID-19 vaccine, for which there is adequate manufacturing information, once studies have demonstrated the safety and effectiveness of the vaccine in a clear and compelling manner, but before the submission and/or formal review of the biologics license application for the vaccine. These guidance documents state that in the case of vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA would be made on a case by case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the relevant available scientific evidence. The FDA has made clear in its October 2020 guidance to industry that for a COVID-19 vaccine for which there is adequate information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner. Because the vaccine would be intended for administration to healthy people as a prophylactic measure, there must be a higher degree of certainty about the risks and benefits of the product than needed for EUAs for medical products intended for treatment of sick patients.

There are no historical examples in which Medicare has covered vaccines for which an EUA was issued by FDA. We recall that during the PHE involving the 2009 H1N1 flu outbreak,⁸ Influenza A (H1N1) 2009 Monovalent Vaccine was approved by the FDA on September 15, 2009 on the basis of a supplement to the applicant's biologics license application (BLA) for influenza virus vaccine.⁹ In our review of PHEs, there are no circumstances in which a vaccine product authorized for emergency use has been covered or paid for by Medicare.

As discussed previously, the CDC recognizes that the categories of people at higher risk of severe illness from COVID-19 include older adults (with risk increasing by age), people with chronic conditions such as cardiovascular disease or diabetes, and

⁸ Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/h1n1.aspx>, accessed on October 14, 2020.

⁹ Available at <https://www.fda.gov/vaccines-blood-biologics/vaccines/influenza-h1n1-2009-monovalent-vaccine-novartis-vaccines-and-diagnostics-limited>, accessed October 14, 2020.

residents of long-term care facilities.¹⁰ The Medicare population includes many beneficiaries who are in these higher-risk categories, primarily because most, (over 85 percent)¹¹ Medicare beneficiaries are over 65 years old. Given the high risk nature of the Medicare population, the circumstances of this nationwide pandemic, and FDA's guidance that an EUA may be appropriate for a COVID-19 vaccine prior to its licensure if there is a demonstration of safety and efficacy in a clear and compelling manner from at least one Phase 3 clinical trial, we believe it is appropriate for Medicare to consider any EUA under section 564 of the FD&C Act issued for a COVID-19 vaccine during the PHE to be tantamount to a license under section 351 of the PHS Act for the sole purpose of considering such a vaccine to be described in section 1861(s)(10)(A) of the Act. That is, even though section 3713 of the CARES Act refers to a COVID-19 vaccine "licensed under section 351 of the PHS Act," CMS could consider any vaccine for which FDA issued an EUA during the PHE, when furnished consistent with terms of the EUA, to be eligible for Medicare coverage and payment. We consider our interpretation of section 3713(d) of the CARES Act to be consistent with Congress' intent to provide for Medicare coverage without deductible or coinsurance of any COVID-19 vaccine (and its administration) that FDA has authorized to be introduced into interstate commerce, which would be the case both for a vaccine for which emergency use is authorized under section 564 of the FD&C Act and for a vaccine that is licensed under section 351 of the PHS Act. Our interpretation also would be consistent with Congress' general intent in the CARES Act and other recent legislation to provide for rapid coverage of COVID-19 vaccines.

We note that section 3713(e) of the CARES Act permits CMS to implement the changes made by that section through "program instruction or otherwise," and we intend to issue any necessary instructions for Medicare providers and suppliers expeditiously in order to ensure beneficiary access to COVID-19 vaccines as quickly as possible.

¹⁰ https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fpeople-at-increased-risk.html.

¹¹ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Beneficiary-Snapshot/Downloads/Bene_Snapshot.pdf.

4. Implementation and Methods of Coding and Payment for COVID-19 Vaccine and Administration

Section 3713 of the CARES Act added the COVID-19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the flu and pneumococcal vaccines and their administration. As such, the Medicare allowed amount for the COVID-19 vaccine will also be 95 percent of the average wholesale price (or reasonable cost, for example under OPSS).

Because COVID-19 vaccines are being developed rapidly and systems to operationalize payment of administration will need to be implemented quickly to ensure beneficiary access, we also recognize the need to establish coding and payment for COVID-19 vaccine and administration under Medicare Part B. Because there are many product-specific factors that are still unknown, including the possibility of differential costs associated with each COVID-19 vaccine product and storage and administration requirements, we anticipate establishing a unique administration code for each COVID-19 vaccine product. We believe it is imperative that coding and payment be in place as soon as possible after COVID-19 vaccines become available. We anticipate establishing specific coding and payment rates through technical direction to the MACs, including instructions to make this information available to the public. We also anticipate posting information on coding, payment, and billing for COVID-19 vaccines and vaccine administration on the CMS website. This approach will maintain public transparency while allowing CMS to pay appropriately for particular vaccines and vaccine administration as quickly as practicable once they are authorized or licensed for use by FDA. We anticipate that payment rates for the administration of other Part B preventive vaccines and related services, such as the flu and pneumococcal vaccines, would serve to inform the payment rates for administration of COVID-19 vaccines.

CMS ordinarily establishes Medicare payment rates for particular items and services, through notice-and-comment rulemaking. Because of the unique circumstances of the PHE for COVID-19 pandemic and the anticipated, specific conditions for the entry of COVID-19 vaccine products into the marketplace, we believe it is necessary to initially dispense with the rulemaking process in order to make Medicare payment available in a timely manner to ensure

widespread access to the new vaccines. Therefore, as soon as practicable after the authorization or licensure of each COVID-19 vaccine product by FDA, we will announce the interim coding and a payment rate for its administration (or, in the case of the OPSS, an APC assignment for each vaccine product's administration code), taking into consideration any product-specific costs or considerations involved in furnishing the service. Such consideration may be necessary, specifically for COVID-19 vaccines in the context of the pandemic, in order to ensure that health care providers can offer prompt access to vaccination for a large number of people as quickly as possible. We then anticipate addressing coding and payment rates for administration of the COVID-19 vaccine products through future notice-and-comment rulemaking. In other words, the approach to payment and coding described in this IFC will ensure efficient and timely beneficiary access to COVID-19 vaccine products, that for public health purposes may need to be administered to a large number of people during a compressed period of time, until further rulemaking, such as annual rulemaking under the Medicare Physician Fee Schedule, is possible.

Given that the COVID-19 vaccine and administration was added to the same subparagraph as the flu and pneumococcal vaccines and administration under section 1861(s)(10)(A) of the Act, we believe it would be appropriate to use billing processes for COVID-19 vaccinations that are similar to those in place for flu and pneumococcal vaccinations. With the pressing need to ensure broad access to a COVID-19 vaccine, it would be appropriate to allow COVID-19 vaccinations to be provided through the mass immunization and roster billing process that is in place for flu and pneumococcal vaccinations. We recognize that, at this time, there is very limited detailed information on COVID-19 vaccines and their administration and that information on these vaccines is likely to evolve as they reach the market and then experience with them is gained. At this time, we believe that the COVID-19 vaccines will be administered as one or two parenteral doses, thus we believe that using the Part B influenza vaccination approach that permits certain providers and mass immunization to bill for the product strikes a balance between the need to vaccinate many millions of Medicare patients promptly and the lack of detailed information about particular COVID-19 vaccine products. Although

influenza vaccination is generally only given once each flu season, CMS has contemplated how to respond to pandemics where payment for additional doses of an influenza vaccine during a season may be required. Thus, a two dose initial COVID-19 vaccination schedule can be accommodated under this general approach. Also, the CARES Act permits the Secretary to implement the provisions of, and the amendments made by, section 3713 by program instruction or otherwise. As information about vaccine products becomes available, we anticipate that updated information, for example information concerning additional doses after initial vaccination, applicability of specific vaccine products to subsets of our beneficiary population, or updates about billing would be disseminated primarily by program instruction.

As part of this IFC, we are updating the following regulations:

- At § 410.57, Pneumococcal vaccine and flu vaccine, we are amending the section heading and adding a new paragraph to reference COVID-19 vaccine.
- At § 410.152, Amounts of payment, we are amending § 410.152(l)(1) to include the COVID-19 vaccine in the list of vaccines for which Medicare Part B pays 100 percent of the Medicare payment amount.
- At § 410.160, Part B annual deductible, we are amending § 410.160(b)(2) to include the COVID-19 vaccine in the list of vaccines that are not subject to the Part B annual deductible and do not count toward meeting that deductible.
- At § 411.15, Particular services excluded from coverage, we are amending § 411.15(e) to add an exception for COVID-19 vaccinations to the general exclusion of coverage for immunizations.
- At § 414.701, Purpose, we are amending the list of statutorily covered drugs to include the COVID-19 vaccine.
- At § 414.707, Basis of Payment, we are amending § 414.707(a)(2)(iii) to include the COVID-19 vaccine in the list of vaccines with a payment limit calculated using 95 percent of the average wholesale price.
- At § 414.900, Basis and scope, we are amending § 414.900(b)(3) to include the COVID-19 vaccine in the list of statutorily covered drugs.
- At § 414.904, Average sales price as the basis for payment, we are amending § 414.904(e)(1) to include the COVID-19 vaccine in the list of vaccines with payment limits calculated using 95 percent of the average wholesale price.

5. Medicare Advantage and Cost Plans

Under sections 1852(a)(1) and 1876(c)(2) of the Act, Medicare Advantage (MA) plans and cost plan organizations must cover all benefits covered under Part A and Part B of Original Medicare, subject to limited exclusions. Therefore, all MA plans and cost plans must cover a COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act. As described previously, the interpretation of section 3713 of the CARES Act adopted in this rule will result in Part B coverage of a COVID-19 vaccine for which FDA issues an EUA during the PHE, and administration of that vaccine when furnished consistent with terms of such EUA. As amended by section 3713 of the CARES Act, section 1852(a)(1)(B)(iv)(VI) of the Act prohibits MA plans from using cost sharing that exceeds the cost sharing imposed under original Medicare for a COVID-19 vaccine and its administration when MA coverage is provided because they are covered under Part B under section 1861(s)(10)(A) of the Act.

Section 1852(a)(5) of the Act and 42 CFR 422.109 provide that when a National Coverage Determination (NCD) or legislative change in benefits, such as the addition of Part B coverage of a COVID-19 vaccine and its administration, results in significant costs that have not been included in the capitation payments made to MA plans, coverage of the new benefit will be provided through the Medicare FFS program until the capitation payments take the new significant costs into account. The payment rates for MA organizations for contract years 2020 and 2021 have been set without including the costs for a COVID-19 vaccine and its administration. Therefore, if coverage of a COVID-19 vaccine and its administration during that period results in significant costs, section 1852(a)(5) of the Act and § 422.109 will apply to require Medicare FFS coverage of the vaccine and its administration.

The cost projection used for the determination whether the legislative change results in significant costs is based on an analysis by the Chief Actuary of CMS of the actuarial costs associated with a NCD or the legislative change in benefits and compared to the thresholds specified in the regulation at § 422.109. This analysis is generally performed once a Medicare FFS payment rate is determined for the service. If the estimated cost of an NCD or legislative change represents at least 0.1 percent of the national average per capita costs or the average cost of

furnishing a single service exceeds the cost threshold established in using the formula in § 422.109(a), it is considered a significant cost and the FFS Medicare program provides coverage for the service until the costs are factored into Medicare Advantage payments. Therefore, this legislative change would be subject to an analysis whether the new benefit results in significant costs. The significant cost threshold will be met assuming that the projected cost per-beneficiary-per-year is greater than approximately \$13, which is 0.1 percent of the national average per capita costs. If the threshold is reached, Medicare beneficiaries enrolled in MA plans will receive coverage of the COVID-19 vaccine and its administration through the Medicare FFS program and would be able to access the COVID-19 vaccine, without cost sharing, at any FFS provider or supplier that participates in Medicare and is eligible to bill under Part B for vaccine administration, including those enrolled in Medicare as a mass immunizer or a physician, non-physician practitioner, hospital, clinic, or group practice.

Section 3713 of the CARES Act added Medicare Part B coverage for a COVID-19 vaccine and its administration and provides that MA plans must cover the new benefit without cost sharing. While section 1876(c)(2) of the Act ensures that enrollees in Medicare cost plans will have coverage of a COVID-19 vaccine and its administration, section 3713 of the CARES Act did not amend section 1876 of the Act to provide similar cost-sharing protections for enrollees in cost plans who receive the vaccine from an in-network provider. Nor is there a provision affirmatively relieving cost plans of the obligation to cover the new Part B benefit. Because the Medicare FFS program covers Part A and Part B items and services furnished to cost plan enrollees by out-of-network health care providers that participate in the Medicare FFS program, cost plan enrollees will receive the COVID-19 vaccine and its administration without cost sharing when they go to a health care provider that is out of the cost plan's network. See 42 CFR 417.436(a)(5) and 417.448. However, there is no requirement for cost plans to cover the COVID-19 vaccine and its administration without cost sharing (that is, with cost sharing that is the same as original Medicare) when the vaccine is furnished by an in-network health care provider. Many enrollees may seek the COVID-19 vaccine from the health care provider they usually see or from whom they receive most of their health care; that provider is likely to be

in-network with the cost plan. CMS believes that it is necessary and appropriate to ensure that cost plan enrollees, like other Medicare beneficiaries, are provided access to the COVID-19 vaccine and its administration without cost sharing. Section 1876(i)(3)(D) of the Act authorizes us to impose "other terms and conditions not inconsistent with [section 1876]" that are deemed "necessary and appropriate." Requiring cost plans to comply with the same cost sharing protections available to Medicare beneficiaries in the FFS program and enrolled in Medicare Advantage plans is necessary and appropriate, so that cost is not a barrier for beneficiaries to get the vaccine, particularly during the public health emergency when ensuring access is of paramount importance. To ensure that cost plan enrollees also do not pay cost sharing for the COVID-19 vaccine and its administration when received from an in-network provider at least until the end of the public health emergency for COVID-19, we are adding a new paragraph (e)(4) to § 417.454 to require section 1876 cost plans to cover without cost sharing the COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act without cost sharing for the duration of the PHE for the COVID-19 pandemic, specifically the end of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Act, which is the PHE declared by the Secretary on January 31, 2020 and any renewals thereof.

B. COVID-19 Vaccine Coverage for Medicaid, CHIP, and BHP Beneficiaries

Under section 6008 of the FFCRA, states' and territories' Medicaid programs may receive a temporary 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP). Under section 6008(b)(4) of the FFCRA, to receive that increase, a state or territory must cover COVID-19 testing services and treatments, including vaccines and the administration of such vaccines, for Medicaid enrollees without cost sharing. That coverage is required during any quarter for which the state or territory claims the temporary FMAP increase under FFCRA section 6008, and the FMAP increase is available through the end of the quarter in which the PHE for COVID-19 ends. CMS is not aware of any states or territories not currently claiming this temporary FMAP increase, or of any state or territory that intends to cease claiming it. Accordingly, Medicaid coverage of a COVID-19 vaccine and its administration, without cost-sharing, is expected to be available for most

Medicaid beneficiaries through the end of the quarter in which the PHE for COVID-19 ends. For the remainder of this section of preamble, references to “state” or “states” in discussions of Medicaid policy also include the territories.

To meet the requirement in FFCRA section 6008(b)(4) to cover a COVID-19 vaccine and its administration without cost sharing, states must compensate Medicaid providers with a vaccine administration fee or reimbursement for a provider visit during which a vaccine dose is administered, even if the vaccine dose is furnished to the provider at no cost.

There are some very limited circumstances in which the FFCRA section 6008(b)(4) coverage requirements would not apply. CMS has not interpreted section 6008(b)(4) of the FFCRA to require that state Medicaid programs cover the services described in that provision for individuals whose Medicaid eligibility is limited by statute to only a narrow range of benefits that would not otherwise include these services. FFCRA section 6008(b)(4) did not amend the varying benefits packages that are required for different Medicaid eligibility groups under section 1902(a)(10) of the Act. In some cases, beneficiaries’ coverage is limited by statute to a very narrow range of benefits and services that typically would not include services described in FFCRA section 6008(b)(4), such as COVID-19 vaccines or their administration (see, e.g., the limitations described in the matter following section 1902(a)(10)(G) of the Act for some Medicaid eligibility groups). Nor did FFCRA section 6008(b)(4) direct states to amend existing demonstration projects under section 1115(a) of the Act, through which states may offer eligibility to groups not otherwise eligible under title XIX of the Act, and can opt to provide these groups with limited benefits. Moreover, after FFCRA was enacted, in section 3716 of the CARES Act (Pub. L. 116-136), Congress defined eligibility for the COVID-19 testing-only optional Medicaid eligibility group described in section 1902(a)(10)(A)(ii)(XXIII) of the Act in a manner that recognized that certain limited-benefit Medicaid eligibility groups are “uninsured,” and therefore eligible to receive coverage for COVID-19 testing under that provision, without referring to or acknowledging the FFCRA section 6008(b)(4) COVID-19 testing coverage requirement. See section 1902(ss) of the Act. Accordingly, CMS does not interpret FFCRA section 6008(b)(4) to require states to provide COVID-19 testing and treatment services without cost-sharing, including

vaccines and their administration, to eligibility groups whose coverage is limited by statute or under an existing section 1115 demonstration to a narrow range of benefits that would not ordinarily include this coverage, such as groups that receive Medicaid coverage only for COVID-19 testing, family planning services and supplies, or tuberculosis-related services. The COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured Program (COVID-19 Claims Reimbursement program) administered by the Health Resources and Services Administration (HRSA) is available for reimbursement of a COVID-19 vaccine and vaccine administration costs for individuals who would not receive Medicaid coverage for a COVID-19 vaccine or its administration because their Medicaid coverage is for limited benefit packages only.

After the requirements in section 6008(b)(4) of FFCRA are no longer in effect in a state, the state must cover COVID-19 vaccines recommended by the ACIP, and their administration, for several populations under existing statutory and regulatory authority. All Medicaid-enrolled children under the age of 21 eligible for the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit must receive ACIP-recommended vaccines pursuant to section 1905(r)(1)(A)(i) and (B)(iii) of the Act.¹² Coverage of ACIP-recommended vaccines without cost-sharing is required for any adult populations who receive coverage through Alternative Benefit Plans (ABPs), including the adult expansion population described at section 1902(a)(10)(A)(i)(VIII) of the Act, pursuant to section 1937(b)(5) of the Act, 42 CFR 440.347(a), and 45 CFR 156.115(a)(4) and 147.130. Some states may also elect to receive a 1 percentage point FMAP increase for their expenditures on certain services, in return for covering ACIP-recommended vaccines and their administration without cost-sharing for adults under section 1905(a)(13) of the Act, pursuant to section 4106 of PPACA (as codified in section 1905(b) of the Act). Children through age 18 who are eligible for Medicaid (funded through both titles XIX and XXI), as well as children who are uninsured, who are not insured with respect to the vaccine and who are administered pediatric vaccines by a

federally qualified health center (FQHC) or rural health clinic, or who are Indians (as defined in section 4 of the Indian Health Care Improvement Act) receive ACIP-recommended vaccinations through the Vaccines for Children (VFC) program, described at section 1928 of the Act. The Centers for Disease Control and Prevention (CDC) will determine if COVID-19 vaccines will be included in the VFC program. Coverage of the administration of a VFC-covered vaccine for Medicaid-eligible children would be provided by the state Medicaid program.

After the FFCRA section 6008(b)(4) requirements are no longer in effect in a state, the state also has the option to cover a COVID-19 vaccine and its administration for other eligibility groups. Such groups include the parent/caretaker relative eligibility group at 42 CFR 435.110, eligibility groups for individuals who are age 65 or older or who are eligible on the basis of blindness or a disability, and pregnant women enrolled under 42 CFR 435.116 who are eligible for full state plan benefits. If a state elects to cover a COVID-19 vaccine and its administration for any one of these groups, it must do so for all of them, except that with respect to the pregnant women group described in 42 CFR 435.116, per 42 CFR 440.250(p) states can cover a vaccine and its administration as a pregnancy-related service while not providing the same coverage for the other eligibility groups. Outside of the period in which FFCRA section 6008(b)(4) applies to a state, the state has the option to apply cost sharing to coverage of a COVID-19 vaccine or its administration unless the beneficiary is in an eligibility group that is exempt from cost-sharing under section 1916 or section 1916A of the Act and regulations at 42 CFR 447.56 (for example, most children under age 18, most pregnant women, most children in foster care, individuals receiving services in an institution that already had their medical assistance reduced by their income, individuals receiving hospice care, and Indians who are currently receiving or have ever received an item or service furnished by an Indian health care provider or through referral under contract health services).

After the FFCRA section 6008(b)(4) requirements are no longer in effect in a state, a COVID-19 vaccine and its administration could also be a covered service for many Medicaid eligibility groups when furnished by a participating provider under certain Medicaid benefits that are mandatory for many Medicaid eligibility groups,

¹² Medicaid enrolled children up to the age of 18 are generally exempt from cost sharing. For children age 19 or 20 cost sharing for an ACIP-recommended vaccine may apply, outside of an Alternative Benefit Plan.

depending on how the state has defined the amount, duration, and scope parameters of the benefit. Because inpatient and outpatient hospital services, physician services, and Federally Qualified Health Center and Rural Health Clinic services are mandatory Medicaid benefits for the categorically needy populations, COVID-19 vaccine administration could be a covered service for many Medicaid beneficiaries when provided by these participating providers, at state option. States might also cover COVID-19 vaccine administration for beneficiaries under various optional state plan benefits, such as the “other licensed practitioner” benefit described in section 1905(a)(6) of the Act and 42 CFR 440.60, or the “preventive services” benefit described in section 1905(a)(13) of the Act and 42 CFR 440.130(c). However, states would generally not have the option to cover a COVID-19 vaccine or its administration for any group whose coverage is limited by statute or under a current section 1115 demonstration to a narrow range of benefits that would not ordinarily include vaccine coverage. As described above, the COVID-19 Claims Reimbursement program administered by HRSA may be used to cover COVID-19 treatment, including the administration of vaccines, for such limited-benefit beneficiaries. In addition, a state might have the option, subject to Federal approval, to propose or amend a section 1115 demonstration to include this coverage for a group that would not otherwise be entitled to receive it under the statute or under current section 1115 authority.

The FFCRA section 6008(b)(4) requirement does not apply to separate CHIPs.¹³ In separate CHIPs, states must cover ACIP-recommended vaccines and their administration for all children under age 19 with no cost sharing. See section 2103(c)(1)(D) and (e)(2) of the Act, and 42 CFR 457.410(b)(2) and 457.520(b)(4). Coverage of uninsured pregnant women in a separate CHIP is optional. Currently, the states that cover pregnant women in a separate CHIP include all ACIP-recommended vaccines with no cost sharing in this coverage. However, current CMS interpretation is that this vaccine coverage is not required.

The FFCRA section 6008(b)(4) requirement also does not apply to the Basic Health Program (BHP). Minnesota and New York are the only states that

currently operate a BHP. BHP coverage must include benefits in at least the ten essential health benefits described in section 1302(b) of the PPACA and must comply with the Exchange’s cost-sharing protections,¹⁴ which includes providing all ACIP recommended vaccines without cost sharing. See sections 1331(a)(1), (a)(2)(B) and (b)(2) of PPACA, and 42 CFR 600.405(a) and 600.510(b).

Section 600.510(b) cross-references 45 CFR 147.130, which establishes requirements related to the coverage of preventive health services for BHP. For ABPs, 42 CFR 440.347 cross-references 45 CFR part 156, which incorporates 45 CFR 147.130, which establishes requirements related to the coverage of preventive health services. Consistent with the changes to 45 CFR 147.130 made through this rulemaking, during the COVID-19 public health emergency BHP plans and Medicaid ABPs must provide coverage for and must not impose any cost-sharing for “qualifying coronavirus preventive services,” including a COVID vaccine, regardless of whether the vaccine is delivered by an in-network or out-of-network provider. For details on the coverage requirements for “qualifying coronavirus preventive services” and the updates to 45 CFR 147.130 see section III of this IFC.

Lastly, we note that CMS intends this section only to be a description of current policy and existing law, with the exception noted directly above for BHP and Medicaid ABPs, and that CMS is not making any changes to its current policy or regulatory requirements in this rule.

C. Price Transparency for COVID-19 Diagnostic Tests

1. Introduction

Robust COVID-19 diagnostic testing is fundamental to the Federal Government’s strategy for controlling the spread of COVID-19.¹⁵ In recognition of the importance of COVID-19 diagnostic testing, the Federal Government has taken several

¹⁴ As explained in rulemaking, this includes the prohibition on cost sharing for preventive health services. See the Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity; Final Rule. 79 FR 14111 at 14128 (March 12, 2014).

¹⁵ The White House, CDC and FDA document: Testing Overview, Opening Up America Again. Available at: <https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Overview-Final.pdf>.

steps to reduce financial barriers to testing for both insured and uninsured individuals, including the following:

- The FFCRA was enacted on March 18, 2020. Section 6001 of the FFCRA generally requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for certain items and services, including *in vitro* diagnostic testing products for the detection of SARS-CoV-2, the virus that causes COVID-19, or the diagnosis of COVID-19 (referred to herein collectively as COVID-19 diagnostic tests) when those items or services are furnished on or after March 18, 2020, and during the PHE for COVID-19. Plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance) or prior authorization or other medical management requirements. Related items and services include those provided during urgent care center visits, in-person and telehealth office visits, and emergency room visits that result in an order for or administration of an *in vitro* diagnostic product, to the extent that such items and services relate to the furnishing or administration of a COVID-19 diagnostic test, or to the evaluation of an individual for purposes of determining the need of the individual for a COVID-19 diagnostic test. Section 3201 of the CARES Act, enacted on March 27, 2020, amended section 6001 of the FFCRA to include a broader range of diagnostic tests that plans and issuers must cover without any cost-sharing requirements or prior authorization or other medical management requirements.

- The COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured Program provides reimbursements on a rolling basis directly to eligible providers for claims that are attributed to the testing and treatment of COVID-19 for certain uninsured individuals. The program is funded via (1) the FFCRA Relief Fund, which includes funds received from the Public Health and Social Services Emergency Fund, as appropriated in the FFCRA and the Paycheck Protection Program and Health Care Enhancement Act (PPHCEA) (Pub. L. 116-139), which each appropriated funding to reimburse providers for conducting COVID-19 testing for the uninsured, and (2) the Provider Relief Fund, as appropriated in the CARES Act and the PPHCEA.¹⁶

¹⁶ FAQs for COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and

¹³ In states that use title XXI funding to expand Medicaid eligibility for children, the FFCRA section 6008(b)(4) requirements apply to these title XXI funded Medicaid beneficiaries in the same way that they do to all other Medicaid beneficiaries.

• HHS has partnered with pharmacies, retail companies, and health centers nationwide to make no-cost COVID-19 diagnostic testing available to Americans in communities across the country.¹⁷

Congress has also taken steps to facilitate the reimbursement for COVID-19 diagnostic testing and to ensure that pricing for performance of such testing is publicly available. Specifically, section 3202(a) of the CARES Act requires group health plans and issuers providing coverage for items and services described in section 6001(a) of the FFCRA to reimburse any provider of a COVID-19 diagnostic test an amount that equals the negotiated rate, or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on a public website. The plan or issuer may also negotiate a rate with the provider that is lower than the cash price. More information related to health insurance issuer and group health plan coverage and reimbursement for COVID-19 diagnostic testing is available at <https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf> and <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf>. Specifically, the Departments note that the reimbursement requirements under CARES Act 3202(a) will apply to COVID-19 diagnostic testing, as defined in this IFC.

Section 3202(b) of the CARES Act establishes a requirement for each provider of a diagnostic test for COVID-19 to publicize cash prices for such COVID-19 diagnostic testing. Specifically, section 3202(b)(1) of the CARES Act requires each provider of a diagnostic test for COVID-19 to make public the cash price for such test on a public internet website of such provider during the emergency period declared under section 319 of the PHS Act. Section 3202(b)(2) of the CARES Act authorizes the Secretary to impose a civil monetary penalty (CMP) on any provider of a diagnostic test for COVID-19 that does not make public its cash price for such test in compliance with section 3202(b)(1) of the CARES Act and that has not completed a corrective action plan (CAP) to comply with that section. The statute states that the amount of the CMP must not exceed

\$300 per day that the violation is ongoing.

We believe that cash price posting by providers of diagnostic tests for COVID-19 is important for not only for plans and issuers that must comply under section 3202(a) of the CARES Act but also for individuals who seek COVID-19 diagnostic testing.

Therefore, we are adopting in this IFC policies that implement the requirement in section 3202(b) of the CARES Act that providers of diagnostic tests for COVID-19 make public their cash price for such tests on the internet. Specifically, we are finalizing the following: (1) Definitions of “provider of a diagnostic test for COVID-19” (herein referred to as “provider”), “diagnostic test for COVID-19” (herein referred to as “COVID-19 diagnostic test”), and “cash price”; (2) requirements for making public cash prices; and (3) penalties for non-compliance with the cash price posting requirements.

2. Requirement That Providers of COVID-19 Diagnostic Tests Make Public Cash Prices for COVID-19 Diagnostic Tests

The rapid expansion of COVID-19 related diagnostic testing capacity is a top priority in HHS’ strategy to combat the pandemic. COVID-19 diagnostic testing is generally performed by laboratories located in a variety of sites, including for example: Government labs; hospital-run labs; clinician offices; stand-alone labs; urgent care centers; and pharmacies. There are several types of COVID-19 tests designed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19, including molecular (RT-PCR) tests, which are used to detect the virus’s genetic material, and antigen tests, which are used to detect specific proteins on the surface of the virus and serology testing, which is used to look for the presence of antibodies produced by the body in response to infections.

For purposes of implementing section 3202(b) of the CARES Act, we are adopting a new 45 CFR part 182, “Price Transparency for COVID-19 Diagnostic Tests,” that will implement price transparency requirements for making public cash prices for performance of a COVID-19 diagnostic test. Section 182.10 states that part 182 implements section 3202(b) of the CARES Act.

For purposes of section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act, and as explained in guidance issued by the Departments, COVID-19 diagnostic tests include all *in vitro* diagnostic tests, which include molecular, antigen, and serological tests. Specifically, section 6001(a) of the FFCRA, as amended by section 3201 of

the CARES Act, requires plans and issuers to provide coverage for an *in vitro* diagnostic test, as defined in 21 CFR 809.3(a) (or its successor regulations), for the detection of SARS-CoV-2 or diagnosis of COVID-19, and the administration of such a test that: (1) Is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the FD&C Act (21 U.S.C. 360(k), 360c, 360e, 360bbb-3); (2) the developer has requested, or intends to request, emergency use authorization under section 564 of the FD&C Act (21 U.S.C. 360bbb-3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe; (3) is developed in and authorized by a state that has notified the Secretary of HHS of its intention to review tests intended to diagnose COVID-19; or (4) other tests that the Secretary of HHS determines appropriate in guidance.¹⁸ We are therefore at § 182.20 defining a “diagnostic test for COVID-19” (also referred to as a “COVID-19 diagnostic test”) as a COVID-19 *in vitro* diagnostic test described in section 6001 of the FFCRA, as amended by section 3201 of the CARES Act. Such COVID-19 diagnostic tests are currently billed by providers using HCPCS and CPT codes including, but not limited to: CPT codes 86408, 86409, 87635, 87426, 86328, and 86769 and HCPCS codes U0001 through U0004. We intend this list of billing codes to be illustrative, however, not exhaustive. Therefore, as noted previously, a “COVID-19 diagnostic test” is defined as a COVID-19 *in vitro* diagnostic test described in section 6001 of the FFCRA, as amended by section 3201 of the CARES Act, even if a particular COVID-19 diagnostic test or its billing code is not included on this list. Codes continue to be created to address new and proprietary tests as they are developed. We therefore anticipate updating this list in guidance as new tests and codes are developed.

Obtaining a diagnostic test for COVID-19 generally can involve up to three separate health care services for an individual including evaluation by a practitioner of the need for such testing, and, once the provider determines the need for a COVID-19 diagnostic test, specimen collection and laboratory analysis of the specimen, that is, actual performance of a COVID-19 diagnostic

Treatment of the Uninsured. Available at <https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions>.

¹⁷ Information on Community-Based Testing Sites for COVID-19 can be found at <https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html>.

¹⁸ See Q3 of FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42 available at: <https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf>.

test. For purposes of implementing section 3202(b), we are defining “provider of a diagnostic test for COVID–19” (herein referred to as “provider”) as any facility that performs one or more COVID–19 diagnostic tests. CMS regulates all laboratory testing performed on humans for the purposes of diagnosis, prevention, or treatment in the U.S. through the Clinical Laboratory Improvement Amendments CLIA program (42 U.S.C. 263a). In order to perform COVID–19 testing, a facility (whether that be a primary care provider’s office, urgent care center, outpatient hospital site or stand-alone laboratory) is required to hold a CLIA certificate based on the complexity of the testing performed by the facility. Therefore, we expect that any “provider of a diagnostic test for COVID–19” would either hold or have submitted a CLIA application necessary to obtain a CLIA certificate (including a certificate of waiver, as applicable) and that such testing would occur in facilities ranging from primary care provider offices to urgent care centers to stand-alone national laboratories.

At § 182.20, we are defining “cash price” as the charge that applies to an individual who pays in cash (or cash equivalent) for a COVID–19 diagnostic test. We believe this definition will provide a clear point of reference not only for individuals who seek such tests, but also for payers who wish to negotiate reimbursement rates with providers of diagnostic tests for COVID–19, or who wish to help direct their members to providers of diagnostic tests for COVID–19 who charge cash prices that payers believe to be reasonable. The “cash price” is generally analogous to the “discounted cash price” as defined at 45 CFR 180.20 for purposes of the Hospital Price Transparency final rule. As we explained in that rule, providers often offer discounts off their gross charges or make other concessions to individuals who pay for their own care (referred to as self-pay individuals) (84 FR 65524). We also stated that the discounted cash price may be generally analogous to the “walk-in” rate that would apply to all self-pay individuals, regardless of insurance status, who pay in cash at the time of the service, and that such charges are often lower than the rate the hospital negotiates with third party payers because billing self-pay individuals would not require many of the administrative functions that exist for hospitals to seek payment from third party payers (for example, prior authorization and billing

functions).^{19 20 21 22} It is therefore our expectation that the “cash price” established by the provider will be generally similar to, or lower than, rates negotiated with in-network plans and insurers. If a provider has not established a “cash price” for a COVID–19 diagnostic test that is lower than its gross charge or retail rate, the provider must make public the undiscounted gross or retail rate found in its master price list (which is analogous to the hospital’s chargemaster). We do not believe that posting a “cash price” should prevent a provider of a diagnostic test for COVID–19 from offering testing for free to individuals as charity care or in an effort to combat the public health crisis, rather, the “cash price” would be the maximum charge that may apply to a self-pay individual paying out-of-pocket. We solicit comment on this approach and whether any additional standards should be implemented to address any potential abuse.

Under new § 182.30(a) and (b), these requirements apply to a “provider of a diagnostic test for COVID–19” as defined at § 182.20 and are applicable during the PHE for COVID–19 determined to exist nationwide as of January 27, 2020, by the HHS Secretary under section 319 of the PHS on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals.

Finally, section 3202(b)(1) of the CARES Act states that each provider of a diagnostic test for COVID–19 shall make public the cash price for such test on a public internet website of such provider. We interpret this to mean that providers must make public the cash prices for performing COVID–19 diagnostic tests on the provider’s internet website. Specifically, as discussed below, § 182.40(a)(1) and (2) require that each provider of a COVID–19 diagnostic test that has a website

¹⁹ Rosato D. How Paying Your Doctor in Cash Could Save You Money. Consumer Reports. May 4, 2018. Available at: <https://www.consumerreports.org/healthcare-costs/how-paying-your-doctor-in-cash-could-save-you-money/>.

²⁰ David Lazarus. Insured price: \$2,758. Cash price: \$521. Could our Healthcare System by any Dumber? Los Angeles Times. July 30, 2019. Available at: <https://www.latimes.com/business/story/2019-07-29/column-could-our-healthcare-system-be-any-dumber>.

²¹ Beck M. How to Cut Your Health-Care Bill: Pay Cash. The Wall Street Journal. February 15, 2016. Available at: <https://www.wsj.com/articles/how-to-cut-your-health-care-bill-pay-cash-1455592277>.

²² Dr. Steven Goldstein. Patients Can Save Money When They Pay Their Doctor In Cash. Houston Healthcare Initiative. August 10, 2020. Available at: <https://houstonhealthcareinitiative.org/patients-can-save-money-when-they-pay-their-doctor-in-cash/>.

make public the cash price information described in § 182.40(c) electronically, and that the information itself, or a link to a web page that contains such information, must appear in a conspicuous location on a searchable homepage on the provider’s website. We recognize that some providers of a COVID–19 diagnostic test, for example, small or rural providers, may not have websites. Therefore, in the event that a provider does not have a website on which to post this cash price information, we are finalizing a policy at § 182.40(b) to require the provider to make public its cash price information in writing upon request within two business days and by posting signage prominently at the location where the provider offers a COVID–19 diagnostic test in a place likely to be viewed by members of the public seeking to obtain and pay for such testing. If the provider does not have its own website or a publicly accessible location then, upon request and within two business days, the provider will be required to make public its cash price information in writing to the requestor but will not be required to post signage at the location where it performs the COVID–19 diagnostic test. For purposes of complying with the requirement that the cash price information be made public in writing, we will consider email correspondence to the requester to be an acceptable written format. We believe these policies will help ensure that the public (including individuals, issuers, health plans, and others) has access to every provider’s COVID–19 diagnostic test cash prices, including those providers who do not perform COVID–19 diagnostic tests at publicly accessible locations. We seek comment on these issues, including the frequency by which providers may not have websites.

