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DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 214 and 274a

[CIS No. 2678–21; DHS Docket No. USCIS–2020–0008]

RIN 1615–AC55

Temporary Changes to Requirements Affecting H–2A Nonimmigrants due to the COVID–19 National Emergency: Extension of Certain Flexibilities

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: As a result of continued disruptions and uncertainty to the U.S. food agriculture sector during the upcoming winter and spring agricultural seasons caused by the global novel Coronavirus Disease 2019 (COVID–19) public health emergency, the Department of Homeland Security, (''DHS'' or ''the Department''), U.S. Citizenship and Immigration Services, has decided it is necessary to temporarily extend the amendments to certain regulations regarding temporary and seasonal agricultural workers, and their U.S. employers, within the H–2A nonimmigrant classification. Through this temporary final rule DHS is extending the provisions of the August 20, 2020, temporary final rule. Namely, DHS will continue to allow H–2A employees whose extensions of stay H–2A petitions are supported by valid temporary labor certifications issued by the U.S. Department of Labor to begin work with a new employer immediately after the extension of stay petition is received by USCIS. DHS will apply this temporary final rule to H–2A petitions requesting an extension of stay, if they were received on or after December 18, 2020, but no later than June 16, 2021. The temporary extension of these flexibilities will ensure that agricultural employers have access to the orderly and timely flow of legal foreign workers, thereby protecting the integrity of the nation's food supply chain and decreasing possible reliance on unauthorized aliens, while at the same time encouraging agricultural employers' use of the H–2A program, which protects the rights of U.S. and foreign workers.

DATES: This final rule is effective from December 18, 2020, through December 18, 2023. Employers may request the flexibilities under this rule by filing an H–2A petition on or after December 18, 2020, and through June 16, 2021.

FOR FURTHER INFORMATION CONTACT: Charles L. Nimick, Chief, Business and Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by mail at 5900 Capital Gateway Dr., Camp Springs, MD 20529–2140; or by phone at 240–721–3000.

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

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I. Background

A. Legal Framework

The Secretary of Homeland Security (Secretary) has the authority to amend this regulation under section 102 of the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, 6 U.S.C. 112, and section 103(a) of the Immigration and Nationality Act (INA), 8 U.S.C. 1103(a), which authorize the Secretary to administer and enforce the immigration and nationality laws. Under section 101 of the HSA, 6 U.S.C. 111(b)(1)(F), a primary mission of DHS is to ''ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland.'' In addition, section 214(a)(1) of the INA, 8 U.S.C. 1184(a)(1), provides the Secretary with authority to prescribe the terms and conditions of any alien's admission to the United States as a nonimmigrant. The INA further requires that ''[t]he question of importing any alien as [an H–2A] nonimmigrant . . . in any specific case or specific cases shall be determined by [DHS], after consultation with appropriate agencies of the Government [the U.S. Department of Labor and the U.S. Department of Agriculture], upon petition by the importing employer.'' INA 214(c)(1), 8 U.S.C. 1184(c)(1). Section 274A(h)(3)(B) of the INA, 8 U.S.C. 1324a(h)(3)(B), states that '''an unauthorized alien' means . . . that the alien is not at that time . . . authorized to be employed by this chapter or by the [Secretary].''

B. Description of the H–2A Program

The H–2A nonimmigrant classification applies to alien workers seeking to perform agricultural labor or services of a temporary or seasonal nature in the United States on a temporary basis, usually lasting no longer than 1 year, for which U.S. workers are not available. INA 101(a)(15)(H)(ii)(a), 8 U.S.C. 1101(a)(15)(H)(ii)(a); *see also* 8 CFR 214.1(a)(2). As noted in the statute, not only must the alien be coming ''temporarily'' to the United States, but the agricultural labor or services that the alien is performing must also be ''temporary or seasonal.'' INA 101(a)(15)(H)(ii)(a). The Department of Homeland Security (''DHS'' or ''the Department'') regulations further define

an employer's temporary need as employment that is of a temporary nature where the employer's need to fill the position with a temporary worker will, except in extraordinary circumstances, last no longer than 1 year. 8 CFR 214.2(h)(5)(iv)(A). An employer's seasonal need is defined as employment that is tied to a certain time of year by an event or pattern, such as a short annual growing cycle or a specific aspect of a longer cycle, and requires labor levels above those necessary for ongoing operations. *Id.*

An employer, agent, or association (''H–2A petitioner'') must submit a petition to U.S. Citizenship and Immigration Services (USCIS) to obtain classification of temporary workers as H–2A nonimmigrants before the employer may begin employing H–2A workers. INA 214(c)(1), 8 U.S.C. 1184(c)(1); 8 CFR 214.2(h)(2)(i). DHS must approve this petition before the alien can be considered eligible for H–2A status or a visa. To qualify for H–2A classification, the H–2A petitioner must, among other things, offer a job that is of a temporary or seasonal nature, and must submit a single, valid temporary labor certification (TLC) from the U.S. Department of Labor (DOL) establishing that there are not enough U.S. workers who are able, willing, qualified, and available to do the temporary work, and that employing H–2A workers will not adversely affect the wages and working conditions of workers in the United States similarly employed.[1] INA 101(a)(15)(H)(ii)(a) and 218, 8 U.S.C. 1101(a)(15)(H)(ii)(a) and 1188; *see also generally* 8 CFR 214.2(h)(5)(i)(A) and (h)(5)(iv). Aliens who are outside of the United States also must first obtain an H–2A visa from the U.S. Department of State (DOS) at a U.S. Embassy or Consulate abroad, if required, and all aliens who are outside of the United States must seek admission with U.S. Customs and Border Protection (CBP) at a U.S. port of entry prior to commencing employment as an H–2A nonimmigrant. Aliens may be admitted for an additional period of up to one week prior to the employment start date for the purpose of travel to the worksite, and a 30-day period following the expiration of the H–2A petition for the purpose of departure or to seek an extension based on a subsequent offer of employment. Unless authorized under 8 CFR 274a.12 or section 214(n) of the Act, the beneficiary may not work except during the validity period of the petition. 8 CFR 214.2(h)(5)(viii)(B).

i. DOL Temporary Labor Certification (TLC) Procedures

Prior to filing the H–2A petition with DHS, the U.S. employer or agent must obtain a valid TLC from DOL for the job opportunity the employer seeks to fill with an H–2A worker(s). As part of the TLC process, the petitioning employer must have demonstrated to the satisfaction of the Secretary of Labor that (a) there are not sufficient U.S. workers who are able, willing, and qualified, and who will be available at the time and place needed to perform the labor or services involved in the petition, and (b) the employment of the alien in such labor or services will not adversely affect the wages and working conditions of workers in the United States similarly employed. 8 U.S.C. 1188(a)(1); *see also* 20 CFR 655.100.

To obtain a TLC from DOL, the employer must first submit an agricultural job order, within 75 to 60 calendar days prior to the start date of work, to the State Workforce Agency (SWA) that serves the state where the actual work will be performed. Once it clears the job order, the SWA will place it into intrastate clearance to initiate the recruitment of U.S. workers. 20 CFR 655.121. After review by the SWA, the employer must submit an *Application for Temporary Employment Certification* with DOL's Office of Foreign Labor Certification (OFLC) no less than 45 calendar days before the start date of work. 20 CFR 655.130. OFLC will review the H–2A application and, if it accepts the application will place a copy of the job order on its electronic job registry. 20 CFR 655.144(a). OFLC will also direct the SWA to place the job order into interstate clearance, may direct the SWA to provide written notice of the job opportunity to relevant organizations and physically post the job order in locations workers may gather, and may direct the employer or authorized hiring agent to engage in positive recruitment. 20 CFR 655.143, 655.150, 655.154. As part of its recruitment obligations, an employer must offer the job to any recently laid-off U.S. worker(s) and contact former U.S. workers employed in the occupation in the previous year. 20 CFR 655.135(g), 655.153. OFLC will grant certification if the application meets all of the requirements in the Department of Labor's regulation, including compliance with all recruitment obligations. 20 CFR 655.161(a). Post-certification, OFLC will keep the job order posted on its electronic registry until 50 percent of the contract period has elapsed, and the SWA must keep the job order on file for the same period of time. 20 CFR 655.144, 655.150. The U.S. employer must also continue to accept referrals of all eligible U.S. workers and must offer employment to any qualified U.S. worker that applies for the job opportunity until 50 percent of the work contract period has elapsed. 20 CFR 655.135(d).

ii. DHS Petition Procedures

After receiving a valid TLC from DOL, the employer listed on the TLC, an employer's agent, or the association of United States agricultural producers named as a joint employer on the TLC (''H–2A petitioner'') may file the H–2A petition with the appropriate USCIS office. INA 214(c)(1), 8 U.S.C. 1184(c)(1); 8 CFR 214.2(h)(2)(i), (h)(5)(i)(A). The H–2A petitioner may petition for one or more named or unnamed H–2A workers, but the total number of workers may not exceed the number of positions indicated on the TLC. 8 CFR 214.2(h)(2)(iii) and (h)(5)(i)(B). H–2A petitioners must name the H–2A worker if the worker is in the United States or if the H–2A worker is a national of a country that is not designated as an H–2A participating country. 8 CFR 214.2(h)(2)(iii). USCIS recommends that petitioners submit a separate H–2A petition when requesting a worker(s) who is a national of a country that is not designated as an H–2A participating country. *See* 8 CFR 214.2(h)(5)(i)(F); *see also Identification of Foreign Countries Whose Nationals Are Eligible To Participate in the H–2A and H–2B Nonimmigrant Worker Programs,* Notice, 85 FR 3067 (Jan. 17, 2020). Petitioners for aliens who are nationals of countries not designated as an H–2A participating country must submit evidence demonstrating the factors by which the request for H–2A workers serves the U.S. national interest. 8 CFR 214.2(h)(5)(i)(F)(*1*)(*ii*). USCIS will review each petition naming a national from a country not on the list and all supporting documentation and make a determination on a case-by-case basis.

A U.S. employer or U.S. agent generally may submit a new H–2A petition, with a new, valid TLC, to USCIS to request an extension of H–2A nonimmigrant status for a period of up to 1 year. 8 CFR 214.2(h)(15)(ii)(C). The H–2A petitioner must name the worker on the Form I–129, Petition for Nonimmigrant Worker, since the H–2A worker is in the United States and requesting an extension of stay. In the event of an emergency circumstance, however, the petitioner may request an

[1] Under certain emergent circumstances, petitions requesting a continuation of employment with the same employer for 2 weeks or less are exempt from the TLC requirement. *See* 8 CFR 214.2(h)(5)(x).

extension not to exceed 14 days without first having to obtain an additional approved TLC from DOL if certain criteria are met, by simply submitting the new H–2A petition. *See* 8 CFR 214.2(h)(5)(x).

In 2008, USCIS promulgated regulations allowing H–2A workers to begin work with a new petitioning employer upon the filing of an H–2A petition, before petition approval, provided that the new employer is a participant in good standing in the E-Verify program.[2] 8 CFR 214.2(h)(2)(i)(D) and 8 CFR 274a.12(b)(21). In such a case, the H–2A worker's employment authorization continues for a period not to exceed 120 days beginning on the ''Received Date'' on the Form I–797, Notice of Action, which acknowledges the receipt of the new H–2A extension petition. With the exception of the new employer and worksite, the employment authorization extension remains subject to the same conditions and limitations indicated on the initial H–2A petition. The continued employment authorization extension will terminate automatically if the new employer fails to remain a participant in good standing in the E-Verify program, as determined by USCIS in its discretion.

iii. Admission and Limitations of Stay

Upon USCIS approval of the H–2A petition, the U.S. employer or agent may hire the H–2A workers to fill the job opening. USCIS will generally grant the workers H–2A classification for up to the period of time authorized on the valid TLC. H–2A workers who are outside of the United States may apply for a visa with DOS at a U.S. Embassy or Consulate abroad, if required, and, as noted above, all H–2A workers who are outside of the United States must seek admission to the United States with CBP at a U.S. port of entry. Spouses and children of H–2A workers may request H–4 nonimmigrant status to accompany the principal H–2A worker. The spouse and children of an H nonimmigrant, if they are accompanying or following to join such H nonimmigrant in the United States, may be admitted, if otherwise admissible, as H–4 nonimmigrants for the same period of admission or extension as the principal spouse or parent. 8 CFR 214.2(h)(9)(iv). H–4 dependents of these H–2A workers are subject to the same limitations on stay, and permission to remain in the country during the pendency of the new employer's petition, as the H–2A beneficiary.

An alien's H–2A status is limited by the validity dates on the approved H–2A petition, which must be less than 1 year. 8 CFR 214.2(h)(5)(viii)(C). H–2A workers may be admitted into the United States for a period of up to 1 week prior to the beginning validity date listed on the approved H–2A petition so that they may travel to their worksites, but may not begin work until the beginning validity date. H–2A workers may also remain in the United States 30 days beyond the expiration date of the approved H–2A petition to prepare for departure or to seek an extension or change of nonimmigrant status. 8 CFR 214.2(h)(5)(viii)(B). Although they will be considered to be maintaining valid nonimmigrant status during this 30-day additional period beyond the petition expiration date, H–2A workers do not have employment authorization outside of the validity period listed on the approved petition unless otherwise authorized. 8 CFR 214.2(h)(5)(viii)(B).

The maximum period of stay for an alien in H–2A classification is 3 years. 8 CFR 214.2(h)(5)(viii)(C). Once an alien has held H–2A nonimmigrant status for a total of 3 years, the alien must depart and remain outside of the United States for an uninterrupted period of 3 months before seeking readmission as an H–2A nonimmigrant. 8 CFR 214.2(h)(5)(viii)(C).

C. COVID–19 National Emergency

On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a public health emergency dating back to January 27, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to the Coronavirus Disease 2019 (COVID–19).[3] On March 13, 2020, President Trump declared a National Emergency concerning the COVID–19 outbreak to control the spread of the virus in the United States.[4] The President's proclamation declared that the emergency began on March 1, 2020. In response to the Mexican government's call to increase social distancing, DOS announced the temporary suspension of routine immigrant and nonimmigrant visa services processed at the U.S. Embassy in Mexico City and all U.S. Consulates in Mexico beginning on March 18, 2020.[5] DOS expanded the temporary suspension of routine immigrant and nonimmigrant visa services to all U.S. Embassies and Consulates on March 20, 2020.[6] DOS designated H–2A visas as mission critical, however, and announced that U.S. Embassies and Consulates have continued to process H–2A cases to the extent possible and implemented a change in its procedures, to include interview waivers.[7] In addition, DHS has identified occupations in food and agriculture as critical to the U.S. public health and safety and economy.[8]

To address disruptions caused by COVID–19 to the U.S. food agriculture sector during the spring and summer agricultural seasons, DHS temporarily

[2] *See* ''Changes to Requirements Affecting H–2A Nonimmigrants,'' 73 FR 76891, 76905 (Dec. 8, 2008).