Furthermore, at § 182.40(a)(3), we are requiring that providers of a COVID–19 diagnostic test display their cash price information in an easily accessible manner, without barriers, including, but not limited to, ensuring the information is accessible: Free of charge; without having to establish a user account or password; and without having to submit personal identifiable information (PII). In addition, we are requiring at § 182.40(a)(4) that the provider’s homepage contain certain keywords that we believe will increase the likelihood that the public will be able to locate the information using a search engine. Specifically, § 182.40(a)(4) requires that all of the following terms be included on the provider’s homepage: The provider’s name; “price”; “cost”; “test”; “COVID”; and “coronavirus.” We seek

comment on whether providers should have flexibility to select between using “COVID” or “coronavirus” and between “cost” and “price” if the provider is linking to the information from its homepage.

Finally, we believe that it is important for the provider to include certain standardized information so that the public can understand the relationship between the posted cash price and the COVID-19 diagnostic test(s) offered by the provider. Therefore, at § 182.40(c)(1) through (4), we are requiring all providers to make public, along with the cash price for each COVID-19 diagnostic test(s) that they offer, information that, at minimum, includes a plain language description of each COVID-19 diagnostic test, the corresponding cash price, the billing code(s) for each such test(s), and any additional information as may be necessary for the public to be certain of the cash price for a particular COVID-19 diagnostic test. For example, if the provider offers the same test at a different cash price that is dependent on location or some other factor, then on its website listing of cash prices, the provider must indicate all the cash prices that apply to the test and relevant distinguishing information as to when each different cash price applies. We believe that this information is necessary for the public, including group health plans and health insurance issuers offering group or individual health insurance coverage that must provide reimbursement for COVID-19 diagnostic testing pursuant to the requirements of section 3202(a) of the CARES Act. This requirement applies to cash price information posted on the provider’s website, made available upon request and, where applicable, on signage.

These requirements are applicable immediately; however, we seek comment on these requirements and may, as a result of public comment, revise these requirements or finalize additional requirements. We also specifically seek comment on the definition of “diagnostic test for COVID-19” as solely a COVID-19 *in vitro* diagnostic test described in section 6001 of FFCRA.

We seek comment on the definition of “provider of a COVID-19 diagnostic test”. We seek comment on whether consumers may benefit from knowing the total cost of care for receiving a COVID-19 test, including the doctor’s visit and specimen collection, in order to protect themselves against potential unexpected health care costs and make a more informed health care purchasing decision and therefore whether we

should adopt a more inclusive definition of a provider of a diagnostic test for purposes of this requirement. Specifically, we seek comment on whether a “provider of a diagnostic test for COVID-19” should be expanded to include providers that perform additional services related to the performance of a COVID-19 diagnostic test, such as for specimen collection or mileage fees that may be billed as part of or in conjunction with the specimen collection, if applicable. We are particularly interested in submissions from stakeholders that include data, both anecdotal and claims-based, on the ways in which consumers request and receive COVID-19 diagnostic testing, including the site of care, frequency, and type of provider.

We seek comment on the definition of “cash price”. We have heard concerns from stakeholders that certain providers may use the posting of a “cash price” as an opportunity to “price gouge”.^{23 24 25} We therefore specifically seek comment on whether this definition or some other definition would help to mitigate concerns for price gouging by out-of-network providers. We seek comment on whether there are additional authorities and safeguards that could be used to mitigate concerns for price gouging both for group health plans and issuers and for consumers receiving a COVID-19 diagnostic test.

We seek comment regarding whether these requirements are sufficient to inform consumers of the cash price for a COVID-19 diagnostic test in advance of receiving one and what, if any, additional requirements or safeguards should be considered to avoid consumer confusion or prevent unintended consequences (for example, balance billing). Specifically, we seek comment regarding how providers should post cash prices so that they do not inadvertently deter consumers from seeking a test that would normally result in no out-of-pocket cost to the consumer.

²³ Morgan Haefner. Out-of-network Providers Price Gouging COVID-19 tests, AHIP says. Becker’s Hospital Review Newsletter. August 28, 2020. Available at: <https://www.beckershospitalreview.com/payer-issues/out-of-network-providers-price-gouging-covid-19-tests-ahip-says.html>.

²⁴ Susannah Luthi. The \$7,000 COVID Test: Why States are Stepping in to Shield Consumers. POLITICO. June 8, 2020. Available at: <https://www.politico.com/news/2020/06/08/coronavirus-test-costs-304058>.

²⁵ Ken Alltucker. ‘I was flooded’: Coronavirus test prices charged by some hospitals and labs stun consumers, spur questions. USA Today. September 15, 2020. Available at: <https://www.usatoday.com/story/news/health/2020/09/15/covid-test-prices-hospitals-scrutinized-congress-insurers-consumers/3472304001/>.

Finally, we seek comment on an approach that balances priorities to further price transparency for consumers and other stakeholders and reduce barriers to COVID-19 testing. We recognize that these final policies become effective as of the date of display of this IFC and are applicable only until the end of the PHE. Even so, we seek comment whether and to what extent these final policies and the alternatives about which we are seeking comment (for instance, expansion of the definition of “provider”) may lead to:

- Potential cost shifting from providers or participants, beneficiaries, and enrollees to group health plans or issuers, if the group health plan and issuer reimbursement obligation for COVID-19 diagnostic testing is expanded to cover such testing without cost-sharing (including deductibles, co-pays, and co-insurance) and as payment in full for items and services that were not previously covered in such a manner by group health plans or issuers.

- Potential for group health plans or issuers to negotiate rates that are lower than the cash price with out-of-network providers with whom they do not have established negotiated rates.

- Price gouging or other anti-competitive behavior (under both the policies and the alternatives for which we seek comment) by providers as well as any potential negative impact on premiums in the future that have not already been accounted for in 2021 rates. Please provide empirical evidence, if any, including based on claims data during the PHE for COVID-19.

- Potential savings to issuers and plans from insured consumers seeking out COVID-19 diagnostic testing from in-network providers, as opposed to the provider of their choice, as a result of these increased price transparency requirements.

- Price sensitivity by consumers covered by group health plans or issuers in their choice of provider, and awareness of any potential cost-shifting to group health plans or issuers, or to consumers themselves through balance billing, as a result of these increased price transparency requirements.

- Transparency benefits for the uninsured, who may already have an incentive to find the lowest price.

- Group health plans or issuers taking on new consumer education or other potential costs, for example, costs associated with incentivizing consumers covered by group health plans or issuers to stay in network or seek care from lower cost providers.

3. Monitoring and Enforcement of Requirements To Publicize Cash Prices for COVID-19 Diagnostic Tests

Section 3202(b)(2) of the CARES Act authorizes and provides the Secretary discretion to impose a CMP on any provider of a diagnostic test for COVID-19 that is not in compliance with section 3202(b)(1) of the CARES Act and has not completed a CAP to comply with the requirements of such paragraph, in an amount not to exceed \$300 per day that the violation is ongoing. In this IFC, we are adopting mechanisms to monitor the requirement that a provider of a diagnostic test for COVID-19 publicize the cash price for diagnostic testing and enforce these requirements, as necessary.

a. Monitoring for Noncompliance and Pre-Penalty Actions

Section 3202(b)(1) of the CARES Act does not prescribe monitoring procedures or the factors we should consider in imposing penalties on providers for noncompliance. We anticipate relying predominantly on complaints made to CMS by the public, including individuals, as well as issuers and plans, regarding providers' potential noncompliance. Specifically, in response to such complaints, we may investigate and evaluate whether a provider has complied with the requirements discussed above. The monitoring methods for determining a provider's compliance with the requirements for publicizing the cash price for a COVID-19 diagnostic test may include, but are not limited to, the following, as appropriate:

- CMS' evaluation of complaints made to CMS.
- CMS' review of an individual's or entity's analysis of noncompliance as stated in the complaint.
- CMS' review of providers' websites or, where a provider does not have a website, its written notice and signage.

The IFC includes these monitoring methods in the regulations at § 182.50(a).

Additionally, at § 182.50(b), we are finalizing discretion for CMS to take any of the following actions if CMS determines the provider is noncompliant with the requirements of § 182.40:

- Provide a written warning notice to the provider of the specific violation(s).
- Request that a provider submit and comply with a CAP under § 182.60.
- Impose a CMP on the provider if the provider fails to respond to CMS' request to submit a CAP or to comply with the requirements of a CAP approved by CMS.

A provider that CMS identifies as noncompliant and to which it offers an opportunity to take corrective action to come into compliance may be notified via a warning notice of its deficiencies. In response to the warning letter, a provider may choose, but is not required, to submit documentation for CMS to review to determine compliance. CMS will review any documentation a provider may submit and, where applicable, a provider's website or other form of written notice, to determine if the provider's noncompliance has been corrected. In the event that a provider does not have its own website on which to post the cash price, CMS will require documentation that the provider has the cash price in written form timely upon request and, where applicable, has posted signage at the provider's facility.

At § 182.60, we specify the requirements for CAPs. Specifically, § 182.60(a) states that a provider may be required to submit a CAP if CMS determines a provider is noncompliant or the provider's noncompliance continues after a warning notice. A violation may include, but is not limited to, a provider's failure to make public its cash price information for COVID-19 diagnostic testing required by § 182.40 and a provider's failure to make public its cash price information in the form and manner required under § 180.40.

Section 182.60(b) states that CMS may request that a provider submit and comply with a CAP, specified in a notice of violation issued by CMS to a provider. Additionally, in § 182.60(c), we specify the following provisions related to CAPs:

- A provider required to submit a CAP must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the provider, and must comply with the requirements of the CAP approved by CMS.
- A provider's CAP must specify elements including, but not limited to, the corrective actions or processes the provider will take to address the deficiency or deficiencies identified by CMS, and the timeframe by which the provider will complete the corrective action.
- A CAP is subject to CMS review and approval. After CMS' review and approval of a provider's CAP, CMS may monitor and evaluate the provider's compliance with the corrective actions specified in the CAP.

Section 182.60(d) outlines the following provisions for identifying a provider's noncompliance with CAP requests and requirements:

- A provider's failure to respond to CMS' request to submit a CAP includes failure to submit a CAP in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the provider.

- A provider's failure to comply with the requirements of a CAP includes failure to correct violation(s) within the specified timeframes.

We seek comment on this approach for monitoring providers of COVID-19 diagnostic testing for compliance with these requirements. Specifically, we seek comments on relying predominantly on complaints to determine a provider's potential noncompliance. We further seek comments on issuing warning letters and requesting CAPs for violations related to making public cash prices for COVID-19 diagnostic testing. Additionally, we seek comments on the length of time we should specify in warning notices to allow corrections of violations before issuance of a request for CAP, and the length of time we should specify for providers to complete and return a CAP to CMS.

b. Civil Monetary Penalties

Under section 3202(b)(2) of the CARES Act, CMS may impose a CMP on a provider that we identify as noncompliant. At § 182.70, we are finalizing requirements related to imposition of CMPs. At § 182.70(a), we finalize a policy that CMS may impose a CMP on a provider that we identify as noncompliant with any of the requirements of § 182.40, and that fails to respond to CMS' request to submit a CAP or to comply with the requirements of a CAP approved by CMS described in § 182.60(d).

Under the statute, the maximum daily dollar amount for a CMP to which a provider may be subject is \$300, even if the provider is in violation of multiple discrete requirements of § 182.40. The maximum daily amount of the CMP will be adjusted annually using the multiplier determined by the Office of Management and Budget (OMB) for annually adjusting CMP amounts under 45 CFR part 102. CMS will provide a written notice of imposition of a CMP to the provider via certified mail or another form of traceable carrier. The elements of this notice to the provider will include but are not limited to the following:

- The basis for the provider's noncompliance, including, but not limited to, the following: CMS' determination as to which requirement(s) the provider has violated; and the provider's failure to respond to CMS' request to submit a

CAP or comply with the requirements of a CAP.

- CMS' determination as to the effective date for the violation(s).
- The amount of the penalty as of the date of the notice.
- A statement that a CMP may continue to be imposed for continuing violation(s).
- Payment instructions.
- A statement of the provider's right to a hearing according to § 182.90 of subpart D.
- A statement that the provider's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal.

CMS may issue subsequent notice(s) of imposition of a CMP, according to the aforementioned requirements (in short, where investigation reveals there is continuing justification), that result from the same instance(s) of noncompliance. A provider must pay the CMP in full within 60 calendar days after the date of the notice of imposition of a CMP from CMS. In the event a provider requests a hearing, under subpart D of 45 CFR part 182, the provider must pay the amount in full within 60 calendar days after the date of a final and binding decision to uphold, in whole or in part, the CMP. If the 60th calendar day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day. Should a provider elect to appeal the CMP, and where the CMP is upheld only in part by a final and binding decision, CMS will issue a modified notice of imposition of a CMP, to conform to the adjudicated finding as specified in § 182.70.

In the event a CMP is not paid in full within 60 days, CMS will follow the collections activities set forth in 45 CFR part 30. Generally, CMS will issue a written demand for payment no later than 30 days after a debt is delinquent. For debts not paid by the date specified in the written demand, interest, charged at a rate established by the Secretary of the Treasury, shall accrue from the date of delinquency. CMS will transfer debts 180 days or more delinquent to the Department of Treasury for collection.

We seek comment on the approach we are establishing for imposing a CMP on a provider noncompliant with the regulations set forth in § 182.40. Specifically, we seek comments on the length of time allowed between issuance of the request for CAP and the imposition of a CMP. In addition, we seek comments on the amount of the CMP imposed per day up to the

statutory maximum daily amount that would be applicable to all noncompliant providers.

c. Appeals Process

We believe it is important to establish a fair administrative process by which providers may appeal CMS' decisions to impose penalties under the requirements established by § 182.40. Through various programs, we have gained experience with administrative hearings and other processes to review CMS' determinations. That experience includes the processes we recently finalized in the CY 2020 Hospital Outpatient Prospective Payment System (OPPS) Price Transparency Final Rule (84 FR 65524) and corresponding regulations at 45 CFR part 180, which requires price transparency for hospitals, and we are aligning the procedures for the appeals process here with those procedures. Therefore, a provider upon which CMS has imposed a penalty under § 182.70 may appeal that penalty in accordance with §§ 180.100 and 180.110, subpart D, with conforming edits.

Generally, under this approach, a provider upon which CMS has imposed a penalty may request a hearing of that penalty before an Administrative Law Judge (ALJ). The CMS Administrator, at his or her discretion, may review in whole or in part the ALJ's decision. A provider against which a final order imposing a CMP is entered may obtain judicial review.

We specify at § 182.80 the procedures for a provider to appeal the CMP imposed by CMS for its noncompliance with the requirements of § 182.40 to an ALJ, and for the CMS Administrator, at his or her discretion, to review in whole or in part the ALJ's decision. In so doing, we apply the following conforming modifications to the text:

- References to "hospital" are replaced by the term "provider." We note that the term "provider," as defined at new 45 CFR 182.20 in this rule, may also include hospitals.
- References to "standard charge" are replaced by the term "cash price."

We seek comment on the approach we are establishing for appeals.

We also set forth in § 182.90 the consequences for failure of a provider to request a hearing. If a provider does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a CMP described in § 182.70(b), CMS may impose the CMP indicated in such notice and may impose additional penalties under continuing violations according to § 182.70(e) without right of appeal. If the 30th calendar day is a weekend or

a Federal holiday, then the timeframe is extended until the end of the next business day. The provider has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with 45 CFR 150.405, unless the provider can show good cause, as determined at § 150.405(b), for failing to timely exercise its right to a hearing.

D. Medicare Inpatient Prospective Payment System (IPPS) New COVID-19 Treatments Add-On Payment (NCTAP) for the Remainder of the Public Health Emergency (PHE)

1. Section 3710 of the CARES Act IPPS Add-On Payment for COVID-19 Patients During the PHE

Section 3710 of the CARES Act amended section 1886(d)(4)(C) of the Act to provide for an increase in the weighting factor of the assigned Diagnosis-Related Group (DRG) by 20 percent for an individual diagnosed with COVID-19 discharged during the period of the PHE for COVID-19. To implement this temporary adjustment, Medicare's claims processing systems apply an adjustment factor to increase the Medicare Severity-DRG (MS-DRG) relative weight that would otherwise be applied by 20 percent when determining IPPS operating payments. For additional information regarding this add-on payment, including which claims are eligible for the 20 percent increase in the MS-DRG weighting factor, please see the Medicare Learning Network (MLN) Matters article "New COVID-19 Policies for Inpatient Prospective Payment System (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the CARES Act" available on the CMS website at <https://www.cms.gov/files/document/se20015.pdf>.

2. Overview of IPPS New Technology Add-On Payment

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as "new technologies")

under the IPPS. The regulations at 42 CFR 412.87 and 412.88 implement these provisions.

As set forth in § 412.88(b)(2), for a new technology other than certain antimicrobial products (for which the maximum add-on payment is 75 percent), if the costs of a discharge involving a new technology exceed the full DRG payment (including payments for Indirect Medical Education (IME) and Disproportionate Share Hospital (DSH), but excluding outlier payments)), Medicare will make a new technology add-on payment equal to the lesser of: (1) 65 percent of the costs of the new technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

For additional information regarding IPPS new technology add-on payments please see the FY 2021 IPPS/LTCH PPS final rule (85 FR 58602 through 58608).

3. Overview of the Food and Drug Administration (FDA) Coronavirus Treatment Acceleration Program

The FDA has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program. The program uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. The FDA continues to support clinical trials that are testing new treatments for COVID-19 so that valuable knowledge about their safety and effectiveness can be gained. Additional information regarding this program is available on the FDA website at <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>.

One aspect of the program is the issuance by the FDA of EUAs during the PHE for COVID-19. On February 4, 2020, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a PHE that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.²⁶ On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the

²⁶ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. 360bbb-3, February 4, 2020.

COVID-19 pandemic, pursuant to section 564 of the FD&C Act, subject to terms of any authorization issued under that section.²⁷

There are currently five drug and biological products with EUAs issued during the PHE for COVID-19. In section “I. Criteria for Issuance of Authorization” of the current letters of authorization for these drug and biological products, the letters for two of the products state that based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in treating COVID-19, and that, when used under the conditions described in the authorization, the known and potential benefits of the product when used to treat COVID-19 outweigh the known and potential risks of such products.^{28[1]} Those two drug and biological products are COVID-19 convalescent plasma and Veklury (remdesivir).

The current letters of authorization for the other three products used in patients with suspected or confirmed COVID-19 do not indicate that those products are treating COVID-19 and instead treat a disease or condition caused or exacerbated by COVID-19.²⁹ Specifically, the letter of authorization for REGIOCIT indicates its use as a replacement solution in adult patients in a critical care setting who are being treated with Continuous Renal Replacement Therapy (CRRT) and for whom regional citrate anticoagulation (RCA) is appropriate; the letter of authorization for Fresenius Propoven 2 percent Emulsion indicates its use to maintain sedation via continuous infusion in patients greater than 16 years old who require mechanical ventilation in an ICU setting; and the letter of authorization for multiFiltrate PRO System and multiBic/multiPlus Solutions indicates its use in delivering CRRT in an acute care environment.

While COVID-19 convalescent plasma has received an EUA for treating COVID-19 in hospitalized patients, Veklury (remdesivir), as of October 22, 2020, is the only drug or biological product approved by FDA for treating

²⁷ U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. 360bbb-3, 85 FR 18250 (April 1, 2020).

²⁸ EUA for COVID-19 convalescent plasma: <https://www.fda.gov/media/141477/download>; EUA for remdesivir: <https://www.fda.gov/media/137564/download>.

²⁹ EUA for REGIOCIT: <https://www.fda.gov/media/141168/download>; EUA for Fresenius Propoven 2 percent Emulsion <https://www.fda.gov/media/137888/download>; EUA for multiFiltrate PRO System and multiBic/multiPlus Solutions: <https://www.fda.gov/media/137520/download>.

COVID-19.³⁰ In order for an item or service to be considered for coverage under Medicare Part A or Part B, the item or service must fall within at least one benefit category established in the Act. Drugs and biologicals are included within several such benefit categories. In general, section 1861(t)(1) of the Act defines drugs and biologicals to include drugs or biologicals approved for inclusion in certain compendia (except for any drugs and biologicals unfavorably evaluated therein) or that are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of a hospital furnishing that drug or biological for use in that hospital. CMS has determined that it is appropriate for CMS to consider drug and biological products which are authorized for emergency use for COVID-19, with letters of authorization, and are used to treat COVID-19 disease, to fall within the drugs and biologicals definition in section 1861(t)(1) of the Act for Medicare purposes if they are included or approved for inclusion in the applicable compendia, or when furnished by a specific hospital if approved for use in that hospital by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of that hospital.

More information regarding EUAs for drug and biological products during the PHE for COVID-19 is available on the FDA website at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>.

4. Overview of IPPS Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for “outlier” cases involving extraordinarily high costs. To qualify for outlier payments, one criterion is that a case must have costs greater than the sum of the prospective payment rate for the MS-DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the “outlier threshold” or “fixed-loss” amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS-DRG (including the Section 3710 of the CARES Act add-on payment if applicable), any IME and DSH payments, uncompensated care

³⁰ FDA approval for remdesivir: https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/214787Orig1s000ltr.pdf.

payments, any new technology add-on payments, and the outlier threshold as the outlier “fixed-loss cost threshold.” Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor is 80 percent for all MS-DRGs except the burn MS-DRGs, where the marginal cost factor is 90 percent. For the complete formula for how an outlier payment is computed, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59043 through 59044). We note, for each claim, per the formula in the FY 2021 IPPS/LTCH PPS final rule, in determining whether the claim is eligible for an operating outlier payment and/or a capital outlier payment, an “operating outlier threshold” and a “capital outlier threshold” are computed, including application of a geographic adjustment to account for local cost variation. If the case is eligible, an “operating outlier payment” and/or “capital outlier payment” will be made for an individual claim. For additional information regarding IPPS outlier payments please see the FY 2021 IPPS/LTCH PPS final rule (85 FR 59034 through 59041).

5. Eligibility Criteria for an IPPS New COVID-19 Treatments Add-on Payment (NCTAP) for the Remainder of the PHE

We believe that as drugs or biological products become available and are authorized or approved by FDA for the treatment of COVID-19 in the inpatient setting, it would be appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide these new treatments during the PHE. Therefore, effective for discharges occurring on or after the effective date of this rule and until the end of the public health emergency, CMS is using the exceptions and adjustment authority under section 1886(d)(5)(I) of the Act to create a New COVID-19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID-19 cases that meet certain criteria.

First, the case must include the use of a drug or biological product authorized to treat COVID-19 as indicated in section “I. Criteria for Issuance of Authorization” of the current letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19. Because the purpose of the NCTAP is to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments, this criterion expeditiously provides assurance in the context of the

urgency of the PHE that a treatment is new and is used to treat COVID-19 during the PHE. Currently, there are only two drug or biological products that meet this criterion: Veklury (remdesivir) and COVID-19 convalescent plasma. However, as additional drug and biological products become available that meet this criterion, cases that use those products would become eligible for the NCTAP if the remaining criteria are met.

Second, the case must also be eligible for the 20 percent increase in the weighting factor for the assigned MS-DRG for an individual diagnosed with COVID-19 discharged during the period of the PHE for COVID-19 under section 3710 of the CARES Act. The primary purposes of this criterion are to help appropriately identify COVID-19 cases to potentially receive the NCTAP, and ensure for program integrity reasons that there is a positive COVID-19 laboratory test documented in the patient’s medical record. CMS may conduct post-payment medical review to confirm the presence of a positive COVID-19 laboratory test and, if no such test is contained in the medical record, the NCTAP will be recouped.

Third, the operating cost of the case must exceed the operating Federal payment under the IPPS, including the add-on payment under section 3710 of the CARES Act. The primary purpose of this criterion is to ensure that the NCTAP is made only when needed. The cost of the case is determined by multiplying the covered charges by the operating cost-to-charge ratio, the same way it is determined for new technology add-on payments and operating outlier payments.

We note that all generally applicable statutory and regulatory requirements during the PHE for Medicare payment for a particular case must continue to be met, and that the NCTAP will only be available to the extent that the new COVID-19 treatment meets all coverage requirements under Medicare, including that the use of a drug or biological product is medically reasonable and necessary for that case. No applicable Medicare requirements during the PHE are being waived by the creation of the NCTAP policy.

6. Determination of the IPPS NCTAP Amount for the Remainder of the PHE

As indicated earlier, the goal of the NCTAP is to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments. These potential financial disincentives are already mitigated in part by the IPPS outlier payment, but we recognize that the costs of a case must exceed

payments by the “outlier threshold” or “fixed-loss” amount before outlier payments are made. For FY 2021, the outlier threshold is approximately \$30,000. As discussed previously, the outlier threshold is adjusted to account for local cost variation in determining whether an individual claim is eligible for outlier payments. As a simplified example for purposes of illustration, if the operating costs of a case using a new COVID-19 treatment exceed the operating IPPS payment by \$10,000, there are no Medicare outlier payments made for this case because the costs are less than the outlier threshold.

We believe that in order to further mitigate any potential financial disincentives for hospitals to provide new COVID-19 treatments, the NCTAP, when needed, should function to partially offset costs that exceed the Medicare payment, but are less than the outlier threshold. By partially rather than fully offsetting these costs, we believe that the NCTAP, similar to the new technology add-on payment policy under the IPPS, preserves some of the incentives inherent under an average-based prospective payment system. One way in which the new technology add-on payment policy accomplishes this goal is by making the new technology add-on payment equal to the lesser of: (1) 65 percent of the costs of the new technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

We believe that the new technology add-on payment calculation provides an appropriate conceptual framework for the NCTAP calculation. In the context of the urgency of the PHE for COVID-19, however, and the practical and operational challenges of individually tailoring the payment calculation to each new treatment, we believe the NCTAP calculation should take into account 65 percent of the amount by which the costs of the case exceed the standard DRG payment, without comparison to 65 percent of the costs of the new treatment itself. As part of the approval process for the new technology add-on payment for a given new technology, the claims processing system is modified and tailored to apply the new technology add-on payment for that technology using cost and coding information according to the “lesser of” policy described above. In order to more expeditiously provide payment for cases meeting the previously described criteria in the context of the urgency of the PHE, we believe the NCTAP calculation should take into account 65 percent of the amount by which the costs of the case exceed the standard DRG payment for all cases that qualify

for the NCTAP, without comparison to the costs of the new treatment as under the “lesser of” policy applicable for the new technology add-on payment.

We note that a hospital should not seek additional payment on the claim for drugs or biologicals procured or provided by a governmental entity to a provider at no cost to the provider to diagnose or treat patients with known or suspected COVID-19, as described in the CMS Medicare Claims Processing Manual, Pub. 100-04, Chapter 32, Section 67.

CMS will use ICD-10-PCS procedure codes XW033E5 (Introduction of Remdesivir Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5) and XW043E5 (Introduction of Remdesivir Anti-infective into Central Vein, Percutaneous Approach, New Technology Group 5) to identify cases using remdesivir and ICD-10-PCS procedure codes XW13325 (Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5) and XW14325 (Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5) to identify cases using convalescent plasma. More information on the new procedure codes implemented into the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) in response to the PHE for COVID-19 is available on the CMS website at <https://www.cms.gov/files/document/icd-10-ms-drgs-version-372-effective-august-01-2020.pdf>. CMS will issue additional operational instructions on how eligible cases will be identified, including any new treatments that may become available.

We also considered in the determination of the NCTAP amount that we did not want to inadvertently reduce the IPPS operating outlier payments that the hospital would have otherwise received for a costly COVID-19 case given that these outlier payments already help to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments. Therefore, we do not believe the calculation of the operating outlier payments should be impacted by the NCTAP.

Taking these factors into account, CMS is setting the NCTAP amount for a case that meets the NCTAP eligibility criteria equal to the lesser of: (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment,

including the adjustment to the relative weight under section 3710 of the CARES Act. As with the new technology add-on payment and outlier payments, the costs of the case are determined by multiplying the covered charges by the operating cost-to-charge ratio. In addition, the NCTAP will not be included as part of the calculation of the operating outlier payments.

Returning to our simplified example, if the cost of a case using a new COVID-19 treatment exceeds the operating IPPS payment by \$10,000 and the operating outlier threshold for the case is for purposes of illustration \$30,000, the NCTAP would be \$6,500 (= \$10,000 excess cost \times 0.65). There would be no outlier payments because the excess cost of the case (\$10,000) does not exceed the operating outlier threshold for the case (\$30,000).

As a simplified example of a case that qualifies for an operating outlier payment, if the cost of a case using a new COVID-19 treatment exceeds the operating IPPS payment by \$100,000, the NCTAP would be equal to the maximum NCTAP amount of 65 percent of the operating outlier threshold for the case. In this illustrative example, if the applicable operating outlier threshold for the claim is \$30,000, that amount is \$19,500 (equals first \$30,000 of the excess cost before the operating outlier threshold for the claim is reached \times 0.65). In addition, the case would receive an outlier payment that is calculated the same way it is currently calculated in the absence of the \$19,500 NCTAP, that is, \$56,000 (= (\$100,000 excess cost – \$30,000 outlier threshold for the case) \times the 0.80 outlier marginal cost factor). The combined NCTAP and outlier payment would be \$75,500 (equals the \$19,500 enhanced payment + the \$56,000 outlier payment).

E. Medicare Outpatient Prospective Payment System (OPPS) Separate Payment for New COVID-19 Treatments Policy for the Remainder of the Public Health Emergency (PHE)

1. FDA Coronavirus Treatment Acceleration Program

The FDA has created a special emergency program to facilitate the development of coronavirus therapies, the Coronavirus Treatment Acceleration Program. One aspect of the program is the issuance by the FDA of EUAs during the PHE for COVID-19. On February 4, 2020, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a PHE that has a significant potential to affect national security or the health and

security of United States citizens living abroad, and that involves the virus that causes COVID-19.³¹ On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biologics during the COVID-19 public health emergency, pursuant to section 564 of the FD&C Act, subject to terms of any authorization issued under that section.³² Readers should refer to Section D.3 of this interim final rule with comment period for a full discussion of the Coronavirus Treatment Acceleration Program.

There are currently five drug and biological products with EUAs issued during the PHE for COVID-19. In section “I. Criteria for Issuance of Authorization” of the current letters of authorization for these drug and biological products, the letters for two of the products state that based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in treating COVID-19, and that, when used under the conditions described in the authorization, the known and potential benefits of the product when used to treat COVID-19 outweigh the known and potential risks of such products.³³ Those drug and biological products are COVID-19 convalescent plasma and Veklury (remdesivir).

While COVID-19 convalescent plasma has received an EUA for treating COVID-19 in hospitalized patients, Veklury (remdesivir), as of October 22, 2020, is the only drug or biological product approved by FDA for treating COVID-19. As discussed in Section II.D.3 of this interim final rule with comment period, in order for an item or service to be considered for coverage under Medicare Part A or Part B, the item or service must fall within at least one benefit category established in the Act. Drugs and biologicals are included within several such benefit categories. In general, section 1861(t)(1) of the Act defines drugs and biologicals to include drugs or biologicals approved for inclusion in certain compendia (except

³¹ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. 360bbb-3, February 4, 2020.

³² U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. 360bbb-3, 85 FR 18250 (April 1, 2020).

³³ EUA for remdesivir: <https://www.fda.gov/media/137564/download>; EUA for COVID-19 convalescent plasma: <https://www.fda.gov/media/141477/download>.

for any drugs and biologicals unfavorably evaluated therein) or that are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of a hospital furnishing that drug or biological for use in that hospital. CMS has determined that it is appropriate for CMS to consider drug and biological products which are authorized for emergency use for COVID-19, with letters of authorization, and are used to treat COVID-19 disease, to fall within the drugs and biologicals definition in 1861(t)(1) of the Act for Medicare purposes if they are included or approved for inclusion in the applicable compendia, or when furnished by a specific hospital if approved for use in that hospital by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of that hospital.

2. OPSS Comprehensive-Ambulatory Payment Classification (C-APC) Policy

To date, no drug or biological product has an EUA for the treatment of patients with COVID-19 in the outpatient setting. However, because treatment of COVID-19 is rapidly evolving, we believe it is important to ensure that separate payment is available under the OPSS for new drug and biological products (including blood products) that receive an EUA for treating COVID-19 in the outpatient setting or are approved by the FDA for treating COVID-19 in the outpatient setting, or where a drug or biological product approved under an existing EUA is authorized for use in settings other than the inpatient setting. As part of that process, we expect to include the addition of new codes describing those treatments as soon as practicable, after their availability, to ensure efficient and timely beneficiary access to those treatments. We anticipate that most drugs and biological products authorized for use in treating COVID-19 in the outpatient setting would be separately paid under our standard OPSS payment policy because drugs and biological products are typically assigned separate Ambulatory Payment Classification payment status indicators in the OPSS unless they meet one of the criteria for packaging, which, with the exception of drug or biological products billed with a Comprehensive Ambulatory Payment Classification (C-APC) service, we do not anticipate that drugs or biological products approved or authorized to treat COVID-19 would meet. However, these products could be packaged into a C-APC when provided on the same claim as a C-APC service,

in which case separate payment would not be made for these products.

Under our C-APC policy, which we adopted beginning in CY 2015, we designate a service described by a HCPCS code assigned to a C-APC as the primary service when the service is identified by OPSS status indicator "J1". When such a primary service is reported on a hospital outpatient claim, with certain exceptions, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as "adjunctive services") and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and self-administered drugs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). Thus, under our current policy, payment for drugs or biological products with an emergency authorization or approved to treat COVID-19 in the outpatient setting would be packaged into payment for a primary C-APC service when billed on the same claim as that service.

Currently, there are 67 C-APCs in the CY 2020 OPSS, with payments ranging from approximately \$1,000 to \$37,000. Most C-APCs are for surgical or other intensive procedures, which we would expect most hospital outpatient departments would not perform on a patient that has an active case of COVID-19. However, observation services can also be paid through the "Comprehensive Observation Services" C-APC (C-APC 8011), which packages payment for qualifying extended assessment and management encounters. It is possible that future COVID treatments that are authorized or approved for use in the outpatient setting might be administered to patients under observation while the provider determines if the patient needs to be admitted to the hospital for COVID-19.

3. Separate Payment Under the OPSS for New COVID-19 Treatments for the Remainder of the PHE for COVID-19

Although we do not expect that many beneficiaries would both receive a primary C-APC service and a drug or biological for treating COVID-19, we nonetheless believe that as drugs or biologicals become available and are authorized or approved for the treatment of COVID-19 in the outpatient setting, it would be appropriate to mitigate any potential financial disincentives for hospitals to provide these new treatments during the PHE for COVID-19. Therefore, effective for services furnished on or after the effective date of this rule and until the end of the PHE for COVID-19, CMS is creating an exception to its OPSS C-APC policy to ensure separate payment for new COVID-19 treatments that meet certain criteria. Under this exception, any new COVID-19 treatment that meets the two criteria below will, for the remainder of the PHE for COVID-19, always be separately paid and will not be packaged into a C-APC when it is provided on the same claim as the primary C-APC service. Note that this separate payment will result in an additional copayment of 20 percent of the cost of the new COVID-19 treatment, up to the amount of the inpatient deductible.

CMS has identified two criteria for COVID-19 treatments to receive this exception. First, the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID-19, as indicated in section "I. Criteria for Issuance of Authorization" of the letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19. Because the purpose of this exception is to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments, this criterion expeditiously provides assurance in the context of the urgency of the PHE for COVID-19 that a treatment is new and is used to treat COVID-19 disease during the PHE for COVID-19.

Second, the EUA for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID-19 disease and not limit its use to the inpatient setting.

We note that during the PHE for COVID-19 this new exception to the C-

APC packaging policy would apply to all drug and biological products that meet both of these criteria. As of the date of issuance of this interim final rule there are two drug or biological products that meet the first criterion (Veklury (remdesivir) and COVID-19 convalescent plasma), but neither of these products is authorized or approved for use in the outpatient setting and, as a result, no product meets the second criterion.

We also note that all generally applicable statutory and regulatory requirements for Medicare payment under the OPSS must continue to be met, and that OPSS payment will only be available to the extent that the new COVID-19 treatment meets all coverage requirements under Medicare, including that the use of a drug or biological product is medically reasonable and necessary for the patient. No applicable Medicare requirements during the PHE are being waived by the creation of this C-APC exception.

4. Effects of This Exception on the OPSS Budget Neutrality Calculation

As we noted in Section II.E.2, we believe it would be a fairly rare occurrence that an outpatient department would perform a C-APC procedure on a beneficiary being treated for COVID-19 because most C-APCs are for surgical or other intensive procedures and we would expect most hospital outpatients departments would not perform outpatient surgery on a patient that has an active case of COVID-19. While it is possible that future COVID-19 treatments that are authorized or approved for use in the outpatient setting might be administered to patients under observation while the provider determines if the patient needs to be admitted to the hospital for COVID-19, it is our expectation that this hypothetical situation would not happen frequently. Because we believe a new COVID-19 treatment will rarely be provided on the same claim as a primary C-APC service, we believe new COVID-19 treatments used in the outpatient setting will be separately paid under current policy the vast majority of the time. As a result, we do not believe it is necessary that we make an adjustment to OPSS budget neutrality calculations at this time to account for this new exception, as any budgetary effect of this new exception is likely to be de minimis. If, once new COVID-19 treatments are being provided in the outpatient setting, the claims data indicates that these treatments are being provided on the same claim as a C-APC more frequently than we expected, we can make a

prospective adjustment to the OPSS budget neutrality calculations through future rulemaking.

F. Temporary Increase in Federal Medicaid Funding

1. Background

Section 6008 of the FFCRA, as amended by section 3720 of the CARES Act, provides a temporary 6.2 percentage point increase to each qualifying state and territory's Federal Medical Assistance Percentage (FMAP) under section 1905(b) of the Act ("temporary FMAP increase"). This temporary FMAP increase is effective beginning January 1, 2020 and could extend through the last day of the calendar quarter in which the PHE for COVID-19, including any extensions, terminates, if the state claims the FMAP increase in that quarter (we refer herein to the entire period where the FMAP increase is potentially applicable as the "increased FMAP period").

To qualify for the temporary FMAP increase in a given quarter, states must meet the four conditions described in subsection (b) of section 6008 of the FFCRA during that quarter. Three of these conditions (described at section 6008(b)(1), (2), and (4) of the FFCRA) could extend through the end of the increased FMAP period, if the state claims the increased FMAP through the end of the quarter in which the PHE for COVID-19 ends. They are: (a) The state must maintain eligibility standards, methodologies, or procedures that are no more restrictive than what the state had in place as of January 1, 2020; (b) the state may not charge premiums that exceed those that were in place as of January 1, 2020;³⁴ and (c) the state must cover, without the imposition of cost sharing, testing services and treatments for COVID-19, including vaccines, specialized equipment, and therapies.

The fourth condition, which is described at section 6008(b)(3) of the FFCRA, extends through the last day of the month in which the PHE for COVID-19 ends. This condition provides that a state may not receive the temporary FMAP increase if "the [s]tate fails to provide that an individual who is enrolled for benefits under [the Medicaid state] plan (or waiver) as of the date of enactment of this section [March 18, 2020] or enrolls for benefits

under such plan (or waiver) during the period beginning on such date of enactment [March 18, 2020] and ending the last day of the month in which the [PHE for COVID-19] ends shall be treated as eligible for such benefits through the end of the month in which such emergency period ends unless the individual requests a voluntary termination of eligibility or the individual ceases to be a resident of the State[.]"

The language in section 6008(b)(3) of the FFCRA is somewhat ambiguous. CMS issued guidance on this condition through frequently asked questions (FAQs) posted on Medicaid.gov on April 13, 2020, May 5, 2020, and June 30, 2020.³⁵ However, our existing interpretation (discussed in section II.F.2 of this preamble) is not the only possible interpretation that could be made. As the PHE for COVID-19 continued, and states requested increased flexibility for managing their programs, we revisited our existing interpretation. Seeking to balance the beneficiary protections in our existing interpretation with the state flexibility that could be afforded through an alternative interpretation, this IFC establishes a blended approach as discussed below.

2. CMS's Existing Interpretation of Section 6008(b)(3) of the FFCRA

CMS first provided an interpretation of section 6008(b)(3) for implementation by states through FAQs issued in April 2020. Our most recent interpretation provided that to receive the increased FMAP under the FFCRA, a state must keep beneficiaries enrolled in Medicaid, if they were enrolled on or after March 18, 2020, with the same amount, duration, and scope of benefits. It also provided that states could not subject such beneficiaries to any increase in cost sharing or beneficiary liability for institutional services or other long-term services and supports (LTSS) during this time period. This interpretation

³⁵ See:

- COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies, available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf> (Updated June 30, 2020)

- Families First Coronavirus Response Act—Increased FMAP FAQs available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-faqs.pdf> (Updated April 13, 2020)

- Families First Coronavirus Response Act (FFCRA), Public Law 116-127 Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136 Frequently Asked Questions (FAQs) available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-faqs.pdf> (Posted April 13, 2020)

³⁴ Section 3720 of the CARES Act added a new subsection (d) to section 6008 of the FFCRA in order to provide states which have increased premiums for any Medicaid beneficiaries above the amounts in effect on January 1, 2020, with a 30-day grace period to restore premiums to amounts no greater than those in effect as of January 1 without jeopardizing the state's eligibility for the temporary 6.2 percentage point FMAP increase.

protects both beneficiary eligibility and access to medically necessary services.

Under this interpretation, if a state receives information about a beneficiary's change in circumstances that would make the beneficiary ineligible for Medicaid, the state may not terminate that beneficiary's eligibility until the end of the month in which the PHE for COVID-19 ends, except in cases where the beneficiary voluntarily disenrolls or is no longer a resident of the state. Further, if the state receives information that would make a beneficiary eligible for a different eligibility group with lesser benefits, greater cost sharing, or increased beneficiary liability, the state may not transition that beneficiary to the new eligibility group but must maintain the beneficiary's enrollment in the current eligibility group until the end of the month in which the PHE for COVID-19 ends.³⁶

In protecting access to medically necessary services pursuant to this interpretation, states must maintain current coverage in the state plan, including alternative benefit plans (ABPs), and must also maintain current coverage under any waivers and section 1115 demonstrations. For example, states may not implement any new restrictions such as a reduction in the number of covered visits or a prior authorization requirement. Beneficiary coverage may not be reduced on an individual basis either. For example, if a beneficiary has reached age 21 and would no longer be eligible for the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, the state must continue to provide EPSDT services to the beneficiary when medically necessary, through the end of the month in which the PHE for COVID-19 ends. Further, if a beneficiary is enrolled in a home and community-based services (HCBS) waiver program authorized under section 1915(c) of the Act, and the individual is determined to no longer

meet the level-of-care requirements or other requirements for that waiver, the state must maintain the beneficiary's enrollment in the HCBS waiver. Under this interpretation, states are not required to provide services that do not meet the state plan amount, duration, and scope criteria for a benefit (such as medical necessity). However, as a condition for receiving the temporary FMAP increase, the state must ensure that a beneficiary can continue to access the benefits package that was available to that beneficiary as of March 18, 2020 (or a later date within the PHE) through the end of the month in which the PHE for COVID-19 ends.

States have expressed concern that our existing interpretation of section 6008(b)(3) of the FFCRA makes it challenging for them to manage their programs effectively and still qualify for the increased Federal financial participation, in frustration of one purpose of section 6008 of the FFCRA to provide additional support to state Medicaid programs in their response to the COVID-19 pandemic. States made clear to CMS that this interpretation, coupled with the prohibition on adopting more restrictive eligibility standards, methodologies, or procedures under section 6008(b)(1) of the FFCRA, would impede the routine, orderly transition of beneficiaries between eligibility groups, and could lead to significant backlogs in redeterminations and appeals after the PHE for COVID-19 ends.

States also noted that our existing interpretation severely limits state flexibility to control program costs in the face of growing budgetary constraints and developing fiscal challenges during the emergency period. For example, it freezes post-eligibility treatment-of-income (PETI) calculations for institutionalized beneficiaries regardless of changes in circumstances. States have pointed out that a beneficiary receiving HCBS through a waiver approved under section 1915(c) of the Act who is subject to the PETI rules and who subsequently moves into an institution would be entitled to retain the higher personal needs allowance allowed for individuals participating in the relevant waiver, even though the beneficiary's personal needs would be far lower once in the institution. The aggregate effects of this interpretation could result in a substantial increase in the state Medicaid program's cost for the needed institutional services as beneficiaries are not contributing as much toward the cost of their care as they would be in the absence of the FFCRA 6008(b)(3) requirement.

In practice, the only cost-controlling measure available to states under our existing interpretation is reducing provider rates to the minimum level permitted under section 1902(a)(30)(A) of the Act. Such rate cuts, combined with a substantially lower volume of visits since the beginning of the pandemic,³⁷ could put some providers out of business. This could undermine the solvency of critical provider networks and their ability to serve beneficiaries in the future, particularly in rural areas where health care workforce shortages may already exist.

3. Alternative Interpretation of Section 6008(b)(3) of the FFCRA

CMS's existing interpretation of section 6008(b)(3) of the FFCRA is not the only possible, reasonable interpretation of that provision. The language in this section could also reasonably be interpreted to mean only that states must maintain the enrollment of beneficiaries who enrolled in the state's Medicaid program as of or after March 18, 2020, through the end of the month in which the PHE ends, but not the specific benefits package they were receiving at that time. In other words, under this alternative interpretation, to fulfill the requirement in section 6008(b)(3) of the FFCRA with respect to a beneficiary who becomes ineligible for enrollment in his current Medicaid eligibility group, states would either (a) transition the beneficiary to another group for which he is eligible and enroll him for the benefits provided to that eligibility group, or (b) retain the beneficiary's enrollment in the original eligibility group, if he did not meet the eligibility criteria for any other group, and maintain the benefits provided to that group. Under this alternative interpretation, a state would be required to move a beneficiary who becomes eligible for another Medicaid eligibility group during the period in which section 6008(b)(3) of the FFCRA applies into that new group, no matter how limited the benefits package is for the new group. We refer to this alternative interpretation as the "enrollment interpretation."

Under the enrollment interpretation, states claiming the 6.2 percentage point temporary FMAP increase would be permitted to make programmatic changes, such as changes to the medical necessity criteria or utilization control procedures in determining coverage for benefits; elimination of optional benefits

³⁶ See Question B.12 of the Families First Coronavirus Response Act—Increased FMAP FAQs available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-faqs.pdf>; Question F.27 of the Families First Coronavirus Response Act (FFCRA), Public Law 116-127 Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136 Frequently Asked Questions posted on April 13, 2020, available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-faqs.pdf>; and Questions relating to Continuing Coverage under Section 6008 of the Families First Coronavirus Response Act in the COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf>

³⁷ Source: Ateev Mehrotra et al., *The Impact of the COVID-19 Pandemic on Outpatient Visits: Practices Are Adapting to the New Normal* (Commonwealth Fund, June 2020). <https://doi.org/10.26099/2v5t-9y63>

coverage; increases in cost-sharing responsibilities (except with respect to testing services and treatments for COVID-19 per section 6008(b)(4) of the FFCRA); or changes to the PETI methodology. For example, states would be permitted to establish a limit on the number of visits permitted for a given service and to require a copayment for a service in accordance with Medicaid statute and regulations. These programmatic changes would not jeopardize the state's receipt of the temporary FMAP increase.

In considering this interpretation, we note that Congress expressly conditioned receipt of the temporary FMAP increase on a state's temporarily not implementing "more restrictive" "eligibility standards, methodologies, or procedures" in section 6008(b)(1), on temporarily not imposing higher premiums in section 6008(b)(2), and on covering COVID-19 testing and treatment services without cost-sharing in section 6008(b)(4). However, Congress did not legislate with the same express clarity in section 6008(b)(3) with respect to states' ability or inability to reduce the amount, duration, and scope of benefits other than COVID-19 testing and treatment services or to eliminate optional benefits. Further, while Congress expressly prohibited states from imposing cost sharing on testing services and treatments for COVID-19 in section 6008(b)(4) of the FFCRA, Congress did not expressly provide in section 6008(b)(3) for any limitation on cost sharing, or on states' ability to modify cost sharing or beneficiaries' liability for the cost of other services (*e.g.*, in accordance with the PETI rules set forth in 42 CFR part 435, subpart H, and 42 CFR 435.832 for beneficiaries receiving institutional services or other long-term services and supports who are subject to the PETI rules).

Under the enrollment interpretation, states would be required to make individual beneficiary eligibility changes short of disenrollment from Medicaid entirely. For example, states would be required to make changes to a beneficiary's eligibility to reflect a change in income, or a change related to age, pregnancy status, need for LTSS or other eligibility factors. A change of service, such as moving from participation in an HCBS waiver authorized under section 1915(c) of the Act into an institution or vice versa, would also require a change in eligibility for a beneficiary enrolled in an eligibility group specific to HCBS recipients, such as the group described at 42 CFR 435.217, or an eligibility group for individuals living in an

institution like the special income level group described at 42 CFR 435.236.

The enrollment interpretation would require states to move a beneficiary who loses eligibility under one Medicaid eligibility group and becomes eligible in a second Medicaid eligibility group into the second eligibility group, even if the second eligibility group confers lesser benefits or results in increased financial liability for the beneficiary. However, as with our existing interpretation, under the enrollment interpretation states would not be permitted to terminate a beneficiary's eligibility unless the individual requested such termination or was no longer a state resident. If a beneficiary loses eligibility under one Medicaid eligibility group and is not eligible for another group, in order to claim the temporary FMAP increase, the state must maintain the beneficiary's enrollment in the current group until the end of the month in which the PHE for COVID-19 ends. Like the programmatic changes discussed previously, individual beneficiary eligibility changes would not jeopardize receipt of the temporary FMAP increase.

In most cases, transferring a beneficiary from one eligibility group to another would not result in a significant change in available benefits. With a few exceptions, Medicaid is considered to be minimum essential coverage (MEC) as defined in section 5000A(f) of the Internal Revenue Code of 1986 ("Code") and implementing regulations at 26 CFR 1.5000A-2. Certain Medicaid eligibility groups, however, such as the optional eligibility group for individuals infected with tuberculosis (described at 42 CFR 435.215), provide only limited benefits pursuant to the matter following section 1902(a)(10)(G) of the Act. This optional coverage of tuberculosis and tuberculosis-related services is excepted from the definition of MEC at 26 CFR 1.5000A-2(b)(2)(ii) and transferring a beneficiary from an eligibility group that provides MEC to the eligibility group for individuals infected with tuberculosis would result in a significant reduction in available benefits.

Another example of non-MEC coverage available through Medicaid is the optional eligibility group limited to family planning and related services at 42 CFR 435.214, which also provides only a limited benefits package pursuant to the matter following section 1902(a)(10)(G) of the Act, and which is excluded from MEC at 26 CFR 1.5000A-2(b)(2)(i). If the enrollment interpretation was adopted, following the postpartum period for coverage of pregnant women at 42 CFR 435.116, states that cover the optional family planning group (or that provide family

planning-only coverage through a section 1115 demonstration) would be required to transfer women who do not qualify for a full-benefit Medicaid eligibility group into family planning-only coverage if they meet the eligibility requirements for the family planning-only group or demonstration.

The enrollment interpretation of section 6008(b)(3) of the FFCRA would make it more challenging for some beneficiaries to access medically necessary services, including services related to the COVID-19 pandemic. A beneficiary transferred to the family planning group following the end of her postpartum period would continue to have access to provider visits for family planning and outpatient drugs and supplies related to those visits, but she would no longer have access to testing services and treatment for COVID-19, pursuant to CMS's interpretation of section 6008(b)(4) of the FFCRA, which is discussed above in section II.B. In addition, she would lose access to inpatient and outpatient hospital services, prescription drugs, and other Medicaid-covered services that are unrelated to family planning.

Beneficiaries with certain chronic conditions like diabetes and sickle cell disease are at higher risk for severe illness from the virus that causes COVID-19.³⁸ Under the enrollment interpretation, individuals who lose eligibility for a group that offers MEC may be transitioned to a limited benefit eligibility group, in a state that offers such coverage, in which they would no longer have access to the benefits needed to manage their chronic conditions. Not only would this negatively impact the beneficiary who loses comprehensive Medicaid coverage as a result of this interpretation, but it could also undermine states' COVID-19 response efforts during the public health emergency.

4. Adopting a Blended Approach

As we considered changing our interpretation of section 6008(b)(3) of the FFCRA, CMS examined the implications of both the existing and alternative interpretations on each of the major Medicaid stakeholder groups. Based on that analysis, this IFC adopts a blended approach. It is intended to balance the interests of states, providers, and beneficiaries, without materially undermining their ability to address the challenges presented by COVID-19.

³⁸ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19); People with Certain Medical Conditions; accessed 10/08/2020 at <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

Looking first at states, the circumstances facing each state during the PHE for COVID-19 are different. States have sent a strong message to CMS that they need more flexibility to make choices that meet their unique needs. They have made clear that our existing interpretation of section 6008(b)(3) of the FFCRA has interfered with their ability to implement cost-saving decisions in the face of increasing beneficiary enrollment and declining state revenues. The enrollment interpretation would allow states to impose coverage limitations that reduce spending and allow for better management of state programs during the PHE for COVID-19. More flexibility in managing their programs could help states to stretch scarce financial resources over the long term, including after the PHE for COVID-19 ends, and that could ultimately benefit both providers and beneficiaries. Supporting states and providers fighting the pandemic is consistent with the protections and the various provider relief funds established by Congress in the FFCRA, the CARES Act, and the PPPHCEA.

While the enrollment interpretation of section 6008(b)(3) of the FFCRA may be the preferred option for states, we recognize that it could negatively impact certain provider types. Under the enrollment interpretation, states could eliminate optional benefits. For example, a state could cut its optional dental benefit, and dentists in that state would lose Medicaid reimbursement. CMS's existing interpretation, however, leaves states with little ability to manage program costs other than by cutting provider rates to the fullest extent permitted under section 1902(a)(30)(A) of the Act. We believe such rate cuts represent a far more significant threat to providers and their continued availability to beneficiaries. Under the enrollment interpretation, states may be less likely to reduce provider rates, which could benefit both providers and beneficiaries.

Considering the impact on beneficiaries, our existing interpretation provided the strongest protections for beneficiary access to medically necessary care during the PHE. It ensured that beneficiaries remained enrolled in Medicaid and that no new coverage restrictions were imposed. Every Medicaid beneficiary who had access to MEC and to testing services and treatment for COVID-19 as of or after March 18, 2020 would continue to have access to these services under the existing interpretation. The enrollment interpretation would also protect beneficiary enrollment in Medicaid. At

the same time, it would expand state flexibility to make cost-saving decisions that could reduce beneficiaries' coverage below what they had access to as of or after March 18, 2020. Under the enrollment interpretation, some beneficiaries would be transitioned from MEC to non-MEC coverage, which may not include testing services and treatment for COVID-19 pursuant to CMS's interpretation of FFCRA section 6008(b)(4). Ensuring access to testing and treatment, along with care for the chronic health conditions that place beneficiaries at higher risk for COVID-19, is important for fighting the pandemic.

Seeking to balance the needs of each stakeholder group, both in fighting the pandemic and ensuring long-term program sustainability, this IFC adopts a blended approach to interpreting section 6008(b)(3) of the FFCRA. This blended approach adopts the state flexibility available through the enrollment interpretation—allowing states to make programmatic changes to benefits and cost sharing and to transition individual beneficiaries between eligibility groups with differing benefit packages—while also establishing parameters to prevent beneficiaries from losing access to comprehensive coverage, consistent with our existing interpretation, through the end of the month in which the PHE for COVID-19 ends.

This blended approach is expected to give states more flexibility, beyond what is available under our existing interpretation, to manage their Medicaid programs. This is consistent with section 1902(a)(4) of the Act, which requires the state plan to provide for such methods of administration as are necessary for the proper and efficient operation of the plan. CMS is also exercising its general rulemaking authority under sections 1102 and 1902(a)(19) of the Act to establish parameters under which states must operate when they exercise the flexibility that CMS is providing with respect to compliance with section 6008(b)(3) of the FFCRA.

The parameters established by this IFC will help to ensure that states are determining eligibility, and providing care and services, in a manner that is consistent with the simplicity of administration, as described in section 1902(a)(19) of the Act. Under this blended approach, CMS is giving states a wider degree of flexibility to effectuate enrollment transitions during the PHE for COVID-19, which could decrease backlogs in redeterminations and appeals following the PHE for COVID-19, thereby simplifying state

implementation of the conditions in FFCRA section 6008(b)(3) and administration of the state plan. These parameters are also expected to help ensure that states are determining eligibility, and providing care and services, in a manner that is consistent with the best interests of beneficiaries, as described in section 1902(a)(19) of the Act. That is because CMS is giving states less flexibility to reduce beneficiaries' coverage under this blended approach than might be available to states under the enrollment interpretation, in an effort to help protect beneficiaries' access to potentially necessary medical care during the period in which the FFCRA 6008(b)(3) requirement applies. We therefore believe this blended approach balances the interests of all stakeholders consistent with the statute.

This IFC adds a new subpart G, Temporary FMAP Increase During the Public Health Emergency for COVID-19, to 42 CFR part 433, including a new § 433.400. Section 433.400(a) describes the statutory basis for this provision, while § 433.400(b) provides definitions specific to this subpart. As described in detail below, § 433.400(c) requires states, as a condition for receiving the temporary FMAP increase, to maintain beneficiary enrollment in an eligibility group that provides one of three tiers of coverage through the end of the month in which the PHE for COVID-19 ends, except under the circumstances specified in paragraph (d). This provision generally does not require states to provide the exact same (or greater) amount, duration, and scope of medical assistance, or maintain the cost-sharing or PETI liability for a particular beneficiary at the same (or lower) level that was applicable to the beneficiary as of March 18, 2020 or subsequent date of initial enrollment during the PHE. Section 433.400 is effective immediately upon display of this rule. CMS' previous interpretation, as described in section II.F.2. of this preamble, continues to apply from the beginning of the quarter up to the date that this IFC is displayed.

5. Maintaining Enrollment in the Same Tier of Coverage

As discussed, we believe that interpreting FFCRA section 6008(b)(3) only to require continued enrollment in a state's Medicaid program (even if benefits are strictly limited), could have significant negative consequences for both beneficiaries and efforts to combat the COVID-19 pandemic. Some beneficiaries may transition from medical assistance that qualifies as MEC to non-MEC coverage, and some may even lose access to COVID-19 testing

services and treatment. CMS has not interpreted section 6008(b)(4) of the FFCRA to require state Medicaid programs to cover COVID-19 testing services and treatment for beneficiaries whose Medicaid eligibility is limited by statute or under existing section 1115 demonstration authority to coverage for care and services that are for a specific (non-COVID-19-related) condition, disease or purpose and that would not otherwise include COVID-19 testing and treatment services.

Consistent with the blended approach to interpreting section 6008(b)(3) of the FFCRA that is described above, and consistent with section 1902(a)(4) and (a)(19) of the Act, we are requiring states to ensure that beneficiaries who were validly enrolled for benefits as of or after March 18, 2020 with access to minimum essential coverage retain access to minimum essential coverage, and to ensure that beneficiaries with access to testing services and treatment for COVID-19 maintain access to those services.

We believe it is reasonable to interpret the term “enrolled for benefits” in section 6008(b)(3) to mean validly enrolled, such that those who were erroneously enrolled are not to be considered “enrolled for benefits” for purposes of FFCRA section 6008. Therefore, we define “validly enrolled” at § 433.400(b) to mean that the beneficiary was enrolled in Medicaid based on a determination of eligibility, including during the retroactive eligibility period, and that the beneficiary was not erroneously granted eligibility at the point of application or last redetermination (if such last redetermination was completed prior to March 18, 2020) because of: (1) Agency error; or (2) fraud (as evidenced by a fraud conviction) or abuse (as determined following the completion of an investigation pursuant to 42 CFR 455.15 and 455.16) attributed to the beneficiary or the beneficiary’s representative which was material to the determination of eligibility. Terminating the eligibility of beneficiaries who are not validly enrolled as defined at § 433.400(b) will not impact a state’s ability to claim the temporary FMAP increase. We note that prior to termination, however, the state must complete a redetermination consistent with 42 CFR 435.916 and provide the beneficiary with advance notice and the opportunity for a fair hearing consistent with 42 CFR part 431, subpart E. Additionally, individuals receiving medical assistance during a presumptive eligibility period in accordance with section 1902(a)(47) of the Act and 42 CFR part 435, subpart L,

have not received a determination of eligibility by the state under the state plan and therefore are not considered to be validly enrolled for continuous coverage under section 6008(b)(3) of the FFCRA.

In order to receive the temporary FMAP increase (defined at § 433.400(b)) for any quarter in which it is available, a state must meet the requirements described in paragraph (c). As described in § 433.400(c)(1)(i), for the quarter in which this rule becomes effective, states would be expected to meet the requirements described in § 433.400(c)(2) and (3) only from the date of display through the end of the quarter. CMS’ previous interpretation, as described in section II.F.2. of this preamble and in the FAQs cited therein, continues to apply from the beginning of the quarter up to the date this rule is effective. For all quarters following the effective date of this rule, states would be expected to meet the requirements of § 433.400(c) for the entirety of the quarter in order to claim the temporary FMAP increase.

Section 433.400(c)(2) requires states to maintain the enrollment of all beneficiaries who were validly enrolled on or after March 18, 2020. Paragraphs (c)(2)(i), (ii), and (iii) of 433.400 establish safeguards for the maintenance of enrollment. For beneficiaries who were not validly enrolled during this period, and whom the state is therefore permitted to disenroll, the state must provide advance notice of termination and fair hearing rights in accordance with 42 CFR 435.917 and 42 CFR part 431, subpart E, when terminating coverage.

Consistent with the Secretary’s rulemaking authority under section 1102 of the Act and section 1902(a)(19) of the Act, which provides for such safeguards as are needed to ensure that care and services are provided in a manner consistent with the best interests of beneficiaries, § 433.400(c)(2) establishes three tiers of Medicaid coverage. These coverage tiers will help to ensure that beneficiaries protected under section 6008(b)(3) of the FFCRA in states claiming the temporary FMAP increase, who no longer meet eligibility requirements for the initial eligibility group in which they are enrolled but who become eligible under a different eligibility group or who lose Medicaid eligibility entirely, do not experience a reduction in covered benefits that would be inconsistent with section 1902(a)(19) of the Act, or with our interpretation of sections 6008(b)(3) and (4) of the FFCRA.

The first tier of coverage, under paragraph (c)(2)(i) of § 433.400, consists

of Medicaid coverage that meets the definition of MEC, as defined in section 5000A(f) of the Code and implementing regulations at regulation at 26 CFR 1.5000A-2. Under § 433.400(c)(2)(i)(A), for beneficiaries whose Medicaid coverage as of or after March 18, 2020 meets the definition of MEC, the state must generally continue to provide Medicaid coverage that meets the definition of MEC throughout the period in which this rule applies. This means that if a state determines a beneficiary ineligible for the group in which he or she is currently enrolled, which provides MEC, and finds the beneficiary eligible for another group that also provides MEC, the state would transition the beneficiary to the new eligibility group. In contrast, if the beneficiary lost eligibility for a group that provides MEC, but gained eligibility for coverage that does not meet the definition of MEC, the state may not move the beneficiary to the new group or demonstration but must instead maintain the beneficiary’s access to coverage meeting the definition of MEC during the period in which the rule applies, except as discussed below.

For example, the state must transition a beneficiary enrolled in the eligibility group for children under age 19 at 42 CFR 435.118 to the adult group described at 42 CFR 435.119 when the beneficiary reaches age 19, provided that the state covers this group and the beneficiary meets the eligibility requirements of the group. That is because the medical assistance provided under the eligibility group for children under age 19 includes full state plan benefits with no cost sharing, which meets the definition of MEC, and the medical assistance offered under the adult group may include a somewhat different set of benefits through the state’s ABP, and may include cost sharing for certain services, but it also meets the definition of MEC. This transition would therefore be permissible under § 433.400(c)(2)(i).

In contrast, a state may not transition a beneficiary from the eligibility group for children under age 19 or the adult group, both of which provide MEC, to a limited benefit group that does not provide MEC, such as the family planning group at 42 CFR 435.214, which covers only family planning and family planning-related services. As described further in § 433.400(c)(2)(iv), if a beneficiary receiving tier 1 coverage no longer meets the eligibility requirements for the original group in which he or she was enrolled, and the beneficiary does not meet the requirements for any other eligibility groups with tier 1 coverage, the state

must continue to provide the medical assistance offered under the eligibility group in which the beneficiary was eligible on or after March 18, 2020.

At § 433.400(c)(2)(i)(B), we establish a variation on this requirement for beneficiaries who have coverage meeting the definition of MEC as of or after March 18, 2020, and whom the state subsequently determines are eligible for coverage under a Medicare Savings Program eligibility group. The Medicare Savings Program is defined at § 433.400(b) to include the eligibility groups described at section 1902(a)(10)(E)(i), (iii), and (iv) of the Act. For such beneficiaries, the state satisfies the requirement described in paragraph (c)(2) of this section if it furnishes the medical assistance available through the Medicare Savings Program, because the coverage that beneficiary receives under the Medicare program qualifies as MEC. Thus, for example, a beneficiary enrolled in the adult group as of or after March 18, 2020, may be transitioned to a Medicare Savings Program eligibility group, such as the qualified Medicare beneficiaries (QMB) group described at section 1902(a)(10)(E)(i) of the Act, when the beneficiary reaches age 65, if the beneficiary meets the eligibility requirements of the QMB group. Such a beneficiary would receive Medicaid coverage of Medicare premiums and Medicare-related cost sharing through the QMB group. However, unless that beneficiary was also eligible for another full-benefit Medicaid eligibility group, all of the beneficiary's health care services would be provided through Medicare and the beneficiary would not receive any other Medicaid covered services. While the medical assistance provided under the adult group differs from the medical assistance provided under the QMB group, the beneficiary maintains access to MEC. Therefore, the state may transition the beneficiary from the adult group to a Medicare Savings Program group.

The second tier of coverage, which is described at § 433.400(c)(2)(ii), consists of coverage that is not defined as MEC but that is robust enough to include access to coverage of both testing services and treatment for COVID-19 under CMS's interpretation of FFCRA section 6008(b)(4). Not all Medicaid coverage qualifies as MEC, and the non-MEC coverage provided to beneficiaries can vary greatly. As noted previously, some beneficiaries' coverage is limited by statute or existing section 1115 demonstration authority to a very narrow range of services that would not include COVID-19 testing or treatment services, and CMS has not interpreted

section 6008(b)(4) of the FFCRA to require states to cover COVID-19 testing and treatment services for those beneficiaries. However, other Medicaid beneficiaries receive a relatively robust set of benefits, such as pregnancy-related services described in the matter following section 1902(a)(10)(G) of the Act, which would include testing services and treatment for COVID-19, including vaccines, specialized equipment, and therapies, during the period when FFCRA section 6008(b)(4) applies in a state, but which does not qualify as MEC in all states.

Section 433.400(c)(2)(ii) of this IFC provides that states must continue to provide Medicaid coverage that includes coverage of COVID-19 testing services and treatments, including vaccines, specialized equipment, and therapies, to beneficiaries who had access to coverage in tier 2 as of or after March 18, 2020. Thus, states must transition beneficiaries who lose eligibility for tier 2 coverage but gain access to MEC coverage in tier 1 or to other coverage in tier 2 to the new eligibility group or demonstration, but they may not transition such beneficiaries to coverage that does not include access to testing services and treatment for COVID-19. This interpretation is consistent with the requirement for states claiming the temporary FMAP increase to provide coverage for testing services and treatments for COVID-19, as described at section 6008(b)(4), and with CMS's interpretation of that requirement.

Consistent with § 433.400(c)(2)(ii), a state must transition a beneficiary from tier 2 coverage to tier 1 coverage if that beneficiary becomes eligible for coverage that qualifies as MEC. For example, a state must transition a woman receiving tier 2 postpartum coverage under the pregnant women group described at 42 CFR 435.116 (in a state in which such coverage is not considered MEC) to the adult group described at 42 CFR 435.119 at the end of the postpartum period, because coverage under the adult group qualifies as MEC and is therefore included in tier 1. If this postpartum beneficiary was not eligible for any eligibility groups with tier 1 coverage, such as in a state that does not cover the adult group, but was eligible for tier 2 coverage, such as through a limited benefit section 1115 demonstration providing non-MEC coverage that includes access to testing services and treatment for COVID-19, the state must move her to that coverage. If such a beneficiary is not eligible for any other tier 1 or tier 2 coverage, the state must continue to provide the medical assistance available

through the pregnant women group until the end of the month in which the PHE for COVID-19 ends, in order to qualify for the temporary FMAP increase, as described at § 433.400(c)(2)(iv). For example, a woman receiving non-MEC pregnancy related coverage that includes coverage of testing services and treatments for COVID-19 could not be transitioned to coverage of only family planning services at the end of the postpartum period.

The third tier, described at § 433.400(c)(2)(iii), includes coverage that is not MEC and that also does not cover testing services and treatment for COVID-19, including vaccines, specialized equipment, and therapies, under CMS's interpretation of FFCRA section 6008(b)(4). Coverage under tier 3 may include coverage for the eligibility group limited to family planning described at 42 CFR 435.214 or the eligibility group for individuals with tuberculosis described at 42 CFR 435.215. Coverage through an existing family planning demonstration or other limited benefit section 1115 demonstration may also be included in tier 3 if it does not cover COVID-19 testing and treatment. If a beneficiary loses eligibility for coverage meeting the tier 3 description during the period in which the FFCRA section 6008(b)(3) requirement applies, and the beneficiary gains eligibility for a group that provides coverage in tier 1 or tier 2, then, under § 433.400(c)(2)(iii), the state must transfer the beneficiary into that new eligibility group as coverage in those tiers is more robust than coverage in tier 3.

The coverage in tier 3 differs from the coverage in tier 1, which is always considered MEC and the coverage in tier 2, which always includes testing services and treatment for COVID-19. The coverage available to a beneficiary in tier 3 is more limited and may vary widely from one group or demonstration to the next. Coverage limited to family planning and family planning-related services is significantly different from coverage in a limited-benefit section 1115 demonstration that focuses, for example, on preventing the progression of a specific disease. Therefore, the requirement in § 433.400(c)(2)(iii) for tier 3 coverage differs somewhat from the requirements in § 433.400(c)(2)(i) and (ii) for tiers 1 and 2. If a beneficiary becomes ineligible for the tier 3 eligibility group or demonstration in which he or she is enrolled and becomes eligible for another eligibility group or demonstration with coverage that is also within tier 3, the state must continue to provide the coverage

available through the eligibility group or demonstration for which the beneficiary was eligible as of or after March 18, 2020, unless the beneficiary requests a voluntary termination to transition to the new eligibility group or demonstration, as discussed below. Transitioning a beneficiary from one eligibility group offering tier 3 coverage to another eligibility group offering tier 3 coverage would not satisfy the requirement in § 433.400(c)(2)(iii).

We note that beneficiaries enrolled in certain limited-benefit state plan eligibility groups may be eligible for coverage in the optional COVID-19 testing group authorized under section 1902(a)(10)(A)(ii)(XXIII), and such individuals can be enrolled in both limited benefit groups. Section 3716 of the CARES Act amended section 1902(ss) of the Act to establish that individuals eligible for certain optional eligibility groups, such as the eligibility group limited to family planning and related services described at 1902(a)(10)(A)(ii)(XXI) of the Act, are considered “uninsured” for purposes of eligibility under the optional COVID-19 testing group and therefore may obtain COVID-19 testing coverage under that group in addition to coverage under the other optional eligibility group.

In addition, beneficiaries in each benefit tier retain the right to request a voluntary transition to a different eligibility group (provided that they meet the applicable eligibility requirements), even if such transition results in a change in the individual’s benefit package that would not otherwise satisfy the conditions of this rule, such as a transition from an eligibility group with coverage in tier 1 to an eligibility group with coverage in tier 3 or a transition from one tier 3 group to another tier 3 group. Such a transition is permissible under the exception at § 433.400(d)(1)(i), as described at § 433.400(d)(3)(i), in which a beneficiary may request a voluntary termination of eligibility, and would not impact the state’s ability to claim the temporary FMAP increase.

Section 42 CFR 430.400(c)(2)(iv) specifies that for any beneficiary who is validly enrolled and receiving medical assistance on or after March 18, 2020, and who is determined ineligible for Medicaid prior to the last day of the month in which the PHE for COVID-19 ends, except as provided in paragraph (d), a state meets the requirements of § 430.400(c)(2)(i), (ii), or (iii) by continuing to provide the same coverage that the individual would have received absent the determination of ineligibility. For example, if a beneficiary is enrolled in the age and

disability-related poverty level group described at section 1902(a)(10)(A)(ii)(X) of the Act, and the beneficiary reports a change in resources that would result in ineligibility for this group, if the beneficiary is not eligible for coverage in any other Medicaid eligibility group, the state would continue to provide that individual with the coverage available to beneficiaries enrolled in the age and disability-related poverty level group.

The requirement at § 430.400(c)(2)(iv) also applies in cases where a state finds a beneficiary ineligible on a procedural basis, such as a failure to respond to a request for additional information, with an exception related to residency described at § 430.400(d)(3). For example, if a state receives information from quarterly wage data, which indicates that a child’s household income exceeds the income standard for the eligibility group for children under age 19 (described at 42 CFR 435.118), the child is not eligible on another basis, and the beneficiary’s family does not respond to a request from the state for additional information, the child may be determined ineligible on a procedural basis. In this case, through the end of the month in which the PHE for COVID-19 ends, the state would continue to provide the child with the same coverage provided to beneficiaries enrolled in the eligibility group for children under age 19. If the beneficiary is subsequently determined eligible for a different eligibility group that provides the same tier of coverage, in this case tier 1, the state would transfer the beneficiary to the new eligibility group.