[3] HHS, *Determination of Public Health Emergency,* 85 FR 7316 (Feb. 7, 2020).

[4] Proclamation 9994 of Mar. 13, 2020, *Declaring a National Emergency Concerning the Coronavirus Disease (COVID–19) Outbreak,* 85 FR 15337 (Mar. 18, 2020). *See also https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/* (last visited Nov. 20, 2020). DHS recognizes that agricultural employers as well as their workers are encountering rapidly changing circumstances and unique public health and safety issues relating to the COVID–19 National Emergency. DHS encourages H–2A employers to regularly consult Federal, State, and local guidance on COVID–19. At the time of this publication, OSHA's guidance on COVID–19 is available at *https://www.osha.gov/SLTC/covid-19/,* including guidance for agricultural employers and workers jointly issued by OSHA and the Centers for Disease Control and Prevention. OFLC's guidance on COVID–19 for H–2A employers is available at *https://www.dol.gov/agencies/eta/foreign-labor.* On November 10, 2020 the CDC and the U.S. Department of Labor published Interim Guidance for all agriculture workers and their employers to protect agriculture workers from coronavirus disease 2019 (COVID–19). *https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-agricultural-workers.html.*

[5] DOS, *Status of U.S. Consular Operations in Mexico in Light of COVID–19, https://mx.usembassy.gov/status-of-u-s-consular-operations-in-mexico-in-light-of-covid-19/* (last updated Nov. 18, 2020). According to DOS, ''The U.S. Embassy in Mexico City and U.S. Consulates in Guadalajara, Monterrey, Nuevo Laredo, and Hermosillo have resumed limited processing of routine student and work visa appointments, including TN visas, as local conditions allow.'' It is further noted, ''Because of limited capacity and safety precautions due to COVID–19, applicants should expect to experience delays in appointment availability.''

[6] DOS, *Suspension of Routine Visa Services, https://travel.state.gov/content/travel/en/News/visas-news/suspension-of-routine-visa-services.html* (last updated Mar. 20, 2020).

[7] *See* DOS website, *Important Announcement on H2 Visas, https://travel.state.gov/content/travel/en/News/visas-news/important-announcement-on-h2-visas.html* (last updated Mar. 26, 2020).

[8] DHS, *Memorandum on Identification of Essential Critical Infrastructure Workers During COVID–19 Response, https://www.cisa.gov/sites/default/files/publications/CISA-Guidance-on-Essential-Critical-Infrastructure-Workers-1-20-508c.pdf* (Mar. 19, 2020). DHS, *Advisory Memorandum on Identification of Essential Critical Infrastructure Workers During COVID_10 Response, https://www.cisa.gov/sites/default/files/publications/Version_3.1_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_0.pdf* (May 19, 2020).), DHS, *Advisory Memorandum on Identification of Essential Critical Infrastructure Workers During COVID_10 Response, https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v3.pdf* (Aug. 18, 2020).

amended its H–2A regulations to provide certain flexibilities to temporary and seasonal agricultural workers and their U.S. employers. On April 20, 2020, DHS issued a temporary final rule (the ''April 20 TFR''), *Temporary Changes to Requirements Affecting H–2A Nonimmigrants Due to the COVID–19 National Emergency,* which allowed H–2A workers to begin work with new H–2A employers, who have valid TLCs issued by DOL, for a period not to exceed 45 days immediately after the H–2A extension of stay petition is received by USCIS. The April 20 TFR also allowed petitioners to employ H–2A workers seeking an extension of stay beyond the 3-year total limitation of stay. In the April 20 TFR, DHS indicated that it would issue a new temporary final rule to extend its termination date in the event DHS determined that economic circumstances related to our food supply demonstrated a continued need for these temporary changes to the regulatory requirements involving H–2A agricultural employers and workers. The April 20 TFR was effective from April 20, 2020 through August 18, 2020. 85 FR 21739. DHS subsequently determined that the public health emergency and economic circumstances resulting from COVID 19 necessitated the continuation of some of the flexibilities implemented through the April 20 TFR, namely the ability of H–2A workers to change employers and begin work before USCIS approves the new H–2A petition for the new employer. Accordingly, DHS issued a TFR on August 20, 2020 (the ''August 20 TFR'') extending those flexibilities, which has been effective for H–2A petitions that were received on or after August 19, 2020 through December 17, 2020. 85 FR 51304.

As discussed in more detail below, due to the continuing health and economic crisis caused by COVID–19, DHS has again determined that the public health emergency and economic circumstances resulting from COVID–19 are necessitating the continuation of the flexibilities implemented through the August 20 TFR. Therefore, DHS is issuing this TFR to extend those flexibilities for an additional 180 days, *i.e.,* through June 16, 2021. This timeframe differs from the most recent renewal of a determination of the public health emergency because DHS believes that the COVID–19 pandemic may have a more lasting impact on the U.S. food agriculture sector beyond the 90 day public health emergency determination signed by HHS Secretary Alex Azar on October 2, 2020.[9] As a result, DHS will continue to monitor the evolving health crisis caused by COVID–19 and may address it in future rules.

II. Discussion

A. Temporary Changes to DHS Requirements for H–2A Change of Employer Requests During the COVID–19 National Emergency

DHS is committed to both protecting U.S. and foreign workers and to helping U.S. businesses receive the legal and work-authorized labor for temporary or seasonal agricultural labor or services that they need.

On October 2, 2020, HHS Secretary Alex Azar signed a renewal of determination, effective October 23, 2020, that extends the current COVID–19 public health emergency by up to 90 days.[10] This determination that a public health emergency exists and has existed since January 27, 2020, nationwide, was previously renewed on April 21, 2020 and July 23, 2020. The renewal of determination signals that the United States is facing continued consequences of the COVID–19 National Emergency, which corresponds to the volume of COVID–19 cases reported by the U.S. Centers for Disease Control and Prevention—13,295,605 as of November 30, 2020.[11]

The COVID–19 pandemic continues to cause disruptions in the domestic food supply chain.[12] As of October 2, 2020, USDA's Economic Research Service reported that ''[t]he coronavirus (COVID–19) pandemic has widely impacted the U.S. economy, including the farm sector and farm households. Farm businesses have experienced disruptions to production due to lowered availability of labor and other inputs . . . [r]eductions in available labor affect crop and livestock production, as well as processing capacity for crop and animal products that leave the farm. Reduced processing capacity results in lower consumption of certain agricultural commodities.''[13] The H–2A program has been crucial to assuring the continued viability of the nation's food supply chain.[14] Notwithstanding the availability of the H–2A program, U.S. farmers are continuing to experience labor shortages as fewer workers are able to get to the United States or are willing to take health risks in coming to this country to perform H–2A work. Media outlets in the United States have continued to report on these shortages. For example, a farmer in North Dakota who typically hires the same eight farmhands from South Africa to tend his crops was short half of his crew this year due to COVID–19.[15] In another instance, an executive director of a farming association noted that they have had access to 10 percent to 12 percent fewer H–2A workers in the area of Idaho in which their farms are located.[16]

As the public health emergency and economic consequences of it continue, DHS has determined it is necessary to issue a new temporary final rule to extend certain flexibilities first implemented through the April 20 TFR, and subsequently partially extended through the August 20 TFR, because DHS has determined that there is a continued need for them. This TFR extends the amendments made by the August 20 TFR to help U.S. agricultural employers reduce disruptions in lawful agricultural-related employment, protect the nation's food supply chain, and lessen impacts from the COVID–19 pandemic and related economic effects, consistent with the declaration of the National Emergency. Due to the continued travel restrictions and visa processing limitations as a result of actions taken to mitigate the spread of COVID–19,[17] as well as the possibility that some H–2A workers may become

[9] *See* HHS Renewal of Determination That A Public Health Emergency Exists, *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx* (Oct. 2, 2020).

[10] *See* HHS Renewal of Determination That A Public Health Emergency Exists, *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx* (Oct. 2, 2020).

[11] See, *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days* (Last visited Nov. 30, 2020). DHS notes that the total number of cases changes daily.

[12] *See, e.g. Food Security and COVID–19, https://www.worldbank.org/en/topic/agriculture/brief/food-security-and-covid-19* (last visited Nov. 19, 2020).

[13] ''Farms and Farm Households During the COVID–19 Pandemic,'' *https://www.ers.usda.gov/covid-19/farms-and-farm-households/* (last visited Nov. 19, 2020).

[14] The Washington Post, ''How one visa program keeps America fed,'' *https://www.washingtonpost.com/video/national/how-one-visa-program-keeps-america-fed/2020/06/17/ac3be98d-1ed1-4d4c-8dc7-85cbbeecb5fc_video.html* (last visited Nov. 20, 2020).

[15] Bloomberg, ''Global Food Output Runs Into Migrant Worker Woes,'' Aug. 7, 2020, *https://www.bloomberg.com/news/newsletters/2020-08-07/supply-chains-latest-migrant-worker-shortages-hit-food-output* (last visited Nov. 20, 2020).

[16] MagicValley.com, ''Indispensable: Foreign workers critical for many Magic Valley farms,'' Oct. 1, 2020, *https://magicvalley.com/business/agriculture/indispensable-foreign-workers-critical-for-many-magic-valley-farms/article_e9720a22-534b-5ccf-b694-27e5f9d6b9fe.html* (last visited Nov. 24, 2020).

[17] U.S. News and World Report, ''U.S., Canada, Mexico to Extend Border Restrictions Until Late December,'' Nov. 18, 2020, *https://www.usnews.com/news/world/articles/2020-11-18/us-travel-restrictions-at-canada-mexico-borders-set-to-be-extended-until-dec-21-official* (last visited Nov. 24, 2020).

unavailable due to COVID–19 related illness or a legitimate fear of contracting COVID–19 under current conditions,[18] U.S. employers who have approved H–2A petitions or who will be filing H–2A petitions might not receive all of the workers requested to fill the temporary positions, and similarly, employers that currently employ H–2A workers may lose the services of workers due to COVID–19 related illness. For example, Purdue University estimates as of November 24, 2020 more than 247,000 agricultural workers have contracted COVID–19.[19] Though not all of these cases involve H–2A nonimmigrant workers, this research highlights the particular serious risks and vulnerabilities to contracting COVID–19 that farmworkers experience.

Under this temporary final rule, any H–2A petitioner with a valid TLC, *i.e.* one who has already tested the U.S. labor market and was unable to find able, willing, and qualified U.S. workers to perform temporary or seasonal agricultural services or labor, can start employing H–2A workers who are currently in the United States and in valid H–2A status and who have been complying with the terms of their H–2A status immediately after receiving notice that USCIS has received the H–2A petition, but no earlier than the start date of employment listed on the petition. This will allow H–2A workers to move to a new employer to meet urgent temporary or seasonal agricultural needs before USCIS approves the new employer's petition. DHS believes this continued flexibility will help address the challenges faced by U.S. employers as well as workers due to COVID–19 as the winter and spring seasons approach.[20] *See* new 8 CFR 214.2(h)(22) and 8 CFR 274a.12(b)(28). However, nothing in this TFR changes the existing DOL requirements for obtaining a TLC which an employer must comply with before filing an H–2A petition with USCIS.

Unlike the permanent regulation at 8 CFR 274a.12(b)(21), which allows the H–2A worker(s) to immediately work for a new H–2A employer in good standing in E-Verify upon the filing of an H–2A extension of stay petition, this TFR, like the April 20 and August 20 TFRs, allows the H–2A worker(s) to immediately work for any new H–2A employer, but no earlier than the start date of employment listed on the H–2A petition, upon the filing of an H–2A extension of stay petition during the COVID–19 National Emergency only.

DHS remains committed to promoting the use of E-Verify to ensure a legal workforce. E-Verify is free, user friendly, and over 98 percent accurate.[21] Notwithstanding the numerous benefits E-Verify offers to ensure all employers only employ a legal workforce, DHS has determined that it is necessary to temporarily amend its regulations affecting H–2A workers to mitigate the impact on the agricultural industry due to COVID–19. These H–2A petitioners will have completed a test of the U.S. labor market, and DOL will have determined that there are no qualified U.S. workers available to fill these temporary positions. DHS believes that granting H–2A workers the option to begin employment with any new H–2A petitioner as soon as the H–2A petition is received by USCIS will also benefit U.S. agricultural employers and help provide stability to the U.S. food supply chain during the unique challenges the country faces because of COVID–19.

To be approved under this final rule, an H–2A petition for an extension of stay with a new employer must be received on or after December 18, 2020, but no later than June 16, 2021. If the new petition is approved, the H–2A worker's extension of stay may be granted for the validity of the approved petition, and for a period not to exceed the validity period of the TLC. In addition, the temporary provisions being extended by this rule are the same as the April 20 and August 20 TFRs provisions but differ from the permanent regulatory provisions in that they grant employment authorization for 45 days from the date of the receipt notice. The 45-day employment authorization associated with the filed petition will automatically terminate 15 days after the date of denial or withdrawal if USCIS denies the petition, or if the petition is withdrawn.

To provide greater certainty to the market for the winter and spring agricultural seasons, the changes made by this final rule will automatically terminate on June 16, 2021. DHS will continue to monitor the rapidly evolving situation surrounding the COVID–19 pandemic and associated economic consequences and will determine whether continued flexibilities are needed beyond the 180 days. USCIS will continue to adjudicate H–2A petitions received no later than June 16, 2021 under the provisions of this rule. Unless the exceptions contained in this temporary final rule are further extended, any H–2A petition received after the termination of this temporary final rule will be adjudicated in accordance with the existing permanent provisions. *See* 8 CFR 214.2(h)(2)(i)(D) and 274a.12(b)(21).

III. Statutory and Regulatory Requirements

A. Administrative Procedure Act

This rule is being issued without prior notice and opportunity to comment and with an immediate effective date pursuant to sections 553(b) and (d) of the Administrative Procedure Act (APA). 5 U.S.C. 551 *et seq.*

[18] See *e.g. See e.g. National Center for Farmworker Health: COVID–19 in Rural America: Impact on Farms & Agricultural Workers* (''As of October 18th, 99% of rural counties in America had reported positive COVID–19 cases and 81% had reported one or more deaths. More than one million rural residents have tested positive for COVID–19 and 22,613 deaths among rural Americans have been attributed to the disease.''), *http://www.ncfh.org/msaws-and-covid-19.html* (Last visited Dec. 1, 2020), and also The Wall Street Journal, ''Coronavirus Hits Nation's Key Apple, Cherry Farms,'' Jul. 6, 2020, *https://www.wsj.com/articles/coronavirus-hits-nations-key-apple-cherry-farms-11594027802* (last visited Nov. 20, 2020). Patch, ''Newsom Opens Hotel Rooms For Farmworkers Exposed To Coronavirus,'' Jul. 29, 2020, *https://patch.com/california/santamonica/s/h6xix/newsom-opens-hotel-rooms-farmworkers-exposed-coronavirus* (last visited Nov. 20, 2020). U.S. News & World Report, ''Nearly 190 Farmworkers Contract Virus in Southern California,'' Jul. 6, 2020, *https://www.usnews.com/news/best-states/california/articles/2020-07-06/nearly-190-farmworkers-contract-virus-in-southern-california* (last visited Nov. 20, 2020).