CMS is available for technical assistance to help states ensure that all beneficiaries retain coverage in either the same tier or in a more robust tier of coverage when their eligibility changes in a manner that would ordinarily result in a transition between eligibility groups.

6. Changes to Benefits, Cost Sharing, and PETI

Section 433.400 of this IFC allows states, during the period when section 6008(b)(3) of the FFCRA applies, to move a beneficiary from one eligibility group to another when the beneficiary becomes ineligible for one group and eligible for another group, as long as the coverage provided under the new group is within the same tier of coverage (applicable to tier 1 and tier 2 coverage only) or a beneficiary may also be moved to a more generous tier of coverage than the coverage available to the beneficiary on or after March 18, 2020. Section 433.400(c)(3) specifies

that states may make programmatic changes to coverage, cost sharing, and beneficiary liability without violating the requirements for receiving the temporary FMAP increase, provided that such changes do not violate the individual beneficiary protections at § 433.400(c)(2) or the requirements under section 6008(b)(4) of the FFCRA to cover COVID-19 testing and treatment services without cost-sharing.

As described at § 433.400(c)(3), states may generally make changes to benefits offered under the state plan (as allowed under relevant provisions of the Act) or a section 1115 demonstration. For example, section 6008(b)(3) of the FFCRA does not prohibit a state from eliminating an optional benefit from its state plan. Therefore, a state could eliminate dental services for individuals age 21 and above, and still comply with section 6008(b)(3) of the FFCRA. Note that under section 1905(r)(5) of the Act, as part of the mandatory EPSDT benefit, states must provide beneficiaries under age 21 with all necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act, to correct or ameliorate defects and physical and mental illnesses and conditions discovered by EPSDT screening services, whether or not such services are covered under the state plan. However, states need not maintain EPSDT benefits for beneficiaries who turn 21 in order to comply with the terms of section 6008(b)(3) of the FFCRA.

Additionally, states are permitted to change the scope of benefits provided to beneficiaries without violating the requirements of section 6008(b)(3) for claiming the temporary FMAP increase, as long as they comply with otherwise applicable Medicaid law, including section 6008(b)(4) of the FFCRA. For example, section 6008(b)(3) of the FFCRA does not prohibit states from applying service authorization criteria, including for services authorized under section 1915(c) of the Act, in determining the amount, duration, or scope of coverage a beneficiary is entitled to receive under the state’s program. Section 440.230(b) still applies as a limit on state flexibility. That regulation requires that each Medicaid service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

In considering optional changes to coverage, states may wish to avoid service authorization changes that lead to more individuals being placed in institutional or congregate settings, as these settings have had a disproportionate share of COVID-19 cases and deaths. We also note that

regardless of the flexibility provided at § 433.400(c)(3), states retain their obligations to provide services and supports in the “most integrated setting” under the integration mandate of Title II of the Americans with Disabilities Act (ADA), as interpreted by the Supreme Court in *Olmstead v. L.C.*, 527 U.S. 581 (1999) (hereafter “*Olmstead*”),³⁹ to avoid unjustified institutionalization or segregation. If the elimination of an optional benefit results in or places an individual with a disability at risk of unjustified institutionalization or segregation, it may be a violation of the state’s obligations under the ADA and *Olmstead*.⁴⁰ States’ *Olmstead* obligations do not confer Medicaid authority or create Medicaid obligations where they do not otherwise exist; states may choose to (and in some cases would be required to) use funds outside of or in addition to Medicaid to comply with *Olmstead* responsibilities.

Finally, states may generally establish or increase cost sharing (consistent with sections 1916 and 1916A of the Act, implementing regulations at 42 CFR 447.50 through 447.90, and the state plan), and increase beneficiary obligations under the PETI rules, and still comply with FFCRA section 6008(b)(3). However, states should also comply with FFCRA 6008(b)(4) if they are claiming the temporary FMAP increase. For example, a state may increase the liability of individuals receiving Medicaid coverage for institutional services under the state plan through otherwise permissible reductions in their standard personal needs allowances or family allowances. In addition, they may transfer a beneficiary from one program furnishing HCBS (for example, a waiver program authorized under section 1915(c) of the Act) to another as a beneficiary’s health status and level of care changes.

Prior to reducing benefits or increasing cost sharing or beneficiary liability a state must provide proper advance notice and comply with other applicable statutory and regulatory requirements. In particular, the advance notice requirements that apply under 42

CFR 431.211 preclude states from reducing benefits or increasing cost sharing or beneficiary liability retroactively. Additionally, 42 CFR 440.230(b) limits states’ flexibility to reduce the amount, duration, or scope of benefits; that regulation requires that each Medicaid service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

7. Exceptions to Maintaining Enrollment

Section 433.400(d) of this IFC describes the exceptions to the continuous enrollment requirement in § 433.400(c)(2). Section 6008(b)(3) of the FFCRA specifies that a beneficiary’s Medicaid enrollment may be terminated if the beneficiary requests a voluntary termination of eligibility or the beneficiary is no longer a resident of the state. These exceptions are described in § 433.400(d)(1)(i) and (ii). Because a beneficiary who dies is no longer a state resident, § 433.400(d)(1)(iii) also provides an exception for deceased beneficiaries.

Section 433.400(d)(2) provides that states that have elected the option under section 1903(v)(4) of the Act to provide coverage to certain lawfully residing children and/or pregnant women, must limit the provision of services for these beneficiaries to services necessary for treatment of an emergency medical condition, as defined in section 1903(v)(3) of the Act, when they no longer meet the criteria at section 1903(v)(4) of the Act. This is because section 1903(v) of the Act prohibits the provision of FFP for otherwise eligible non-citizens who are not in a satisfactory immigration status, except as provided under paragraphs (2) (authorizing FFP for services necessary to treat an emergency medical condition) and (4) (relating to coverage of certain lawfully residing children and/or pregnant women) of section 1903(v) of the Act.

Finally, § 433.400(d)(3) clarifies the exceptions at § 433.400(d)(1). As noted above, § 433.400(d)(1)(i) provides an exception for beneficiaries who request a voluntary termination. Section 433.400(d)(3)(i) provides that this exception applies not only to beneficiaries who request that their Medicaid coverage be terminated in its entirety, but also to beneficiaries who request a voluntary transition to a different eligibility group (provided that they meet the applicable eligibility requirements), even if such transition results in a change in the individual’s benefit package that would not otherwise satisfy the conditions of § 433.400(c)(2). For example, a state may transition a beneficiary from an

eligibility group with coverage in tier 1 to an eligibility group with coverage in tier 3, at the beneficiary’s request. Such a transition would not impact the state’s ability to claim the temporary FMAP increase because the change resulted from a beneficiary request for voluntary termination from the original eligibility group.

Additionally, as described at § 433.400(d)(3)(ii), individuals who are identified as receiving benefits in more than one state via a data match with the Public Assistance Reporting Information System (PARIS) interstate matching service in accordance with § 435.945(d) and who fail to respond to a request for information to verify their residency in the reasonable period permitted by the state, consistent with § 435.952(c)(2)(iii), are generally considered to no longer be residents of the state for purposes of section 6008(b)(3) of the FFCRA, provided that the state takes all available reasonable measures to determine state residency prior to termination. These measures include, but are not limited to, reviewing existing information in the beneficiary’s record to validate state residency, checking available state electronic data sources such as the Department of Motor Vehicles records or other state benefit programs, and coordinating with agencies in the other state(s) in which the PARIS interstate match identified the beneficiary as receiving benefits to determine the state in which the individual is a resident for purposes of Medicaid eligibility. If the state is unable to verify the beneficiary’s continued residency in the state because the beneficiary fails to respond to requests for additional information and the state’s alternative efforts cannot verify the beneficiary’s continued residency in the state through other sources, that beneficiary’s Medicaid enrollment may be terminated in accordance with § 435.400(d)(1)(ii). Such an individual will be considered a non-resident for purposes of section 6008(b)(3) of the FFCRA until such time as the state has information verifying residency. If, after termination, the state obtains information that verifies residency, the state must reinstate the individual’s eligibility back to the date of termination.

G. Updates to the Comprehensive Care for Joint Replacement (CJR) Model, Performance Year (PY) 5 During the COVID-19 Public Health Emergency (PHE)

1. Background

Under the authority of section 1115A of the Act, through notice-and-comment

³⁹ Under title II of the ADA and *Olmstead*, the unjustified isolation of individuals with disabilities constitutes unlawful discrimination. States are required to provide community-based treatment where such treatment would be appropriate, the affected person does not oppose such treatment, and the treatment can be reasonably accommodated.

⁴⁰ See DOJ’s Statement of the Department of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and *Olmstead v. L.C.*, Question 9, updated February 25, 2020, available at: https://www.ada.gov/olmstead/q&a_olmstead.htm.

rulemaking, the Innovation Center established the CJR model in a final rule titled “Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services” published in the November 24, 2015 **Federal Register** (80 FR 73274) (referred to as the “November 2015 final rule”). The CJR model, which was implemented on April 1, 2016, aims to support better and more efficient care for beneficiaries undergoing the most common inpatient surgeries for Medicare beneficiaries: Hip and knee replacements (also called lower extremity joint replacements or LEJR). This model tests bundled payment and quality measurement for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization through recovery. All related care covered by Medicare Parts A and B within 90 days of hospital discharge from the LEJR procedure is included in the episode of care. During the first CJR model performance period, the CJR model required hospitals located in the 67 MSAs selected participation to participate in the model through December 31, 2020 unless the hospital was an episode initiator for an LEJR episode in the risk-bearing phase of Models 2 or 4 of the Bundled Payments for Care Improvement (BPCI) initiative. Hospitals located in one of the 67 MSAs that participated in Model 1 of the BPCI initiative, which ended on December 31, 2016, were required to begin participating in the CJR model when their participation in the BPCI model ended.

In the December 1, 2017 **Federal Register**, we published another final rule (82 FR 57066), titled “Medicare Program; Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model: Extreme and Uncontrollable Circumstances Policy for the Comprehensive Care for Joint Replacement Payment Model” (referred to as the “December 2017 final rule”), that implemented revisions to the CJR model, including giving rural and low volume hospitals selected for participation in the CJR model as well as those hospitals located in 33 of the 67 metropolitan statistical areas

(MSAs)⁴¹ a one-time option to choose whether to continue their participation in the model through December 31, 2020 (that is, continue their participation through PY5). An interim final rule with comment period was also issued in conjunction with the December 2017 final rule (82 FR 57092) in order to address the need for a policy to provide some flexibility in the determination of episode costs for providers located in areas impacted by extreme and uncontrollable circumstances. This extreme and uncontrollable circumstances policy was adopted as final in the final rule (83 FR 26604) we published in the June 8, 2018 **Federal Register**, titled “Medicare Program; Changes to the Comprehensive Care for Joint Replacement Payment Model (CJR): Extreme and Uncontrollable Circumstances Policy for the CJR Model.”

In the February 24, 2020 **Federal Register** (85 FR 10516), we published the proposed rule titled “Medicare Program; Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing” (hereinafter referred to as the “February 2020 proposed rule”). Among other changes, this proposed rule proposed to add three additional performance years to the CJR model (*i.e.*, performance years 6 through 8).

In the April 6, 2020 **Federal Register** (85 FR 19230), we published an interim final rule with comment period (IFC) titled “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (hereinafter referred to as the “April 2020 IFC”). In the April 2020 IFC, to account for the impact of the PHE for COVID-19 on CJR participant hospitals, we extended PY5 through March 31, 2021, and adjusted the extreme and uncontrollable circumstances policy to account for COVID-19 by specifying that all episodes with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs through the termination of the emergency period (as described in section 1135(e) of the Act), actual episode payments are capped at the

target price determined for that episode under § 510.300.

Additionally, in the May 29, 2020 **Federal Register** (85 FR 32460), CMS published a proposed rule titled “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promotion Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals: (hereinafter referred to as the FY 2021 IPPS/LTCH proposed rule). In the FY 2021 IPPS/LTCH proposed rule (85 FR 32510), we solicited comment on the effect of the proposal to create new MS-DRG 521 and MS-DRG 522, the effect this proposal would have on the CJR model and whether to incorporate MS-DRG 521 and MS-DRG 522, if finalized, into the CJR model’s proposed extension to December 31, 2023.

Through this IFC we are implementing four changes to the CJR model. These are: (1) Extending performance year 5 an additional 6 months to provide for continuity of model operations with the same scope while we continue to consider comments received on our proposal to extend the model to performance years 6 through 8 and adopt other changes to the model; (2) making changes to the reconciliation process for PY5 to allow for two periods and to enable more frequent receipt of reconciliation reports by participants; (3) making a technical change, retroactive to October 1, 2020, to ensure that the model continues to include the same inpatient Lower Extremity Joint Replacement (LEJR) procedures, despite the adoption of new MS-DRGs to describe those procedures; and (4) making changes to the extreme and uncontrollable circumstances policy for COVID-19 to adapt to an increase in CJR episode volume and renewal of the PHE, while providing protection against financial consequences of COVID-19 after the extreme and uncontrollable circumstances policy no longer applies.

2. Extension of Performance Year 5 to September 30, 2021

We are implementing a 6-month extension to CJR performance year (PY) 5 such that the model will now end on September 30, 2021. In the February 2020 proposed rule, we proposed to extend the CJR model by adding three performance years (PY6 through 8), from January 1, 2021 to December 31, 2023, to revise target prices, to change the definition of an episode of care to

⁴¹ Metropolitan Statistical Area (MSA) means a core-based statistical area associated with at least one urbanized area that has a population of at least 50,000. MSAs included in the CJR model are available in the December 2017 final rule available at <https://www.federalregister.gov/documents/2017/12/01/2017-25979/medicare-program-cancellation-of-advancing-care-coordination-through-episode-payment-and-cardiac>.

include outpatient procedures for Total Knee Arthroplasty and Total Hip Arthroplasty, as well as to revise other sections of 42 CFR part 510.⁴² In response to the PHE for COVID-19, in the April 2020 IFC we extended PY 5 an additional 3 months to end on March 31, 2021 rather than on December 31, 2020 as finalized in November 2015 final rule.

While we continue to consider the addition of performance years to the model and other changes proposed in the February 2020 proposed rule, we also do not want to create a disruption to the model by allowing the model to end on March 31, 2021, which could be disruptive to hospitals and patient care during the PHE if it is still ongoing at that time. Implementing an additional six months of PY5, so that PY5 now ends on September 30, 2021, provides participant hospitals additional relief

and stability in model operations. In the event the three-year extension is finalized, participant hospitals would be in a worse position if PY 5 was not extended to September 30, 2021 because participant hospitals would have made operational choices in reliance on the model ending on March 31, 2021 and then have to adjust to model changes on top of the significant burden of managing COVID-19 treatment and under COVID-19 safety protocols and utilization changes. Overall, this means a nine-month extension from the original conclusion of the model as finalized in the November 2015 final rule (80 FR 73274), which had established that the model would end on December 31, 2020 with no new episodes initiating after October 4, 2020.

We received several comments on the April 2020 IFC supporting the policy to extend PY5 an additional three months

and asking that we extend PY5 by 12 months instead, not just the 3 months in the April 2020 IFC. In addition, commenters noted that though state and local guidelines have laid out a process for regions and facilities to determine when to re-open elective procedures, the progression of COVID-19 could impact elective procedures well into 2021. We appreciate commenters' request to extend PY 5 by 12 additional months because of the impact COVID-19 has had on LEJR procedures. We observe that COVID-19 has had an impact on CJR procedures from February 2020 to August 2020. Table 1 depicts recent Medicare claims data comparing February to August of 2019 and February to August of 2020. These numbers reflect episode volume for each month, accounting for any CJR episode that began within that month.

TABLE 1—CJR EPISODE VOLUME COMPARISON

	February	March	April	May	June	July	August
2019	6214	6174	6515	6019	5836	6060	5838
2020	5245	3374	876	2242	4036	3838	3090

In light of these data, we believe providing an additional 6 months beyond what we adopted in the April 2020 IFC provides participant hospitals relief from COVID-19 challenges. Therefore, we are implementing an additional 6-month extension of CJR PY 5 and amending the provisions at 42 CFR 510.2 and 510.200(a) to reflect this extension.

We note that in our February 2020 proposed rule to extend and modify the CJR model through PYs 6 to 8 (CMS-5529-P), we proposed PY 6 would comprise all CJR episodes ending on or after January 1, 2021 and on or before December 31, 2021. However, since we are amending PY 5 such that it comprises all CJR episodes ending on or after January 1, 2020 and on or before September 30, 2021, we seek comment on the duration of PY 6, if finalized. In particular, we seek comment on the potential for PYs 6 through 8 to remain 12-month performance years and each begin with episodes ending on or after October 1 each year. We also seek comment on increasing the duration of proposed PY 6 to 15 months. Under this alternative, PY 6 would comprise all CJR episodes ending on or after October 1, 2021 and on or before December 31, 2022; PY 7 and PY 8 would remain 12 months and each begin with episodes

ending on or after January 1, 2023 or January 1, 2024, respectively.

3. Additional Reconciliations for Performance Year 5

Currently, following the end of each performance year, CMS determines actual episode payments and calculates the amount of a reconciliation payment or repayment amount, as described in 42 CFR 510.305. Each performance year is reconciled twice. The first reconciliation calculation process begins after a 2-month period of claims runoff, while the final reconciliation calculation process begins after a 14-month period of claims runoff. The initial reconciliation of a given performance year is conducted concurrently with the final reconciliation of the previous performance year, and the resulting amounts are netted against one another for one annual reconciliation payment or repayment amount, as set forth in 42 CFR 510.305. The initial reconciliation process typically begins in late February of the calendar year following the performance year, with reports and reconciliation amounts issued in June. Final reconciliation for the performance year is issued the following June.

Absent modification to the reconciliation process, the extension of

PY 5 to a total of 21 months, from January 1, 2020 through September 30, 2021 would mean that participant hospitals would experience a 21-month gap between the PY4 final reconciliation in June of 2020 and initial PY 5 reconciliation in early 2022. We believe this significant gap is problematic because participant hospitals gain important feedback from their annual reconciliation reports that they can use to gauge their quality performance and efforts at cost-savings. These annual reports also facilitate the relationships that participant hospitals have established with clinicians and other entities with whom they coordinate care and/or have gainsharing arrangements. Further, not having an initial reconciliation for PY5 until early 2022 is not consistent with the model design goal of reconciling one time a year and netting against final reconciliation amounts from the prior year. Therefore, we believe there is good cause to conduct two initial, and two final, reconciliations of PY5. The first initial reconciliation will apply to the first 12 months of PY5 in order to maintain consistency with the 12 month reconciliation cycles for previous PYs 2-4 (we note that PY 1 was 9 months rather than 12 months), and the second initial reconciliation will apply to the

⁴² For proposed changes to the CJR Model in "Medicare Program: Comprehensive Care for Joint

Replacement Model Three Year Extension and

Changes to Episode Definition and Pricing" See 85 FR 10516.

remaining 9 months of PY5. To minimize confusion, we will refer to these two subsets of PY5 as performance year subset 5.1 and 5.2, respectively.

The initial reconciliation of performance year subset 5.1 will occur fourteen months after the start of PY5, which is the same timeline as would have occurred PY5 under the December 2017 final rule. After the usual 2-month period of claims runout, the initial reconciliation for performance year subset 5.1 episodes will begin in late February of 2021 using 12 months of claims from CY 2020 to calculate reconciliation payments, with the resulting amounts netted against the results of the concurrent PY4 final reconciliation calculation when we issue reports and reconciliation amounts to participants in June 2021. Participants can expect to receive their 2021 reconciliation reports on approximately the same schedule as in previous model years.

The nine additional months of PY 5 (performance year subset 5.2) will be reconciled one full calendar year after the reconciliation of PY 4 final/ performance year subset 5.1 initial. We will use claims data for the initial reconciliation of performance year subset 5.2 that reflect a 2-month period of claims runout (as set forth in 42 CFR 510.305(e)(1)(i)), as we have for PY 1–4 and performance year subset 5.1. In short, performance year subset 5.2 will run from January 1, 2021 through September 30, 2021. Consistent with using two months of claims run out, we will pull claims for the initial reconciliation in December 2021. However, we will not reconcile performance year subset 5.2 until late February 2022 along with the final reconciliation for performance year subset 5.1. This means that we will not begin reconciliation calculation for performance year subset 5.2 until five months after the end of performance year subset 5.2 in order to align the

initial reconciliation calculation for performance year subset 5.2 with the timing of the subsequent reconciliation calculation for performance year subset 5.1. While alignment with the performance year subset 5.1 subsequent reconciliation calculation is the primary reason for this delay in the performance year subset 5.2 initial reconciliation, it is also necessary to allow time to receive certain input files to perform the initial reconciliation calculation, including standardized claims files and quality data. These data are generally not available more than a few weeks prior to the usual reconciliation process start date in late February. Therefore, the reconciliation process will occur on the same schedule as PY 1 through 4 and performance year subset 5.1, with the reconciliation report available one year after the reports from the previous year's reconciliation.

We note that, as part of the separate reconciliation calculation processes for performance year subsets 5.1 and 5.2, we will calculate a separate Composite Quality Score (CQS) for each of performance year subsets 5.1 and 5.2, including a separate set of quality improvement points and quality performance points for each performance year subset. In order to conduct separate CQS calculations for each time period, we are amending 42 CFR 510.400 to indicate that the required data submissions that previously applied to PY 5 will now apply to performance year subset 5.1, and we are adding a required data submission for performance year subset 5.2. These additional requirements will reflect the timeframe of performance year subset 5.2, but will otherwise parallel the requirements for performance year subset 5.1, and will not require an increased amount of data for performance year subset 5.2 as compared to performance year subset 5.1. We recognize that some of the timeframe for both performance year

subsets 5.1 and 5.2 quality data collection overlap with the effective dates of the COVID–19 waiver⁴³ that provided reporting exemptions for hospitals participating in quality reporting programs, so we will use quality data reported before and after the effective dates of the COVID–19 waiver, for those quality measures to which the waiver applied.

The final reconciliation calculation for performance year subset 5.2 will occur one year after the initial reconciliation of performance year subset 5.2. Although we will use claims data that were available 14 months after the end of performance year subset 5.2 for the subsequent reconciliation (as set forth in 42 CFR 510.305(i)(1)), as with the initial reconciliation, we will not begin the subsequent reconciliation calculation process until 17 months after the end of performance year subset 5.2. We would begin the final reconciliation calculation for performance year subset 5.2 in late February 2023 with reconciliation payment amounts and reports issued in June, because input files that are required for the final reconciliation will not be available until 17 months after the end of performance year subset 5.2. In particular, we need to receive the reconciliation results from Accountable Care Organizations (ACOs) that overlap with CJR in order to conduct the ACO overlap calculation. Since we cannot state with confidence that we will have access to those data prior to the normal reconciliation process start date in late February 2023, we will perform the reconciliation calculation at the same time of year that we have performed previous reconciliations. As noted above, we will conduct the final reconciliation of performance year subset 5.2 independently. Table 2 illustrates the timelines for performance year subsets 5.1 and 5.2.

TABLE 2—TIMELINES FOR PERFORMANCE YEARS 4 AND 5

Performance year (PY)	Performance period	Initial reconciliation calculation start	Subsequent reconciliation calculation start	Reconciliation amount (+/–)
4	01/01/2019 to 12/31/2019	2 months after 12/31/2019: Late February 2020.	14 months after 12/31/2019: Late February 2021.	Net PY3 and PY4 reconciliation amounts.
5 (two periods)	01/01/2020 to 09/30/2021.			
Subset 5.1	01/01/2020 to 12/31/2021	2 months after 12/31/2020: Late February 2021.	14 months after 12/31/2020: Late February 2022.	Net PY4 and PY5.1 reconciliation amounts.

⁴³ <https://www.cms.gov/files/document/covid-ifc-3-8-25-20.pdf>.

TABLE 2—TIMELINES FOR PERFORMANCE YEARS 4 AND 5—Continued

Performance year (PY)	Performance period	Initial reconciliation calculation start	Subsequent reconciliation calculation start	Reconciliation amount (+/-)
Subset 5.2	01/01/2021 to 09/30/2021	5 months after 09/30/2021: Late February 2022.	17 months after 09/30/2021: Late February 2023.	Net PY5.1 and PY5.2 reconciliation.

In order to reflect the changes in reconciliation timing and other changes associated with additional reconciliations in PY5, we are amending the following provisions: 42 CFR 510.2, 42 CFR 510.200, 42 CFR 510.305(b), (d)(1), (e), (i)(1) and (2), and (j)(1) and (2), and 42 CFR 510.400(b)(3)(v), and adding 42 CFR 510.400(b)(3)(vi).

4. DRG 521 and DRG 522

In this IFC we are amending our regulations at § 510.300(a) to specify that, as of October 1, 2020, the CJR model includes episodes when the MS-DRG assigned at discharge for an anchor hospitalization is one of two new MS-DRGs we adopted in the FY 2021 IPPS/LTCH final rule (85 FR 58432): MS-DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with Major Complications and Comorbidities (MCC)) and MS-DRG 522 (Hip Replacement with Principal Diagnosis of Hip Fracture, without MCC). As indicated in 42 CFR 510.300(a)(1), the CJR model episode definition historically included MS-DRG 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC) and MS-DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC). For purposes of calculating quality adjusted target prices, we further subdivided episodes within each MS-DRG based on the presence or absence of a primary hip fracture. In the FY 2021 IPPS/LTCH final rule, we stated that because the CJR model would continue until at least March 31, 2021, we intended to adopt a policy in the CJR final rule that incorporates these new MS-DRGs into the CJR model as of October 1, 2020 to avoid disruption to the model for the remainder of PY5 (as extended) and thereafter, if our proposal to extend the CJR model through PY8 were finalized (85 FR 58502). To this end, we are adopting the change in this IFC, with retroactive effect to October 1, 2020. This change ensures that hip replacements with a principal diagnosis of hip fracture, with and without MCC, will continue to trigger CJR model episodes even though they are now

assigned to these new DRGs rather than MS-DRGs 469 and 470.

As background, in the FY 2021 IPPS/LTCH proposed rule (85 FR 32510), CMS proposed the creation of two new MS-DRGs, 521 and 522 (Hip Replacement with primary hip fracture, with and without major complications and comorbidities, respectively). Because the FY2021 IPPS/LTCH proposed rule was published after the CJR February 2020 proposed rule, the new MS-DRGs 521 and 522 were not addressed in the February 2020 proposed rule. We solicited comment in the FY2021 IPPS/LTCH proposed rule on the effect this proposal would have on the CJR model and whether to incorporate MS-DRG 521 and MS-DRG 522, if finalized, into the CJR model's proposed extension to December 31, 2023. The public also had the opportunity to address this issue in comments responding to the CJR February 2020 proposed rule, as the comment period for that rule had been extended.

We received three comments in response to the February 2020 proposed rule and 20 comments in response to the FY2021 IPPS/LTCH proposed rule addressing the effects of the proposed new MS-DRGs on the CJR model. Most commenters agreed that MS-DRGs 521 and 522 should be included in the definition of a CJR model episode, noting their assumption that this would have a neutral economic impact on the model and participants, as the CJR model already provides for separate quality adjusted target prices for hip fracture cases for MS-DRGs 469 and 470. Multiple commenters stated their belief that there is value in maintaining hip fracture cases in the CJR model, including that it is administratively simpler and that maintaining hip fractures in the CJR model would mean those procedures remain subject to the value-based care incentives of the CJR model. Some commenters suggested that quality adjusted target prices for episodes previously triggered by MS-DRG 469 and MS-DRG 470 with hip fracture could apply to episodes triggered by the new MS-DRGs. Others noted that if the DRGs were added retroactively, they would not want the

new DRGs to retroactively impact quality adjusted target prices.

As of October 1, 2020, MS-DRGs 521 and 522 separately identify a subset of LEJR procedures that were previously grouped to MS-DRGs 469 and 470, and if the definition of a CJR model episode is not revised to accommodate this technical change the LEJR procedures associated with these new codes will no longer be part of the CJR model. This result would be highly disruptive to the CJR model, because it would remove a significant number of episodes midway through a performance year. Therefore, we believe there is good cause for this rulemaking to change the definition of a CJR model episode to include MS-DRGs 521 and 522. Indeed, it would be contrary to the public interest to undertake traditional notice and comment rulemaking to adopt these regulatory changes because they are intended to preserve the model's scope in light of underlying technical changes in the IPPS. Based on the public comments previously described, we believe that including DRGs 521 and 522 in the CJR episode definition is less disruptive to participant hospitals than the alternative, which would be to allow hip replacements with a primary hip fracture to drop abruptly out of the model (or to drop out of the model until we were able to undertake full notice and comment rulemaking to add them back at a later point). We believe that failure to retroactively incorporate MS-DRGs 521 and 522 into the CJR model as of October 1, 2020 would be contrary to the public interest because it would result in approximately 20–25% of all LEJR episodes to be dropped from the CJR model. The categories of episodes that would be dropped tend to be associated with emergent surgeries, high-costs, and complex post-acute care needs. Dropping these episodes from the model would create confusion, increase administrative burden for participant hospitals, and remove the opportunity for participant hospitals to earn reconciliation payments by coordinating care for these complex, high-cost episodes.

Operationally, this is a seamless transition for participant hospitals, which have continued to bill Medicare

FFS as usual for hip replacements with hip fractures. Beginning on October 1, 2020, the Medicare IPPS grouper began to assign those hospitalizations to one of the new MS-DRGs, with no billing changes required of participant hospitals. The new MS-DRGs will be incorporated into the CJR episode reconciliation data system, and will be included in participant hospitals' monthly data feeds going forward. Participant hospitals were notified of their quality adjusted target prices for episodes beginning on October 1, 2020 for MS-DRGs 469 and 470, with and without hip fracture. As of October 1, 2020, the quality adjusted target prices for MS-DRGs 469 and 470 with hip fracture will apply to episodes initiated by the new MS-DRGs 521 and 522, respectively, for the remainder of PY5 (including both performance year subsets 5.1 and 5.2).

Given that the CJR model currently provides separate quality adjusted target prices for episodes with and without a hip fracture, incorporating the new DRGs would have minimal financial impact on the model. The PY5 quality adjusted target price calculation methodology includes the application of update factors (80 FR 73342–73346), which incorporate annual changes to each CMS payment system (for example, IPPS, OPSS, and SNF). The update factor is calculated and applied twice per year, in order to incorporate both fiscal year and calendar year payment system updates. The MS-DRG weights assigned to the new MS-DRGs 521 and 522 in the FY 2021 IPPS/LTCH final rule (84 FR 42044) will be incorporated into the IPPS update factor as part of the calculation of the quality adjusted target prices for episodes beginning between October 1, 2020 and December 31, 2020. These FY 2021 MS-DRG weights will continue in the quality adjusted target prices for episodes that begin between January 1, 2021 and September 30, 2021, which will incorporate CY 2021 payment system updates. As a result, baseline prices for hip replacements with primary hip fracture, which would have been assigned the MS-DRGs 469 and 470 and stratified by hip fracture status, are comparable to those same episodes in the performance period that are assigned to MS-DRGs 521 and 522, respectively. For the remainder of PY5, we will calculate quality adjusted target prices for episodes initiated by MS-DRGs 521 and 522 using baseline episodes initiated by MS-DRG 469 with fracture and MS-DRG 470 with fracture, respectively, but updated to include the MS-DRG weights assigned to MS-DRGs 521 and 522 for FY 2021.

In this IFC we are incorporating the new MS-DRGs 521 and 522 into the CJR model episode definition as of October 1, 2020, updating quality adjusted target prices to reflect the applicable MS-DRG weights, and amending the provisions at 42 CFR 510.300(a)(1)(i) and (iii) to reflect these changes.

5. Changes to Extreme and Uncontrollable Circumstances Policy for the PHE for COVID-19

We are also modifying the extreme and uncontrollable circumstances adjustment for COVID-19 in § 510.300(k)(4) to expire on March 31, 2021 or the last day of the emergency period, whichever is earlier. In addition, we are adopting a more targeted adjustment, which will apply after March 31, 2021 or the last day of emergency period (whichever is earlier), so that financial safeguards continue to apply for CJR episodes during which a CJR beneficiary receives a positive COVID-19 diagnosis.

Currently, the extreme and uncontrollable circumstances adjustment for COVID-19 provides financial safeguards for participant hospitals that have a CCN primary address that is located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary issued a waiver or modification of requirements under section 1135 of the Act on March 13, 2020, effectively applying the financial safeguards to all participant hospitals. These financial safeguards, wherein actual episode payments are capped at the target price determined for that episode, apply to fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs through the termination of the emergency period (as described in section 1135(e) of the Act). In the April 2020 IFC we explained this extreme and uncontrollable circumstances adjustment, noting that the previous CJR model policy for extreme and uncontrollable circumstances was not applicable to the PHE for the COVID-19 pandemic. We also indicated that we did not expect many new CJR episodes to initiate in light of the COVID-19 virus and the related guidance to avoid elective surgeries. We further stated that we wanted to avoid inadvertently creating incentives to place cost considerations above patient safety within the CJR model, given the challenges to the health care delivery system in

responding to COVID-19 cases and the expenses associated with treating the virus.

We received comments on both the April 2020 IFC and the CJR February 2020 proposed rule about the extreme and uncontrollable circumstances adjustment. Commenters favored the extreme and uncontrollable circumstances policy for COVID-19 and commended CMS for providing relief to participant hospitals. Some commenters questioned what steps CMS would take once the PHE ends and noted the uncertainty in the current policy since there is not a concrete end date for the PHE. A commenter recommended CMS hold participant hospitals harmless from performance-related penalties for the 2020 performance year and urged CMS to make appropriate adjustments for the 2020 and 2021 performance years and to address the impact of COVID-19 on financial expenditures, performance scores and risk adjustment.

We appreciate commenters' positive feedback on the April 2020 IFC and our decision to provide relief to participant hospitals. At the onset of the PHE, we quickly developed financial safeguards in the April 2020 IFC due to the mandatory nature of the model and the location of all 471-participant hospitals in MSAs where COVID-19 was most prevalent. For example, there are 98 participant hospitals in the New York/New Jersey Metropolitan Area, which was the epicenter for COVID-19.⁴⁴ Further, at that time, we did not possess data that allowed CMS to determine the COVID-19 virus's effect on the CJR model, and believed it was most prudent to waive downside risk for all episodes through the duration of the PHE.

Since publishing the April 2020 IFC, we reviewed Medicare claims data and observe a steep decline in the initiation of episodes in April 2020 (See Table 1). Post April 2020, CJR episodes are increasing, and though not at normal utilization as compared to 2019 Medicare claims data, the data reflects a continual initiation of CJR episodes despite the ongoing PHE. In addition, related Federal guidance to avoid elective surgeries has expired, which allows certain participant hospitals to initiate elective LEJR procedures.⁴⁵ The continual initiation of CJR episodes during the PHE is contrary to our assumption in the April 2020 IFC, that

⁴⁴ "New York City Region Is Now an Epicenter of the Coronavirus Pandemic" March 22, 2020. Available at <https://www.nytimes.com/2020/03/22/nyregion/coronavirus-new-york-epicenter.html>.

⁴⁵ <https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf>.

is, we did not expect many new CJR episodes to initiate during the PHE.

Absent a change to specify an end date, the current extreme and uncontrollable adjustment in 42 CFR 510.300(k)(4) would continue as long as the PHE. Unfortunately, the combination of CJR episode volume increasing to levels we did not anticipate during the PHE and the continued renewal of the PHE threatens the ability of the CJR model to generate any savings over the course of the model. With greater surgical volume, we do not believe such a broad extreme and uncontrollable circumstances policy for COVID-19 remains necessary.

For these reasons, we are implementing an end date to the extreme and uncontrollable circumstances adjustment for COVID-19. Specifically, for a fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs on or before March 31, 2021 or the last day of such emergency period, whichever is earlier, actual episode payments are capped at the quality adjusted target price determined for that episode under § 510.300. We are amending the provisions at 42 CFR 510.305(k)(4) to reflect this change.

In addition, in order to account for CJR beneficiaries with a positive COVID-19 diagnosis during a CJR episode that initiates after the adjustments for extreme and uncontrollable circumstances specified in § 510.305(k)(4) end, we are amending our regulations at § 510.305(e)(1)(i) to cap actual episode payments at the quality adjusted target price for the episode, effectively waiving downside risk for all episodes with actual episode payments that include a claim with a COVID-19 diagnosis code. This policy will apply after March 31, 2021 or the last day of the PHE, whichever occurs earlier.