[19] Purdue University, College of Agriculture, ''Food and Agricultural Vulnerability Index Dashboard'', *https://ag.purdue.edu/agecon/Pages/FoodandAgVulnerabilityIndex.aspx?_ga=2.56793390.563531196.1602252382-1692557252.1601925927* (last visited Dec. 1, 2020).

[20] The Apr. 20 TFR provided temporary exceptions to DHS regulations at 8 CFR 214.2(h)(5)(viii)(C), (h)(13)(i)(B), and (h)(15)(ii)(C) that had allowed aliens to extend their H–2A period of stay beyond the 3-year limitation, without first requiring them to remain outside of the United States for an uninterrupted period of 3 months. As described in the Aug. 20 TFR, DHS determined that it was necessary to provide stability to the U.S. food supply chain, address the urgent needs of U.S. agricultural producers, and ensure that those aliens admitted into the United States as temporary workers in the H–2A nonimmigrant classification in fact remain in this country on a temporary basis, as required by the Act. 8 U.S.C. 1101(a)(15)(H)(ii)(a). Therefore, DHS did not extend the Apr. 20 TFR temporary exceptions to its regulations at 8 CFR 214.2(h)(5)(viii)(C), (h)(13)(i)(B), and (h)(15)(ii)(C). With this TFR, DHS maintains the belief that a balance is required between providing stability to the U.S. food supply chain and ensuring foreign agricultural workers are in the country on a temporary basis, and therefore, DHS is not including temporary exceptions to allow aliens to extend their H–2A period of stay beyond the 3-year limitation. Consequently, USCIS will continue to apply the 3-year limit reflected in permanent DHS regulations to any H–2A petition that is received on or after Dec. 18, 2020. Petitioners who seek foreign workers to fill a permanent need and/or to remain in the country permanently, must comply with requirements applicable to permanent positions. See 8 U.S.C. 1153(b)(3).

[21] *See https://www.e-verify.gov/about-e-verify/e-verify-data/e-verify-performance* (last updated Oct. 1, 2020).

1. Good Cause To Forgo Notice and Comment Rulemaking

The APA, 5 U.S.C. 553(b)(B), authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The good-cause exception for forgoing notice-and-comment rulemaking ''excuses notice and comment in emergency situations, or where delay could result in serious harm.'' *Jifry* v. *FAA,* 370 F.3d 1174, 1179 (D.C. Cir. 2004). Although the good cause exception is ''narrowly construed and only reluctantly countenanced,'' *Tenn. Gas Pipeline Co.* v. *FERC,* 969 F.2d 1141, 1144 (D.C. Cir. 1992), DHS has appropriately invoked the exception in this case, for the reasons set forth below. As also discussed earlier in this preamble, on January 31, 2020, the Secretary of Health and Human Services declared a public health emergency, dating back to January 27, 2020, under section 319 of the Public Health Service Act in response to COVID–19.[22] On March 13, 2020, President Trump declared a National Emergency concerning the COVID–19 outbreak, dated back to March 1, 2020, to control the spread of the virus in the United States.[23] In response to the Mexican government's call to increase social distancing in that country, DOS announced the temporary suspension of routine immigrant and nonimmigrant visa services processed at the U.S. Embassy in Mexico City and all U.S. Consulates in Mexico beginning on March 18, 2020.[24] DOS expanded the temporary suspension of routine immigrant and nonimmigrant visa services at all U.S. Embassies and Consulates on March 20, 2020.[25] On October 2, 2020, the U.S. Department of Health and Human Services (HHS) Secretary Alex Azar signed a renewal of determination, effective October 23, that extends the current COVID–19 public health emergency by up to 90 days.[26] This determination that a public health emergency exists and has existed since January 27, 2020, nationwide, was previously renewed on April 21, 2020 and on July 23, 2020.

DOS designated H–2A visas as mission critical, and announced that U.S. Embassies and Consulates will continue to process H–2 cases to the extent possible and implemented a change in its procedures, to include interview waivers.[27] In addition, DHS identified occupations in food and agriculture as critical to the U.S. public health and safety and economy.[28] Due to extended travel restrictions, the limited resumption of routine visa services, as well as the possibility that some U.S. and H–2A workers may become unavailable due to illness related to the spread of COVID–19[29], as well as reasonable health concerns of workers outside of the United States regarding accepting employment in this country during the current health crisis, U.S. employers who have approved temporary agricultural labor certifications and/or who will be filing H–2A petitions might not receive, or be able to continuously employ, all of the workers requested to fill all of their DHS-approved temporary or seasonal agricultural positions. Due to these anticipated labor shortages, these employers may continue to experience adverse economic impacts to their agricultural operations. Finally, COVID–19 continues to cause disruptions in domestic food supply chains which has led to food insecurity on a global level.[30] To partially address these concerns, DHS is acting expeditiously to put in place rules that will facilitate the continued employment of H–2A workers already present in the United States. It is intended that this action will reduce labor disruptions that could affect business operations of U.S. employers for the upcoming labor-intensive winter and spring seasons, and continue to support the critical U.S. food supply network.

Courts have found ''good cause'' under the APA when an agency is moving expeditiously to avoid significant economic harm to a program, program users, or an industry. Courts have held that an agency may use the good-cause exception to address ''a serious threat to the financial stability of [a government] benefit program,'' *Nat'l Fed'n of Fed. Emps.* v. *Devine,* 671 F.2d 607, 611 (D.C. Cir. 1982), or to avoid ''economic harm and disruption'' to a given industry, which would likely result in higher consumer prices, *Am. Fed'n of Gov't Emps.* v. *Block,* 655 F.2d 1153, 1156 (D.C. Cir. 1981). Consistent with the above authorities, DHS has bypassed notice and comment to facilitate the employment of H–2A workers already in the United States, and prevent potential economic harms to H–2A agricultural employers and downstream employers engaged in the processing of agricultural products, as well as potential harms to the American economy and people that could result from ongoing uncertainty over the availability of H–2A agricultural workers, and potential associated negative impacts on food security in the United States. *See Bayou Lawn & Landscape Servs.* v. *Johnson,* 173 F. Supp. 3d 1271, 1285 & n.12 (N.D. Fla. 2016). This action is temporary in nature, and includes appropriate conditions to ensure that it is narrowly tailored to the National Emergency caused by COVID–19.

2. Good Cause To Proceed With an Immediate Effective Date

The APA also authorizes agencies to make a rule effective immediately, upon a showing of good cause, instead of imposing a 30-day delay. 5 U.S.C. 553(d)(3). The good-cause exception to the 30-day effective date requirement is easier to meet than the good-cause exception for forgoing notice and comment rulemaking. *Riverbend Farms, Inc.* v. *Madigan,* 958 F.2d 1479, 1485 (9th Cir. 1992); *Am. Fed'n of Gov't Emps., AFL–CIO* v. *Block,* 655 F.2d 1153, 1156 (D.C. Cir. 1981); *U.S. Steel Corp.* v. *EPA,* 605 F.2d 283, 289–90 (7th Cir. 1979). An agency can show good cause for eliminating the 30-day delayed effective date when it demonstrates urgent conditions the rule seeks to correct or unavoidable time limitations. *U.S. Steel Corp.,* 605 F.2d at 290; *United States* v. *Gavrilovic,* 511 F.2d 1099, 1104 (8th Cir. 1977). For the same reasons set forth above, DHS also concludes that the Department has good cause to dispense with the 30-day effective date requirement given that

[22] *Determination of Public Health Emergency.*

[23] Proclamation 9994.

[24] *Status of U.S. Consular Operations in Mexico in Light of COVID–19.*

[25] *Suspension of Routine Visa Services.*

[26] *See* HHS Renewal of Determination That A Public Health Emergency Exists, *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx* (Oct. 2, 2020).

[27] *Important Announcement on H2 Visas.*

[28] *DHS Memorandum on Identification of Essential Critical Infrastructure Workers During COVID–19 Response. DHS Advisory Memorandum on Identification of Essential Critical Infrastructure Workers During COVID_10 Response.*

[29] *See e.g. National Center for Farmworker Health: COVID–19 in Rural America: Impact on Farms & Agricultural Workers* (''As of October 18th, 99% of rural counties in America had reported positive COVID–19 cases and 81% had reported one or more deaths. More than one million rural residents have tested positive for COVID–19 and 22,613 deaths among rural Americans have been attributed to the disease.''), *http://www.ncfh.org/msaws-and-covid-19.html* (Last visited Dec. 1, 2020).

[30] *See, e.g. Food Security and COVID–19, https://www.worldbank.org/en/topic/agriculture/brief/food-security-and-covid-19* (last visited Nov. 23, 2020). *See also,* ''Farms and Farm Households During the COVID–19 Pandemic'' *https://www.ers.usda.gov/covid-19/farms-and-farm-households/* (last visited Nov. 23, 2020) indicating that ''Farm businesses have experienced disruptions to production due to lowered availability of labor and other inputs . . . [r]eductions in available labor affect crop and livestock production, as well as processing capacity for crop and animal products that leave the farm. Reduced processing capacity results in lower consumption of certain agricultural commodities.''

this rule is necessary to prevent serious economic harms to U.S. employers in the agricultural industry caused by unavailability of workers due to COVID–19, and to ensure food stability for the American people.

B. Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule is designated a significant regulatory action under E.O. 12866. Accordingly, the Office of Management and Budget (OMB) has reviewed this regulation. DHS, however, is proceeding under the emergency provision of Executive Order 12866 Section 6(a)(3)(D) based on the need to move expeditiously during the current public health emergency to secure labor for our food supply.

This rule will help U.S. employers fill critically necessary agricultural job openings, protect their economic investments in their agricultural operations, and contribute to U.S. food security. In addition, it will benefit H–2A workers already in the United States by making it easier for employers to hire them. As this rule helps fill critical labor needs for agricultural employers, DHS believes this rule will help ensure a continual food supply chain in the United States.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (RFA), imposes certain requirements on Federal agency rules that are subject to the notice and comment requirements of the APA. *See* 5 U.S.C. 603(a), 604(a). This final rule is exempt from notice and comment requirements for the reasons stated above in Part III.A. Therefore, the requirements of the RFA applicable to final rules, 5 U.S.C. 604, do not apply to this final rule. Accordingly, DHS is not required to either certify that the final rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

D. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, 2 U.S.C. 1501, *et seq.* (UMRA), is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed rule, or final rule for which the agency published a proposed rule that includes any Federal mandate that may result in $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector. 2 U.S.C. 1532. This rule does not contain such a mandate. The requirements of Title II of UMRA, therefore, do not apply, and DHS has not prepared a statement under UMRA.

E. Executive Order 13132 (Federalism)

This rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of E.O. 13132, 64 FR 43255, 43258 (Aug. 4, 1999), this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, 61 FR 4729 (Feb. 5, 1996).

G. Congressional Review Act

The Office of Information and Regulatory Affairs, of the Office of Management and Budget, has determined that this final rule is not a ''major rule'' as defined by the Congressional Review Act, 5 U.S.C. 804(2), and thus is not subject to a 60-day delay in the rule becoming effective. DHS will send this temporary final rule to Congress and to the Comptroller General under the Congressional Review Act, 5 U.S.C. 801 *et seq.*

H. National Environmental Policy Act

DHS analyzes actions to determine whether the National Environmental Policy Act, Public Law 91–190, 42 U.S.C. 4231, *et seq.* (NEPA), applies to them and, if so, what degree of analysis is required. DHS Directive 023–01 Rev. 01 (Directive) and Instruction Manual 023–01–001–01 Rev. 01 (Instruction Manual) establish the policies and procedures that DHS and its components use to comply with NEPA and the Council on Environmental Quality (CEQ) regulations for implementing NEPA, 40 CFR parts 1500–1508.

The CEQ regulations allow federal agencies to establish, with CEQ review and concurrence, categories of actions (''categorical exclusions'') which experience has shown do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment (EA) or Environmental Impact Statement (EIS). 40 CFR 1507.3(b)(2)(ii), 1508.4. Categorical exclusions established by DHS are set forth in Appendix A of the Instruction Manual. Under DHS NEPA implementing procedures, for an action to be categorically excluded, it must satisfy each of the following three conditions: (1) The entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect. Instruction Manual section V.B(2)(a)–(c). This rule temporarily amends regulations governing the H–2A nonimmigrant visa program to facilitate the continued employment of H–2A nonimmigrants in the United States by allowing them to change employers in the United States and begin working in the same visa classification for a period not to exceed 45 days before the nonimmigrant visa petition is approved, due to the National Emergency caused by the COVID–19 global pandemic. This rule does not change the number of H–2A workers that may be employed by U.S. employers as there is not an established statutory limit. It also does not change rules for where H–2A nonimmigrants may be employed; only employers with approved temporary labor certifications for workers to perform temporary or seasonal agricultural work may be allowed to employ H–2A workers under these temporary provisions. Generally, DHS believes NEPA does not apply to a rule intended to make it easier for H–2A employers to hire workers who are already in the United States in addition to, or instead of, also hiring H–2A workers from abroad because any attempt to analyze its potential impacts would be largely speculative, if not completely so. DHS cannot reasonably estimate how many petitions will be filed under these temporary provisions,

and therefore how many H–2A workers already in the United States will be employed by different employers, as opposed to how many petitions would have been filed for H–2A workers employed under normal circumstances. DHS has no reason to believe that the temporary amendments to H–2A regulations would change the environmental effect, if any, of the existing regulations. Therefore, DHS has determined that even if NEPA were to apply to this action, this rule clearly fits within categorical exclusion A3(d) in the Instruction Manual, which provides an exclusion for ''promulgation of rules . . . that amend an existing regulation without changing its environmental effect.''

This rule maintains the current human environment by helping to prevent irreparable harm to certain U.S. businesses and to prevent significant adverse effects on the human environment that would likely result from loss of jobs or income, or disruption of the nation's food supply chain. This rule is not a part of a larger action and presents no extraordinary circumstances creating the potential for significant environmental effects. Therefore, this action is categorically excluded and no further NEPA analysis is required.

I. Signature

The Acting Secretary of Homeland Security, Chad F. Wolf, having reviewed and approved this document, is delegating the authority to electronically sign this document to Chad R. Mizelle, who is the Senior Official Performing the Duties of the General Counsel for DHS, for purposes of publication in the **Federal Register**.

List of Subjects

8 CFR Part 214

Administrative practice and procedure, Aliens, Cultural exchange programs, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

8 CFR Part 274a

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

Accordingly, DHS amends chapter I of title 8 of the Code of Federal Regulations as follows:

PART 214—NONIMMIGRANT CLASSES

■ 1. The authority citation for part 214 continues to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305 and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 115–218.

■ 2. Amend § 214.2 by adding paragraph (h)(22) to read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(h) * * *

(22) *Change of employers during COVID–19 National Emergency.* (i) If an H–2A nonimmigrant who is physically present in the United States seeks to change employers during the COVID–19 National Emergency, the prospective new H–2A employer may file an H–2A petition on Form I–129, accompanied by a valid temporary agricultural labor certification, requesting an extension of the alien's stay in the United States. To be approved under this paragraph (h)(22), an H–2A petition must be received on or after December 18, 2020 but no later than June 16, 2021. If the new petition is approved, the extension of stay may be granted for the validity of the approved petition for a period not to exceed the validity period of the temporary agricultural labor certification. Notwithstanding paragraph (h)(2)(i)(D) of this section and 8 CFR 274a.12(b)(21), an alien in valid H–2A nonimmigrant status on December 18, 2020, or lawfully obtaining such status thereafter pursuant to this paragraph (h)(22), is authorized to begin employment with the new petitioner after the petition described in this paragraph (h)(22) is received by USCIS, but no earlier than the start date of employment, indicated in the H–2A petition. The H–2A worker is authorized to commence employment with the petitioner before the petition is approved and subject to the requirements of 8 CFR 274a.12(b)(28) for a period of up to 45 days beginning on the Received Date on Form I–797 (Notice of Action) or, if the start date of employment occurs after the I–797 Received Date, 45 days beginning on the start date of employment indicated in the H–2A petition. If USCIS adjudicates the petition prior to the expiration of this 45-day period and denies the petition for extension of stay, or if the petition is withdrawn by the petitioner before the expiration of the 45-day period, the employment authorization associated with the filing of that petition under 8 CFR 274a.12(b)(28) will automatically terminate 15 days after the date of the denial decision or the date on which the petition is withdrawn.

(ii) Authorization to initiate employment changes pursuant to this paragraph (h)(22) begins at 12 a.m. on December 18, 2020, and ends at the end of June 16, 2021.

* * * * *

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

■ 3. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a; Title VII of Pub. L. 110–229; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 114–74, 129 Stat. 599; Pub. L. 115–218.

■ 4. Amend § 274a.12 by adding paragraph (b)(28) to read as follows:

§ 274a.12 Classes of aliens authorized to accept employment.

* * * * *

(b) * * *

(28)(i) Pursuant to 8 CFR 214.2(h)(22) and notwithstanding 8 CFR 214.2(h)(2)(i)(D) and paragraph (b)(21) of this section, an alien is authorized to be employed, but no earlier than the start date of employment indicated in the H–2A petition, by a new employer that has filed an H–2A petition naming the alien as a beneficiary and requesting an extension of stay for the alien, for a period not to exceed 45 days beginning from the ''Received Date'' on Form I–797 (Notice of Action) acknowledging receipt of the petition requesting an extension of stay, or 45 days beginning on the start date of employment if the start date of employment indicated in the H–2A petition occurs after the filing. The length of the period (up to 45 days) is to be determined by USCIS in its discretion. However, if USCIS adjudicates the petition prior to the expiration of this 45-day period and denies the petition for extension of stay, or if the petitioner withdraws the petition before the expiration of the 45-day period, the employment authorization under this paragraph (b)(28) will automatically terminate upon 15 days after the date of the denial decision or the date on which the petition is withdrawn.

(ii) Authorization to initiate employment changes pursuant to 8 CFR 214.2(h)(22) and paragraph (b)(28)(i) of this section begins at 12 a.m. on

December 18, 2020, and ends at the end of June 16, 2021.

* * * * *

Chad R. Mizelle,

Senior Official Performing the Duties of the General Counsel, U.S. Department of Homeland Security.

[FR Doc. 2020–27661 Filed 12–17–20; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1121; Project Identifier MCAI–2020–01546–T; Amendment 39–21356; AD 2020–26–01]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2019–03–18, which applied to all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes. AD 2019–03–18 required repetitive general visual inspections for cracks, and replacement if necessary, of certain main landing gear (MLG) sliding tubes that were subject to improperly performed magnetic particle inspections. This AD continues to require repetitive general visual inspections of the affected MLG sliding tubes for cracks and replacement if necessary, and requires inspections, and replacement if necessary, of additional MLG sliding tubes; as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD was prompted by the identification of additional MLG sliding tubes that might have been subject to the same improperly performed magnetic particle inspection. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective January 4, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 4, 2021.

The FAA must receive comments on this AD by February 1, 2021.

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

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

For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1121.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1121; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued AD 2019–03–18, Amendment 39–19570 (84 FR 7804, March 5, 2019) (AD 2019–03–18), which applied to all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes. AD 2019–03–18 required repetitive general visual inspections of the MLG sliding tubes for cracks, and replacement if necessary. The FAA issued AD 2019–03–18 to address cracks on the MLG sliding tubes, which could cause MLG sliding tube fracture, and could result in the MLG collapsing, damage to the airplane, and injury to occupants.

Actions Since AD 2019–03–18 Was Issued

Since the FAA issued AD 2019–03–18, additional MLG sliding tubes have been identified that might also have been subject to the same improperly performed magnetic particle inspection.

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0258, dated November 18, 2020; corrected November 19, 2020 (EASA AD 2020–0258) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus SAS Model A318–111, A318–112, A318–121, A318–122, A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A320–211, A320–212, A320–214, A320–215, A320–216, A320–231, A320–232 and A320–233 airplanes. EASA AD 2020–0258 supersedes EASA AD 2018–0136, dated June 26, 2018 (which corresponds to FAA AD 2019–03–18). Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD, therefore, does not include those airplanes in the applicability.

This AD was prompted by reports of cracks found on additional MLG sliding tubes that may have been subject to the same improperly performed magnetic particle inspection. The FAA is issuing this AD to address cracks on the MLG sliding tubes, which could cause MLG sliding tube fracture, and could result in the MLG collapsing, damage to the airplane, and injury to occupants. See the MCAI for additional background information.

Explanation of Retained Requirements

Although this AD does not explicitly restate the requirements of AD 2019–03–18, this AD retains certain requirements of AD 2019–03–18. Those requirements are referenced in EASA AD 2020–0258, which, in turn, is referenced in paragraph (g) of this AD.

Relationship Between This AD and AD 2020–21–09

EASA AD 2020–0258 notes that EASA AD 2020–0193, dated September 7, 2020 (EASA AD 2020–0193), requires a one-

time inspection using the Airbus alert operators transmission identified in EASA AD 2020–0258. EASA AD 2020–0193 corresponds to FAA AD 2020–21–09, Amendment 39–21282 (85 FR 65200, October 15, 2020; corrected October 27, 2020 (85 FR 67965)) (AD 2020–21–09). AD 2020–21–09 requires a general visual inspection of the MLG sliding tubes for cracks, and replacement, if necessary. That AD applies to all Airbus SAS Model A318 series airplanes; Model A319 series airplanes; Model A320 series airplanes; and Model A321 series airplanes.

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0258 describes procedures for repetitive general visual inspections of the MLG sliding tubes for cracks, and replacement if necessary. EASA AD 2020–0258 also describes terminating actions for the repetitive inspections of affected MLG sliding tubes by either overhauling an affected MLG sliding tube or replacing an affected MLG sliding tube with an MLG sliding tube that is not affected. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD because the FAA has evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Requirements of This AD

This AD requires accomplishing the actions specified in EASA AD 2020–0258 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2020–0258 is incorporated by reference in this final rule. This AD, therefore, requires compliance with EASA AD 2020–0258 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD. Service information specified in EASA AD 2020–0258 that is required for compliance with EASA AD 2020–0258 is available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1121.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because cracks on the MLG sliding tubes, if not detected and corrected, could lead to MLG sliding tube fracture, resulting in MLG collapse with consequent damage to the airplane and injury to occupants. In addition, the compliance time for the required action is shorter than the time necessary for the public to comment and for publication of the final rule. Therefore, the FAA finds good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reasons stated above, the FAA finds that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–1121; Project Identifier MCAI–2020–01546–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 1,467 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Actions	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2019–03–18.	Up to 2 work-hours × $85 per hour = Up to $170.	$0	Up to $170	Up to $138,890 (817 airplanes).
New actions	Up to 2 work-hours × $85 per hour = Up to $170.	0	Up to $170	Up to $249,390 (1,467 airplanes).

The FAA estimates the following costs to do any necessary on-condition action that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
19 work-hours × $85 per hour = $1,615	$185	$1,800

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing airworthiness directive (AD) 2019–03–18, Amendment 39–19570 (84 FR 7804, March 5, 2019), and

■ b. Adding the following new AD:

2020–26–01 Airbus SAS: Amendment 39–21356; Docket No. FAA–2020–1121; Project Identifier MCAI–2020–01546–T.

(a) Effective Date

This airworthiness directive (AD) becomes effective January 4, 2021.

(b) Affected ADs

This AD replaces AD 2019–03–18, Amendment 39–19570 (84 FR 7804, March 5, 2019) (AD 2019–03–18).

(c) Applicability

This AD applies to all Airbus SAS airplanes identified in paragraphs (c)(1) through (3) of this AD, certificated in any category.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by reports of cracks that were found on main landing gear (MLG) sliding tubes after improperly performed magnetic particle inspections of the MLG sliding tubes were done. The FAA is issuing this AD to address cracks on the MLG sliding tubes, which could cause MLG sliding tube fracture, and could result in the MLG collapsing, damage to the airplane, and injury to occupants.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020–0258, dated November 18, 2020; corrected November 19, 2020 (EASA AD 2020–0258).

(h) Exceptions to EASA AD 2020–0258

(1) Where EASA AD 2020–0258 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2020–0258 refers to July 10, 2018 (the effective date of EASA AD 2018–0136, dated June 26, 2018), this AD requires using April 9, 2019 (the effective date of AD 2019–03–18).

(3) The ''Remarks'' section of EASA AD 2020–0258 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2020–0258 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending

information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD and as specified in paragraph (i) of this AD, if any service information referenced in EASA AD 2020–0258 contains paragraphs that are labeled as RC, the instructions in RC paragraphs, including subparagraphs under an RC paragraph, must be done to comply with this AD; any paragraphs, including subparagraphs under those paragraphs, that are not identified as RC are recommended. The instructions in paragraphs, including subparagraphs under those paragraphs, not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the instructions identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to instructions identified as RC require approval of an AMOC.

(k) Related Information

For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on January 4, 2021.

(i) European Union Aviation Safety Agency (EASA) AD 2020–0258, dated November 18, 2020; corrected November 19, 2020.

(ii) [Reserved]

(4) For EASA AD 2020–0258, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(5) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1121.

(6) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on December 7, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–27975 Filed 12–15–20; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1032; Project Identifier MCAI–2020–00856–E; Amendment 39–21338; AD 2020–24–08]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) (RRD) RB211 Trent 768–60, 772–60, 772B–60 and 772C–60 model turbofan engines. This AD requires replacement of high-pressure turbine (HPT) blades with parts eligible for installation before exceeding specified flight cycles since new. This AD was prompted by several reports from the manufacturer that HPT blades on RB211 Trent 700 model turbofan engines have been subject to high levels of corrosion fatigue, leading to blade cracking and eventual release, resulting in an aborted take-off and in-flight shut-downs. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 4, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 4, 2021.

The FAA must receive comments on this AD by February 1, 2021.

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

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

For service information identified in this final rule, contact Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom, phone: +44 (0)1332 242424; website: *https://www.rolls-royce.com/contact-us.aspx.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1032.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1032; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; fax: (781) 238–7199; email: *Scott.M.Stevenson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD No. 2018–0291, dated December 21, 2018 (referred to after this as ''the MCAI''), to address the unsafe condition for the specified products. The MCAI states:

HP turbine blades on a number of Trent 700 engines have been subject to high levels of corrosion fatigue, leading to blade cracking and eventual release. This has caused a

number of aborted take-off and in-flight shut-down events. Sampling has identified that corrosion fatigue affects blades at varying rates, likely dependent on environmental, operational and individual blade conditions.

This condition, if not corrected, could lead to blade failure and subsequent increased risk of high energy debris release, possibly resulting in damage to, and reduced control of, the aeroplane.

To address this potential unsafe condition, RR issued the NMSB to provide instructions for removal from service of certain engines where a higher level of corrosion exposure is expected for the affected blades.

For the reason described above, this [EASA] AD requires removal from service of certain engines, to be corrected in shop.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1032.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Rolls-Royce RB211 Trent 700 Series Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AK165, dated November 26, 2018. The Alert NMSB describes procedures for removal of specific engines, identified by serial number, to enable replacement of potentially corrosion-fatigued HPT blades. The FAA also reviewed Task 72–41–52–200–800—General Data for the Inspection of the High Pressure (HP) Turbine Blades, dated June 10, 2011, from the (Rolls-Royce) RR Trent-768–60/15 Engine Manual. This Task describes procedures for inspection of the HPT blades. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA's Determination

This product has been approved by EASA and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD because it evaluated all the relevant information provided by EASA and determined that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires replacement of HPT blades on affected engines prior to accumulating a specified number of flight cycles since new, or before further flight, whichever occurs later.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C.) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than 30 days, upon a finding of good cause.

The FAA has found the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because no domestic operators use this product. It is unlikely that the FAA will receive any adverse comments or useful information about this AD from U.S. operators. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reasons, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, the FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the FAA–2020–1032 and Project Identifier MCAI–2020–00856–E at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this final rule contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this final rule, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this final rule. Submissions containing CBI should be sent to Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 0 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Remove and replace HPT blades	52 work hours × $85 per hour = $4,420	$1,500,000	$1,504,420	$0

Authority for This Rulemaking

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–24–08 Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc): Amendment 39–21338; Docket No. FAA–2020–1032; Project Identifier MCAI–2020–00856–E.

(a) Effective Date

This AD is effective January 4, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) (RRD) RB211 Trent 768–60, 772–60, 772B–60, and 772C–60 model turbofan engines with an engine serial number (ESN) identified in Table 1 or Table 2 of Appendix 1 of Rolls-Royce (RR) RB211 Trent 700 Series Alert Non-Modification Service Bulletin RB.211–72–AK165, dated November 26, 2018 (the NMSB).

(d) Subject

Joint Aircraft System Component (JASC) Code/Air Transport Association (ATA) of America Code 7250—Turbine Section.

(e) Unsafe Condition

This AD was prompted by a determination by the manufacturer that high-pressure turbine (HPT) blades on several RB211 Trent 700 model turbofan engines have been subject to high levels of corrosion fatigue, leading to HPT blade cracking and eventual release. The FAA is issuing this AD to prevent failure of the HPT blades. The unsafe condition, if not addressed, could result in blade failure and subsequent release of high-energy debris, possibly resulting in damage to, and reduced control of, the airplane.

(f) Compliance

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

(g) Required Actions

(1) For engines with an ESN listed in Table 1 of Appendix 1 of the NMSB, prior to each HPT blade accumulating 3,500 flight cycles since new, or before further flight after the effective date of this AD, whichever occurs later, remove the HPT blade from service and replace with a part eligible for installation.