In response to commenters' questions about how the CJR model will alleviate financial risk associated with COVID-19 once the PHE expires, we explored the flexibilities provided by other CMMI models and found them to be consistent with a targeted, episode-based approach to providing financial relief from COVID-19. In order to be responsible stewards of the Medicare Trust Fund, we are adopting a policy to provide participant hospitals continuing financial protection from the effect of COVID-19 on the CJR model that may continue beyond the end of the PHE for COVID-19 or March 31, 2021

(whichever is earlier). Specifically, at the initial and subsequent reconciliations of performance year subset 5.2, which will include episodes subject to this new adjustment policy, we will identify episodes with actual episode payments with any claim containing a COVID-19 diagnosis and costs for those episodes will be capped at the quality adjusted target price, effectively waiving downside risk for that episode. A COVID-19 diagnosis is identified by the following ICD-10-CM diagnosis codes: B97.29; U07.1; or any other ICD-10-CM diagnosis code that is recommended by the Centers for Disease Control and Prevention for the coding of a confirmed case of COVID-19.⁴⁶ We understand that ICD-10 diagnosis codes B97.29 (which was used for dates of service on or after January 27, 2020 through March 31, 2020) and U07.1 (which was used for dates of service on or after April 1, 2020 through September 30, 2020) might not be used for dates of service to which our new adjustment policy will apply. Nevertheless, given the potential for uncertainty as to whether either of these codes will be used for dates of service after September 30, 2020, we are including them in the definition of "COVID-19 diagnosis code" that we are adding to § 510.2 for completeness.

In order to provide participant hospitals continuing financial protection from the effect of COVID-19 on the CJR model that may continue beyond the end of the PHE for COVID-19 or March 31, 2021, whichever occurs earlier, we are implementing that actual episode payments are capped at the quality adjusted target price determined for that episode under § 510.300 for episodes with actual episode payments that include a claim with a COVID-19 diagnosis code and initiate after the earlier of March 31, 2021 or the last day of the emergency period.

III. Provisions of the Interim Final Rule—Departments of the Treasury, Labor and Health and Human Services

A. Rapid Coverage of Preventive Services for Coronavirus

1. Background

In addition to the steps Congress took to ensure coverage of COVID-19 diagnostic testing, in section 3203 of the CARES Act, Congress required group health plans and health insurance issuers offering group or individual health insurance coverage to cover,

without cost sharing, qualifying coronavirus preventive services. This coverage is required to be provided "pursuant to section 2713(a) of the [PHS] Act," including its implementing regulations or any successor regulations.

Section 2713 of the PHS Act was added by section 1001 of PPACA and incorporated by reference into ERISA by section 715 of ERISA and into the Code by section 9815 of the Code. Section 2713 of the PHS Act and the regulations implementing section 2713 of the PHS Act require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to provide coverage of certain specified preventive items and services without cost sharing. These services include:

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the USPSTF with respect to the individual involved.

- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from ACIP with respect to the individual involved. A recommendation of ACIP is considered to be "in effect" after it has been adopted by the Director of the CDC. A recommendation is considered to be for "routine use" if it appears on the Immunization Schedules of the CDC.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

- With respect to women, preventive care and screenings provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the USPSTF), subject to certain exemptions and accommodations (see 45 CFR 147.131 through 147.133).

The Departments' current regulations (herein referred to as the 2015 Final Regulations) under section 2713 of the PHS Act at 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; and 45 CFR 147.130 require that plans and issuers provide coverage of recommended preventive services for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

Under the 2015 Final Regulations, if a recommended preventive service is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer

⁴⁶ https://www.cdc.gov/nchs/data/icd/ICD-10-CM-Official-Coding-Guidance-Interim-Advice-coronavirus-feb-20-2020.pdf?fbclid=IwAR2c9LrGMAhum_Ogu-LrxPJ-S4u_j4wGW1615l_fm0iDB5AA0wKHKItj0Xo.

may impose cost-sharing requirements with respect to the office visit. However, if a preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

The 2015 Final Regulations generally do not require a plan and issuer that has a network of providers to provide benefits for applicable preventive items or services that are delivered by an out-of-network provider. Moreover, the 2015 Final Regulations generally do not preclude a plan or issuer that has a network of providers from imposing cost-sharing requirements for preventive services that are delivered by an out-of-network provider. However, if a plan or issuer does not have in its network a provider who can provide a preventive service, then the plan or issuer must cover the recommended preventive service when performed by an out-of-network provider and may not impose cost sharing with respect to the recommended preventive service.

Many items and services required to be covered under section 2713 of the PHS Act typically are provided as part of the usual course of preventive care, often according to regularly scheduled intervals. Examples include immunizations provided according to schedules established by the CDC and other annual screenings or counseling. Therefore, the 2015 Final Regulations require coverage without cost sharing for applicable immunizations that are recommended by ACIP for routine use, and state that a recommendation is considered to be for “routine use” if it appears on the Immunization Schedules of the CDC.

Section 3203 of the CARES Act establishes a more accelerated timeline for required coverage of qualifying coronavirus preventive services than other recommended preventive services under PHS Act section 2713. As stated above, coverage of qualifying coronavirus preventive services must be provided no later than 15 business days following an applicable recommendation. In addition, it is possible that items, services, and immunizations used to prevent or mitigate COVID–19 will not, in the immediate future, be recommended as part of a usual course of preventive care, but rather for more urgent use. As reflected by the expedited timeline for coverage Congress established in section 3203 of the CARES Act, the need to provide coverage of qualifying

coronavirus preventive services is urgent. Therefore, as discussed below, this IFC requires coverage of COVID–19 immunizations within 15 business days after the immunization has been recommended by ACIP and adopted by the CDC, regardless of whether it appears on the Immunization Schedules of the CDC for routine use.

Additionally, in light of the current PHE for COVID–19, it is imperative that group health plans and health insurance issuers provide full coverage for these items and services, including costs for the administration of vaccines, and ensure timely access to coverage as Congress intended. Accordingly, in this IFC, the Departments provide certain clarifications previously made with respect to the 2015 Final Regulations and amend those regulations to implement unique requirements related to covering qualifying coronavirus preventive services.⁴⁷

2. Scope of Requirement To Cover Certain Recommended Preventive Services Under Section 2713 of the Public Health Service Act

a. Related Items and Services

In implementing section 2713 of the PHS Act, the 2015 Final Regulations addressed whether office visit charges associated with certain recommended preventive services must be covered without cost sharing. Specifically, *Example 1* in the 2015 Final Regulations illustrates how the requirements apply in situations where a provider bills a plan for an office visit where a preventive screening for cholesterol abnormalities (which has in effect a rating of A or B from the USPSTF) is conducted and for the laboratory work of the cholesterol screening test. In that example, the plan may not impose any cost-sharing requirements with respect to the separately billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the 2015 Final Regulations provide that the plan may impose cost-sharing requirements for the office visit.

⁴⁷ The 2015 Final Regulations address the obligation to continue to provide coverage for recommended preventive services that are in effect on the first day of a plan or policy year when there are changes in recommendations or guidelines. See 26 CFR 54.9815–2713(b)(2)(i) and (ii); 29 CFR 2590.715–2713(b)(2)(i) and (ii); 45 CFR 147.130(b)(2)(i) and (ii). Given the expedited timeline for coverage under section 3203 of the CARES Act, this IFC amends the 2015 Final Regulations to make clear that these paragraphs apply to recommended preventive services that are covered on the first day of the plan or policy year or, with respect to qualifying coronavirus preventive services, “as otherwise specified in paragraph (b)(3) of this section.”

Prior to the publication of the 2015 Final Regulations, the Departments received questions from stakeholders regarding discrete coverage issues related to certain recommended preventive services. In particular, with respect to colonoscopies, stakeholders asked whether certain related services (such as the cost of polyp removal or anesthesia) must also be covered without cost sharing. The Departments clarified in subregulatory guidance that a plan or issuer may not impose cost sharing for polyp removal during a preventive screening colonoscopy, as such service is an integral part of a colonoscopy, and also stated that anesthesia provided in connection with a preventive colonoscopy must be covered without cost sharing.⁴⁸

Consistent with the examples provided in the 2015 Final Regulations and subregulatory guidance cited in the preamble to the rulemaking promulgating the 2015 Final Regulations, the Departments further clarify that under the 2015 Final Regulations and this IFC, plans and issuers subject to section 2713 of the PHS Act must cover, without cost sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately. For example, several of the recommended preventive services involve screenings for the presence of certain health conditions, such as diabetes, or a variety of sexually transmitted infections. These recommended screenings, typically performed by laboratories, cannot be conducted without first collecting a specimen. Accordingly, plans and issuers subject to section 2713 of the PHS Act must cover without cost sharing both the specimen collection and the recommended preventive service, regardless of how the specimen collection is billed. Similarly, a recommended immunization generally cannot be furnished without being administered by a medical professional. As qualifying coronavirus preventive services are expected to include immunizations, plans and issuers subject to section 2713 of the PHS Act

⁴⁸ See FAQs About Affordable Care Act Implementation Part 12, Q5 (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12 and FAQs About Affordable Care Act Implementation Part XXVI, Q7 (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

must cover without cost sharing such an immunization and its administration, regardless of how the administration is billed, and regardless of whether a COVID-19 vaccine or any other immunization requires the administration of multiple doses in order to be considered a complete vaccination. This includes coverage without cost sharing of the administration of a required preventive immunization in instances where a third party, such as the Federal Government, pays for the preventive immunization. Further, if a COVID-19 immunization is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the visit is the delivery of the recommended COVID-19 immunization, then consistent with the 2015 Final Regulations, the plan or issuer may not impose cost-sharing requirements with respect to the office visit. The Departments seek comment on this clarification.

b. Out-of-Network Coverage During the PHE for COVID-19

The 2015 Final Regulations permit a group health plan or issuer that has a network of providers to omit coverage or to impose cost-sharing requirements for recommended preventive services when such services are provided by an out-of-network provider, unless the plan or issuer does not have in its network a provider who can provide the service.⁴⁹ This approach reflects that, as noted earlier in this section of the preamble, recommended preventive services generally are obtained as part of a regular course of preventive care, so participants, beneficiaries, and enrollees typically have the opportunity to seek such care from an in-network provider. By contrast, in the immediate term, newly developed qualifying coronavirus preventive services might be available from a narrower range of providers than other, more established recommended preventive services. To help ensure full access to and the widespread use of qualifying coronavirus preventive services to mitigate the effect of the PHE for COVID-19 and slow transmission of the virus, it is critical that individuals be able to receive such services from any provider authorized to provide the service. Therefore, this IFC amends the 2015 Final Regulations to require that plans and issuers subject to section 2713 of the PHS Act must cover without cost sharing a qualifying coronavirus preventive service, regardless of

whether such service is delivered by an in-network or out-of-network provider. This is based on the Departments' view that participants, beneficiaries, and enrollees may not be able to locate in-network providers consistently during the emergency period.

To satisfy this requirement, the Departments are of the view that plans and issuers must administer this out-of-network coverage requirement in such a way that makes receiving out-of-network services for qualifying coronavirus preventive services a meaningful benefit for participants, beneficiaries, and enrollees. To be a meaningful benefit, the Departments are of the view that plans and issuers must administer this out-of-network coverage requirement in a way that ensures that participants, beneficiaries, and enrollees have access to a variety of out-of-network providers for such services. To the extent plans and issuers reimburse out-of-network providers an unreasonably low amount for qualifying coronavirus preventive services, including for administration of a COVID-19 vaccine, this approach could severely limit the number of such providers that are willing to provide the service, which would contravene the purpose of the requirement to provide out-of-network coverage without cost sharing of qualifying coronavirus preventive services. Therefore, this IFC provides that with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service. The Departments will consider the amount of payment to be reasonable, for example, if the plan or issuer pays the provider the amount that would be paid under Medicare for the item or service. In the Departments' view, these minimum payment standards are necessary and appropriate because providers that participate in the CDC COVID-19 Vaccination Program contractually agree to administer a COVID-19 vaccine regardless of an individual's ability to pay and regardless of their coverage status, and also may not seek any reimbursement, including through balance billing, from a vaccine recipient.

The Departments request comment on all aspects of this approach. The Departments request comment on the issue of network adequacy and whether and, if so, how long provider networks are expected to be inadequate. The

Departments also request comment on the safeguards in this IFC to ensure that out-of-network reimbursement rates are reasonable and that providers administering a publicly funded COVID-19 vaccine are reimbursed by group health plans and issuers prevailing market rates in the absence of a negotiated rate, and whether other examples of reasonable reimbursement rates, in addition to Medicare rates, would be useful.

3. Definition of Qualifying Coronavirus Preventive Services

Section 3203(b)(1) of the CARES Act defines "qualifying coronavirus preventive service" as an item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is—(A) an evidence-based item or service that has in effect a rating of 'A' or 'B' in the current recommendations of the USPSTF; or (B) an immunization that has in effect a recommendation from ACIP with respect to the individual involved. The statutory provisions describing USPSTF and ACIP recommendations in this definition are substantively identical to the ones at section 2713(a)(1) and (2) of the PHS Act. However, as stated above, under the 2015 Final Regulations, only "immunizations for routine use in children, adolescents, and adults" that are recommended by ACIP must be covered without cost sharing.⁵⁰ A recommendation is considered to be for routine use if it is listed on the CDC's Immunization Schedules.⁵¹

This IFC provides a definition of qualifying coronavirus preventive services that is consistent with the statutory definition in section 3203 of the CARES Act. However, the Departments note that unlike the other preventive service immunizations required to be covered without cost sharing under section 2713 of the PHS Act and the 2015 Final Regulations, this definition and related coverage requirement are not limited to COVID-19 immunizations recommended by ACIP for "routine use." While other preventive items and services may be recommended for routine use, for reasons described elsewhere in this section of the preamble, the PHE for COVID-19 presents unique circumstances and qualifying coronavirus preventive services might not, in the immediate term, be recommended for routine use, according to specified schedules. Rather, the

⁵⁰ See 75 FR 41726, 41728 (July 19, 2010), codified at 26 CFR 54.9815-2713(a)(1)(ii); 29 CFR 2590.715-2713(a)(1)(ii); 45 CFR 147.130(a)(1)(ii).

⁵¹ *Id.*

⁴⁹ 26 CFR 54.9815-2713(a)(3); 29 CFR 2590.715-2713(a)(3); 45 CFR 147.130(a)(3).

Departments generally expect consumers should receive an immunization for COVID–19 as soon as it becomes available to the general public, or as soon as it becomes available to them based on their status as part of a high-risk or high-priority population, as recommended by ACIP. Plans and issuers subject to section 2713 of the PHS Act must cover, without cost sharing, COVID–19 immunizations that are recommended by ACIP and adopted by the Director of CDC, even if not listed for routine use on the CDC Immunization Schedules, pursuant to 26 CFR 54.9815–2713T(a); 29 CFR 2590.715–2713(a); and 45 CFR 147.130(a), and subject to the additional changes described later in this section of the preamble.⁵²

4. Qualifying Coronavirus Preventive Services—Timing Requirement

Section 2713 of the PHS Act and the 2015 Final Regulations require plans and issuers to cover recommended preventive items and services beginning with the first plan year (or in the individual market, policy year) that is one year after the date the recommendation or guideline is issued. Section 3203 of the CARES Act accelerates the timeline for coverage of qualifying coronavirus preventive services without cost sharing, requiring coverage to be provided within 15 business days after the date on which a recommendation is made relating to such service. This IFC codifies these timing requirements at 26 CFR 54.9815–2713T(b)(3); 29 CFR 2590.715–2713(b)(3); and 45 CFR 147.130(b)(3).

In addition, the IFC adds a sunset provision at 26 CFR 54.9815–2713T(e); 29 CFR 2590.715–2713(e); and 45 CFR 147.130(e), under which the amendments made to the regulations will not apply with respect to qualifying coronavirus preventive services furnished on or after the expiration of the PHE for COVID–19. The Departments note, however, that coverage under section 3203 of the CARES Act is not limited to the duration of the PHE for COVID–19 and therefore the statutory provisions will continue to apply.

⁵² HHS reminds states that the HHS Office for Civil Rights enforces applicable Federal civil rights laws as described above, as well as laws protecting the exercise of conscience and religious freedom, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb–4). HHS's requirements are subject to these laws, and states may have obligations under these laws to protect conscience, prohibit coercion, and to ensure the free exercise of religion. U.S. Department of Health & Human Services, Office for Civil Rights, Conscience and Religious Freedom, <https://www.hhs.gov/conscience/index.html> (last visited Aug. 20, 2020).

B. Diagnostic Testing for COVID–19

Section 6001 of the FFCRA generally requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits for COVID–19 diagnostic tests and certain items and services related to diagnostic testing for COVID–19 when those items or services are furnished on or after March 18, 2020, and during the duration of the PHE for COVID–19. Under the FFCRA, plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance) or prior authorization or other medical management requirements. Section 3201 of the CARES Act, enacted on March 27, 2020, amended section 6001 of the FFCRA to include a broader range of diagnostic tests that plans and issuers must cover without any cost-sharing requirements or prior authorization or other medical management requirements.

Section 3202(a) of the CARES Act provides that a plan or issuer providing coverage of items or services described in section 6001(a) of the FFCRA shall reimburse the provider of the diagnostic testing at a rate negotiated with the provider, or if there is no negotiated rate, at an amount that equals the cash price for such service as listed by the provider on a public internet website. As previously articulated in guidance, the Departments interpret the requirement to provide coverage without cost sharing in section 6001 of the FFCRA, together with section 3202(a) of the CARES Act, as establishing a process for setting reimbursement rates and protecting participants, beneficiaries, and enrollees from being balance billed for an applicable COVID–19 test.⁵³ These provisions help ensure consumers can be tested for COVID–19 without barriers related to cost, and are critical to the ability to detect the virus and stop its spread. However, testing efforts have continued to be hampered by challenges, such as delays in obtaining results, issues with test accuracy, and supply shortages.⁵⁴

⁵³ FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43 (June 23, 2020), available at <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf> and <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf>.

⁵⁴ American Society for Microbiology, “Supply Shortages Impacting COVID–19 and Non-COVID Testing” (Oct. 15, 2020), available at <https://asm.org/Articles/2020/September/Clinical-Microbiology-Supply-Shortage-Collecti-1>.

The Departments encourage group health plans and issuers of group or individual health insurance coverage to consider market-driven approaches to addressing these continued challenges surrounding COVID–19 diagnostic testing. The Departments encourage plans and issuers to explore using payment arrangements that create incentives for providers to reduce the time it takes to provide results for diagnostic testing for COVID–19, while maintaining the accuracy rates of their test results in instances where it is within the ability of providers to address a delay.

At certain points in this PHE, there have been wide variations in the time it takes providers to make test results available to consumers. These delays in obtaining test results increase the risk that infected individuals may unknowingly infect others. These delays could be caused by large volumes of tests to process and/or inadequate resources. Pay-for-performance arrangements, where reimbursement rates are based on the time it takes to make test results available, could encourage innovative approaches by providers to reduce the turnaround time. The Departments encourage group health plans and issuers of group or individual health insurance coverage to consider developing such arrangements with providers, and strongly encourage plans and issuers that do so to incorporate safeguards to ensure that the payment arrangements are not structured in a way that prioritizes speed over accuracy or that result in unintended consequences, such as reduction in access to COVID–19 diagnostic testing or non-compliance with balance billing restrictions.

IV. Provisions of the Interim Final Rule Regarding State Innovation Waivers—Department of the Treasury and Health and Human Services

A. State Innovation Waivers Policy and Regulatory Revisions in Response to the PHE for COVID–19 Public Health Emergency

1. Background

Section 1332 of the PPACA permits states to apply for a State Innovation Waiver (also referred to as “section 1332 waivers” or “State Relief and Empowerment Waivers”) to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. The overarching goal of section 1332 waivers is to give all Americans the opportunity to obtain high value and affordable health coverage regardless of income, geography, age, sex, or health status,

while simultaneously empowering states to develop health coverage strategies that best meet the needs of their residents. Section 1332 waivers provide states an opportunity to promote a stable health insurance market that offers more choice and affordability to their residents. Under section 1332 of the PPACA, a State Innovation Waiver can be approved by HHS and the Department of the Treasury if it provides access to quality health coverage that is at least as comprehensive and affordable as would be provided absent the waiver, provides coverage to a comparable number of residents of the state as would be provided coverage absent a waiver, and does not increase the Federal deficit. To date, HHS and the Department of the Treasury have approved 15 state waiver requests, 14 of which implement state-based reinsurance programs.⁵⁵ As noted in a recent data brief issued by CMS, section 1332 state-based reinsurance waivers have resulted in a statewide average premium reduction ranging from four to 37 percent in calendar year 2020 for residents in states with approved waivers.⁵⁶ Reinsurance provides a direct benefit to consumers by paying a portion of provider claims that would otherwise be paid by consumers through higher premiums and lowering premiums for people in the individual health insurance market. HHS and the Department of the Treasury continue to encourage states to take advantage of the flexibilities available through section 1332 waivers in order to pursue solutions to help lower costs and increase coverage choices for Americans faced with unaffordable premiums and reduced competition in the insurance market both during and after the PHE for COVID-19.

Section 1332(a)(4)(B) of the PPACA requires the Secretary of HHS and the Secretary of the Treasury (the Secretaries) to issue regulations regarding procedures for State Innovation Waivers. On March 14, 2011, HHS and the Department of the Treasury published the “Application, Review, and Reporting Process for Waivers for State Innovation” proposed rule (76 FR 13553) to implement section

1332(a)(4)(B) of the PPACA.⁵⁷ On February 27, 2012, HHS and the Department of the Treasury published the “Application, Review, and Reporting Process for Waivers for State Innovation” final rule (77 FR 11700) (hereinafter referred to as the “2012 Final Rule”).⁵⁸ On October 24, 2018, HHS and the Department of the Treasury issued the “State Relief and Empowerment Waivers” guidance (83 FR 53575) (hereinafter referred to as the “2018 Guidance”), which superseded the previous guidance published on December 16, 2015 (80 FR 78131), and provided additional information about the requirements that states must meet regarding section 1332 waiver proposals, the Secretaries’ application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations.⁵⁹ ⁶⁰

Section 1332(a)(4)(B) of the PPACA also directs HHS and the Department of the Treasury to issue regulations that provide for state and Federal public notice and comment sufficient to ensure a meaningful level of public input regarding a state’s section 1332 waiver plan, both during the application process and after a waiver is implemented. Current regulations and guidance address how states may apply for a waiver, information states must include in an application, public notice and comment requirements, and HHS’ and the Department of the Treasury’s monitoring and compliance activities, including state reporting requirements (collectively referred to as public notice procedures).

The Secretaries are setting forth a process for states to request modifications to the public notice procedures during the PHE for COVID-19 prior to and after approval of a section 1332 waiver that continue to meet the statutory and regulatory requirements that the public has an opportunity to provide meaningful input. Further the Secretaries are promulgating this rule so that HHS and the Department of the Treasury do not impose requirements that are unreasonable or unnecessarily burdensome regarding state compliance consistent with section 1332(a)(4)(B)(iii) of the PPACA during the PHE for COVID 19. This IFC promulgates rules to establish a framework for the

Secretaries to modify some of the existing regulatory public notice procedures to expedite a decision on a proposed waiver request during the PHE for COVID-19 when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. The Secretaries will also make available such flexibility regarding public notice procedures should any state with an approved section 1332 waiver request an extension or amendment of an approved section 1332 waiver during the PHE for COVID-19.

Similarly, this IFC also establishes a framework for the Secretaries to modify, in part, post award public notice procedures for an approved waiver request that would otherwise take place or become due during the PHE for COVID-19. The Secretaries will also make available such flexibility for post award public notice procedures for approved waiver extensions, amendments, or phase-out for a waiver should those otherwise take place or become due during the PHE for COVID-19. HHS and the Department of the Treasury are of the view that section 1332 waivers are a critical tool for states to ensure patients have stable access to health care coverage, including during the PHE for COVID-19. These interim final provisions are effective immediately for the duration of the PHE for COVID-19. HHS and the Department of the Treasury note that existing threats to consumers’ access to health coverage or care—such as in geographic areas in which issuer participation has been low for some time—would not be considered emergency situations for purposes of applying the flexibilities adopted in this rulemaking.

2. Public Notice Procedures and Approval Processes During the PHE (31 CFR 33.118 and 45 CFR 155.1318)

Section 1332(a)(4)(B) of the PPACA provides that the Secretary of HHS and the Secretary of the Treasury shall issue regulations providing a process for public notice and comment at the state level, including public hearings, and a process for providing public notice and comment after the application is received by the Secretaries, that are both sufficient to ensure a meaningful level of public input. Current regulations at §§ 33.112 and 155.1312 specify state public notice and participation requirements for proposed waiver requests, and §§ 33.116(b) and 155.1316(b) specify the accompanying public notice and comment period requirements under the Federal public notice and approval process.

⁵⁵ More information on section 1332 waivers that are approved is available online: https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-.

⁵⁶ CCHIO Data Brief Series: State Relief and Empowerment Waives: State-based Reinsurance Programs. June 2020. Available online: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Data-Brief-June2020.pdf>.

⁵⁷ <https://www.govinfo.gov/content/pkg/FR-2011-03-14/pdf/2011-5583.pdf>.

⁵⁸ <https://www.govinfo.gov/content/pkg/FR-2012-02-27/pdf/2012-4395.pdf>.

⁵⁹ <https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf>.

⁶⁰ <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

Under the current regulations at §§ 33.112 and 155.1312, states are required to provide a public notice and comment period prior to submitting an application for a new section 1332 waiver. The notice must include a comprehensive description of the section 1332 waiver application; information about where the application is available for public review; where the written comments may be submitted; and the location, date, and time of public hearings that will be convened by the state to seek public input on the application for a section 1332 waiver.⁶¹ After issuing the public notice and prior to submitting an application for a section 1332 waiver, the state must hold public hearings to allow the public to learn about and comment on the state's application, and must publish the date, time, and location of the hearings in a prominent location on the state's public website.⁶² As set forth in §§ 33.112(a)(2) and 155.1312(a)(2), as part of the public notice and comment period, a state with one or more federally recognized tribes must conduct a separate process for meaningful consultation with such tribes, if applicable. As HHS and the Department of the Treasury explained in the 2012 Final Rule preamble, this tribal consultation must be conducted in accordance with Executive Order (E.O.) 13175, and, as E.O. 13175 also applies to Medicaid, a state may use a Medicaid consultation process to satisfy the consultation needed for a section 1332 waiver (77 FR 11700, 11706). Furthermore, the state should include in its section 1332 waiver application a description of issues raised and comments received.

In addition, under section 1332(a)(4)(B)(iii) of the PPACA and the existing implementing regulations at §§ 33.116(b) and 155.1316(b), the Secretary of HHS and the Secretary of the Treasury are required to provide a Federal public notice and comment period following their preliminary

⁶¹ 31 CFR 33.112(b); 45 CFR 155.1312(b).

⁶² In response to a question from a commenter, the 2012 Final Rule states that "hearings," as used in 31 CFR 33.112(c)(1) and 45 CFR 155.1312(c)(1), means no less than two hearings. (77 FR 11700, 11706). The HHS and the Department of Treasury continue to interpret the regulatory requirement that a State shall hold "hearings" to refer to at least two hearings, except as otherwise provided by the amendments made in this IFC. The existing regulation does not expressly rely on the statutory requirement that the Secretaries of HHS and Treasury establish "a process for public notice and comment at the State level, including public hearings . . ." and HHS and the Department of the Treasury are of the view that language, by itself, does not require a particular state to hold more than one hearing. Rather, the statutory language describes a process applicable across multiple states, which will, in the aggregate, necessarily involve multiple hearings.

determination that a state's section 1332 waiver application is complete.

Section 1332 waivers may vary significantly in their complexity and breadth. The existing regulations generally provide states and the Federal Government flexibility in determining and/or extending the length of the comment periods. Both the state and the Federal public notice and comment periods must be sufficient to ensure a meaningful level of public input. The 2018 Guidance⁶³ further specifies that the state comment period should be no less than 30 days, and explains that consistent with HHS regulations, waiver applications must be posted online in a manner that meets technical standards for website accessibility similar to applicable national standards⁶⁴ to ensure access for individuals with disabilities.

HHS and the Department of the Treasury recognize that the current section 1332 regulations regarding state and Federal public notice procedures and comment period requirements may impose barriers for states pursuing a proposed waiver request during the PHE for COVID-19.⁶⁵ It is the mission of HHS to enhance and protect the health and well-being of all Americans. As such, HHS and the Department of the Treasury are issuing this guidance to protect public health and to prevent the spread of COVID-19 by limiting the need for in-person gatherings related to

⁶³ 83 FR 53575 (<https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf>).

⁶⁴ "National standards" refers to standards issued by the Architectural and Transportation Barriers Compliance Board (often referred to as "section 508" standards), or alternatively, the World Wide Web Consortium's Web Content Accessibility Guidelines (WCAG) 2.0 Level AA standards. See 83 FR 53575, 53583 (Oct. 24, 2018).

⁶⁵ During the PHE for COVID-19, under the Secretaries' discretion, HHS and the Department of the Treasury have allowed states to conduct their public forums virtually, both prior to application submission and post award. For example, following the scheduling and notice of the hearings, and in consultation with CMS, the New Hampshire Insurance Department rescheduled planned in-person public hearings to an online webinar format in response to social distancing guidance provided by New Hampshire Governor Chris Sununu and the Federal government. (<https://www.nh.gov/insurance/lah/documents/nh-section-1332-waiver-draft.pdf>). Georgia also offered public hearings virtually because of public health concerns regarding large, in-person gatherings during the COVID-19 pandemic. In addition, as of July 13, 2020, several states with approved waivers conducted their post award forum virtually due to COVID-19, including Alaska, Colorado, Delaware, Maine, Maryland, Minnesota, Montana, Oregon, North Dakota, Rhode Island, and Wisconsin. In this IFC, the Secretaries expand and build upon this approach by providing more flexibility to allow HHS and the Department of the Treasury to expedite a decision on a proposed waiver request. (<https://medicaid.georgia.gov/document/document/georgia/1332waiverapplicationfinal07312020vfpdf/download>).

section 1332 waivers during the PHE. Additionally, states may face uncertainty as to whether their waiver request will be approved in time, given the state and Federal public notice procedures or other public participation requirement associated with state procedures that would otherwise require an in-person gathering, to expeditiously reform their health insurance markets and to protect consumers from the effects of the PHE for COVID-19. Some states may not consider more robust changes because they are concerned that the current section 1332 waiver application requirements are too time-consuming or burdensome to pursue during the PHE for COVID-19. Therefore, HHS and the Department of the Treasury are of the view that having the flexibility to modify certain public notice procedures and participation requirements during the PHE for COVID-19 will protect public health and health insurance markets, and will increase flexibility and reduce burdens for states seeking to use section 1332 waivers as a means of innovation for providing coverage, lowering premiums, and improving their health care markets.

Section 1332 waivers are a critical tool for states to ensure patients across the country have access to health care coverage. About 10.7 million individuals on average rely on the Exchanges to purchase individual health insurance coverage throughout the year.⁶⁶⁶⁷ Although recently there have been positive premium stabilization and insurer participation trends, the COVID-19 pandemic has introduced new uncertainties in the individual and small group markets such that past trends resulting in limited access and affordability may return in some areas. For example, in response to the uncertainty created by the PHE for COVID-19 regarding health care utilization rates and claims costs, such as those associated with testing and treatment for COVID-19, premiums may increase and issuers may reduce their presence or coverage options in the individual and small group markets. Additionally, due to the PHE for COVID-19, some issuers may have difficulty predicting the composition of their risk pools given uncertainty about

⁶⁶ American Health Benefit Exchanges, or "Exchanges," are entities established under PPACA through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs).

⁶⁷ First Half of 2020 Average Effectuated Enrollment Data, available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Early-2020-2019-Effectuated-Enrollment-Report.pdf>.

the risk profiles of many new enrollees coming from employer-sponsored coverage and the potential transition of other enrollees to Medicaid due to income loss. Therefore, HHS and the Department of the Treasury are concerned that past trends that threaten the stability of the individual market risk pool may return, leading some issuers to cease offering coverage on the Exchanges in some states and counties and leading other issuers to increase their rates, leaving some geographic areas with limited or no affordable Exchange coverage options. Permitting the Secretary of HHS and the Secretary of the Treasury to modify the public notice procedures, in part, will help states seeking section 1332 waivers to address such circumstances more quickly and develop innovative ways to ensure consumers have access to affordable health care coverage. As such, HHS and the Department of the Treasury are of the view that, if certain safeguards are met, it is in the best interest of the public to provide states applying for section 1332 waivers with the option to request to modify public notice procedures during the PHE for COVID-19.

This IFC adds the new §§ 33.118 and 155.1318 and provides that the Secretary of HHS and the Secretary of the Treasury may modify, in part, the state public notice requirements specified in §§ 33.112 and 155.1312 and the Federal public notice requirements specified at §§ 33.116(b) and 155.1316(b) to expedite a decision on a proposed waiver request during the PHE for COVID-19 when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. Examples of the public notice procedures that currently apply under the aforementioned regulations that a state may seek to have waived or modified include the requirement that states notify the public and hold hearings prior to submitting an application, that the state hold more than one public hearing in more than one location and that HHS and the Department of the Treasury provide for public notice and comment after an application is determined to be complete. States may also seek to modify the state and/or Federal comment periods to be less than 30 days and to host public hearings virtually rather than in-person.

For a state to qualify for modification of the state or Federal public notice requirements to expedite a decision on a proposed waiver request during the PHE for COVID-19, a delay must undermine or compromise the purpose

of the proposed waiver request and be contrary to the interests of consumers. During the PHE for COVID-19, the Secretary of HHS and the Secretary of the Treasury (the Secretaries) may modify the Federal and/or state public notice procedures, in part, if the state meets all of the following:

- The state requests a modification in the form and manner specified by the Secretaries.
- The state acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the request for the modification for the waiver, and the waiver application request.
- The state details in its request for a modification, as applicable, the reason(s) the state seeks a modification from the state public notice procedures, describes how the state meets the modification criteria, and describes the alternative public notice procedures it proposes to implement at the state level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the state's request for a modification.
- The state details in its request for a modification, as applicable, the justification for the request and the alternative public notice procedures it requests to be implemented at the Federal level.
- The state must, as applicable, implement the alternative public notice procedures at the state level if the state's modification request is approved and, if required, amend the waiver application to specify that it is the state's intent to comply with those alternative public notice procedures in the state's modification request.

Any state submitting a proposed waiver request during the PHE for COVID-19 can submit a request to the Secretary of HHS and the Secretary of the Treasury for this modification from the state and/or Federal public notice procedures or include such a request in its section 1332 waiver application request.

The Secretary of HHS and the Secretary of the Treasury's review and consideration of a modification request will vary based on the state's circumstances, its modification request, and the complexity and breadth of the state's proposed section 1332 waiver request. For example, during the PHE for COVID-19, many states are prohibiting in-person public gatherings or establishing stay-at-home orders due

to the public health threat.⁶⁸ States seeking new section 1332 waiver(s) that have such prohibitions in effect at the time they would have otherwise have to conduct public notice would most likely be unable to comply with the public notice requirements to hold two in-person public hearings prior to submission of their section 1332 waiver applications in accordance with the 2018 Guidance addressing requirements under §§ 33.112(b) and 155.1312(b). In such cases, this IFC will allow the Secretaries to grant the state's request to hold the two public hearings virtually, rather than in-person, or to hold one public hearing at the state level, rather than two public hearings at the state level. As another example, the Secretaries may agree with a state that, due to emergency circumstances that have arisen related to the PHE for COVID-19, there is insufficient time for the state to provide public notice and hold any public hearings at the state level prior to submitting its section 1332 waiver application as required by §§ 33.112(a) and 155.1312(a), and grant the state's request to provide public notice and hold public hearings at the state level after the state submits its section 1332 waiver application.

In situations where HHS and the Department of the Treasury determine that public notice and hearings are warranted on a different timeframe and may occur after the submission of a state's waiver application request, the state will be required to amend the application request as necessary to reflect public comments or other relevant feedback received during the alternative public notice procedures. HHS and the Department of the Treasury will evaluate a state's request for a modification and issue their modification determination within approximately 15 calendar days after the request is received. In assessing whether a state acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the modification request for the waiver, and for the waiver application, HHS and the Department of the Treasury will evaluate whether the relevant circumstances constitute an emergency.

HHS and the Department of the Treasury remind states that any public participation processes must continue to comply with applicable Federal civil rights laws, including taking reasonable steps to provide meaningful access for individuals with limited English

⁶⁸ <https://khn.org/morning-breakout/states-declare-emergencies-ban-large-gatherings-as-coronavirus-sweeps-the-nation/>. <https://www.axios.com/states-shelter-in-place-coronavirus-66e9987a-a674-42bc-8d3f-070a1c0ee1a9.html>.

proficiency and taking appropriate steps to ensure effective communication with individuals with disabilities, including accessibility of information and communication technology. Please note that virtual meetings may present additional accessibility challenges for people with communications and mobility disabilities, as well as to those who lack broadband access. Ensuring effective communication may include providing American Sign Language interpretation and real-time captioning, and ensuring that the platform is interoperable with assistive technology for those with mobility difficulties. HHS and the Department of the Treasury especially encourage states to strive to obtain meaningful input from potentially affected populations, including low-income residents, residents with high expected health care costs, persons less likely to have access to care, and members of federally-recognized tribes, if applicable, as part of any alternative public participation process.⁶⁹

The Secretary of HHS will publish on the CMS website any modification determinations within 15 calendar days of the Secretary of HHS and the Secretary of the Treasury making such a determination, as well as the approved revised timeline for public comment at the state and Federal level, as applicable. In addition, under the new §§ 33.118 and 155.1318, the state will be required to publish on its website any modification requests and determinations within 15 calendar days of receipt of the determination, as well as the approved revised timeline for public comment at the state and Federal level, as applicable.

3. Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320)

As section 1332 waivers are likely to have a significant impact on individuals, states, and the Federal Government, the 2012 Final Rule established processes and methodologies to ensure that the Secretary of HHS and the Secretary of the Treasury receive adequate and appropriate information regarding

⁶⁹ As noted above, the HHS Office for Civil Rights enforces applicable Federal civil rights laws as described above, as well as laws protecting the exercise of conscience and religious freedom, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb-4). HHS's requirements are subject to these laws, and states may have obligations under these laws to protect conscience, prohibit coercion, and to ensure the free exercise of religion. U.S. Department of Health & Human Services, Office for Civil Rights, Conscience and Religious Freedom, <https://www.hhs.gov/conscience/index.html> (last visited Aug. 20, 2020).

section 1332 waivers (consistent with section 1332(a)(4)(B)(iv) of the PPACA). Under §§ 33.120(c) and 155.1320(c), to ensure continued public input within at least 6 months after the implementation date, and annually thereafter, states are required to hold a public forum at which members of the public have an opportunity to provide comments on the progress of the program authorized by the section 1332 waiver and to provide a summary of this forum to the Secretary of HHS as part of the quarterly and annual reports required under §§ 33.124 and 155.1324. Under §§ 33.120(c)(1) and 155.1320(c)(1), states are required to publish the date, time, and location of the public forum in a prominent location on the state's public website at least 30 days prior to the date of the planned public forum.

This IFC adds new §§ 33.120(c)(2) and 155.1320(c)(2), which provide that the Secretary of HHS and the Secretary of the Treasury (the Secretaries) may waive, in part, post award public notice requirements for an approved waiver outlined in §§ 33.120(c) and 155.1320(c) during the PHE for COVID-19 when the application of the post award public notice procedures would be contrary to the interests of consumers during the PHE for COVID-19.

The Secretaries may modify the post award public notice procedures, in part, when the state meets all of the following:

- The state requests a modification in the form and manner specified by the Secretaries.
- The state acts in good faith, and in a diligent, timely, and prudent manner to comply with the monitoring and compliance requirements under the regulations and specific terms and conditions of the waiver and to submit and prepare the request for a modification.
- The state details in its request for a modification the reason(s) the state seeks a modification from the state post award public notice procedures, describes how the state meets the modification criteria, and describes the alternative post award public notice procedures it proposes to implement at the state level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the state's request for a modification.

As part of HHS and the Department of the Treasury's monitoring and oversight of approved section 1332 waivers, the Secretary of HHS and the Secretary of the Treasury, at their discretion,

monitor the state's compliance with the specific terms and conditions of the waiver including, but not limited to, compliance with the guardrails, reporting requirements, and the post award forum requirements. Under the flexibilities provided in this IFC, the Secretaries may, for example, allow the public forum for an approved waiver that would take place or become due during the PHE for COVID-19 to be held virtually rather than as an in person gathering. HHS and the Department of the Treasury will work closely with states that have these approved flexibilities through oversight and monitoring activities to ensure open communication with states during the PHE for COVID-19. HHS and the Department of the Treasury also will remain focused on ensuring the public is informed about the implementation of programs authorized by section 1332 waivers and have a meaningful opportunity to comment on the implementation.

The Secretary of HHS and the Secretary of the Treasury will evaluate a state's request for a modification and issue their modification determination within approximately 15 calendar days after the request is received. The state is required to publish on its website any modification requests and determinations by HHS and the Department of the Treasury within 15 calendar days of receipt of the determination, as well as information on the approved revised timeline for the state's post award public notice procedures, as applicable. Since the state is already required to post materials as part of post award annual reporting requirements, such as the notice for the public forum and annual report, states will be responsible for ensuring that the public is aware of the determination to modify the public notice procedures and must include this information along with the information required under §§ 33.120(c)(1) and 155.1320(c)(1) in a prominent location on the state's public website.

HHS and the Department of the Treasury are of the view that post award forums are critical to ensure that the public has a regular opportunity to learn about and comment on the progress of section 1332 waivers. States that receive approval, to modify, in part, these post award public notice procedures would still need to meet all other requirements specified in §§ 33.112(b) and 155.1312(b). For example, should the state receive a modification approval that permits it to hold the post award public forum virtually instead of in person, the state must still publish the notice of its post award public notice on

the state's public website and use other effective means to communicate the required information to the public. The public notice must include the website, date, and time of the public forum that will be convened by the state, information related to the timeframe for comments, and how comments from the public on the section 1332 waiver must be submitted. HHS and the Department of the Treasury remind states that they still must also comply with Federal civil rights requirements, including laws pertaining to accessibility, if the Secretary of HHS and the Secretary of the Treasury approve a modification from all or a portion of the post award public notice procedures. In such a circumstance, the state would need to ensure these virtual public hearings are as accessible as possible during the PHE for COVID-19 so members of the public can participate and submit comments. The state should also track how many people are attending these forums, if possible.

V. Waiver of Proposed Rulemaking

Section 553(b) of the APA requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Section 553(c) further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Section 553(b)(B) authorizes the agency to waive these procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Section 553(d) ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Finally, the Congressional Review Act (CRA) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2).

As noted earlier in this preamble, on January 30, 2020, the International Health Regulations Emergency Committee of the WHO declared the

outbreak a "Public Health Emergency of international concern." On January 31, 2020, pursuant to section 319 of the PHS, the HHS Secretary determined that a PHE exists for the United States to aid the nation's health care community in responding to COVID-19. On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, the President declared the COVID-19 pandemic a national emergency. Effective October 23, 2020, the HHS Secretary renewed the January 31, 2020 determination, which was previously renewed on April 21, 2020 and July 25, 2020, that a PHE exists and has existed since January 27, 2020. This declaration, along with the HHS Secretary's January 30, 2020 declaration of a PHE, conferred on the HHS Secretary certain waiver authorities under section 1135 of the Act. On March 13, 2020, the HHS Secretary authorized waivers under section 1135 of the Act, effective March 1, 2020.⁷⁰

It is critically important that the Departments implement the policies in this IFC as quickly as possible. As the United States is in the midst of the PHE for COVID-19, the Departments find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 553(b)(B). For those same reasons, as authorized by section 808(2) of the CRA, the Departments find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under section 801 of the CRA. Therefore, the Departments find there is good cause to waive the CRA's delay in effective date pursuant to section 808(2) of the CRA. Thus, the Departments find good cause to waive the applicable delays in the effective date and, moreover, to establish these policies in this IFC applicable as of the date of display at the Office of the Federal Register.

In this IFC, consistent with section 1902(a)(4) and (a)(19) of the Act, the Department adds a new subpart G to 42 CFR part 433 to provide states with more flexibility, subject to certain safeguards, in implementing the requirement in section 6008(b)(3) of the FFCRA that states maintain Medicaid beneficiary enrollment in order to receive the temporary increase in Federal funding in the FFCRA. This temporary funding increase is effective beginning January 1, 2020 and could extend through the last day of the calendar quarter in which the PHE for COVID-19, including any extensions, terminates, if the state claims the

temporary funding increase in that quarter. This provision of the IFC is immediately necessary to ensure that states can determine eligibility and provide care and services during the PHE in a manner that is consistent with simplicity of administration and the best interests of beneficiaries and also claim the temporary funding increase.

In this IFC, HHS and the Department of the Treasury are setting forth flexibilities in the public notice and post award public participation requirements for a State Innovation Waiver described in section 1332 of PPACA during the PHE for COVID-19. HHS and the Department of the Treasury recognize that following the normal state and Federal public notice procedures and the state post award requirements for section 1332 waivers may impose barriers for states pursuing a proposed waiver request during the PHE for COVID-19. This guidance is intended to protect public health and prevent the spread of COVID-19 by limiting the need for in-person gatherings related to a section 1332 waiver. Additionally, states may face uncertainty as to whether their waiver requests will be approved in time to expeditiously reform their health insurance markets and to protect consumers from the effects of the PHE for COVID-19. Some states may not consider more robust changes because they were concerned that the current section 1332 waiver application requirements are too time-consuming or burdensome to be helpful during the PHE for COVID-19. HHS and the Department of the Treasury are of the view that the flexibility to modify certain public notice procedures and participation requirements will increase flexibility and reduce burden for states seeking to use section 1332 waivers as a means of innovation for providing coverage, lowering premiums, and improving their health care markets during the PHE for COVID-19. As such, these flexibilities are immediately necessary to provide states applying for a section 1332 waiver or during the post award period with the option to request a modification from the state and/or Federal public notice requirements when a delay would undermine or compromise the purpose of the waiver and be contrary to the interests of consumers. HHS and the Department of the Treasury are of the view that it could be contrary to the public interest to require full notice and comment during the current PHE for COVID-19 because following the normal timeframes and requirements could result in waiver approvals for

⁷⁰ <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>.

innovative waivers taking effect after issuers have already made their decisions regarding issuer participation in the individual market and after rates for the upcoming plan year have been submitted. A modification from the public participation requirements would be beneficial to the public interest by providing states and the Federal Government the flexibilities necessary to review and approve, as appropriate, section 1332 waivers that expand access to coverage on a faster timeframe.

In this IFC, the Departments amend the regulations under section 2713 of the PHS Act to implement the requirement in section 3203 of the CARES Act that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage without cost sharing for qualifying coronavirus preventive services. This coverage must be provided within 15 business days after the date on which a recommendation is made by the USPSTF or ACIP. The Departments also establish in this IFC that this coverage must be provided regardless of whether the service is delivered by an in-network or out-of-network provider.

The Departments are issuing these amendments under the authority of section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. These sections authorize the Secretaries of the Treasury, Labor, and HHS to promulgate any interim final rules that the Secretaries determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815. In addition, section 7805(e) of the Code restricts any temporary regulation issued by Treasury and the IRS under the Code, such as interim final regulations, to a duration of 3 years.

Several COVID-19 vaccine candidates are currently in late-stage development. Once a vaccine is authorized or approved by FDA, the Departments expect that ACIP may move expeditiously to recommend the immunization. In addition, unlike other preventive items and services typically provided according to regularly scheduled intervals, items and services intended to prevent or mitigate COVID-19 will not, in the immediate future, be provided as part of a usual course of preventive care. Instead, the Departments expect consumers to

receive these services once they are recommended for the general public or specific high-risk or high-priority populations. To help ensure full access to and the widespread use of qualifying coronavirus preventive services to mitigate the PHE for COVID 19, it is critical that individuals be able to receive such services from any provider authorized to provide the service. This is consistent with the objectives of Operation Warp Speed, which, as mentioned above, is a partnership among components of the Federal Government that engages with private firms to accelerate the development, manufacture, and distribution of a COVID-19 vaccine to the American people.

The provisions of this IFC therefore are immediately necessary to ensure group health plan and group and individual health insurance coverage of these items and services is prompt and broad, to ensure timely access to combat the pandemic. In this IFC, the Department adds a requirement at § 417.454 to require section 1876 cost plans to cover without cost sharing the COVID 19 vaccine and its administration described in section 1861(s)(10)(A) of the Act without cost sharing for the duration of the PHE for the COVID-19 pandemic, specifically the end of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Act, which is the PHE declared by the Secretary on January 31, 2020 and any renewals thereof. While section 1876(c)(2) of the Act ensures that enrollees in Medicare cost plans will have coverage of a COVID-19 vaccine and its administration, section 3713 of the CARES Act did not amend section 1876 of the Act to provide similar cost-sharing protections for enrollees in cost plans who receive the vaccine from an in-network provider. Currently, there is no requirement for cost plans to cover the COVID-19 vaccine and its administration without cost sharing (that is, with cost sharing that is the same as original Medicare) when the vaccine is furnished by an in-network health care provider. This provision of the IFC is immediately necessary to ensure that cost plan enrollees, like other Medicare beneficiaries, are provided access to the COVID-19 vaccine and its administration without cost sharing. This immediate action will ensure that cost is not a barrier for beneficiaries to get the vaccine, particularly during the public health emergency when ensuring access is paramount importance. The delay necessary for notice and comment rulemaking is both contrary to the

public interest and impractical here as it would delay access to a COVID-19 vaccine without cost sharing and be contrary to the need to ensure access to a COVID-19 vaccine for enrollees in cost plans on the same basis as is ensured for other Medicare beneficiaries.

Further, as underscored by the timeline for coverage Congress established in section 3203 of the CARES Act, the need to provide coverage of qualifying coronavirus preventive services is urgent. Following a recommendation of the USPSTF or ACIP, the requirement to provide coverage without cost sharing of qualifying coronavirus preventive services, which are expected to include immunizations, takes effect within 15 business days. Plans and issuers need immediate guidance to understand their obligations under section 3203 of the CARES Act and to take steps that will enable them to comply with those requirements as soon as the coverage requirement goes into effect. Delaying these provisions would likewise delay plans' and issuers' ability to prepare for the availability of a COVID-19 vaccine, resulting in barriers in access to coverage of these critical services during the PHE for COVID-19. As of the date of display of this regulation, there are not any coronavirus preventive services including vaccines for coronavirus that are required to be covered. However, because emergency use authorization or approval of a COVID-19 vaccine may be imminent, the Departments are of the view it is critical that these regulations under section 2713 of the PHS Act be issued and effective prior to such authorization or approval. The Departments are of the view that it would be impracticable and contrary to the public interest to undertake normal notice and comment rulemaking procedures in light of the urgent need to ensure coverage of and access to qualifying coronavirus preventive services to protect the public health as well as the health and safety of individuals and communities to prevent the spread of COVID-19. For these same reasons, the Departments are of the view a delayed effective date would also be contrary to the public interest. Ensuring individuals have access to a COVID-19 vaccine as soon as it becomes available is critical to ending the PHE for COVID-19, and therefore it is imperative that these regulations are in effect on the date such a vaccine becomes available and recommended by ACIP. Undertaking the standard rulemaking process of publishing a proposed rule, seeking public comment, carefully

analyzing those public comments, and subsequently publishing a final rule would possibly and perhaps likely jeopardize such an effective date.

The Departments are of the view that it would be impracticable and contrary to the public interest to undertake normal notice and comment procedures and to thereby delay the effective date of this IFC. The Departments find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 553(b)(B). For those same reasons, as authorized by section 808(2) of the CRA, the Departments find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under section 801 of the CRA. Therefore, the Departments find there is good cause to waive the CRA's delay in effective date pursuant to section 808(2) of the CRA. The provisions in this IFC will go into effect on the date of display.

This IFC implements the requirement that providers of diagnostic tests for COVID-19 make public their cash prices for COVID-19 diagnostic tests and specifies the COVID-19 diagnostic tests to which this requirement applies. This IFC further defines "provider of a diagnostic test for COVID-19" (referred to as "provider") as any facility that performs one or more COVID-19 diagnostic tests. In addition, this IFC defines "cash price" as the charge that applies to an individual who pays cash (or cash equivalent) for a COVID-19 diagnostic test. This IFC gives CMS discretion to take any of the following actions if CMS determines a provider is noncompliant with the requirements of new 45 CFR 182.50:

- Provide a written warning notice to the provider of the specific violation(s).
- Request that a provider submit and comply with a CAP.
- Impose a CMP on the provider if the provider fails to respond to CMS' request to submit a CAP or to comply with the requirements of a CAP approved by CMS.

As indicated above, these requirements are applicable during the PHE for COVID-19 (and any extensions to the PHE for COVID-19); therefore, it is critically important that we implement the policies in this IFC as quickly as possible in order for stakeholders to know with certainty during the PHE for COVID-19 how to comply with the law and what penalties they will face for noncompliance during the PHE for COVID-19. Moreover, these rules are necessary for CMS to enforce section 3202(b) of the CARES Act and to ensure plans, issuers, and consumers know in advance the price for a diagnostic test for COVID-19 during the PHE for COVID-19. For these reasons,

we believe it would be impracticable and contrary to the public interest to undertake normal notice and comment rulemaking procedures and to delay the effective date of the new requirements being adopted at 45 CFR part 182.

In this IFC, the Department creates a New COVID-19 Treatments Add-on Payment (NCTAP) under the Inpatient Prospective Payment System (IPPS) for COVID-19 cases that meet certain criteria. The Department is of the view that it would be impracticable and contrary to the public interest to undertake normal notice and comment procedures and to thereby delay the effective date of this IFC. As drug and biological products become available and are authorized or approved by FDA for the treatment of COVID-19 in the inpatient setting, there may be potential financial disincentives for hospitals to provide these new COVID-19 treatments to Medicare inpatients during the PHE because the costs of these new treatments are not yet reflected in Medicare payment rates and there are no new technology add-on payments for these treatments. The delay necessary for notice and comment rulemaking is both contrary to the public interest and impracticable because of the urgency in ensuring there are not financial disincentives for hospitals to provide COVID-19 treatments to beneficiaries during the PHE. We expect that increasing the current IPPS payment amounts for sufficiently costly cases to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE will potentially improve and speed access to these treatments for Medicare patients. We also believe that the establishment of the NCTAP provides greater transparency and predictability to the public, including innovators that are developing new COVID-19 treatments, as to how Medicare payments for cases involving these treatments will be determined when those treatments become available.

In this IFC, the Department assures separate payment for new COVID-19 treatments provided in the outpatient setting for the remainder of the Public Health Emergency for COVID-19. The Department is of the view that it would be impracticable and contrary to the public interest to undertake normal notice and comment procedures and to thereby delay the effective date of this IFC. We anticipate that most drugs and biological products authorized or approved for use in treating COVID-19 in the outpatient setting would be separately paid under our standard OPSS payment policy; however, these

products could be packaged into a Comprehensive Ambulatory Payment Classification (C-APC) payment when provided on the same claim as a C-APC service, in which case separate payment would not be made for these products. Although we do not expect that many beneficiaries would both receive a primary C-APC service and a drug or biological for treating COVID-19, we nonetheless believe that as drugs or biologicals become available and are authorized or approved for the treatment of COVID-19 in the outpatient setting, it would be appropriate to mitigate any potential financial disincentives for hospitals to provide these new treatments during the PHE for COVID-19. The delay necessary for notice and comment rulemaking to address this issue is both contrary to the public interest and impracticable because of the urgency in ensuring there are not financial disincentives for hospitals to provide COVID-19 treatments to beneficiaries. Therefore, effective for services furnished on or after the effective date of this rule and until the end of the PHE for COVID-19, CMS is creating an exception to its OPSS C-APC policy to ensure separate payment for new COVID-19 treatments that meet certain criteria.

In this IFC, the Department adds changes to the CJR model that are immediately necessary to continue the CJR model consistent with model goals to, cover inpatient major lower joint replacements without interruption, and to reduce operational and financial uncertainty for CJR hospital participants during and beyond the PHE. Ending on March 31, 2021 would be disruptive to hospitals and patient care during the PHE. The end date of March 31, 2021, means hospitals stop initiating episodes under the model after January 2, 2021, before the end of the public health emergency as renewed on October 23, 2020.⁷¹ Extending the model through an additional six months of performance year (PY) 5, so that PY 5 now ends on September 30, 2021, provides participant hospitals with greater certainty in model operations during the remainder of the PHE.

Through this IFC we are implementing four changes to the CJR model needed to extend PY 5. These are: (1) Extending PY 5 an additional 6 months to provide for continuity of model operations with the same scope while we continue to consider comments received on our proposal to extend the model to PYs 6 through 8 and adopt other changes to the model

⁷¹ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx>

(42 CFR 510.2 and 510.200(a)); (2) making changes to the reconciliation process for PY 5 to allow for two periods and to enable more frequent receipt of reconciliation reports by participants (42 CFR 510.2, 42 CFR 510.200, 42 CFR 510.305(b), (d)(1), (e), (i)(1) and (2), and (j)(1) and (2), and 42 CFR 510.400(b)(3)(v), and adding 42 CFR 510.400(b)(3)(vi)); (3) making a technical change, retroactive to October 1, 2020, to ensure that the model continues to include the same inpatient Lower Extremity Joint Replacement (LEJR) procedures, despite the adoption of new MS-DRGs to describe those procedures (42 CFR 510.300(a)(1)(i) and (iii)); and (4) making changes to the extreme and uncontrollable circumstances policy for COVID-19 to adapt to an increase in CJR episode volume and renewal of the PHE, while providing protection against financial consequences of COVID-19 after the extreme and uncontrollable circumstances policy no longer applies (42 CFR 510.300).

Implementing an additional six months of PY 5, so that PY 5 now ends on September 30, 2021 (hospitals stop initiating new episodes under the model after July 2, 2021) provides participant hospitals additional relief and stability in model operations while the end of the PHE remains unknown. We have modified the reconciliation process to provide payments consistent with the current annual reconciliation schedule for hospitals for greater stability. Absent modification to the reconciliation process, the extension of PY 5 to a total of 21 months, from January 1, 2020 through September 30, 2021 would mean that participant hospitals would experience a 21-month gap between the PY4 final reconciliation in June of 2020 and initial PY 5 reconciliation in early 2022. In the FY 2021 IPPS/LTCH final rule, we stated that because the CJR model would continue until at least March 31, 2021, we intended to adopt a policy in the CJR final rule that incorporates new MS-DRGs for the same procedures currently included in the CJR model, under prior MS-DRGs, as of their effective date to avoid disruption to the model for the remainder of PY5 (as extended) and thereafter, if our proposal to extend the CJR model through PY8 were finalized (85 FR 58502). We are adopting the change in this IFC, retroactive to October 1, 2020 because without a change the model ceases to continue as a comprehensive joint replacement model. Not making this change would have a significant impact on operational stability. Finally, this interim final rule

with comment specifies an end for the current extreme and uncontrollable adjustment in 42 CFR 510.300(k)(4). In order to provide participant hospitals continuing financial protection from the effect of COVID-19 on the CJR model that may continue beyond the end of the PHE for COVID-19 or March 31, 2021, whichever occurs earlier, we are implementing that actual episode payments are capped at the quality adjusted target price determined for that episode under § 510.300 for episodes with actual episode payments that include a claim with a COVID-19 diagnosis code and initiate after the earlier of March 31, 2021 or the last day of the emergency period. This policy is consistent with flexibilities and protections for impact of COVID-19 in other Innovation Center models. For all of these revisions, we believe it is contrary to the public interest to undertake traditional notice and comment rulemaking to adopt these regulatory changes because they preserve the model's scope and operations at current levels, fostering model stability now and in the future for hospital operations during and beyond the PHE.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, the Departments are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that the Departments solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the agency.
- The accuracy of the estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The Departments are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). The requirements and burden will be submitted to under OMB Control Number 0938-NEW.

A. ICRs for Price Transparency for COVID-19 Diagnostic Tests

As discussed in section II.C of this IFC, section 3202(b) of the CARES Act establishes a requirement to publicize cash prices for COVID-19 diagnostic tests during the PHE. For purposes of implementing section 3202(b) of the CARES Act, we are adding new 45 CFR part 182, "Price Transparency for COVID-19 Diagnostic Tests," that will codify price transparency requirements for the performance of a COVID-19 diagnostic test.

There are several types of COVID-19 tests designed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19, including: molecular (RT-PCR) tests, which are used to detect the virus's genetic material; antigen tests, which are used to detect specific proteins on the surface of the virus; and serology testing, which is used to look for the presence of antibodies produced by the body in response to infections.

For purposes of 45 CFR part 182, we are defining "provider of a diagnostic test for COVID-19" as any facility that performs one or more COVID-19 diagnostic tests. In order to perform a diagnostic test for COVID-19 and report patient-specific results, a facility (whether that be a primary care provider's office, urgent care center, outpatient hospital site or stand-alone laboratory) is required to hold a CLIA certificate based on the complexity of the testing performed by the facility. Therefore, we expect that any "provider of a COVID-19 diagnostic test" would hold a CLIA certificate (including a certificate of waiver or certificate of registration) and that such testing would occur in facilities ranging from primary care provider offices to urgent care centers to stand-alone national laboratories.

As explained in section VIII.B of this IFC, we estimate that approximately 83,309 CLIA providers could potentially be performing COVID-19 diagnostic tests and need to publicize their cash prices. For purposes of this IFC, we are estimating it will take a business operations specialist (13-1000), on average 1 hour for a total of 83,309 burden hours to compile and make public the cash prices for COVID-19 diagnostic tests, at an hourly wage of \$36.31 as published by the BLS in 2019.⁷² We estimate the overhead and fringe benefit cost to be 100 percent of wages. Therefore, we estimate a one-time cost per provider to be \$72.62

⁷² Bureau of Labor Statistics, National Occupational Employment and Wage Estimates, May 2019. Available at: https://www.bls.gov/oes/current/oes_nat.htm#13-0000.

(\$36.31 × 2) and the total cost estimated to be \$6,049,900 (83,309 hours × \$72.62) to collect, compile and post the required information.

B. ICRs for State Innovation Waivers Policy and Regulatory Revision in Response to COVID-19 Public Health Emergency

This IFC provides that states are required to submit modification requests to the Secretary of HHS and the Secretary of the Treasury in order to obtain approval for the modifications made available by this IFC. Any state can submit a request to the Secretaries for a modification from the state and/or Federal public notice procedures or include such a request in their section 1332 waiver application if the waiver application is submitted during the PHE for COVID-19. The request must describe the reason the state seeks a modification from the state public notice procedures, describe how the state meets the modification criteria, describe the alternative public notice procedures it proposes to implement at the state level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the state’s request for a modification. The request must describe the reason the state seeks a modification

from the Federal public notice procedures and the alternative public notice procedures it requests to be implemented at the Federal level, as applicable.

A state with an approved section 1332 waiver can submit a request to HHS and the Department of Treasury for a modification from post award public notice procedures. The request must specify the reason the state seeks a modification from the post award public notice procedures, describe how the state meets the modification criteria, and describe the alternative procedures it proposes to implement at the state level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the state’s request for a modification.

While HHS and the Department of Treasury do not have data available to predict the number of states that will likely request a modification of either the waiver application or the post award public notice procedures, HHS and the Department of Treasury estimate it will take a senior manager 1 hour to prepare a state’s request, with an equivalent cost of approximately \$118.⁷³ In addition, if HHS and the Department of Treasury approve a state’s modification request, the state will have to post the

determination on their website within 15 days of the approval. HHS and the Department of Treasury estimate that for each state, it will take a network and computer systems administrator 15 minutes to post the approval with an equivalent cost of approximately \$21.⁷⁴ Assuming that approximately 15 states will submit a modification request, the total burden hours for all states will be 15 hours, with an equivalent cost of approximately \$1,775. HHS and the Department of Treasury have assumed that 15 states will submit a request because, as of display of this IFC, 15 states have an approved 1332 waiver. This is an upper bound, since some states may not need to request the available modification for their waivers, and therefore, will incur no burden. Furthermore, assuming that approximately 15 states receive approval of the modification request and then must post the approval, the total burden hours for all states will be approximately 3.75 hours, with an equivalent cost of approximately \$319. This is an upper bound, since some states may not receive approval, and therefore, will incur a lower (or no) burden. The total estimated burden hours assuming approximately 15 states apply for and receive approval of the modification request is 18.75 hours, with an equivalent cost of approximately \$2,094.

TABLE 3—ESTIMATED COST AND BURDEN HOURS PER RESPONDENT

BLS occupation	Average burden hour per respondent (in hours)	Hourly wage rates	Total cost per respondent
Senior Manager	1	\$118.30	\$118.30
Network and Computer Systems Administrator	0.25	85.02	21.26
Total	1.25	139.56

TABLE 4—ESTIMATED TOTAL COST AND BURDEN FOR ALL RESPONDENTS

	Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
Modification Request	15	15	1	15	\$1,775
Posting modification approval	15	15	0.25	3.75	319
Total	15	1.25	18.75	2,094

⁷³ Using data from the Bureau of Labor Statistics (BLS) for General and Operations Managers (Code 11-1020), we estimate that the average hourly labor cost will be \$118.30, including 100 percent increase

for overhead and fringe benefits. https://www.bls.gov/oes/current/oes_stru.htm.
⁷⁴ Using data from the BLS for Network and Computer Systems Administrators (Code 15-1244),

we estimate that the average hourly labor cost will be \$85.02, including 100 percent increase for overhead and fringe benefits. https://www.bls.gov/oes/current/oes_stru.htm.

C. ICRs Regarding the Comprehensive Joint Replacement (CJR) Model

Section 1115A(d)(3) of the Social Security Act exempts the Center for Medicare and Medicaid Innovation (CMMI) model tests and expansions, from the PRA. The section provides that Chapter 35 of title 44, United States Code, which includes such provisions as the PRA, shall not apply to the testing and evaluation of CMMI models or expansion of such models.

D. ICRs Regarding Enrollment as Mass Immunization Roster Biller

As discussed in section II.A.1. of this IFC, a mass immunizer may be enrolled in Medicare as another type of provider

or supplier such as a physician, non-physician practitioner, hospital outpatient department, home health agency, or skilled nursing facility. However, an entity that does not otherwise qualify as a Medicare provider or supplier but wishes to furnish mass immunization services may be eligible to enroll in Medicare as a “Mass Immunization Roster Biller” via the Form CMS–855B enrollment application (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB Control No.: 0938–0685; Expires 12/21).

This section discusses our burden estimates for the enrollment of mass immunization roster billers via the Form CMS–855B application as well as the

PRA exemption we are claiming for the appeals process.

1. Cost of Completing Form CMS–855B

Using our internal data, we generally estimate that approximately 60,000 entities (the preponderance of which will be pharmacies) will seek to enroll as mass immunization roster billers pursuant to the IFC, all of whom will attempt enrollment in the 12-month period following the IFC’s display. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2019 (see http://www.bls.gov/oes/current/oes_nat.htm), the mean hourly wages for the following categories are:

TABLE 5—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
Healthcare Diagnosing or Treating Practitioners	29–1000	49.26	49.26	98.52
Medical Secretaries and Administrative Assistants	43–6013	18.31	18.31	36.62

Consistent with Form CMS–855B projections made in recent rulemaking efforts, it will take each entity an average of 2.5 hours to obtain and furnish the information on the Form CMS–855B. Per our experience, the entity’s medical secretary will secure and report this data, a task that would take approximately 2 hours. Additionally, a health diagnosing and treating practitioner of the entity will review and sign the form, a process we estimate takes 30 minutes. We therefore project a total burden of 150,000 hours (60,000 suppliers × 2.5 hrs) at a cost of \$7,350,000 (60,000 suppliers × ((2 hrs × \$36.62/hr) + (0.5 hrs × \$98.52/hr))). When averaged over the typical 3-year OMB approval period, we estimate an annual burden of 50,000 hours (150,000 hrs/3) at a cost of \$2,450,000 (\$7,350,000/3).

2. Appeals

Pursuant to 42 CFR part 498, a mass immunization roster biller may appeal the denial or revocation of its enrollment. While there are information collection requirements associated with the appeals process, we believe they are exempt from the PRA. In accordance with the implementing regulations of the PRA at 5 CFR 1320.4(a)(2), the information collection requirements associated with the appeals process are subsequent to an administrative action (specifically, the denial or revocation of a mass immunization roster biller’s enrollment). Therefore, we have not

developed burden estimates. We also believe that any costs associated with mass immunization roster biller enrollment will, in any event, be *de minimis*; this is because we anticipate, based on past experience, there would be comparatively few denials and revocations of such enrollments.

Response to Comments

Because of the large number of public comments normally received on **Federal Register** documents, the Departments are not able to acknowledge or respond to them individually. All comments received by the date and time specified in the **DATES** section of this preamble will be considered, and, when the Departments proceed with a subsequent document, the Departments will respond to the comments in the preamble to that document.

Regulatory Impact Analysis

A. Statement of Need

The flexibilities and changes contained within this IFC are responsive to the PHE for COVID–19. The policies implemented in this IFC will provide flexibilities, during the PHE for COVID–19, to states pursuing waivers under section 1332 of the PPACA and to states with approved section 1332 waivers. Additionally, the policies and regulatory updates implemented in this IFC will increase the affordability with regards to section 1332 waiver applications and support continuity of health insurance coverage for

consumers in the individual and small group (or merged) market during the PHE for COVID–19. This IFC also implements section 3202(b) of the CARES Act, which requires that providers of COVID–19 diagnostic tests make public their cash prices for those tests and establishes an enforcement scheme to enforce those requirements during the PHE for COVID–19.

In section 3203 of the CARES Act, Congress required group health plans and issuers of group or individual health insurance coverage to cover without cost sharing qualifying coronavirus preventive services, and required such coverage to be provided within 15 business days after the date on which an applicable recommendation is made relating to such service. The Departments codify these requirements in this IFC, and finalize amendments to the regulations implementing section 2713 of the PHS Act at 26 CFR 54.9815–2713; 29 CFR 2590.715–2713; and 45 CFR 147.130 that are intended to help ensure full access to and the widespread use of qualifying coronavirus preventive services to mitigate the public health emergency.

B. Overall Impact

The Departments have examined the potential impacts 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 (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the 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). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting 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) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and a “significant” regulatory action is subject to review by the OMB. The Departments have determined that these rules are likely to have economic impacts of \$100 million or more in at least one year, and thus, meet the definition of “economically significant” under Executive Order 12866 and a major rule under the Congressional Review Act. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

C. Detailed Economic Analysis

1. Effect of Price Transparency for COVID–19 Diagnostic Tests During the PHE

As discussed in section ILC of this IFC, Section 3202(b) of the CARES Act establishes a requirement to publicize cash prices for COVID–19 diagnostic tests during the PHE. For purposes of implementing section 3202(b) of the CARES Act, we are adding new 45 CFR part 182, “Price Transparency for COVID–19 Diagnostic Tests,” that will codify price transparency requirements for the actual performance of a COVID–19 diagnostic test. At § 182.20, we are defining a “COVID–19 diagnostic test” as a COVID–19 *in vitro* diagnostic test described in section 6001 of the FFCRA, as amended by section 3201 of the CARES Act.

This IFC defines a “provider of a diagnostic test for COVID–19” (referred to as “provider”) as any facility that performs one or more COVID–19 diagnostic tests. In order to perform a COVID–19 diagnostic tests and report patient-specific results, a facility is required to hold a CLIA certificate based on the complexity of the testing performed by the facility. This IFC requires providers of COVID–19 diagnostic tests to make public the cash price for such tests on a public internet website of such provider during the emergency period declared under section 319 of the PHS Act. In the event that a provider does not have its own website on which to post this cash price information, § 182.40(b) states that the provider would be required to make public its cash price information in writing, within two business days upon request, and by posting signage prominently at the provider’s COVID–19 diagnostic testing location, if such location is accessible to the public.

We anticipate that price transparency has potential beneficial marketplace benefits generally, as discussed in detail in the CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates, Price Transparency Requirements for Hospitals To Make Standard Charges Public Final Rule (84 FR 65524) and the Transparency in Coverage Proposed Rule (84 FR 65464). As noted in section ILC of this IFC, section 3202 of the CARES Act addresses reimbursement of COVID–19 diagnostic tests. Section 3202(a) of the CARES Act requires group health plans and issuers that provide coverage for items and services described in section 6001(a) of the FFCRA to reimburse any provider of a COVID–19 diagnostic test an amount

that equals the negotiated rate, or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on a public website. We anticipate that price transparency in COVID–19 diagnostic testing, in particular, will help improve clarity for consumers and the plans and issuers that are required to cover the cost of performing a COVID–19 diagnostic test when there is no negotiated rate between the plan or issuer and the provider. For individuals without insurance and for health plans and health insurance issuers attempting to negotiate a rate for performance of a COVID–19 diagnostic test with a provider that has posted its cash price, that cash price could provide some context and a baseline against which those negotiations can occur. Moreover, price transparency in COVID–19 diagnostic tests will assist the uninsured in determining the cash price at various providers when price shopping for COVID–19 diagnostic tests.

Assessments of broader transparency policies yield per-capita estimates of annual expenditure reductions ranging from between \$3 and \$5 (= \$2.8 million + \$1.3 million + \$7.0 million + \$2.3 million two-year savings, across 1.3 million California public employees and their family members, per Boynton and Robinson (2015)), to \$6.50 (= \$7.9 million + \$36 million five-year savings found by Brown (2018), divided across the 1.36 million residents of New Hampshire), to \$17 (= \$13.2 million three-year savings across 0.26 million beneficiaries, per Rhoads (2019)).⁷⁵ If the \$6.50 median result is extrapolated from the context of general health spending—which is approximately \$10,000 per capita in the United States—to a range of between \$60 and \$1,200 in COVID–19 diagnostic testing (= \$60 per test, across between one and 20 tests), the estimate of rule-induced reductions in annual consumer expenditures could range from \$13 million to \$254 million. (This expenditure change combines transfers (to patients or insurers from providers)

⁷⁵ Boynton, A., and Robinson, J. “Appropriate Use of Reference Pricing Can Increase Value.” Health Affairs Blog, July 7, 2015. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20150707.049155/full/>. Brown, Z. Y. “Equilibrium Effects of Health Care Price Information.” 100 Rev. of Econ. and Stat. 1. July 16, 2018. Available at: http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf. Rhoads, J. “Right to Shop for Public Employees: How health care incentives are saving money in Kentucky.” The Dartmouth Institute for Health Policy and Clinical Practice. March 8, 2019. Available at: <https://thefga.org/wp-content/uploads/2019/03/RTS-Kentucky-HealthCareIncentivesSavingMoney-DRAFT8.pdf>.

with potential societal resource cost savings; only the latter portion should be compared against estimates of the provision's administrative and paperwork costs.) We note, however, that this estimate is based on annual expenditure reductions; because this requirement is only applicable for the remainder of the PHE, which may be less than a year, the saving impact is likely to be lower.