(2) For engines with an ESN listed in Table 2 of Appendix 1 of the NMSB, prior to each HPT blade accumulating 5,800 flight cycles since new, or before further flight after the effective date of this AD, whichever occurs later, remove the HPT blade from service and replace with a part eligible for installation.

(3) If the flight cycles since new of an HPT blade are unable to be determined, use the flight cycles since new, flight cycles since refurbishment, or flight cycles since overhaul of the HPT module.

(h) Definition

For the purpose of this AD, ''a part eligible for installation'' is:

(1) An HPT blade that has:

(i) Been removed from an engine with a serial number listed in Table 1 of the NMSB; and

(ii) not exceeded 3,500 flight cycles since new; and

(iii) before installation, passed an inspection (no crack detected) in accordance with Task 72–41–52–200–800—General Data for the Inspection of the High Pressure (HP) Turbine Blades, dated June 10, 2011, from the (Rolls-Royce) RR Trent-768–60/15 Engine Manual (RR Task 72–41–52–200–800); or

(2) An HPT blade that has:

(i) Been removed from an engine with a serial number listed in Table 2 of the NMSB; and

(ii) not exceeded 5,800 flight cycles since new; and

(iii) before installation, passed an inspection (no crack detected) in accordance with Task 72–41–52–200–800—General Data for the Inspection of the High Pressure (HP) Turbine Blades, dated June 10, 2011, from the RR Trent-768–60/15 Engine Manual (RR Task 72–41–52–200–800); or

(3) An HPT blade with zero flight cycles since new.

(i) No Reporting Requirements

The reporting requirements specified in paragraph R. of RR Task 72–41–52–200–800 are not required by this AD.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

(1) For more information about this AD, contact Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; fax: (781) 238–7199; email: *Scott.M.Stevenson@faa.gov.*

(2) Refer to European Aviation Safety Agency (EASA) AD No. 2018–0291, dated December 21, 2018, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2018–1032.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Rolls-Royce RB211 Trent 700 Series Alert Non-Modification Service Bulletin RB.211–72–AK165, dated November 26, 2018.

(ii) Task 72–41–52–200–800—General Data for the Inspection of the High Pressure (HP) Turbine Blades, dated June 10, 2011, from

the (Rolls-Royce) RR Trent-768–60/15 Engine Manual.

(3) For service information identified in this AD, contact Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom, phone: +44 (0)1332 242424; website: *https://www.rolls-royce.com/contact-us.aspx.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 17, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–27897 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0572; Product Identifier 2017–SW–056–AD; Amendment 39–21358; AD 2020–26–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2007–26–51 which applied to certain Airbus Helicopters Deutschland GmbH Model EC135 helicopters. AD 2007–26–51 required inspecting the tail rotor control rod (control rod) and ball pivot and, depending on findings, replacing those parts. This new AD requires inspecting certain ball pivots, applying corrosion preventative compound on the ball pivot, and corrective action, as applicable. This AD also requires replacing the control rod with a newly developed control rod. This AD was prompted by the manufacturer's development of a new control rod, which the FAA has determined must be installed in order to address the identified unsafe condition. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD is effective January 22, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 22, 2021.

ADDRESSES: For service information identified in this final rule, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0572.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov in* Docket No. FAA–2020–0572; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, any service information that is incorporated by reference, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: David Hatfield, Aviation Safety Engineer, Aircraft Systems Section, Technical Innovation Policy Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5116; email *David.Hatfield@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to remove AD 2007–26–51, Amendment 39–15357 (73 FR 6008, February 1, 2008) (AD 2007–26–51), and add a new AD. AD 2007–26–51 applied to certain Airbus Helicopters Deutschland GmbH (type certificate previously held by Eurocopter Deutschland GmbH) Model EC135 helicopters, serial number (S/N) 0005 up to and including S/N 0444, except S/N 0028, and with control rod part number (P/N) L672M2005207, installed. The NPRM was published in the **Federal Register** on June 18, 2020 (85 FR 36816). The NPRM proposed to require inspecting certain ball pivots for damage and freedom of movement, applying corrosion preventative compound on the ball pivot, and corrective action, as applicable. The NPRM also proposed to require replacing the control rod with the newly developed control rod that the FAA determined was necessary to address the unsafe condition.

The NPRM was prompted by EASA AD No. 2010–0227R1, dated April 7, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for all Model EC135 P1, EC135 P2, EC135 P2+, EC135 T1, EC 135 T2, and EC135 T2+ helicopters; and Model EC635 T1, EC635 P2+, and EC635 T2+ helicopters. EASA advises that in 2007 an accident occurred on an EC135 helicopter in Japan. Preliminary investigation results indicated that loss of control was due to failure of the control rod. EASA issued EASA Emergency AD 2007–0301–E, dated December 13, 2007 (EASA AD 2007–0301–E) to inspect the affected control rod P/N L672M2005207 and the ball pivot (which correspond to the actions required by AD 2007–26–51). EASA AD 2007–0301–E was subsequently superseded by EASA AD 2007–0313, dated December 21, 2007, to require repetitive inspections and, depending on findings, the replacement of the control rod and ball pivot, only for helicopters not equipped with an automatic flight control system (AFCS). After review of the inspection results, EASA issued EASA AD 2008–0064, dated April 4, 2008, and later revised to EASA AD 2008–0064 R1, dated April 15, 2008 (EASA AD 2008–0064 R1), to apply the requirements to helicopters equipped with an AFCS.

EASA also advises that after EASA AD 2008–0064R1 was issued, Eurocopter Deutschland GmbH developed a new control rod P/N L672M2006101, installation of which constituted terminating action for the repetitive inspections. Consequently, EASA issued EASA AD 2010–0227, dated November 3, 2010, and corrected November 8, 2010, retaining the requirements of EASA AD 2008–0064R1, and requiring the replacement of control rod P/N L672M2005207 with the new control rod P/N L672M2006101. The FAA has determined that this new control rod must be installed in order to address the unsafe condition.

In addition, EASA advises that following a review of data and feedback received from in-service helicopters, it

has been determined that the repetitive inspections of the ball pivot are no longer required to address the unsafe condition. The repetitive inspections of the ball pivot are now included in Chapter 05 of the aircraft maintenance manual. Therefore, EASA issued EASA AD 2010–0227R1 to remove the requirement for repetitive inspections of the control rod and of the ball pivot.

You may examine the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0572.

Comments

The FAA gave the public the opportunity to participate in developing this final rule, but the FAA did not receive any comments on the NPRM or on the determination of the cost to the public.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA of the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all of the information provided by EASA and determining the unsafe condition exists and is likely to exist or develop on other helicopters of the same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the MCAI or Service Information

The MCAI includes a compliance time of 50 flight hours for the inspection of a certain ball pivot; 100 flight hours or 43 days for the inspection of a certain other ball pivot; and 400 flight hours or 12 months for the replacement of the control rod. This AD requires all actions be accomplished within 50 hours time-in-service.

The MCAI applies to Airbus Helicopters Deutschland GmbH Model EC635 T1, EC635 P2+, and EC635 T2+ helicopters. Model EC635 T1, EC635 P2+, and EC635 T2+ helicopters are not certified by the FAA and are not included on the U.S. type certificate data sheet except where the U.S. type certificate data sheet explains that the Model EC635T2+ helicopter having serial number 0858 was converted from Model EC635T2+ to Model EC135T2+; this AD therefore does not include those Model EC 635 helicopters in the applicability.

Additionally, although the MCAI and service information specify to contact the manufacturer, this AD does not include that requirement.

Related Service Information Under 1 CFR Part 51

Airbus Helicopters has issued Alert Service Bulletin ASB EC135–67A–017, Revision 4, dated April 3, 2017, including the Appendix (watermarked as Appendix to SB EC135–67A–017 Revision 4). This service information describes procedures for, among other actions, an inspection of ball pivots, P/Ns 92–201–00 and 92–207–00, for freedom of movement, and for damage (*e.g.,* cracks, missing hardware, loose bearing, or play), application of corrosion preventative compound, and corrective actions. Corrective actions include replacing the ball pivot and the control rod with serviceable parts, and applying corrosion preventative compound.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

Eurocopter has issued Service Bulletin EC135–67–018, Revision 01, dated May 15, 2008, which describes procedures for replacing the control rod having P/N L672M2005207 with a control rod having P/N L672M2006101.

Eurocopter has also issued Alert Service Bulletin EC135–67A–017, Revision 03, dated July 26, 2010, which describes procedures for ball pivot inspections and replacements.

Costs of Compliance

The FAA estimates that this AD affects 311 helicopters of U.S. Registry. The FAA estimates that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at $85 per work-hour.

Inspecting the ball pivot takes about 1 work-hour, for an estimated cost of $85 per helicopter and $26,435 for the U.S. fleet. If applicable, applying corrosion preventative compound takes a minimal amount of additional time for a nominal cost.

Replacing the control rod takes about 3 work-hours, and parts cost about $800 for an estimated cost of $1,055 per helicopter and $328,105 for the U.S. fleet.

Replacing the control rod and ball pivot takes up to about 6 work-hours, and parts cost up to about $2,150 for an estimated cost of up to $2,660 per helicopter.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2007–26–51, Amendment 39–

15357 (73 FR 6008, February 1, 2008), and

■ b. Adding the following new AD:

2020–26–03 Airbus Helicopters Deutschland GmbH: Amendment 39–21358; Docket No. FAA–2020–0572; Product Identifier 2017–SW–056–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective January 22, 2021.

(b) Affected ADs

This AD replaces AD 2007–26–51, Amendment 39–15357 (73 FR 6008, February 1, 2008) (AD 2007–26–51).

(c) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH Model EC135P1, EC135T1, EC135P2, EC135T2, EC135P2+, EC135T2+, EC135P3, and EC135T3 helicopters, certificated in any category, all serial numbers.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6700, Rotorcraft Flight Control.

(e) Reason

This AD was prompted by an accident involving the failure of a tail rotor control rod. The FAA is issuing this AD to address failure of a tail rotor control rod and subsequent loss of control of the helicopter.

(f) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(g) Definitions

(1) *Group 1:* Helicopters that, on the effective date of this AD, have a tail rotor control rod installed having part number (P/N) L672M2005207.

(2) *Group 2:* Helicopters that, on the effective date of this AD, do not have a tail rotor control rod installed having P/N L672M2005207.

(h) Ball Pivot Inspection

Within 50 hours time-in-service after the effective date of this AD: Inspect the ball pivot, P/N 92–201–00 and P/N 92–207–00, for damage and freedom of movement, in accordance with step 3.C.(3) or step 3.D.(3), as applicable, of the Accomplishment Instructions of the Appendix (watermarked as Appendix to SB EC135–67A–017 Revision 4) to Airbus Helicopters Alert Service Bulletin ASB EC135–67A–017, Revision 4, dated April 3, 2017. For purposes of this inspection, damage to the ball pivot may be indicated by cracks, missing hardware, loose bearings, or play.

(i) Corrective Action

If, during the inspection required by paragraph (h) of this AD, there is any damage on any ball pivot or the ball pivot cannot be moved: Before further flight, replace the ball pivot in accordance with step 3.C.(3) or step 3.D.(3), as applicable, of the Accomplishment Instructions of the Appendix (watermarked as Appendix to SB EC135–67A–017 Revision 4) to Airbus Helicopters Alert Service Bulletin ASB EC135–67A–017, Revision 4, dated April 3, 2017, and the tail rotor control rod as required by paragraph (j) of this AD.

(j) Tail Rotor Control Rod Replacement

Group 1: Unless already done as required by paragraph (i) of this AD, within 50 hours time-in-service after the effective date of this AD, replace the tail rotor control rod having P/N L672M2005207 with a tail rotor control rod having P/N L672M2006101.

Note 1 to paragraph (j): Guidance for replacing the tail rotor control rod can be found in Eurocopter Service Bulletin EC135–67–018, Revision 01, dated May 15, 2008.

(k) Parts Installation Prohibition

(1) *Group 1:* After modification of a helicopter as required by paragraphs (i) or (j) of this AD, no person may install on any helicopter a tail rotor control rod having P/N L672M2005207.

(2) *Group 2:* As of the effective date of this AD, no person may install on any helicopter a tail rotor control rod having P/N L672M2005207.

(l) Credit for Previous Actions

This paragraph provides credit for the inspection and ball pivot replacements required by paragraphs (h) and (i) of this AD, if those actions were performed before the effective date of this AD using Eurocopter Alert Service Bulletin EC135–67A–017, Revision 03, dated July 26, 2010.

(m) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed.

(n) No Reporting Requirement

Although the Appendix (watermarked as Appendix to SB EC135–67A–017 Revision 4) to Airbus Helicopters Alert Service Bulletin ASB EC135–67A–017, Revision 4, dated April 3, 2017, specifies to contact the manufacturer, this AD does not include that requirement.

(o) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Strategic Policy Rotorcraft, FAA, may approve AMOCs for this AD. Send your proposal to: David Hatfield, Aviation Safety Engineer, Aircraft Systems Section, Technical Innovation Policy Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5116; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, the FAA suggests that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(p) Related Information

(1) The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD No. 2010–0227R1, dated April 7, 2017. This EASA AD may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0572.

(2) For service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(q) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Airbus Helicopters Alert Service Bulletin ASB EC135–67A–017, Revision 4, dated April 3, 2017.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov, or go to: https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on December 8, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–27808 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0574; Product Identifier 2019–CE–015–AD; Amendment 39–21340; AD 2020–24–10]

RIN 2120–AA64

Airworthiness Directives; Aerostar Aircraft Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Aerostar Aircraft Corporation (Aerostar) Model PA–60–601P (Aerostar 601P), PA–60–602P (Aerostar 602P), and PA–60–700P (Aerostar 700P) airplanes. This AD was prompted by reports of corrosion on the elevator and aileron balance tubes. This AD requires repetitively inspecting the elevator and aileron balance tubes for corrosion and rust and replacing the tube. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 22, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 22, 2021.

ADDRESSES: For service information identified in this final rule, contact Aerostar Aircraft Corporation, 2265 West Aerostar Way, Hayden Lake, ID 83835; telephone: (208) 762–0338; fax: (208) 762–8349; internet: *https://aerostaraircraft.com.* You may review this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0574.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0574; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: David Herron, Aerospace Engineer, Seattle ACO Branch, FAA, 2200 S 216th St., Des Moines, WA 98198; phone: (206) 231–3544; email: *david.herron@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Aerostar Model PA–60–601P (Aerostar 601P), PA–60–602P (Aerostar 602P), and PA–60–700P (Aerostar 700P) airplanes. The NPRM published in the **Federal Register** on June 26, 2020 (85 FR 38338). The NPRM was prompted by reports of corrosion on the elevator and aileron balance tubes, which may be hidden by rubber boots. In the NPRM, the FAA proposed to require repetitively inspecting the elevator and aileron balance tubes for corrosion (pitting and flaking) and rust (discoloration) and replacing the tube.

The FAA is issuing this AD to detect corrosion on the elevator and aileron balance tubes. The unsafe condition, if not addressed, could result in failure of the aileron and elevator balance tubes, jamming of the aileron and/or elevator balance tubes, and loss of control of the airplane.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received comments from three commenters. The commenters were Yankee Aviation Services, Inc. and two individuals. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Withdraw NPRM

An individual commenter requested that the NPRM be withdrawn. The commenter stated there is insufficient data supporting the unsafe condition and questioned the motive for the proposed AD, as Aerostar would benefit financially from the sale of parts needed to comply with the proposed requirements. The commenter observed that Aerostar's service information did not provide details concerning the number, source, or content of the reported events of corrosion and the degree to which the unsafe condition is present in the fleet of Aerostar airplanes. The commenter further stated that the service information and the traditional diligence of the Aerostar owner community are sufficient to address the unsafe condition.

The FAA disagrees. The FAA issues an AD after finding that an unsafe condition exists or is likely to develop in aircraft of a particular type design. For this AD, the FAA reviewed the reports received from Aerostar and the effects that failure of these tubes could have on an airplane. Aerostar initially discovered corrosion on the elevator and aileron balance tubes while conducting maintenance on an airplane. This discovery prompted Aerostar to inspect the other four airplanes in its facility, which resulted in the identification of three additional incidents of corrosion on elevator and aileron balance tubes. The FAA's analysis of this data determined an unsafe condition exists and warrants corrective action through an AD. To the extent Aerostar has issued service information on this issue, while an operator may incorporate into its maintenance program the inspections in the manufacturer's service bulletin, not all operators are required to do so. In order for these inspections to become mandatory, and to correct the unsafe condition identified in the NPRM, the FAA must issue an AD.

The FAA did not change this AD based on this comment.

Request To Remove Requirement To Replace All Tubes

All three commenters requested that the FAA remove the proposed requirement to replace the elevator and aileron balance tubes even if no corrosion and rust is found during the inspection. Two commenters noted that requiring the replacement of parts found to be airworthy does not promote safety and instead subjects owners to unnecessary expenses. Yankee Aviation Services, Inc., stated the new tubes are the same as those being replaced and do not have corrosion proofing.

The FAA disagrees. The FAA determined that the root cause of the rust and corrosion on the elevator and aileron balance tubes is likely a deficient corrosion protection specification in the initial design and manufacture of these tubes. The commenter is not correct that the new tubes are the same as those being replaced. The existing balance tubes are part number (P/N) 26003–003, Revision L or earlier, while the new replacement balance tubes are P/N 26003–003, Revision M or later, as specified in the service information. The Revision M and later balance tubes have been manufactured with corrosion protection (Zinc Chromate primer) that was not applied on the earlier versions of the tubes. The FAA did not change this AD based on these comments.

Request To Allow Part Repair Instead of Replacement

Yankee Aviation Services, Inc., requested the FAA revise the proposed AD to allow the repair of tubes with rust instead of replacement. The commenter stated that a tube with light rust and a wall thickness of 0.049 inch could be repaired by being wire brushed and painted with an epoxy paint.

The FAA disagrees. Repairing the tubes without replacement would not address the root cause of the rust and

corrosion, which the FAA determined is likely a deficient corrosion protection specification in the initial design and manufacture of these tubes. The Revision M or later balance tubes have been manufactured with corrosion protection (Zinc Chromate primer) that was not applied on the earlier versions of the tubes. The commenter's request would allow the tubes to remain installed on the airplane without this additional corrosion protection. The FAA did not change this AD based on this comment.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products.

Related Service Information Under 1 CFR part 51

The FAA reviewed Aerostar Service Bulletin SB600–138, dated August 30, 2018. The service bulletin contains procedures for repetitively inspecting the elevator and aileron balance tubes for corrosion (pitting and flaking) and rust (discoloration) and replacing the tubes at a specified time and repetitively if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Differences Between This AD and the Service Information

This AD does not require completing the reply card and returning it to Aerostar as specified in Step 13 of Part II of the service information.

Costs of Compliance

The FAA estimates that this AD affects 404 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect elevator and aileron balance tubes.	1 work-hour × $85 per hour = $85 per inspection cycle.	Not Applicable	$85 per inspection cycle..	$34,340 per inspection cycle.
Replace elevator and aileron balance tubes.	8 work-hours × $85 per hour = $680 ..	$1,187	$1,867	$754,268.

The FAA estimates the following costs to do any necessary replacements that are required based on the results of the repetitive inspections, assuming separate replacement intervals. The FAA has no way of determining the number of airplanes that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace elevator balance tube	8 work-hours × $85 per hour = $680	$594	$1,274
Replace aileron balance tube	8 work-hours × $85 per hour = $680	594	1,274

Authority for This Rulemaking

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–24–10 Aerostar Aircraft Corporation: Amendment 39–21340; Docket No. FAA–2020–0574; Product Identifier 2019–CE–015–AD.

(a) Effective Date

This airworthiness directive (AD) is effective January 22, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Aerostar Aircraft Corporation Model PA–60–601P (Aerostar 601P), PA–60–602P (Aerostar 602P), and PA–60–700P (Aerostar 700P) airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 27; Flight Controls.

(e) Unsafe Condition

This AD was prompted by reports of corrosion on the elevator and aileron balance tubes. The FAA is issuing this AD to detect corrosion on the elevator and aileron balance tubes. The unsafe condition, if not addressed, could result in failure of the aileron and elevator balance tubes, jamming of the aileron and/or elevator balance tubes, and loss of control of the airplane.

(f) Compliance

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

(g) Repetitive Inspections

Within 10 hours time-in-service after the effective date of this AD, inspect the elevator and aileron balance tubes for corrosion (pitting and flaking) and rust (discoloration) by following steps 1. through 3. of Part I (Inspection) of the Instructions in Aerostar Aircraft Corporation Service Bulletin SB600–138, dated August 30, 2018 (Aerostar SB600–138). For each tube replaced as required by paragraph (h) of this AD, using a borescope, repeat the inspection within 10 years after replacing the tube and thereafter as follows:

(1) At intervals not to exceed 10 years as long as no rust is found.

(2) At intervals not to exceed 2 years if only rust is found (without any signs of corrosion).

(h) Replacements

At the following compliance times, replace each elevator and aileron balance tube by following Part II (Replacement) of the Instructions in Aerostar SB600–138, except you are not required to report information to the manufacturer:

(1) Before further flight if corrosion or rust is found (inside or outside the tubes) during the initial inspection required by paragraph (g) of this AD.

(2) At the next 100-hour inspection or at the next annual inspection, whichever occurs first, if no corrosion and no rust is found (inside or outside the tubes) during the initial inspection required by paragraph (g) of this AD.

(3) Before further flight if corrosion is found (inside or outside the tubes) during any repetitive inspection required by paragraph (g) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(j) Related Information

For more information about this AD, contact David Herron, Aerospace Engineer, Seattle ACO Branch, FAA, 2200 S 216th St, Des Moines, WA 98198; phone: (206) 231–3544; email: *david.herron@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Aerostar Aircraft Corporation Service Bulletin SB600–138, dated August 30, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Aerostar Aircraft Corporation, 2265 West Aerostar Way, Hayden Lake, ID 83835; telephone: (208) 762–0338; fax: (208) 762–8349; internet: *https://aerostaraircraft.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on December 15, 2020.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–27894 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31345; Amdt. No. 556]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: Effective 0901 UTC, December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73125. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that

good cause exists for making the amendment effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC, on November 25, 2020.

Wade Terrell,

Aviation Safety, Manager, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, December 31, 2020.

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44719, 44721.

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES AND CHANGEOVER POINT

[Amendment 556 effective date December 31, 2020]

FROM	TO	MEA
Color Routes		
§ 95.10 Amber Federal Airway A1 is Amended to Delete		
ORCA BAY, AK NDB *8300—MOCA	CAMPBELL LAKE, AK NDB	*9000
CAMPBELL LAKE, AK NDB *9500—MOCA	TAKOTNA RIVER, AK NDB	*10000
§ 95.107 Amber Federal Airway A7 is Amended to Delete		
CAMPBELL LAKE, AK NDB	MINERAL CREEK, AK NDB COP 069 CMQ	10000
§ 95.51 Green Federal Airway G11 is Amended to Delete		
CAMPBELL LAKE, AK NDB	GLENNALLEN, AK NDB	10000
GLENNALLEN, AK NDB	NABESNA, AK NDB	10000

FROM	TO	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes			
§ 95.3301 RNAV Route T301 is Added to Read			
CAPE GIRARDEAU, MO DME	CENTRALIA, IL VORTAC	3500	17500
CENTRALIA, IL VORTAC	TYMME, IL WP	2400	17500
TYMME, IL WP	SPINNER, IL VORTAC	2500	17500
SPINNER, IL VORTAC	PEORIA, IL VORTAC	2400	17500
§ 95.3305 RNAV Route T305 is Added to Read			
CAPE GIRARDEAU, MO DME	AMART, IL WP	3300	17500
AMART, IL WP	TYMME, IL WP	2400	17500
TYMME, IL WP	DELCO, IL FIX	2400	17500
DELCO, IL FIX	JIBKA, IN WP	2400	17500

FROM	TO	MEA
§ 95.6001 Victor Routes—U.S		
§ 95.6063 VOR Federal Airway V63 is Amended to Delete		
BOWIE, TX VORTAC	TEXOMA, OK VOR/DME	3000
§ 95.6154 VOR Federal Airway V154 is Amended to Read in Part		
OCONE, GA FIX *11000—MRA #UNUSABLE	*LOTTS, GA FIX	#

FROM	TO	MEA
§ 95.6157 VOR Federal Airway V157 is Amended to Read in Part		
ALMA, GA VORTAC	*LOTTS, GA FIX	**10000
*11000—MRA		
*11000—MCA LOTTS, GA FIX, NE BND		
**2000—GNSS MEA		
LOTTS, GA FIX	ALLENDALE, SC VOR	*11000
*1800—MOCA		
*2000—GNSS MEA		
§ 95.6289 VOR Federal Airway V289 is Amended to Read in Part		
TEXARKANA, AR VORTAC	*PROVO, AR FIX.	
N BND		4300
S BND		2200
*4500—MRA		
PROVO, AR FIX	UMPIR, AR FIX.	
N BND		*4300
S BND		*3900
*3400—MOCA		
§ 95.6427 Alaska VOR Federal Airway V427 is Amended to Read in Part		
*KING SALMON, AK VORTAC	TOMMY, AK FIX.	
SW BND		**3000
NE BND		**16000
*7200—MCA	KING SALMON, AK VORTAC, NE BND.	
**3000—GNSS MEA		
TOMMY, AK FIX NUTUW, AK FIX.		
SW BND		*7000
NE BND		*16000
*5300—MOCA		
*6000—GNSS MEA		
NUTUW, AK FIX	RINGO, AK FIX.	
SW BND		*9000
NE BND		*16000
*5300—MOCA		
*6000—GNSS MEA		
RINGO, AK FIX	*NONDA, AK FIX	**16000
*16000—MCA NONDA, AK FIX, SW BND.		
**9000—MOCA		
**9000—GNSS MEA		
§ 95.6456 Alaska VOR Federal Airway V456 is Amended to Read in Part		
*KING SALMON, AK VORTAC	STREW, AK FIX.	
SW BND		**3000
NE BND		**11000
*5400—MCA KING SALMON, AK VORTAC, NW BND.		
**2300—MOCA		
STREW, AK FIX	BITOP, AK FIX.	
SW BND		*5000
NE BND		*11000
*5000—MOCA		
*6000—GNSS MEA		
BITOP, AK FIX	*NOSKY, AK FIX	**11000
*15000—MCA NOSKY, AK FIX, NE BND.		
**5900—MOCA		
**6000—GNSS MEA		
NOSKY, AK FIX	*TUCKS, AK FIX	**15000
*10300—MCA TUCKS, AK FIX, SW BND		
**12300—MOCA		
**13000—GNSS MEA		

FROM	TO	MEA	MAA
§ 95.7001 Jet Routes			
§ 95.7227 Jet Route J227 is Amended to Read in Part			
ARMEL, VA VOR/DME	ELMIRA, NY VOR/DME	#18000	23000
#ARMEL R–009 UNUSABLE BYD 74 NM			
ELMIRA R–205 UNUSABLE BYD 73 NM			

Airway Segment		Changeover Points	
FROM	TO	DISTANCE	FROM
§ 95.8003 VOR Federal Airway Changeover Point V157 is Amended to Add Changeover Point			
ALMA, GA VORTAC	ALLENDALE, SC VOR	58	ALMA
J8 is Amended to Modify Changeover Point			
GALLUP, NM VORTAC	FORT UNION, NM VORTAC	103	GALLUP
J19 is Amended to Modify Changeover Point			
BUKKO, NM FIX	FORT UNION, NM VORTAC	80	BUKKO

[FR Doc. 2020–26551 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 36 and 37

RIN 3038–AE94

Swap Execution Facility Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is adopting final rules to amend certain parts of its regulations relating to the execution of package transactions on swap execution facilities (''SEFs'') and the resolution of error trades on SEFs. These matters are currently the subject of relief in certain no-action letters from Commission staff.

DATES: The rules will become effective February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Roger Smith, Associate Chief Counsel, (202) 418–5344, *rsmith@cftc.gov,* Division of Market Oversight, Commodity Futures Trading Commission, 525 West Monroe Street, Suite 1100, Chicago, Illinois 60661, or Michael Penick, Senior Economist, (202) 418–5279, *mpenick@cftc.gov,* Office of the Chief Economist, Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Part 37 of the Commission's Regulations

The Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') amended the Commodity Exchange Act (''CEA'' or ''Act'') by adding section 5h, which establishes registration requirements and core principles for swap execution facilities (''SEFs'').[1] The Commission implemented CEA section 5h by adopting regulations that establish various trading requirements for swaps traded on SEFs[2] and articulating, where appropriate, guidance and acceptable practices. In particular, the Commission promulgated part 37 of its regulations to implement section 5h of the CEA and set forth the registration and operational requirements for SEFs.[3] Among those are requirements in part 37 specifying minimum trading functionality that a SEF must offer to participants for all listed swaps, *i.e.,* an ''order book,'' as defined in § 37.3 (''Order Book'');[4] specifying the types of systems or platforms that a SEF must offer for swaps trading, including swaps subject to the trade execution requirement under CEA section 2(h)(8);[5] and setting forth other relevant regulations applicable to the fifteen core principles with which a SEF must comply to obtain and maintain registration with the Commission.

Commission regulation 37.9 prescribes the methods of execution that a SEF must offer to market participants to execute swap transactions on the SEF. In particular, § 37.9(a) defines ''Required Transactions'' as swaps subject to the trade execution requirement. Section 37.9(a) also requires a SEF to offer, as required methods of execution, either (i) an Order Book or (ii) a request-for-quote

[1] 7 U.S.C. 7b–3.