To comply with the regulatory updates in this IFC, providers would need to review their billing practices and determine their "cash price" for COVID-19 diagnostic tests. They would further need to publicly post the cash prices for all COVID-19 diagnostic tests along with associated plain language descriptions and HCPCS or CPT billing codes. The provider would be required to make all of this information public on the provider's internet website. As discussed in section VI.C, we estimate it would take a Business Operations Specialist, on average 1 hour to compile and make public the cash prices for the COVID-19 diagnostic tests that the facility offers at an hourly wage of \$36.31 as published by the 2019 Bureau of Labor Statistics.⁷⁶ We estimate the overhead and fringe benefit cost to be 100 percent of wages. Therefore, we estimate a one-time cost per provider to be \$72.62 (36.31×2).

We expect that approximately 30 percent⁷⁷ (n = 83,309) of the total CLIA-certified laboratories (n = 277,699⁷⁸) could potentially be performing COVID-19 diagnostic tests and need to publicize their cash prices in such form and manner as prescribed in new 45 CFR part 182 during the PHE for COVID-19, including any subsequent renewals. The total cost is estimated to be \$6,049,900 (83,309 hours \times \$72.62) to collect, compile and post the required information.

We seek comment on the burden estimate for providers of a diagnostic test for COVID-19, specifically the number of burden hours estimated to post their cash price for COVID-19 diagnostic test.

⁷⁶ Bureau of Labor Statistics. National Occupational Employment and Wage Estimates, May 2019. Available at: https://www.bls.gov/oes/current/oes_nat.htm#13-0000.

⁷⁷ Consistent with the percent of laboratories required to report COVID-19 diagnostic test results in CMS-3401-IFC.

⁷⁸ As of October 11, 2020, according to the Certification and Survey Provider Enhanced Reporting system this includes Certificate of Waiver (210,669), Certificate of Provider-Performed Microscopy (31,992), Certificate of Compliance (19,044) and Certificate of Accreditation (15,994). Available at: https://qcor.cms.gov/CLIA_wizard.jsp?which=4&report=active_CLIA.jsp.

2. Effects of Medicare Inpatient Prospective Payment System (IPPS) New COVID-19 Treatments Add-on Payment (NCTAP) for the Remainder of the Public Health Emergency (PHE)

As drug and biological products become available and are authorized or approved by FDA for the treatment of COVID-19 in the inpatient setting, there may be potential financial disincentives for hospitals to provide these new COVID-19 treatments to Medicare inpatients during the PHE because the costs of these new treatments are not yet reflected in Medicare payment rates and there are no new technology add-on payments for these treatments. We expect that increasing the current IPPS payment amounts for sufficiently costly cases to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE will potentially improve and speed access to these treatments for Medicare patients. We also believe that the establishment of the NCTAP provides greater transparency and predictability to the public, including innovators that are developing new COVID-19 treatments, as to how Medicare payments for cases involving these treatments will be determined when those treatments become available.

Given it is unknown what the cost and utilization of inpatient stays using these new treatments will be, the net overall cost of the NCTAP policy is not estimable. On one extreme, if all of the new COVID-19 treatments decrease the net cost of hospitalizations (for example, due to shortened lengths of stay), including the cost of the new treatment, below the Medicare payment as increased by section 3710 of the CARES Act then there would be no NCTAP payments made and no additional cost to the Medicare program as a result of this policy. On the other extreme, if all of the new COVID-19 treatments result in the net cost of hospitalizations that exceed the outlier threshold (for example, due to the cost of the new treatment), the cost to the Medicare program would be the sum over all NCTAP cases of 0.65 times the outlier threshold for each case.

3. Effects of the Medicare Outpatient Prospective Payment System (OPPS) Separate Payment for New COVID-19 Treatments Policy for the Remainder of the Public Health Emergency (PHE) for COVID-19

This IFC provides for separate payment for New COVID-19 Treatments under the Outpatient Prospective Payment System (OPPS) for the remainder of the PHE for COVID-19

when these treatments are provided at the same time as a Comprehensive Ambulatory Payment Classification (C-APC) service. As we noted in Section II.E.2, we believe it would be a fairly rare occurrence that an outpatient department would perform a C-APC procedure on a beneficiary being treated for COVID-19 because most C-APCs are for surgical or other intensive procedures and we would expect most hospital outpatient departments would not perform outpatient surgery on a patient that has an active case of COVID-19. While it is possible that future COVID-19 treatments that are authorized or approved for use in the outpatient setting might be administered to patients under observation while the provider determines if the patient needs to be admitted to the hospital for COVID-19, it is our expectation that this hypothetical situation would not happen frequently. Because we believe a new COVID-19 treatment will rarely be provided on the same claim as a primary C-APC service, we believe new COVID-19 treatments used in the outpatient setting will be separately paid under current policy the vast majority of the time. As a result, we believe any budgetary effect of this new exception is likely to be de minimis.

4. Effects of Temporary Increase in Federal Medicaid Funding

This IFC interprets the requirement in section 6008(b)(3) of the FFCRA that states maintain Medicaid beneficiary enrollment as a condition of receiving the temporary FMAP increase described at section 6008(a) of the FFCRA. This IFC provides states with greater flexibility than current CMS guidance to transition beneficiaries between eligibility groups, to modify the amount, duration, and scope of coverage available to beneficiaries, and to make changes to applicable cost sharing and beneficiary liability. At the same time, this IFC protects beneficiary access to medical assistance by requiring states to maintain each beneficiary's coverage in one of three tiers, thereby protecting access to the basic coverage a beneficiary was receiving as of or after March 18, 2020.

We anticipate that this IFC will result in lessened financial burden on state Medicaid agencies and the Federal Government as compared to CMS's existing interpretation of the FFCRA 6008(b)(3) requirement. It would be highly challenging to estimate specific cost savings resulting from this IFC because such an estimate would be almost entirely dependent on state behavior under the unique circumstances of the PHE for COVID-

19. First, we believe that some savings may result from transitioning beneficiaries to different eligibility groups with greater cost sharing or beneficiary liability. However, we know that states have faced both system and operational constraints that may prevent them from processing routine actions, such as transitioning a beneficiary from one group to another following a change in circumstances. A state that has been processing eligibility renewals and redeterminations during the PHE may be able to make such transitions relatively quickly, while a state that has been unable to process changes without violating the requirements for receiving the temporary FMAP increase may need more time to begin transferring beneficiaries between groups.

Second, we anticipate that states will implement the new flexibilities offered by this rule in a variety of ways and to different degrees. States may, for example, look for cost savings through the elimination of an optional benefit, establishing new copayments for services that are unrelated to the PHE, or increasing beneficiary liability for institutional care through a reduction to the personal needs allowance. Because each state's financial situation is unique and the characteristics of each Medicaid program are different, it is difficult to predict how states will respond to this IFC. While one state may elect to implement just one cost saving flexibility, another state may utilize all available options, and yet another state may elect not to make any program changes. Based on the recent feedback we have received from states, we do anticipate that some states will implement some of these cost saving measures, which will result in decreased financial burden for states and cost savings for the Federal Government.

While our current interpretation of section 6008(b)(3) of the FFCRA provides the strongest protections for beneficiary access to coverage, the safeguards established by this IFC will ensure that all beneficiaries maintain the same basic level of access to coverage that they were receiving as of or after March 18, 2020. All beneficiaries who had access to minimum essential coverage will maintain access to such coverage, and every beneficiary who had access to testing services and treatment for COVID-19, including vaccines, will retain such access. Individual beneficiaries may be required to pay cost sharing that they were not previously charged (except with respect to testing and treatment services related to COVID-19, which states cannot

charge under section 6008(b)(4) of the FFCRA if they are claiming the temporary FMAP increase), or they may need to meet additional prior authorization or medical necessity requirements.

5. Effects of Updates to the Comprehensive Care for Joint Replacement (CJR) Model, Performance Year (PY) 5 During the PHE

The evolving impact of the PHE for the COVID-19 has created difficulties in forecasting the state of the LEJR market for 2021. For example, Table 1 indicates CJR episode volume increasing and moving back toward traditional levels from April to June, but then decreasing again in July and August. It is difficult to predict the impact of extending PY 5 an additional 6 months with the amended policies described above because there exists a potential for variation between PY 5 target prices and PY 5 actual episode costs (as a result of COVID-19) which creates uncertainty in calculating anticipated net reconciliation amounts for PY 5. As a result, the Office of the Actuary was unable create projections regarding Medicare program spending in 2021 for MS-DRGs 469, 470, 521, or 522 or discrete impact estimates regarding the effect of extending CJR PY 5 an additional 6 months with the amended policies described above. In assessing the potential cost or savings for this extension, CMMI internal analysis considered the following data points. First, the Second Annual CJR Evaluation Report,⁷⁹ indicates participant hospitals reduced spending by 3.7 percent (difference in claims) during the first 2 years of the CJR model. Additionally, if the episode definition policy were not amended to include the new MS-DRGs and fracture episodes were no longer included in the CJR episode definition October 1, 2020—March 31, 2021, episode volume would decrease significantly and the cost saving effect of the CJR model would be limited to only non-fracture episodes, which are generally the less costly episodes. We also know that while the CJR model achieves program savings, this observation is not net of reconciliation payments and administrative costs. Further, our February 2020 proposed rule (85 FR 10516) proposes payment methodology revisions to the target price methodology to improve payment accuracy as the current methodology tends to excessive payment. Given the

confluence of factors affecting payments, including episode volume, actual episode costs, and even target prices, we cannot confidently estimate cost or savings associated with the CJR model changes in this final rule, specifically, the provisions: to add reconciliation periods to PY 5, to add MS-DRGs 521 and 522 to the episode definition, to change the extreme and uncontrollable circumstances policy, and to extend PY5 6 months. We will continue to refine this analysis. If the February 2020 proposed rule is finalized after review and response to comment, we will strive to provide a more detailed estimate for future model performance years.

6. Effects of Rapid Coverage of Preventative Services for Coronavirus

This IFC requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage for qualifying coronavirus preventive services, including recommended COVID-19 immunizations and their administration, without any cost sharing. It also requires plans and issuers to provide coverage within 15 business days after the date on which an applicable recommendation is made by USPSTF or ACIP relating to such a service. In addition, it requires that during the PHE for COVID-19 a group health plan or issuer that has a network of providers to provide coverage without cost sharing regardless of whether the service is delivered by an in-network or out-of-network provider. Making these qualifying coronavirus preventive services, including COVID-19 immunizations, available without any delay is in the interest of public health, as making these services available as quickly as possible may encourage individuals to take advantage of these services and therefore may slow the transmission of COVID-19. Access to qualifying coronavirus preventive services without cost sharing will encourage more individuals to obtain them. Increased use of qualifying coronavirus preventive services may reduce the transmission and spread of the disease and thus potentially result in better overall health outcomes. In the immediate term, newly developed qualifying coronavirus preventive services might be available from a narrower range of providers than other, more established recommended preventive items and services. If COVID-19 immunizations require specialized storage and administration services, only a limited number of

⁷⁹ CMS Comprehensive Care for Joint Replacement Model: Performance Year 2 Evaluation Report Available at <https://innovation.cms.gov/files/reports/cjr-secondannrpt.pdf>.

providers may be able to offer them at first. If consumers have to incur additional burdens, long wait times, and increased travel times to find an in-network provider that can provide such services, it will limit access and discourage them from obtaining such services. Therefore, the Departments are of the view that requiring out-of-network coverage without cost sharing for qualifying coronavirus preventive services will help ensure that consumers are able to obtain the preventive services without cost sharing as soon as possible.

Plans and issuers will incur the cost of the qualifying coronavirus preventive services and administration of such services. Providing coverage within 15 business days after a recommendation is made relating to such services is likely to impose significant administrative costs on issuers, group health plans, and other service providers to update systems to include billing codes for the preventive services, negotiate prices with network providers, determine reimbursements for out-of-network providers, and conduct outreach to providers, participants, beneficiaries, and enrollees in a very short time period. Depending on the magnitude of the costs of qualifying coronavirus preventive services and administration of such services relative to the potential cost of treatment for the disease, this may have an impact on premiums. There are uncertainties regarding the price of potential qualifying coronavirus preventive services, including COVID-19 immunizations. If the prices are high and there is widespread use of such services, premiums may increase. If the timing of availability of the preventive services is such that plans and issuers are unable to take them into account when setting premiums, it may result in lower profits or losses for plans and issuers. The costs to plans and issuers will be lower if a third party, such as the Federal Government, covers the cost of the immunizations. In addition, the costs associated with providing coverage for qualifying coronavirus preventive services may be offset by savings from avoidance of treatment for COVID-19.

During the PHE for COVID-19, costs to group health plans or issuers that have networks of providers will be higher if a significant number of participants, beneficiaries, or enrollees go to out-of-network providers, and the issuers and plans reimburse those out-of-network providers at higher levels than their negotiated rate with in-network providers. However, if consumers can obtain the qualifying coronavirus preventive services where

they usually obtain health care services, consumers are likely to receive the services from an in-network provider. Plans and issuers may also wish to educate participants, beneficiaries, or enrollees about the availability of the services from in-network providers and encourage them to obtain these services from their usual providers. This approach could limit the number of participants, beneficiaries, or enrollees going to out-of-network providers instead of staying in network, but there will be associated administrative burdens and costs.

The total cost to plans and issuers related to qualifying coronavirus preventive services that are immunizations will depend on the cost and number of required immunization doses to be administered, the number of people who will choose to get immunized against COVID-19 and which providers will be able to provide the preventive services. For the 2018-19 influenza season, 62.6 percent of children 6 months through 17 years and 45.3 percent of adults 18 years and older obtained the influenza vaccine.⁸⁰ Given the severity of COVID-19, the Departments anticipate the immunization rates for COVID-19 are likely to ultimately be higher than for influenza, although initial rates may be lower until an adequate supply is available. Total costs to plans and issuers will depend on the cost of covering qualifying coronavirus preventive services, the number of people choosing to obtain such services, and whether a third party such as the Federal Government covers the costs of any immunizations.

The Departments seek comment on any potential costs and burdens that may be incurred by plans and issuers due to the requirements to cover the costs and administration of such qualifying coronavirus preventive services without any cost sharing regardless of whether the service is delivered by an in-network or out-of-network provider. The Departments also seek comment on the potential effects and costs consumers may face as a result of this provision.

7. Effects of Changes to State Innovation Waivers Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

This IFC establishes a framework for states to request the Secretary of HHS and the Secretary of the Treasury to

⁸⁰ See Flu Vaccination Coverage, United States, 2018-19 Influenza Season. Center for Disease Control and Prevention, available at <https://www.cdc.gov/flu/fluview/coverage-1819estimates.htm>.

modify, in part, the public notice procedures outlined in 31 CFR 33.112 and 33.116 and 45 CFR 155.1312 and 155.1316 to expedite a decision on a proposed section 1332 waiver request during the PHE for COVID-19. Regulations at §§ 33.112 and 155.1312 require a state to provide a public notice and comment period at the state level prior to submitting an application for a section 1332 waiver. The regulations at §§ 33.116 and 155.1316 establish Federal public notice requirements for state section 1332 waiver applications. This IFC also establishes a framework at the new 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2) for states to request the Secretaries to modify, in part, the post award public notice procedures outlined in §§ 33.120(c) and 155.1320(c) for an approved waiver that would otherwise take place or become due during the PHE for COVID-19. As stated above, HHS and the Department of the Treasury are of the view that requiring states that meet the criteria outlined in this IFC to comply with the full public notice procedures during the PHE for COVID-19 could cause undue harm to the public. Allowing the Secretaries to modify, in part, these requirements will enable states to request and receive approval for waiver requests more quickly and also implement changes that will provide consumers with access to affordable health insurance coverage during the current PHE for COVID-19. States that request modifications from the public notice procedures will incur some burden, as discussed in the Collection of Information Requirements section. For a state that requests and receives a modification of the public notice procedures, we acknowledge that consumers may receive less prior notice than would occur without the modification. Through this IFC, the HHS and the Department of Treasury intend to provide an appropriate balance and permit flexibility where a state can ensure a sufficient opportunity for meaningful public input given the circumstances in the PHE for COVID-19 while also ensuring the safety of the public. If a state's modification request is approved there may be a shorter comment period at the state or Federal level, or the comment periods may be the same number of days (for example 30 days) but perhaps on a different timeframe. For example, a state may conduct the state public comment period concurrently with the Federal public comment period instead of before. States with approved modification requests may experience a reduction in costs related to post award public notice procedures. However, if

the state's modification request is approved, the state must also implement alternative public notice procedures and, if required, amend the waiver application to specify that it is the state's intent to comply with those alternative public notice requirements in the state's modification request. States may also need to employ additional technologies to host virtual hearings instead of in person gatherings. In this case, there may be no reduction in costs related to public notice procedures.

HHS and the Department of the Treasury seek comment on any potential costs and burdens that may be incurred by states due to the flexibilities afforded in this IFC. HHS and the Department of the Treasury also seek comment on the potential effects and costs consumers may face as a result of a state's action taken as a result of the flexibilities in this IFC.

8. Effects of Medicare Coding and Payment for COVID-19 Vaccine

This IFC discusses CMS's implementation of section 3713 of the CARES Act (Pub. L. 116-136), which established Medicare Part B coverage and payment for a COVID-19 vaccine and its administration. This IFC requires that Medicare provide coverage for qualifying COVID-19 vaccines administration, without any cost sharing. Making COVID-19 vaccines, available without any delay is in the interest of public health, as making these services available as quickly as possible may encourage individuals to take advantage of these services and therefore may slow the transmission of COVID-19. Access to COVID-19 vaccines without cost sharing will encourage more individuals to obtain them. In the immediate term, any newly developed COVID-19 vaccines might be available from a narrower range of providers than other, more established recommended preventive items and services. If COVID-19 vaccines require specialized storage and administration services, only a limited number of providers may be able to offer them at first. If beneficiaries have to incur additional burdens, long wait times, and increased travel times to find Medicare providers and suppliers that can provide such services, it will limit access and discourage them from obtaining such services. Medicare providers and suppliers will incur costs for providing COVID-19 vaccines and administration of such services. There are uncertainties regarding the cost to the Medicare program for COVID-19 vaccines and administration at this time. The total cost to Medicare related

to COVID-19 vaccines and administration cost are dependent on and the number of required immunization doses to be administered, the number of people who will choose to get immunized against COVID-19 and which providers and suppliers will be able to provide the preventive services.

9. Effects of Application Fee as Part of Form CMS-855B Enrollment as Mass Immunization Roster Biller

Consistent with § 424.514, an entity enrolling in Medicare as a mass immunization roster biller via the Form CMS-855B must pay an application fee at the time of enrollment. The application fees for each of the past 3 calendar years were or are \$569 (CY 2018), \$586, (CY 2019), and \$595 (CY 2020). The differing fee amounts are 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 cannot predict future changes to the CPI, the fee amounts between 2018 and 2020 increased by an average of \$13 per year. We believe this is a reasonable barometer with which to establish a CY 2021 fee estimate (strictly for purposes of this IFC) of \$608.

Applying this prospective fee amount to the previously mentioned 60,000 projected mass immunization roster biller applicants in the first year of this rule, we estimate a total application fee cost to enrollees of \$36,400,000 (or $60,000 \times \$608$). This represents a transfer from mass immunizer suppliers to the Federal Government.

D. Regulatory Alternatives Considered

The Department considered not implementing the changes to the CJR model but determined the effect of the changes, particularly relief from financial risk for COVID-19 cases and stability in model operations, to be very important for participant hospitals during the PHE. Further, if the three-year extension of the CJR model is finalized, it would be much more difficult for participant hospitals to stop model value-based operations, and then restart value operations when hospitals already have significant burden managing COVID-19 treatment and under COVID-19 safety protocols and utilization changes.

The Departments considered not requiring plans and issuers to provide coverage for qualifying coronavirus preventive services without cost sharing from out-of-network providers. However, in the near term, newly developed qualifying coronavirus

preventive services might be available from a narrower range of providers than other, more established recommended preventive services because of specialized storage and administration requirements. If there are only a limited number of in-network providers that can administer these services, consumers may incur additional burden related to travel and long wait times to obtain these services, which can result in lower utilization. The Departments are concerned that allowing plans and issuers to impose cost sharing for COVID-19 immunizations provided by out-of-network providers would discourage individuals from seeking immunization, potentially leading to reduced administration of any COVID-19 vaccine and prolonging the PHE for COVID-19, contrary to the intent of the CARES Act. In order to ensure that the immunization services will be available to all consumers enrolled in non-grandfathered group health plans and non-grandfathered group and individual health insurance coverage, the Departments are therefore requiring such plans and issuers to cover without cost sharing a qualifying coronavirus preventive service, regardless of whether such service is delivered by an in-network or out-of-network provider. The Departments anticipate that as such services become more widely available over time, consumers will be able to obtain them more easily from in-network providers.

HHS and the Department of the Treasury considered providing states with the flexibility to waive all of the public notice procedures outlined in 31 CFR 33.112 and 33.116 and 45 CFR 155.1312 and 155.1316 to expedite a decision on a proposed section 1332 waiver request during the PHE for COVID-19. This approach would have allowed a state to request to completely eliminate a public notice or reporting requirement pre- or post-award. However, HHS and the Department of the Treasury were concerned that that this would violate the statutory requirements regarding a meaningful level of input from the public. In addition, HHS and the Department of Treasury are committed to transparency and value public input on waiver proposals and value public feedback to ensure consumers are aware of waiver proposals that may affect them. HHS and the Department of the Treasury anticipate working with states on their modification request to ensure the public is provided the opportunity to provide feedback on waiver proposals and the progress of the program authorized by the section 1332 waiver.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to analyze options for regulatory relief of small entities to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. This IFC is not preceded by a general notice of proposed rulemaking, and thus the requirements of RFA do not apply.

In addition, section 1102(b)(2) of the Act provides that whenever the Secretaries promulgate a final version of a rule or regulation with respect to which an initial regulatory impact analysis is required, the Secretaries shall prepare a final regulatory impact analysis with respect to the final version of such rule or regulation. Such analysis is required to set forth, with respect to small rural hospitals, the matters required under section 604 of title 5, United States Code, to be set forth with respect to small entities. The Departments are not required to prepare a final regulatory impact analysis, because this regulatory action is being issued as an interim final rule without being preceded by a general notice of proposed rulemaking.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing any proposed rule or any final rule for which a general notice of proposed rulemaking was published that includes any Federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation.

In 2020, that threshold is approximately \$156 million. This IFC was not preceded by a general notice of proposed rulemaking, and thus the requirements of UMRA do not apply.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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 rule aims to alleviate burden on State and local governments, the requirements of Executive Order 13132 are not applicable.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, the Departments have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the NAIC, and consulting with state insurance officials on an individual basis.

While developing this rule, the Departments attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, the Departments complied with the requirements of Executive Order 13132.

H. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This IFC's designation under Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), which was issued on January 30, 2017, will be informed by public comments received.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Employee benefit plans, Health care, Health insurance, Penalties, Pensions, Privacy, Reporting and recordkeeping requirements.

31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 410

Diseases, Health facilities, Health professions, 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, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 510

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirement.

45 CFR Part 147

Age discrimination, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State flexibility, Technical assistance, Women and youth.

45 CFR Part 182

COVID–19 diagnostic testing, Reporting and recordkeeping requirements.

Dated: October 21, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 26, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Sunita Lough,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: October 28, 2020.

David J. Kauter,

Assistant Secretary of the Treasury (Tax Policy).

Signed at Washington DC, this 29th day of October, 2020.

Jeanne Klinefelter Wilson,

Acting Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Amendments to the Regulations

For the reasons set forth in the preamble, the Department of the Treasury amends 26 CFR part 54 as set forth below:

PART 54—PENSION EXCISE TAXES

■ **Par. 1.** The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

Section 54.9815–2713T also issued under 26 U.S.C. 9833.

* * * * *

■ **2.** Section 54.9815–2713T is added to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for purposes of this paragraph (a)(1)(ii), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration;

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131, 147.132, and 147.133; and

(v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID–19) and that is, with respect to the individual involved—

(A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (regardless of whether the immunization is recommended for routine use). For purposes of this paragraph (a)(1)(v)(B), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.

(2) *Office visits.* (i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing

requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(2) *Conclusion.* In paragraph (a)(2)(iv)(A)(1) of this section, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

(B) *Example 2—(1) Facts.* Same facts as in paragraph (a)(2)(iv)(A)(1) of this section (*Example 1*). As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(2) *Conclusion.* In paragraph (a)(2)(iv)(B)(1) of this section, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

(C) *Example 3—(1) Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual

has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(2) *Conclusion.* In paragraph (a)(2)(iv)(C)(1) of this section, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

(D) *Example 4—(1) Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(2) *Conclusion.* In paragraph (a)(2)(iv)(D)(1) of this section, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) *Out-of-network providers.* (i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost-sharing with respect to the item or service.

(iii) A plan or issuer must provide coverage for and must not impose any cost-sharing requirements (such as a

copayment, coinsurance, or a deductible) for any qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, regardless of whether such service is delivered by an in-network or out-of-network provider. For purposes of this paragraph (a)(3)(iii), with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing—(1) In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued, except as provided in paragraph (b)(3) of this section.

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any

items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year, or as otherwise provided in paragraph (b)(3) of this section, must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the applicable plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year, or as otherwise provided in paragraph (b)(3) of this section, is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a Federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the applicable plan or policy year.

(3) *Rapid coverage of preventive services for coronavirus.* In the case of a qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, a plan or issuer must provide coverage for such item, service, or immunization in accordance with this section by the date that is 15 business days after the date on which a recommendation specified in paragraph (a)(1)(v)(A) or (B) of this section is made relating to such item, service, or immunization.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of paragraphs (a)(1)(i) through (iv), (a)(2), (a)(3)(i) and (ii), (a)(4) through (5), (b)(1) and (2), and (c) of this section are applicable as of April 16, 2012.

(e) *Sunset date.* The provisions of paragraphs (a)(1)(v), (a)(3)(iii), and (b)(3) of this section will not apply with respect to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency determined on January 31, 2020, to exist nationwide as of January 27, 2020, by the Secretary of Health and

Human Services pursuant to section 319 of the Public Health Service Act, as a result of COVID-19, including any subsequent renewals of that determination.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 4. Section 2590.715–2713 is amended—

- a. In paragraph (a)(1)(iii) by removing “and” after the semicolon;
 - b. In paragraph (a)(1)(iv) by removing the period at the end of the paragraph and adding “; and” in its place;
 - c. By adding paragraph (a)(1)(v);
 - d. By revising paragraph (a)(3)(i);
 - e. By adding paragraph (a)(3)(iii);
 - f. By revising paragraphs (b)(1) and (b)(2)(i) and (ii); and
 - g. By adding paragraphs (b)(3) and (e).
- The revisions and additions read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) * * *

(1) * * *

(v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved—

(A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (regardless of whether the

immunization is recommended for routine use). For purposes of this paragraph (a)(1)(v)(B), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.

* * * * *

(3) * * *

(i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

* * * * *

(iii) A plan or issuer must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for any qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, regardless of whether such service is delivered by an in-network or out-of-network provider. For purposes of this paragraph (a)(3)(iii), with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service.

* * * * *

(b) * * *

(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued, except as provided in paragraph (b)(3) of this section.

(2) * * *

(i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year, or as otherwise provided in paragraph (b)(3) of this section, must provide coverage through the last day of the plan or policy year,

even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the applicable plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year, or as otherwise provided in paragraph (b)(3) of this section, is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a Federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the applicable plan or policy year.

(3) *Rapid coverage of preventive services for coronavirus.* In the case of a qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, a plan or issuer must provide coverage for such item, service, or immunization in accordance with this section by the date that is 15 business days after the date on which a recommendation specified in paragraph (a)(1)(v)(A) or (B) of this section is made relating to such item, service, or immunization.

* * * * *

(e) *Sunset date.* The provisions of paragraphs (a)(1)(v), (a)(3)(iii), and (b)(3) of this section will not apply with respect to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency determined on January 31, 2020, to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, as a result of COVID-19, including any subsequent renewals of that determination.

DEPARTMENT OF THE TREASURY

Office of the Secretary

Amendments to the Regulations

For the reasons set forth in the preamble, the Department of Treasury amends 31 CFR part 33 as set forth below:

PART 33—WAIVERS FOR STATE INNOVATION

■ 5. The authority citation for part 33 continues to read as follows:

Authority: Sec. 1332, Pub. L. 111–148, 124 Stat. 119.

■ 6. Section 33.118 is added to read as follows:

§ 33.118 Modification from the normal public notice requirements during the public health emergency.

(a) The Secretary and the Secretary of Health and Human Services may modify, in part, the State public notice requirements under § 33.112 and the Federal public notice procedures under § 33.116 to expedite a decision on a proposed waiver request during the public health emergency for COVID–19, as defined in 42 CFR 400.200, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. These flexibilities are limited to event-triggered, emergent situations, and the flexibilities outlined in this section will not be available for States seeking to address a threat to consumers’ access to health coverage or care that existed prior to the public health emergency for COVID–19.

(b) A State must meet all of the following criteria to request a modification under paragraph (a) of this section:

(1) The State must request a modification under paragraph (a) of this section, in the form and manner specified by the Secretaries.

(2) The State must have acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the request for a modification under paragraph (a) of this section, and the waiver application request, as applicable.

(3) The State must, as applicable, detail in its request for a modification from State-level notice procedures under paragraph (a) of this section the justification for the request and the alternative public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State’s request for a modification. As a condition of receiving a modification approval, a State must implement public notice procedures, including public hearings, at the State level and, if required, amend the waiver application request.

(4) The State must, as applicable, detail in its request for a modification from Federal-level notice procedures under paragraph (a) of this section the justification for the request as it relates to the public health emergency and the

alternative public notice procedures it requests to be implemented at the Federal level.

(c) The Secretary and the Secretary of Health and Human Services will evaluate a State’s request for a modification under paragraph (a) of this section and issue their exemption determination within approximately 15 calendar days after the request is received.

(d) The Secretary of Health and Human Services will publish on the Centers for Medicare and Medicaid Services (CMS) website any modification determinations within 15 calendar days of the Secretary and the Secretary of Health and Human Services making such a determination, as well as the approved revised timeline for public comment under the approved alternative State or Federal public notice procedures, as applicable.

(e) The State must publish on its website any modification requests and determinations within 15 calendar days of receipt of the determination, as well as the approved revised timeline for public comment under the alternative State or Federal public notice procedures, as applicable.

(f) The State must, as applicable, implement the alternative public notice procedures at the State level if the State’s exemption request is approved and, if required, amend the waiver application request.

■ 7. Section 33.120 is amended—

■ a. In paragraph (c)(1) by adding a paragraph heading; and

■ b. By adding paragraph (c)(2).

The additions read as follows:

§ 33.120 Monitoring and compliance.

* * * * *

(c) * * *

(1) *Notification requirements for public forum.* * * *

(2) *Modification from the normal post-award requirements during the public health emergency.* (i) The

Secretary and the Secretary of Health and Human Services may modify, in part, State post-award requirements under this paragraph (c)(2) for an approved waiver request during the public health emergency for COVID–19, as defined in 42 CFR 400.200, when the application of the post award public notice requirements would be contrary to the interests of consumers during the public health emergency. These flexibilities are limited to event-triggered, emergent situations, and the flexibilities outlined in this section will not be available for States seeking to address a threat to consumers’ access to health coverage or care that existed

prior to the public health emergency for COVID–19.

(ii) A State must meet all of the following criteria to request a modification under paragraph (c) of this section:

(A) The State must request a modification under this paragraph (c)(2), in the form and manner specified by the Secretaries.

(B) The State must have acted in good faith, and in a diligent, timely, and prudent manner to comply with the monitoring and compliance requirement under the waiver and the terms and conditions of the agreement between the Secretary and the Secretary of Health and Human Services, as applicable, and the State to implement a section 1332 waiver and to submit and prepare the request for a modification under this paragraph (c)(2).

(C) The State must detail in its request for a modification under this paragraph (c)(2) the alternative post award public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State’s request for a modification.

(D) The Secretary and the Secretary of Health and Human Services will evaluate a State’s request for a modification under this paragraph (c)(2) and issue their modification determination within approximately 15 calendar days after the request is received.

(E) The State must publish on its website any modification requests and determinations within 15 calendar days of the receipt of the determination as well as information on the approved revised timeline for the state’s post award public notice procedures, as applicable.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 8. The authority citation part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 9. Section 410.57 is amended by adding paragraph (c) to read as follows:

§ 410.57 Pneumococcal vaccine, flu vaccine, and COVID-19 vaccine.

* * * * *

(c) Medicare Part B pays for the COVID-19 vaccine and its administration.

■ 10. Section 410.152 is amended by revising paragraph (l)(1) to read as follows:

§ 410.152 Amounts of payment.

* * * * *

(l) * * *

(1) Pneumococcal (as specified in paragraph (h) of this section), influenza, hepatitis B, and COVID-19 vaccine and administration.

* * * * *

■ 11. Section 410.160 is amended by revising paragraph (b)(2) to read as follows:

§ 410.160 Part B annual deductible.

* * * * *

(b) * * *

(2) Pneumococcal, influenza, and hepatitis b, and COVID-19 vaccines and their administration.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 12. The authority citation part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

■ 13. Section 411.15 is amended by:

- a. Removing “and” at the end of paragraph (e)(3);
- b. Removing the period at the end of paragraph (e)(4) and adding “; and” in its place; and
- c. Adding paragraph (e)(5).
The addition reads as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(e) * * *

(5) COVID-19 vaccinations that are reasonable and necessary for the prevention of illness.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 14. The authority citation part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 15. Section 414.701 is revised to read as follows:

§ 414.701 Purpose.

This subpart implements section 1842(o) of the Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Part B of Title XVIII of the Act (hereafter in this subpart referred to as the “program”) that are not paid on a cost or prospective payment system basis. Examples of drugs that are subject to the rules contained in this subpart are: Drugs furnished incident to a physician’s service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal, hepatitis, and COVID-19 vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anti-cancer drugs.

■ 16. Section 414.707 is amended by revising paragraph (a)(2)(iii) to read as follows:

§ 414.707 Basis of payment.

(a) * * *

(2) * * *

(iii) Pneumococcal, influenza, and COVID-19 vaccines as well as hepatitis B vaccine that is furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary).

* * * * *

■ 17. Section 414.900 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 414.900 Basis and scope.

* * * * *

(b) * * *

(3) * * *

(ii) Pneumococcal, Hepatitis B, and COVID-19 vaccines.

* * * * *

■ 18. Section 414.904 is amended by revising paragraph (e)(1) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(e) * * *

(1) *Vaccines.* The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary), pneumococcal vaccine, influenza vaccine, and COVID-19 vaccine are calculated using 95 percent of the average wholesale price.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 19. The authority citation for part 417 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e-5, and 300e-9, and 31 U.S.C. 9701.

■ 20. Section 417.454 is amended by adding paragraph (e)(4) to read as follows:

§ 417.454 Charges to Medicare enrollees.

* * * * *

(e) * * *

(4) A COVID-19 vaccine and its administration described in section 1861(s)(10)(A) for the duration of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Act.

PART 433—STATE FISCAL ADMINISTRATION

■ 21. The authority citation for part 433 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

■ 22. Subpart G, consisting of § 433.400, is added to read as follows:

Subpart G—Temporary FMAP Increase During the Public Health Emergency for COVID-19

§ 433.400 Continued Enrollment for Temporary FMAP Increase.

(a) *Statutory basis.* This subpart interprets and implements section 6008(b)(3) of the Families First Coronavirus Response Act (FFCRA) and section 1902(a)(4) and (a)(19) of the Social Security Act.

(b) *Definitions.* For purposes of this subpart—

COVID-19 means Coronavirus Disease 2019.

Medicare Savings Program means the coverage of Medicare premiums and cost sharing furnished to individuals described in, and determined by the state to be eligible under, section 1902(a)(10)(E)(i), 1902(a)(10)(E)(iii), or 1902(a)(10)(E)(iv) of the Act.

Minimum essential coverage (MEC) has the meaning provided under section 5000A(f)(1) of the Internal Revenue Code and implementing regulations at 26 CFR 1.5000A-2 and includes minimum essential coverage determined by the Secretary under 26 CFR 1.5000A-2(f).

Public Health Emergency for COVID-19 has the same definition provided in § 400.200 of this chapter.

Temporary FMAP increase means the 6.2 percentage point increase in the

State's Federal medical assistance percentage (FMAP) that is authorized under section 6008(a) of the FFCRA through the end of the fiscal quarter in which the Public Health Emergency for COVID-19 ends.

Validly enrolled means that the beneficiary was enrolled in Medicaid based on a determination of eligibility. A beneficiary is not validly enrolled if the agency determines the eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility (if such last redetermination or renewal was completed prior to March 18, 2020) because of agency error or fraud (as evidenced by a fraud conviction) or abuse (as determined following the completion of an investigation pursuant to §§ 455.15 and 455.16 of this chapter) attributed to the beneficiary or the beneficiary's representative, which was material to the determination of eligibility. Individuals receiving medical assistance during a presumptive eligibility period in accordance with part 435, subpart L, of this chapter have not received a determination of eligibility by the state under the state plan and are not considered validly enrolled beneficiaries for purposes of this section.

(c) *General requirements.* (1) In order to claim the temporary FMAP increase for:

(i) The quarter in which November 2, 2020, falls, a state must meet the requirements described in paragraph (c)(2) of this section from November 2, 2020, through the end of the quarter.

(ii) Any quarter beginning after November 2, 2020, through the quarter in which the public health emergency for COVID-19, including any extensions, ends, a state must meet the requirements described in paragraphs (c)(2) of this section.

(2) Except as provided in paragraph (d) of this section, for all beneficiaries validly enrolled for benefits under the state plan, a waiver of such plan, or a demonstration project under section 1115(a) of the Act as of or after March 18, 2020, the state must maintain the beneficiary's enrollment as follows, through the end of the month in which the public health emergency for COVID-19 ends:

(i)(A) For beneficiaries whose Medicaid coverage meets the definition of MEC in paragraph (b) of this section as of or after March 18, 2020, the state must continue to provide Medicaid coverage that meets the definition of MEC, except as provided in paragraph (c)(2)(i)(B) of this section.

(B) For beneficiaries described in paragraph (c)(2)(i)(A) whom the state subsequently determines are eligible for coverage under a Medicare Savings Program eligibility group, the state satisfies the requirement described in paragraph (c)(2) of this section if it furnishes the medical assistance available through the Medicare Savings Program.

(ii) For beneficiaries whose Medicaid coverage as of or after March 18, 2020 does not meet the definition of MEC in paragraph (b) of this section but does include coverage for testing services and treatments for COVID-19, including vaccines, specialized equipment, and therapies, the state must continue to provide Medicaid coverage that includes such testing services and treatments.

(iii) For beneficiaries not described in paragraph (c)(2)(i) or (ii) of this section, the state must continue to provide at least the same level of medical assistance as was provided as of or after March 18, 2020.

(iv) If a state determines that a validly enrolled beneficiary is no longer eligible for Medicaid, including on a procedural basis, the state meets the requirements described in paragraph (c)(2)(i), (ii), or (iii) of this section by continuing to provide the same Medicaid coverage that the beneficiary would have received absent the determination of ineligibility.

(3) Otherwise permissible changes to beneficiary coverage, cost sharing, and post-eligibility treatment of income, including both changes affecting an individual beneficiary and approved changes to the state plan, a section 1115 demonstration and/or a waiver authorized under section 1915 of the Act impacting multiple beneficiaries, will not impact a state's ability to claim the temporary FMAP increase provided that any such changes do not violate the requirement to maintain beneficiary enrollment described at paragraph (c)(2) of this section or the requirement in section 6008(b)(4) of the FFCRA.

(d) *Exceptions.* (1) Consistent with the condition to claim the temporary FMAP increase described in paragraph (c)(2) of this section, a state may terminate a beneficiary's Medicaid enrollment prior to the first day of the month after the public health emergency for COVID-19 ends in the following circumstances:

(i) The beneficiary or the beneficiary's representative requests a voluntary termination of eligibility;

(ii) The beneficiary ceases to be a resident of the state; or

(iii) The beneficiary dies.

(2) States which have elected the option under section 1903(v)(4) of the

Act to provide full benefits to lawfully residing children or pregnant women must limit coverage for such beneficiaries if they no longer meet the definition of a lawfully residing child or pregnant woman under such section to services necessary for treatment of an emergency medical condition, as defined in section 1903(v)(3) of the Act.

(3)(i) For purposes of paragraph (d)(1)(i) of this section, a beneficiary may request a voluntary termination of eligibility from the Medicaid coverage in which the beneficiary is enrolled to transition to other Medicaid coverage for which the beneficiary is eligible, even if the transition to the new Medicaid coverage would not be consistent with paragraph (c)(2) of this section.

(ii) For purposes of paragraph (d)(1)(ii) of this section, beneficiaries who were identified through a data match with the Public Assistance Reporting Information System in accordance with § 435.945(d) of this chapter indicating simultaneous enrollment in two or more states, and who fail to respond to a request for information to verify their residency, may be treated as not being a state resident for purposes of paragraph (d)(1)(ii) of this section, provided that the state takes all reasonably available measures to attempt to verify the beneficiary's state residency. If a beneficiary's enrollment is terminated under the exception at paragraph (d)(1)(ii) of this section based on a PARIS data match and the state subsequently obtains information verifying residency, the state must reinstate the beneficiary's Medicaid enrollment retroactive to the date of termination.

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

■ 23. The authority citation for part 510 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1315(a), and 1395hh.

■ 24. Section 510.2 is amended by—
 ■ a. Adding a definition for “COVID-19 Diagnosis Code” in alphabetical order; and
 ■ b. Revising the definitions for “Lower-extremity joint replacement (LEJR)”, “Performance year”, and “Quality improvement points”.

The addition and revisions read as follows:

§ 510.2 Definitions.

* * * * *

COVID-19 Diagnosis Code means any of the following ICD-10-CM diagnosis codes:

- (1) B97.29;
- (2) U07.1; or
- (3) Any other ICD-10-CM diagnosis code that is recommended by the Centers for Disease Control and Prevention for the coding of a confirmed case of COVID-19.

* * * * *

Lower-extremity joint replacement (LEJR) means any procedure that is within MS-DRG 469 or 470, or, on or after October 1, 2020, MS-DRG 521 or 522, including lower-extremity joint replacement procedures or reattachment of a lower extremity.

* * * * *

Performance year means one of the years in which the CJR model is being tested. Performance years for the model correlate to calendar years with the exceptions of performance year 1, which is April 1, 2016 through December 31, 2016 and performance year 5, which is January 1, 2020 through September 30, 2021. For reconciliation purposes, performance year 5 is divided into two subsets, performance year subset 5.1 (January 1, 2020 through December 31, 2020) and performance year subset 5.2 (January 1, 2021 through September 30, 2021).

* * * * *

Quality improvement points are points that CMS adds to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure for performance years 2 through 4 and for performance year subsets 5.1 and 5.2, increases from the previous performance year or performance year subset by at least 2 deciles on the performance percentile scale, as described in § 510.315(d). For performance year 1, CMS adds quality improvement points to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure increases from the corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, as described in § 510.315(d).

* * * * *

■ 25. Section 510.200 is amended by revising paragraphs (a) and (d)(6) to read as follows:

§ 510.200 Time periods, included and excluded services, and attribution.

(a) *Time periods.* All episodes must begin on or after April 1, 2016 and end on or before September 30, 2021.

* * * * *

(d) * * *

(6) For performance years 1 through 4 and for performance year subsets 5.1

and 5.2, payments for otherwise included items and services in excess of 2 standard deviations above the mean regional episode payment in accordance with § 510.300(b)(5).

* * * * *

■ 26. Section 510.300 is amended by revising paragraphs (a) introductory text, (a)(1)(i), (a)(1)(iii), (a)(2) and (3), (b)(1)(iii), (b)(2)(iii), (b)(8), (c)(1) and (2), and (c)(3)(iii) to read as follows:

§ 510.300 Determination of episode quality-adjusted target prices.

(a) *General.* CMS establishes episode quality-adjusted target prices for participant hospitals for each performance year or performance year subset of the model as specified in this section. Episode quality-adjusted target prices are established according to the following:

(1) * * *

(i)(A) MS-DRG 469 with hip fracture; or

(B) For episodes beginning on or after October 1, 2020, MS-DRG 521;

* * * * *

(iii)(A) MS-DRG 470 with hip fracture; or

(B) For episodes beginning on or after October 1, 2020, MS-DRG 522; or

* * * * *

(2) *Applicable time period for performance year or performance year subset episode quality-adjusted target prices.* Episode quality-adjusted target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated quality-adjusted target prices effective October 1 and January 1, and at other intervals if necessary.

(3) *Episodes that straddle performance years or performance year subsets or payment updates.* The quality-adjusted target price that applies to the type of episode as of the date of admission for the anchor hospitalization is the quality-adjusted target price that applies to the episode.

* * * * *

(b) * * *

(1) * * *

(iii) Episodes beginning in 2016 through 2018 for each of performance year subsets 5.1 and 5.2.

(2) * * *

(iii) Regional historical episode payments for performance year 4 and each of performance year subsets 5.1 and 5.2.

* * * * *

(8) *Inclusion of reconciliation payments and repayments.* For performance years 3, 4, and each of performance year subsets 5.1 and 5.2 only, reconciliation payments and

repayment amounts under § 510.305(f)(2) and (3) and from LEJR episodes included in the BPCI initiative are included in historical episode payments.

(c) * * *

(1) *Discount factors affected by the quality incentive payments and the composite quality score.* In all performance years and performance year subsets, the discount factor may be affected by the quality incentive payment and composite quality score as provided in § 510.315 to create the effective discount factor or applicable discount factor used for calculating reconciliation payments and repayment amounts. The quality-adjusted target prices incorporate the effective or applicable discount factor at reconciliation.

(2) *Discount factor for reconciliation payments.* The discount factor for reconciliation payments in all performance years and performance year subsets is 3.0 percent.

(3) * * *

(iii) In performance year 4 and each of performance year subsets 5.1 and 5.2, 3.0 percent.

* * * * *

■ 27. Section 510.305 is amended by revising paragraphs (b), (d)(1) introductory text, (e) introductory text, (e)(1) introductory text, (e)(1)(i), (ii), and (iii), (e)(1)(v)(A) introductory text, (e)(1)(v)(A)(3), (e)(1)(v)(B) introductory text, (e)(1)(v)(B)(3), (e)(1)(v)(C), (f)(1)(ii), (g)(1) and (3), (h) introductory text, (h)(5) and (6), (i), (j), and (k)(4) to read as follows:

§ 510.305 Determination of the NPRA and reconciliation process.

* * * * *

(b) *Reconciliation.* CMS uses a series of reconciliation processes, which CMS performs as described in paragraphs (d) and (f) of this section, after the end of each performance year 1 through 4 to establish final payment amounts to participant hospitals for CJR episodes for a given performance year. Following the end of each performance year 1 through 4, CMS determines actual episode payments for each episode for the performance year (other than episodes that have been canceled in accordance with § 510.210(b)), and determines the amount of a reconciliation payment or repayment amount. Within performance year 5, CMS separately performs the reconciliation processes described in paragraphs (d) and (f) of this section for performance year subsets 5.1 and 5.2 and following the end of each performance year subset 5.1 and 5.2, CMS separately determines the actual

episode payment for each episode for the subset of the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) and determines the amount of a reconciliation payment or repayment for each of performance year subsets 5.1 and 5.2.

* * * * *

(d) * * *

(1) Beginning 2 months after the end of each of performance years 1 through 4 and performance year subset 5.1 and 5 months after the end of performance year subset 5.2, CMS does all of the following:

* * * * *

(e) *Calculation of the NPRA.* By comparing the quality-adjusted target prices described in § 510.300 and the participant hospital's actual episode spending for each of performance years 1 through 4 and each of performance year subsets 5.1 and 5.2 and applying the adjustments in paragraph (e)(1)(v) of this section, CMS establishes an NPRA for each participant hospital for each such performance year or performance year subset.

(1) *Initial calculation.* In calculating the NPRA for each participant hospital for each of performance years 1 through 4 and each of performance year subsets 5.1 and 5.2, CMS does the following:

(i) Determines actual episode payments for each episode included in the performance year or performance year subset (other than episodes that have been canceled in accordance with § 510.210(b)) using claims data that is available 2 months after the end of the performance year or performance year subset. Actual episode payments are capped, as applicable, at the amount determined in accordance with § 510.300(b)(5) for the performance year or performance year subset at the amount determined in paragraph (k) of this section for episodes affected by extreme and uncontrollable circumstances, or at the quality adjusted target price determined for that episode under § 510.300 for an episode with actual episode payments that include a claim with a COVID-19 diagnosis code and initiate after the earlier of March 31, 2021 or the last day of the emergency period described in paragraph (k)(4) of this section.

(ii) Multiplies each episode quality-adjusted target price by the number of episodes included in the performance year or performance year subset (other than episodes that have been canceled in accordance with § 510.210(b)) to which that episode quality-adjusted target price applies.

(iii) Aggregates the amounts computed in paragraph (e)(1)(ii) of this section for all episodes included in the performance year or performance year subset (other than episodes that have been canceled in accordance with § 510.210(b)).

* * * * *

(v) * * *

(A) *Limitation on loss.* Except as provided in paragraph (e)(1)(v)(C) of this section, the total amount of the NPRA and subsequent reconciliation calculation for a performance year or performance year subset cannot exceed the following:

* * * * *

(3) For performance year 4 and each of performance year subsets 5.1 and 5.2, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year or performance year subset.

* * * * *

(B) *Limitation on gain.* The total amount of the NPRA and subsequent reconciliation calculation for a performance year or performance year subset cannot exceed the following:

* * * * *

(3) For performance year 4 and each of performance year subsets 5.1 and 5.2, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year or performance year subset.

* * * * *

(C) *Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs.* If a participant hospital is a rural hospital, SCH, MDH, or RRC, then for performance year 2, the total repayment amount for which the participant hospital is responsible due to the NPRA and subsequent reconciliation calculation cannot exceed 3 percent of the amount calculated in paragraph (e)(1)(iii) of this section. For performance years 3 and 4 and for performance year subsets 5.1 and 5.2, the amount cannot exceed 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section.

(f) * * *

(1) * * *

(ii) Subject to paragraph (f)(1)(iii) of this section, for performance years 2 through 4 and for each of performance year subsets 5.1 and 5.2, results from the subsequent reconciliation calculation for a prior year's reconciliation as described in paragraph (i) of this section and the post-episode spending and ACO overlap calculations as described in paragraph (j) of this section are added to the current year's NPRA in order to

determine the reconciliation payment or repayment amount.

* * * * *

(g) * * *

(1) CMS assesses each participant hospital's performance on quality metrics, as described in § 510.315, to determine whether the participant hospital is eligible to receive a reconciliation payment for a performance year or performance year subset.

* * * * *

(3) If the hospital's composite quality score described in § 510.315 is below acceptable, defined as less than 4.00 for a performance year or performance year subset, the hospital is not eligible for a reconciliation payment.

* * * * *

(h) *Reconciliation report.* CMS issues each participant hospital a CJR reconciliation report for the performance year or performance year subset. Each CJR reconciliation report contains the following:

* * * * *

(5) As applicable, the NPRA and subsequent reconciliation calculation amount for the previous performance year or performance year subset.

(6) As applicable, the post-episode spending amount and ACO overlap calculation for the previous performance year or performance year subset.

* * * * *

(i) *Subsequent reconciliation calculation.* (1) Fourteen months after the end of each of performance years 1 through 4 and performance year subset 5.1 and seventeen months after the end of performance year subset 5.2, CMS performs an additional calculation, using claims data available at that time, to account for final claims run-out and any additional episode cancellations due to overlap between the CJR model and other CMS models and programs, or for other reasons as specified in § 510.210(b).

(2) The subsequent calculation for each of performance years 1 through 4 and performance year subset 5.1 occurs concurrently with the first reconciliation process for the following performance year (or in the case of performance year subset 5.1, with the first reconciliation of performance year subset 5.2). If the result of the subsequent calculation is different than zero, CMS applies the stop-loss and stop-gain limits in paragraph (e) of this section to the aggregate calculation of the amounts described in paragraphs (e)(1)(iv) and (i)(1) of this section for that performance year or performance year subset (the initial reconciliation

and the subsequent reconciliation calculation) to ensure such amount does not exceed the applicable stop-loss or stop-gain limits. The subsequent reconciliation calculation for performance year subset 5.2 will occur independently in 2023.

(j) *Additional adjustments to the reconciliation payment or repayment amount.* (1) In order to account for shared savings payments, CMS will reduce the reconciliation payment or increase the repayment amount for the subsequent performance year (for performance years 1 through 4 and performance year subset 5.1) by the amount of the participant hospital's discount percentage that is paid to the ACO in the prior performance year as shared savings. (This amount will be assessed independently for performance year subset 5.2 in 2023.) This adjustment is made only when the participant hospital is a participant or provider/supplier in the ACO and the beneficiary in the CJR episode is assigned to one of the following ACO models or programs:

- (i) The Pioneer ACO model.
- (ii) The Medicare Shared Savings Program (excluding Track 3 for CJR episodes that initiate on or after July 1, 2017).
- (iii) The Comprehensive ESRD Care Initiative (excluding a track with downside risk for CJR episodes that initiate after July 1, 2017).
- (iv) The Next Generation ACO model (excluding CJR episodes that initiate on or after July 1, 2017).

(2) If the average post-episode Medicare Parts A and B payments for a participant hospital in the prior performance year or performance year subset is greater than 3 standard deviations above the regional average post-episode payments for the same performance year or performance year subset, then the spending amount exceeding 3 standard deviations above the regional average post-episode payments for the same performance year or performance year subset is subtracted from the net reconciliation or added to the repayment amount for the subsequent performance year for years 1 through 4 and performance year subset 5.1, and assessed independently for performance year subset 5.2.

(k) * * *

(4) For a fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs on or before March 31, 2021 or the last day of such emergency period, whichever is earlier, actual episode

payments are capped at the quality adjusted target price determined for that episode under § 510.300.

■ 28. Section 510.315 is amended by revising paragraphs (a), (b) introductory text, and (d) to read as follows:

§ 510.315 Composite quality scores for determining reconciliation payment eligibility and quality incentive payments.

(a) *General.* A participant hospital's eligibility for a reconciliation payment under § 510.305(g), and the determination of quality incentive payments under paragraph (f) of this section, for a performance year or performance year subset depend on the hospital's composite quality score (including any quality performance points and quality improvement points earned) for that performance year or performance year subset.

(b) *Composite quality score.* CMS calculates a composite quality score for each participant hospital for each performance year or performance year subset which equals the sum of the following:

* * * * *

(d) *Quality improvement points.* For performance year 1, if a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, then the hospital is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points. For each of performance years 2 through 4 and for each of performance year subsets 5.1 and 5.2, if a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the previous performance year or performance year subset by at least 2 deciles on the performance percentile scale, then the hospitals is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points.

* * * * *

- 29. Section 510.400 is amended by—
- a. Revising paragraphs (a) introductory text, (b)(2) introductory text, (b)(2)(i), (b)(2)(ii) introductory text, and (b)(3)(v) introductory text; and
- b. By adding paragraph (b)(3)(vi).

The revisions and addition read as follows:

§ 510.400 Quality measures and reporting.

(a) *Reporting of quality measures.* The following quality measures are used for public reporting, for determining whether a participant hospital is eligible for reconciliation payments under § 510.305(g), and whether a participant hospital is eligible for quality incentive payments under § 510.315(f) in the performance year or performance year subset:

* * * * *

(b) * * *

(2) Hospitals must also submit the amount of requested THA/TKA patient-reported outcomes data required for each performance year or performance year subset of the model in order to be considered successful in submitting voluntary data.

(i) The amount of requested THA/TKA patient-reported outcomes data to submit, in order to be considered successful will increase each subsequent year of the model over the 5 years of the model (with the exception of performance year subset 5.2, for which CMS will request the same amount of THA/TKA patient-reported outcomes data as performance year subset 5.1, updated to reflect the timeframe applicable to performance year subset 5.2).

(ii) A phase-in approach that determines the amount of requested THA/TKA patient-reported outcomes data to submit over performance years 1 through 4 and performance year subset 5.1 (with the exception of performance year subset 5.2, for which CMS will request the same amount of THA/TKA patient-reported outcomes as performance year subset 5.1, updated to reflect the timeframe applicable to performance year subset 5.2) of the program will be applied so that in year 1 successful submission of data would mean CMS received all requested THA/TKA patient-reported outcomes and limited risk variable data on both of the following:

* * * * *

(3) * * *

(v) Year 5 (subset 5.1, January 1, 2020–December 31, 2020). Submit—

* * * * *

(vi) Year 5 (subset 5.2, January 1, 2021–September 30, 2021). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2020 and June 30, 2021, unless CMS requests a more limited data set, in

which case, submit all requested data elements.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 147, 155, and 182 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 30. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92, as amended, and section 3203, Pub. L. 116-136, 134 Stat. 281.

■ 31. Section 147.130 is amended—

- a. In paragraph (a)(1)(iii) by removing "and" after the semicolon;
b. In paragraph (a)(1)(iv) by removing the period at the end of the paragraph and adding "; and" in its place;
c. By adding paragraph (a)(1)(v);
d. By revising paragraph (a)(3)(i);
e. By adding paragraph (a)(3)(iii);
f. By revising paragraphs (b)(1) and (b)(2)(i) and (ii); and
g. By adding paragraphs (b)(3) and (e).

The revisions and additions read as follows:

§ 147.130 Coverage of preventive health services.

- (a) * * *
(1) * * *

(v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved—

(A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (regardless of whether the immunization is recommended for routine use). For purposes of this paragraph (a)(1)(v)(B), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of

the Centers for Disease Control and Prevention.

* * * * *

(3) * * *

(i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

* * * * *

(iii) A plan or issuer must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for any qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, regardless of whether such service is delivered by an in-network or out-of-network provider. For purposes of this paragraph (a)(3)(iii), with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service.

* * * * *

(b) * * *

(1) In general. A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued, except as provided in paragraph (b)(3) of this section.

(2) * * *

(i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the applicable plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, is downgraded to a "D" rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a Federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the applicable plan or policy year.

(3) Rapid coverage of preventive services for coronavirus. In the case of a qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, a plan or issuer must provide coverage for such item, service, or immunization in accordance with this section by the date that is 15 business days after the date on which a recommendation specified in paragraph (a)(1)(v)(A) or (B) of this section is made relating to such item, service, or immunization.

* * * * *

(e) Sunset date. The provisions of paragraphs (a)(1)(v), (a)(3)(iii), and (b)(3) of this section will not apply with respect to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency determined on January 31, 2020, to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, as a result of COVID-19, including any subsequent renewals of that determination.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 32. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021-18024, 18031-18033, 18041-18042, 18051, 18054, 18071, and 18081-18083.

■ 33. Section 155.1318 is added to read as follows:

§ 155.1318 Modification from the normal public notice requirements during the public health emergency.

(a) The Secretary and the Secretary of the Treasury may modify, in part, the State public notice requirements under

§ 155.1312 and the Federal public notice procedures under § 155.1316 to expedite a decision on a proposed waiver request during the public health emergency, as defined in 42 CFR 400.200, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. These flexibilities are limited to event-triggered, emergent situations, and the flexibilities outlined in this section will not be available for States seeking to address a threat to consumers' access to health coverage or care that existed prior to the public health emergency for COVID-19.

(b) A State must meet all of the following criteria to request a modification under paragraph (a) of this section:

(1) The State must request a modification under paragraph (a) of this section, in the form and manner specified by the Secretaries.

(2) The State must have acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the request for a modification under paragraph (a) of this section, and the waiver application request, as applicable.

(3) The State must, as applicable, detail in its request for a modification from State-level notice procedures under paragraph (a) of this section the justification for the request as it relates to the public health emergency and the alternative public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State's request for a modification.

(4) The State must, as applicable, detail in its request for a modification from Federal-level notice procedures under paragraph (a) of this section the justification for the request and the alternative public notice procedures it requests to be implemented at the Federal level.

(c) The Secretary and the Secretary of the Treasury will evaluate a State's request for a modification under paragraph (a) of this section and issue their modification determination within approximately 15 calendar days after the request is received.

(d) The Secretary will publish on the CMS website any modification determinations within 15 calendar days of the Secretary and the Secretary of the Treasury making such a determination, as well as the approved revised timeline for public comment under the approved

alternative State or Federal public notice procedures, as applicable.

(e) The State must publish on its website any modification requests and determinations within 15 calendar days of receipt of the determination, as well as the approved revised timeline for public comment under the alternative State or Federal public notice procedures, as applicable.

(f) The State must, as applicable, implement the alternative public notice procedures at the State level if the State's modification request is approved and, if required, amend the waiver application request.

■ 34. Section 155.1320 is amended—

■ a. In paragraph (c)(1) by adding a paragraph heading; and

■ b. By adding paragraph (c)(2).

The additions read as follows:

§ 155.1320 Monitoring and compliance.

* * * * *

(c) * * *

(1) *Notification requirements for public forum.* * * *

(2) *Modification from the normal post award requirements during the public health emergency.* (i) The Secretary and the Secretary of the Treasury may modify, in part, State post award requirements under this paragraph (c)(2) for an approved waiver request during the public health emergency, as defined in 42 CFR 400.200, when the application of the post award public notice requirements would be contrary to the interests of consumers during the public health emergency. These flexibilities are limited to event-triggered, emergent situations, and the flexibilities outlined in this section will not be available for States seeking to address a threat to consumers' access to health coverage or care that existed prior to the public health emergency for COVID-19.

(ii) A State must meet all of the following criteria to request a modification under paragraph (c) of this section:

(A) The State must request a modification under paragraph (c)(2) of this section, in the form and manner specified by the Secretaries.

(B) The State must have acted in good faith, and in a diligent, timely, and prudent manner to comply with the monitoring and compliance requirement under the waiver and the terms and conditions of the agreement between the Secretary and the Secretary of the Treasury, as applicable, and the State to implement a section 1332 waiver and to submit and prepare the request for a modification under paragraph (c)(2) of this section.

(C) The State must detail in its request for a modification under paragraph (c)(2) of this section the alternative post award public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State's request for a modification.

(D) The Secretary and the Secretary of the Treasury will evaluate a State's request for a modification under paragraph (c)(2) of this section and issue their modification determination within approximately 15 calendar days after the request is received.

(E) The State must publish on its website any modification requests and determinations within 15 calendar days of receipt of the determination, as well as information on the approved revised timeline for the State's post award public notice procedures, as applicable.

* * * * *

■ 35. Subchapter E–T, consisting of part 182, is added to subtitle A to read as follows:

Subchapter E–T—Price Transparency

PART 182—PRICE TRANSPARENCY FOR COVID-19 DIAGNOSTIC TESTS

Subpart A—General Provisions

Sec.

182.10 Basis and scope.

182.20 Definitions.

182.30 Applicability.

Subpart B—Public Disclosure Requirements

182.40 Requirements for making public cash prices for a diagnostic test for COVID-19.

Subpart C—Monitoring and Penalties for Noncompliance

182.50 Monitoring and enforcement.

182.60 Corrective action plans.

182.70 Civil monetary penalties.

Subpart D—Appeals of Civil Monetary Penalties

182.80 Appeal of penalty.

182.90 Failure to request a hearing.

Authority: Section 3202(b), Pub. L. 116-136, 134 Stat. 281.

Subpart A—General Provisions

§ 182.10 Basis and scope.

This part implements section 3202(b)(1) of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136, March 27, 2020) (CARES Act), which requires that during the emergency period declared under section 319 of the PHS Act (42 U.S.C.

247d), providers of diagnostic tests for COVID-19 make public the cash price for such tests on a public internet website of such provider. This part also implements section 3202(b)(2) of the CARES Act, which authorizes the Secretary to impose a civil monetary penalty (CMP) on any provider of a diagnostic test for COVID-19 that does not comply with section 3202(b)(1) of the CARES Act and that has not completed a corrective action plan to comply with that section, in an amount that does not exceed \$300 per day that the violation is ongoing.

§ 182.20 Definitions.

The following definitions and abbreviated terms apply to this part:

Cash price means the charge that applies to an individual who pays cash (or cash equivalent) for a COVID-19 diagnostic test.

COVID-19 for purposes of this part is the abbreviated term for the virus called SARS-CoV-2 and the disease it causes, called coronavirus disease 2019.

Diagnostic test for COVID-19 (“*COVID-19 diagnostic test*”) means a COVID-19 *in vitro* diagnostic test described in section 6001 of the Families First Coronavirus Response Act (Pub. L. 116-127, March 18, 2020), as amended by section 3201 of the CARES Act (Pub. L. 116-136, March 27, 2020).

Provider of a diagnostic test for COVID-19 (“*provider*”) means any facility that performs one or more COVID-19 diagnostic tests.

§ 182.30 Applicability.

(a) *General applicability.* The requirements of this part apply to each provider of a diagnostic test for COVID-19 as defined at § 182.20.

(b) *Duration of requirements.* The requirements of this part are applicable during the public health emergency (PHE) determined to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the PHS Act on January 31, 2020, as a result of confirmed cases of COVID-19, including any subsequent renewals.

Subpart B—Public Disclosure Requirements

§ 182.40 Requirements for making public cash prices for a diagnostic test for COVID-19.

(a) *General rules.* (1) Except as provided under paragraph (b) of this section, a provider of a COVID-19 diagnostic test must make public the information described in paragraph (c) of this section electronically via the internet.

(2) The information described in paragraph (c) of this section, or a link to such information, must appear in a conspicuous location on a searchable homepage of the provider’s website.

(3) The information described in paragraph (c) of this section must be displayed in a manner that is easily accessible, without barriers, and ensures that the information is accessible:

- (i) Free of charge;
- (ii) Without having to establish a user account or password; and
- (iii) Without having to submit personal identifiable information (PII).

(4) The provider must include all of the following terms on its homepage:

- (i) The provider’s name;
- (ii) The term “price”;
- (iii) The term “cost”;
- (iv) The term “test”;
- (v) The term “COVID”; and
- (vi) The term “coronavirus”.

(b) *Exception.* A provider of a COVID-19 diagnostic test that does not have its own website must make public the information described in paragraph (c) of this section:

- (1) In writing, within two business days upon request; and
- (2) On a sign posted prominently at the location where the provider offers a COVID-19 diagnostic test, if such location is accessible to the public.

(c) *Required information.* For purposes of paragraphs (a) and (b) of this section, the provider must make public the following information:

- (1) A plain-language description of each COVID-19 diagnostic test that is offered by the provider;
- (2) The billing code used for each COVID-19 diagnostic test;
- (3) The provider’s cash price for each such COVID-19 diagnostic test; and
- (4) Any additional information as may be necessary for the public to have certainty of the cash price that applies to each COVID-19 diagnostic test.

Subpart C—Monitoring and Penalties for Noncompliance

§ 182.50 Monitoring and enforcement.

(a) *Monitoring.* (1) CMS may evaluate whether a provider has complied with the requirements under § 182.40.

(2) CMS may use methods to monitor and assess provider compliance with the requirements under this part, including, but not limited to, the following, as appropriate:

- (i) CMS’ evaluation of complaints made to CMS.
- (ii) CMS review of an individual’s or entity’s analysis of noncompliance as stated in the complaint.
- (iii) CMS review of providers’ websites.

(b) *Actions to address provider noncompliance.* If CMS concludes that the provider is noncompliant with one or more of the requirements of § 182.40, CMS may take any of the following actions:

(1) Provide a written warning notice to the provider of the specific violation(s).

(2) Request that the provider submit and comply with a corrective action plan under § 182.60.

(3) Impose a civil monetary penalty on the provider if the provider fails to respond to CMS’ request to submit a corrective action plan or to comply with the requirements of a corrective action plan approved by CMS.

§ 182.60 Corrective action plans.

(a) *Violations requiring a corrective action plan.* If CMS determines a provider’s noncompliance with the requirements of this part continues after a warning notice, a corrective action plan may be required. A violation may include, but is not limited to, the following:

(1) A provider’s failure to make public its cash price information required by § 182.40.

(2) A provider’s failure to make public its cash price information in the form and manner required under § 182.40.

(b) *Notice of violation.* CMS may request that a provider submit and comply with a corrective action plan, specified in a notice of violation issued by CMS to a provider.

(c) *Compliance with corrective action plan requests and corrective actions.* (1) A provider required to submit a corrective action plan must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the provider, and must comply with the requirements of the corrective action plan approved by CMS.

(2) A provider’s corrective action plan must specify elements including, but not limited to:

(i) The corrective actions or processes the provider will take to address the deficiency or deficiencies identified by CMS.

(ii) The timeframe by which the provider will complete the corrective action.

(3) A corrective action plan is subject to CMS review and approval.

(4) After CMS’ review and approval of a provider’s corrective action plan, CMS may monitor and evaluate the provider’s compliance with the corrective actions specified in the corrective action plan.

(d) *Noncompliance with corrective action plan requests and requirements.* (1) A provider’s failure to respond to

CMS' request to submit a corrective action plan includes failure to submit a corrective action plan in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the provider.

(2) A provider's failure to comply with the requirements of a corrective action plan includes failure to correct violation(s) within the specified timeframes.

§ 182.70 Civil monetary penalties.

(a) *Basis for imposing civil monetary penalties.* CMS may impose a civil monetary penalty on a provider identified by CMS as noncompliant according to § 182.50, and that fails to respond to CMS' request to submit a corrective action plan or to comply with the requirements of a corrective action plan approved by CMS as described in § 182.60(d).

(b) *Notice of imposition of a civil monetary penalty.* (1) If CMS imposes a penalty in accordance with this part, CMS will provide a written notice of imposition of a civil monetary penalty to the provider via certified mail or another form of traceable carrier.

(2) This notice to the provider may include, but is not limited to, the following:

(i) The basis for the provider's noncompliance, including, but not limited to, the following:

(A) CMS' determination as to which requirement(s) the provider has violated.

(B) The provider's failure to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan, as described in § 182.60(d).

(ii) CMS' determination as to the effective date for the violation(s). This date is the latest date of the following:

(A) The first day the provider is required to meet the requirements of this part.

(B) A date determined by CMS, such as one resulting from monitoring activities specified in § 182.50, or development of a corrective action plan as specified in § 182.60.

(iii) The amount of the penalty as of the date of the notice.

(iv) A statement that a civil monetary penalty may continue to be imposed for continuing violation(s).

(v) Payment instructions.

(vi) A statement of the provider's right to a hearing according to subpart D of this part.

(vii) A statement that the provider's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties

pursuant to continuing violations, without right of appeal in accordance with § 182.90.

(3) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty, to conform to the adjudicated finding.

(c) *Amount of the civil monetary penalty.* (1) CMS may impose a civil monetary penalty upon a provider for a violation of each requirement of this part.

(2) The maximum daily dollar amount for a civil monetary penalty to which a provider may be subject is \$300. Even if the provider is in violation of multiple discrete requirements of this part, the maximum total sum that a single provider may be assessed per day is \$300.

(3) The maximum daily amount of the civil monetary penalty will be adjusted annually using the multiplier determined by the Office of Management and Budget for annually adjusting civil monetary penalty amounts under part 102 of this title.

(d) *Timing of payment of civil monetary penalty.* (1) A provider must pay the civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

(2) In the event a provider requests a hearing, pursuant to subpart D of this part, the provider must pay the amount in full within 60 calendar days after the date of a final and binding decision, according to subpart D of this part, to uphold, in whole or in part, the civil monetary penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(4) In the event a civil money penalty is not paid in full within 60 days, CMS will follow the collections activities set forth in 45 CFR part 30.

(e) *Continuing violations.* CMS may issue subsequent notice(s) of imposition of a civil monetary penalty, according to paragraph (b) of this section, that result from the same instance(s) of noncompliance.

Subpart D—Appeals of Civil Monetary Penalties

§ 182.80 Appeal of penalty.

(a) A provider upon which CMS has imposed a penalty under this part may appeal that penalty in accordance with subpart D of part 150 of this title, except

as specified in paragraph (b) of this section.

(b) For purposes of applying subpart D of part 150 of this title to appeals of civil monetary penalties under this part:

(1) "Respondent" means a provider, as defined in § 182.20 that received a notice of imposition of a civil monetary penalty according to § 182.70(b).

(2) In deciding whether the amount of a civil money penalty is reasonable, the administrative law judge (ALJ) may only consider evidence of record relating to the following:

(i) The provider's posting(s) of its cash price information, if available.

(ii) Material the provider timely previously submitted to CMS (including with respect to corrective actions and corrective action plans).

(iii) Material CMS used to monitor and assess the provider's compliance according to § 182.70(a)(2).

(3) The ALJ's consideration of evidence of acts other than those at issue in the instant case under § 150.445(g) of this title does not apply.

§ 182.90 Failure to request a hearing.

(a) If a provider does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty described in § 182.70(b), CMS may impose the civil monetary penalty indicated in such notice without right of appeal in accordance with this part.

(1) If the 30th calendar day described paragraph (a) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(2) [Reserved]

(b) The provider has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 of this title, unless the provider can show good cause, as determined at § 150.405(b) of this title, for failing to timely exercise its right to a hearing.

PART 182 [Transferred to Subchapter E]

■ 36. Effective January 1, 2021, transfer part 182 from subchapter E–T to subchapter E.

Subchapter E–T [Removed]

■ 37. Effective January 1, 2021, remove subchapter E–T.

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