[2] The Dodd-Frank Act also added to the CEA certain provisions related to the trading of swaps on designated contract markets (''DCMs''). Given that almost all platform trading of swaps in the U.S. occurs on SEFs, the Commission is not at this time amending any regulatory requirements pertaining to DCMs within part 38 of the Commission's regulations.

[3] Core Principles and Other Requirements for Swap Execution Facilities, 78 FR 33476 (June 4, 2013) (hereinafter ''SEF Core Principles Final Rule'').

[4] 17 CFR 37.3(a)(2). An Order Book is defined as (i) an ''electronic trading facility,'' as that term is defined in CEA section 1a(16); (ii) a ''trading facility,'' as that term is defined in CEA section 1a(51); or (iii) a trading system or platform in which all market participants have the ability to enter multiple bids and offers, observe or receive bids and offers entered by other market participants, and transact on such bids and offers. *See* 17 CFR 37.3(a)(3).

[5] CEA section 2(h)(8) requires that transactions involving swaps subject to the CEA section 2(h)(1) clearing requirement be executed on or pursuant to the rules of a DCM or SEF, or a SEF that is exempt from registration, unless no DCM or SEF makes such swaps available to trade (''MAT'') or such swaps qualify for the clearing exception under CEA section 2(h)(7) (the ''trade execution requirement''). *See* 7 U.S.C. 2(h)(8).

system that sends a request-for-quote to no less than three unaffiliated market participants and operates in conjunction with an Order Book (''RFQ System'') for the execution of these transactions.[6] Swaps that are not subject to the trade execution requirement are defined as ''Permitted Transactions,'' for which a SEF may offer any execution method and for which market participants may voluntarily trade on a SEF.[7] The Commission's regulations specify additional requirements that correspond to the use of an Order Book or RFQ System to execute Required Transactions.[8]

B. Summary of Proposed Changes to Parts 36 and 37

During the implementation of part 37, market participants and SEFs identified certain operational and compliance burdens related to various requirements. To mitigate these burdens, Commission staff issued to SEFs and market participants time-limited no-action relief from certain provisions of the CEA and the Commission's regulations.[9] Based on this implementation experience, on February 19, 2020, the Commission released a proposal [10] (the ''Proposal'') to amend the SEF regulatory framework to address the following issues, which had been identified in staff no-action letters. In particular, within the Proposal:[11]

- The Commission proposed to amend part 37 to allow the swap components of certain categories of ''package transactions'' [12] to be executed on-SEF through flexible means of execution pursuant to § 37.9(c)(2), rather than through the required methods of execution under § 37.9(a) for ''Required Transactions.'' In addition, the Commission proposed to amend part 36 to include an exemption from the trade execution requirement for swap transactions that are executed as a component of a package transaction that also includes a component that is a new issuance bond (''New Issuance Bond package transactions''). CFTC No-Action Letter No. 20–31 (''NAL No. 20–31''),[13] which extended and replaced NAL 17–55, currently provides no-action relief for the swap components of certain categories of package transactions from the required methods of execution, and in some instances, from the trade execution requirement.

- The Commission proposed to amend part 37 to establish a principles-based approach for SEF error trade policies that incorporated relief from the required methods of execution under § 37.9(a) for Required Transactions for trades intended to resolve error trades. The amendment would enable SEFs to permit market participants to execute swaps transactions to correct operational or clerical errors using execution methods other than those required under § 37.9(a) for Required Transactions. The Proposal did not seek to codify the specific conditions contained in CFTC No-Action Letter No. 17–27 (''NAL No. 17–27'').[14] Rather, the Proposal intended to capture the intent of NAL No. 17–27 to permit market participants to correct error trades in Required Transactions through non-required methods of execution while providing flexibility for SEFs to determine the most suitable error trade

[6] 17 CFR 37.9(a). With the exception of block trades, as defined in § 43.2 of the Commission's regulations, Required Transactions must be executed on a SEF's Order Book or RFQ System. *See* 17 CFR 37.9(a)(2)(i).

[7] 17 CFR 37.9(c).

[8] For example, under § 37.9(b), the Commission implemented a fifteen-second time-delay requirement for Required Transactions that are pre-arranged or pre-negotiated by a broker and submitted as cross trades for execution through the SEF's Order Book. This requirement allows a broker or dealer to execute a Required Transaction by trading against a customer's order, or executing two customers' orders against each other, through pre-negotiation or pre-arrangement, provided that one side of the transaction is exposed to the Order Book for fifteen seconds before the other side of the transaction is submitted for execution. *See* 17 CFR 37.9(b).

[9] As defined in § 140.99(a)(2) of the Commission's regulations, a no-action letter is a written statement issued by a Division stating that it will not recommend enforcement action to the Commission for failure to comply with a specific provision of the Act or a Commission rule, regulation, or order. A no-action letter represents only the issuing Division's position and binds only that Division. 17 CFR 140.99(a)(2).

[10] *See* Swap Execution Facility Requirements and Real-Time Reporting Requirements, 85 FR 9407 (Feb. 19, 2020). The relief in many instances also applies to DCMs. *See supra* note 2.

[11] In addition to what is specified below, in the Proposal, the Commission proposed to amend the definition of ''block trade'' in § 43.2 to enable SEFs to offer non-Order Book methods of execution for market participants to execute swap block trades on the SEF. The proposed amendment would codify CFTC No-Action Letter No. 17–60 (''NAL No. 17–60'') while also allowing block trades for swaps that are not intended to be cleared (''ITBC'') to be executed on SEF via non-Order Book methods of execution. On September 17, 2020, the Commission adopted final rules amending certain regulations setting forth the real-time public swap reporting and dissemination requirements. Within those final rules, the Commission adopted, with minor technical changes, the Proposal's proposed amendment to the definition of ''block trade'' in § 43.2. Real-Time Public Reporting Requirements, 85 FR 75422 (Nov. 25, 2020) (''2020 Part 43 Final Rules'').

[12] As used herein a package transaction consists of two or more component transactions executed between two or more counterparties where: (i) At least one component transaction is a Required Transaction; (ii) execution of each component transaction is contingent upon the execution of all other component transactions; and (iii) the component transactions are priced or quoted together as one economic transaction with simultaneous or near-simultaneous execution of all components.

[13] NAL No. 20–31, Re: Extension of No-Action Relief from Sections 2(h)(8) and 5(d)(9) of the Commodity Exchange Act and from Commission Regulations 37.3(a)(2) and 37.9 for Swaps Executed as Part of Certain Package Transactions (Oct. 9, 2020). NAL No. 20–31 extended no-action relief and related conditions previously granted by Commission staff. *See* CFTC Letter No. 14–12, No-Action Relief from the Commodity Exchange Act Sections 2(h)(8) and 5(d)(9) and from Commission Regulation § 37.9 for Swaps Executed as Part of a Package Transaction (Feb. 10, 2014) (''NAL No. 14–12''); CFTC Letter No. 14–62, No-Action Relief from the Commodity Exchange Act Sections 2(h)(8) and 5(d)(9) and from Commission Regulation § 37.9 for Swaps Executed as Part of Certain Package Transactions and No-Action Relief for Swap Execution Facilities from Compliance with Certain Requirements of Commission Regulations § 37.9(a)(2), § 37.203(a) and § 38.152 for Package Transactions (May 1, 2014) (''NAL No. 14–62''); CFTC Letter No. 14–121, Extension of No-Action Relief for Swap Execution Facilities and Designated Contract Markets from Compliance with Certain Requirements of Commission Regulations § 37.9(a)(2), § 37.203(a) and § 38.152 for Package Transactions (Sept. 30, 2014) (''NAL No. 14–121''); CFTC Letter No. 14–137, Extension of No-Action Relief from the Commodity Exchange Act Sections 2(h)(8) and 5(d)(9) and from Commission Regulation § 37.9 and Additional No-Action Relief for Swap Execution Facilities from Commission Regulation § 37.3(a)(2) for Swaps Executed as Part of Certain Package Transactions (Nov. 10, 2014) (''NAL No. 14–137''); CFTC Letter No. 15–55, Extension of No-Action Relief from the Commodity Exchange Act Sections 2(h)(8) and 5(d)(9) and from Commission Regulation § 37.9 and No-Action Relief for Swap Execution Facilities from Commission Regulation § 37.3(a)(2) for Swaps Executed as Part of Certain Package Transactions (Oct. 15, 2015) (''NAL No. 15–55''); CFTC Letter No. 16–76, Re: Extension of No-Action Relief from the Commodity Exchange Act Sections 2(h)(8) and 5(d)(9) and from Commission Regulation § 37.9 and No-Action Relief for Swap Execution Facilities from Commission Regulation § 37.3(a)(2) for Swaps Executed as Part of Certain Package Transactions (Nov. 1, 2016) (''NAL No. 16–76''); CFTC Letter No. 17–55, Re: Extension of No-Action Relief from Sections 2(h)(8) and 5(d)(9) of the Commodity Exchange Act and from Commission Regulations 37.3(a)(2) and 37.9 for Swaps Executed as Part of Certain Package Transactions (Oct. 31, 2017) (''NAL No. 17–55''). NAL No. 20–31 also provides relief for package transactions where at least one individual swap component is subject to the trade execution requirement and all other components are futures contracts (''MAT/Futures package transactions''). The Commission did not propose any regulations related to the MAT/Futures package transactions in the Proposal. As such, the Commission continues to evaluate MAT/Futures package transactions and their regulatory treatment.

Further, NAL No. 20–31 also applies to package transactions occurring on a DCM. *See supra* note 2.

[14] The Proposal also did not propose to codify the supplemental conditions to NAL No. 17–27 contained in CFTC No-Action Letter No. 20–01, Re: Supplemental No-Action Relief for Swap Execution Facilities and Designated Contract Markets in Connection with Swaps with Operational or Clerical Errors Executed on a Swap Execution Facility or Designated Contract Market (Jan. 8, 2020) (''NAL No. 20–01''), conditions that allow market participants to correct error trades that have been accepted for clearing with an *ex post facto* review by the SEF. As discussed below, nothing in this adopting release would prohibit SEFs from incorporating such conditions within their error trade rules.

rules for their markets and participants.[15]

The Commission received six comment letters regarding the Proposal.[16] After considering the comments, the Commission is adopting the rules as proposed. The Commission believes the rules adopted herein will decrease execution risks, improve efficiency, decrease transaction costs, promote operational efficiency, and lead to a more effective regulatory framework for SEFs.

C. Consultation With Other U.S. Financial Regulators

In adopting these rules, the Commission has consulted with the Securities and Exchange Commission, pursuant to section 712(a)(1) of the Dodd-Frank Act.[17]

II. Final Rules

A. Addition of § 37.9(d) and Amendment of § 37.9(a) for the Execution of Certain Package Transactions

1. Proposed Rules

Package transactions generally involve the execution of multiple component transactions together that market participants consider to represent one economic transaction.[18] The types of transactions that constitute a package transaction are wide-ranging and diverse. In particular, there are package transactions that consist solely of swaps subject to the trade execution requirement; those that include a mix of swaps subject to the trade execution requirement and swaps that are not; those made up of swaps and non-swaps; and those comprised of both swaps that are and swaps that are not exclusively subject to the Commission's jurisdiction.[19] These components range from being very liquid and standardized to being illiquid and bespoke.[20] The variety of package transactions derives, in part, from the fact that the different types of package transactions are fit for distinct purposes. The Commission understands that certain package transactions are utilized as tools within market participants' portfolio management and hedging programs, while other types of package transactions are used to allow market participants to express views of the market—for example, by allowing participants to trade the spread between certain products or different maturities in the same product.

Given the diverse characteristics of the component transactions that may be involved, the Commission understands that package transactions often pose unique pricing and execution characteristics. The Commission understands that the negotiation or arrangement of each of these components generally occurs concurrently or on a singular basis; in particular, negotiations for the pricing of such package transactions may be based primarily on the components that are not subject to the trade execution requirement. Further, given the individual liquidity and trading characteristics of each component, certain package transactions will have to trade through methods of execution that are suitable for an illiquid and bespoke component, which in many cases are not the required methods of execution.[21]

Notwithstanding the complexity of their pricing and execution, the Commission is aware of the benefits of such package transactions. By executing multiple components together as part of a package transaction, market participants can improve transaction pricing and cost, increase execution efficiency, and decrease execution risk beyond what would have been possible if the market participant had executed each component individually, *i.e.,* ''legged'' or ''legging'' into the transaction.[22]

During the implementation of the trade execution requirement for certain interest rate swaps and credit default swaps, SEFs and market participants informed the Commission that requiring swaps that are otherwise Required Transactions—but are components of a package transaction [23]—to be executed through the required methods of execution [24] under § 37.9 was in many cases impracticable and increased execution risks and operational challenges. Market participants and

[15] NAL No. 17–27, Re: No-Action Relief for Swap Execution Facilities and Designated Contract Markets in Connection with Swaps with Operational or Clerical Errors Executed on a Swap Execution Facility or Designated Contract Market (May 30, 2017). NAL No. 17–27 extended no-action relief and related conditions previously granted by Commission staff. *See* CFTC Letter No. 16–58, Re: No-Action Relief for Swap Execution Facilities and Designated Contract Markets in Connection with Swaps with Operational or Clerical Errors Executed on a Swap Execution Facility or Designated Contract Market (June 10, 2016) (''NAL No. 16–58''); CFTC Letter No. 15–24, Re: No-Action Relief for Swap Execution Facilities and Designated Contract Markets in Connection with Swaps with Operational or Clerical Errors Executed on a Swap Execution Facility or Designated Contract Market (Apr. 22, 2015) (''NAL No. 15–24''); and CFTC Letter No. 13–66, Time-Limited No-Action Relief for Swap Execution Facilities from Compliance with Certain Requirements of Commission Regulation 37.9(a)(2) and 37.203(a) (Oct. 25, 2013) (initial relief provided by Commission staff with respect to error trades that are rejected from clearing)(''NAL No. 13–66''). NAL No. 17–27 also applies to swap transactions occurring on a DCM. *See supra* note 2. In addition, DMO released NAL No. 20–01, which supplements the conditions in NAL No. 17–27 to allow market participants, *sua sponte,* to correct error trades that have been accepted to clearing with an *ex post facto* review by the SEF. NAL No. 20–01, Re: Supplemental No-Action Relief for Swap Execution Facilities and Designated Contract Markets in Connection with Swaps with Operational or Clerical Errors Executed on a Swap Execution Facility or Designated Contract Market (Jan. 8, 2020).

Further, NAL 17–27 and NAL 20–01 also apply to operational or clerical errors occurring on a DCM. *See supra* note 2.

[16] The following entities submitted comment letters: Citadel; The Futures Industry Association (''FIA''); IHS Markit (''Markit''); International Energy Credit Association (''IECA''); International Swaps and Derivatives Association, Inc. (''ISDA''); and ICAP Global Derivatives Limited (''IGDL'') and tpSEF, Inc. (''tpSEF'') (collectively the ''TP ICAP SEFs''). In addition, the Commission received five letters from Better Markets; Carnegie Mellon; Chris Barnard; Foreign Exchange Professionals Association (''FXPA''); and Massachusetts Institute of Technology (''MIT'') that commented exclusively on proposals that were addressed in the 2020 Part 43 Final Rules. As such, they are not addressed further in this rulemaking. *See* 2020 Part 43 Final Rules.

[17] Dodd-Frank Act, Public Law 111–203, title VII, sec. 712(a)(1), 124 Stat. 1376 (2010).

[18] *See supra* note 12. The Commission notes that there are transactions that otherwise meet the package transaction definition but do not involve a swap subject to the trade execution requirement. While these transactions may colloquially be referred to as package transactions, the Commission notes that such transactions are not the subject of these final rules.

[19] *See infra* note 29 for a more precise description of various package transactions.

To the extent that counterparties may be facilitating package transactions that involve a ''security,'' as defined in section 2(a)(1) of the Securities Act of 1933 or section 3(a)(10) of the Securities Exchange Act of 1934, or any component agreement, contract, or transaction over which the Commission does not have exclusive jurisdiction, the Commission does not opine on whether such activity complies with other applicable law and regulations.

[20] Some non-swap components may be subject to different regulatory requirements than the swap components in the package transactions.

[21] For example, while a swap that is subject to the trade execution requirement is suitable to be executed through the required methods of execution as an outright transaction, when that same swap is bundled together with an illiquid and bespoke component in a package transaction, the package transaction takes on the liquidity and trading profile of the illiquid and bespoke component.

[22] For example, a market participant seeking to execute two component transactions independent of one another, instead of executing the two components together in a package transaction, would be forced to pay the bid/offer spread on each leg, which in many cases is more costly and less efficient than paying the single bid/offer spread for a package transaction composed of the same two components.

[23] *See supra* note 12. Consistent with the definition of package transaction under § 37.9(d) the Commission notes that, unless otherwise stated, the term ''swap component(s)'' as used herein refers to a swap component that is subject to the trade execution requirement under CEA section 2h(8), and therefore a Required Transaction.

[24] As noted above, pursuant to § 37.9(a), SEFs must provide as the required methods of execution for Required Transactions either an Order Book or an RFQ System.

SEFs informed the staff and the Commission that these risks and challenges generally reflect (i) an initial lack of market infrastructure available to trade and clear certain package transactions;[25] and (ii) the complex, bespoke, and idiosyncratic nature of several categories of package transactions that precluded them from being suitable for execution through required methods of execution.[26]

Since the Division of Market Oversight's (DMO's) issuance of this no-action relief, the Commission has gained considerable knowledge and experience with the dynamics of the trading of package transactions, particularly with respect to the existing no-action relief from the required methods of execution. Based on this knowledge and experience, the Commission believed that certain aspects of the current requirements for the required methods of execution under § 37.9 should be enhanced to better account for the complex nature of the relevant package transactions.

As a result, in the Proposal the Commission proposed to add § 37.9(d) and amend § 37.9(a)(2) to permit the swap components of certain package transactions to be executed via flexible methods of execution pursuant to § 37.9(c)(2). The Commission proposed to define a ''package transaction'' as a transaction consisting of two or more component transactions executed between two or more counterparties where: (i) At least one component transaction is a Required Transaction; (ii) execution of each component transaction is contingent upon the execution of all other component transactions; and (iii) the component transactions are priced or quoted together as one economic transaction with simultaneous or near-simultaneous execution of all components.[27] Based on this proposed definition and consistent with existing no-action relief, the Commission proposed to allow the Required Transaction swap component of the following three categories of package transactions to be executed via flexible means of execution pursuant to § 37.9(c)(2):

(1) A package transaction where at least one of the components is a swap exclusively within the Commission's jurisdiction that is not subject to the clearing requirement (''MAT/Non-MAT Uncleared'');

(2) A package transaction where at least one of the components is not a swap (excluding certain package transaction categories as discussed below) (''MAT/Non-Swap Instrument'');[28] and

(3) A package transaction where at least one of the components is a swap for which the CFTC does not have exclusive jurisdiction, *e.g.,* a mixed swap (''MAT/Non-Exclusive CFTC Swap'').[29]

2. Public Comment

Citadel, IHS Markit, IECA, ISDA, and the TP ICAP SEFs generally support the proposed addition of § 37.9(d) and amendment of § 37.9(a)(2) to permit the swap components of certain package transactions to be executed via flexible methods of execution pursuant to § 37.9(c)(2).[30]

In particular, ISDA commends the Commission for codifying no-action relief, such as the package transaction relief, as it will ''will reduce operational and compliance uncertainty, enhance efficiency, and improve regulatory oversight.''[31]

Citadel notes that the transition of package transactions from no-action relief to SEF trading has: (i) ''improved pricing and liquidity as SEFs offer access to more competitive and transparent trading with a greater number of liquidity providers;'' (ii) ''enhanced market stability and integrity given the monitoring and surveillance capabilities of SEFs;'' and (iii) ''reduced operational risk through the pre-trade credit check and straight-through-processing requirements that are applicable to SEF trades.''[32] Citadel believes that such benefits would be threatened if the scope of package transactions eligible for flexible execution methods were expanded,

[25] *See, e.g.,* NAL No. 14–12 at 2–3 n.10 (describing the inability of a derivatives clearing organization (''DCO'') to simultaneously screen and accept all components of a package transaction for clearing).

[26] *See, e.g.,* CFTC Public Roundtable: Trade Execution Requirements and Package Transactions, 72, 84–85 (Feb. 12, 2014), *available at https://www.cftc.gov/sites/default/files/idc/groups/public/@newsroom/documents/file/transcript021214.pdf* (commenting on the challenges of applying required methods of execution to package transactions with complex component swaps).

[27] The Commission notes that there are transactions which otherwise meet the package transaction definition but do not involve a swap that is subject to the trade execution requirement. While these transactions may colloquially be referred to as package transactions, the Commission notes that such transactions are not the subject of these final rules. *See supra* note 12.

[28] Under § 37.9(d)(3), consistent with the no-action relief, this category specifically excludes package transactions in which all non-swap components are U.S. Treasury securities (''U.S. Dollar Spreadover package transactions''); MAT/Futures package transactions; package transactions in which all other non-swap components are agency mortgage-backed securities (''MAT/Agency MBS package transactions''); and New Issuance Bond package transactions. *See also* Section II.A.7—Exemption of New Issuance Bond Package Transactions from the Trade Execution Requirement—Addition of § 36.1.

To the extent that counterparties may be facilitating package transactions that involve a ''security,'' as defined in section 2(a)(1) of the Securities Act of 1933 or section 3(a)(10) of the Securities Exchange Act of 1934, or any component agreement, contract, or transaction over which the Commission does not have exclusive jurisdiction, the Commission does not opine on whether such activity complies with other applicable law and regulations.

[29] The Commission notes that the swap components of different categories of package transactions have been subject to time-limited no-action relief provided by Commission staff from the trade execution requirement and required methods of execution. These categories of package transactions include those where: (i) Each of the components is a swap subject to the trade execution requirement (''MAT/MAT package transactions''); (ii) at least one of the components is subject to the trade execution requirement and each of the other components is subject to the clearing requirement (''MAT/Non-MAT (Cleared)''); (iii) U.S. Dollar Spreadover package transactions; (iv) MAT/Agency MBS package transactions; (v) New Issuance Bond package transactions; (vi) MAT/Futures package transactions; (vii) MAT/Non-MAT (Uncleared); (viii) excluding aforementioned categories, MAT/Non-Swap Instruments; and (ix) MAT/Non-Exclusive CFTC Swap. *See* NAL No. 14–12; NAL No. 14–62; NAL No. 14–121; NAL No. 14–137; NAL No. 15–55; NAL No. 16–76; NAL No. 17–55; and NAL No. 20–31.

Subsequently, the swap components of the following categories of package transactions were no longer provided relief: MAT/MAT package transactions, MAT/Non-MAT (Cleared) package transactions, U.S. Dollar Spreadover package transactions, and MAT/Agency MBS package transactions. As a result, the swap components of these package transactions must be executed through the required methods of execution under § 37.9(a).

Currently, the swap components of the following categories of package transactions receive no-action relief from the required methods of execution under § 37.9 pursuant to NAL No. 20–31: (i) MAT/Non-MAT (Uncleared) package transactions; (ii) MAT/Non-Swap Instruments package transactions (subject to the exclusions previously discussed); and (iii) MAT/Non-Exclusive CFTC Swap package transactions. The addition of § 37.9(d) is consistent with the relief from the required methods of execution under NAL No. 20–31. Within section II, the term ''relevant package transactions,'' unless context requires otherwise, refers to these three categories of package transactions.

In addition to the relief from the required methods of execution in § 37.9(a), NAL No. 20–31 also provides relief from the trade execution for the swap components of MAT/Futures package transactions and New Issuance Bond Package transactions. As discussed above, the Commission is still evaluating MAT/Futures package transactions. *See supra* note 13.

Further, as discussed in more detail below, the Commission is exempting the swap components of New Issuance Bond package transactions from the trade execution requirement. This is consistent with the relief currently provided to New Issuance Bond package transactions under NAL No. 20–31. To the extent that counterparties may be facilitating package transactions that involve a ''security,'' as defined in section 2(a)(1) of the Securities Act of 1933 or section 3(a)(10) of the Securities Exchange Act of 1934, or any component agreement, contract, or transaction over which the Commission does not have exclusive jurisdiction, the Commission does not opine on whether such activity complies with other applicable law and regulations.

[30] Citadel at 1–2; IHS Markit at 8; IECA at 1–4; ISDA at 1; and TP ICAP SEFs at 1–3.

[31] ISDA at 1.

[32] Citadel at 1–2.

such as altering block treatment for package transactions that have successfully transitioned onto SEFs.[33] However, Citadel supports codifying the remaining no-action relief for the ''small number of categories'' of package transactions as proposed in the Proposal.[34]

The TP ICAP SEFs believe that the proposed rules for package transactions strike ''an appropriate balance between the 'utility of package transactions against the policy goals of the trade execution requirement'[.]'' [35] The TP ICAP SEFs support the increased flexibility for execution methods for swap components of the relevant package transactions ''to be executed on-SEF through flexible means of execution pursuant to proposed Rule 37.9(c)(2), rather than through the required methods of execution under Commission Rule 37.9. . . .'' [36] The TP ICAP SEFs support allowing SEF trades to be executed through any means of interstate commerce.[37] As such, the TP ICAP SEFs believe that Proposal for package transactions brought the SEF ''regime closer to the flexible framework envisioned by Congress in 2010, and will assist in the liquidity formation and trade execution of package transactions, further promoting the trading of swaps on SEFs.'' [38]

Similarly, IECA supports flexible methods of execution for package transactions.[39] IECA believes that allowing flexible methods of execution for package transactions ''will encourage SEFs to develop new and innovative trade execution methods'' for package transactions and the development of new and innovative execution methods may result in commercial end-users and their hedging affiliates executing more transactions on SEFs.[40]

The Commission received two comments regarding MAT/Future package transactions. Citadel recommends that the Commission work to bring MAT/Futures package transactions onto SEFs to bring ''greater price transparency to market participants.'' [41] However, ISDA recommends that MAT/Futures package transactions be exempted from the Trade Execution Requirement.[42]

The Commission received one comment, from IECA, requesting that the Commission clarify that § 37.203(a)'s prohibition of pre-arranged trading does not apply to package transactions.[43]

ISDA requested that the Commission reevaluate the process for determining the scope of the trade execution (''MAT Process'') requirement in order to permit SEFs and market participants ''to modify the scope of contracts subject to the trade execution requirement, which is particularly important during times of increased market stress.'' [44]

Finally, the TP ICAP SEFs requested that the Commission adopt other Commission staff no-action letters not included in the Proposal.[45]

3. Commission Determination

The Commission is adopting the addition of § 37.9(d) and amendment of § 37.9(a)(2) to permit the swap components of certain package transactions to be executed via flexible methods of execution pursuant to § 37.9(c)(2) as proposed and as was supported by commenters.[46] While, as noted above and commented on by Citadel, the swap components of several types of package transactions have been successfully transitioned to SEFs and are executed via the required methods of execution, the Commission believes, and agrees with IHS Markit, that the types of package transactions covered by this final rulemaking are not suitable to be traded through the required methods of execution due to their specific characteristics.[47] In particular, the Commission recognizes that these package transactions contain components that are illiquid and bespoke, such as swaptions, or contain components that are subject to regulatory requirements other than or in addition to the CEA and the Commission's regulations issued thereunder.[48]

The Commission believes that if market participants are unable to utilize flexible methods of execution for the swap components of these package transactions, they would potentially be forced to break the package transaction into its individual components, otherwise known as ''legging'' into the transaction. The Commission understands from market participants that legging into a package transaction is inefficient and increases transaction costs and execution risks. Given that components of package transactions are each priced or quoted together as part of one economic transaction, the Commission recognizes the impracticality of breaking the package transaction into individual legs or components in order to trade the swap components via the required methods of execution under § 37.9(a).

Based on its experience with the existing no-action relief and supported by commenters, the Commission believes that the addition of § 37.9(d) and amendment of § 37.9(a) will allow market participants to choose the most suitable execution method for their package transactions, which will decrease execution risks, improve efficiency, and decrease transaction costs because market participants will no longer be forced to leg into transactions.[49] Given the inherent complexity of the relevant package transactions, the Commission believes that this final rule ensures that market participants are able to trade these package transactions in the most effective, efficient, transparent, and economical manner. As a result of this final rulemaking, SEFs will be able to offer, and market participants would be able to utilize, methods of execution that best suit the characteristics of the relevant package transaction being traded. The Commission believes this will help preserve the benefits and purpose of executing such package transactions.

In addition to causing inefficient execution and increasing risks and cost, forcing the swap components of the relevant package transactions through required methods of execution may also limit the commercial utility of such transactions or entirely frustrate the purposes of entering in such package transactions in the first place. For example, the Commission understands that in some of the relevant package

[33] *Id.* at 2.

[34] *Id.*

[35] TP ICAP SEFs at 2.

[36] *Id.*

[37] *Id.* at 3.

[38] *Id.*

[39] IECA at 4.

[40] *Id.*

[41] Citadel at 2.

[42] ISDA at 1–2.

[43] IECA at 5. Further, IECA requested clarification that uncleared bilateral swaps that are permitted transactions, in particular such swaps that include a counterparty that has elected the end-user or affiliate exceptions under CEA section 2(h)(7), ''are exempt from the prohibition against pre-arranged trading.'' *See* IECA at 7. The Commission did not propose any changes to the pre-arranged trading prohibition in § 37.203(a) in the Proposal. Accordingly, § 37.203(a) continues to apply, as applicable, to such transactions.

[44] ISDA at 2.

[45] TP ICAP SEFs at 4–5.

[46] Citadel at 1–2; IHS Markit at 8; IECA at 1–4; ISDA at 1; and TP ICAP SEFs at 1–3. The Commission is also re-designating existing § 37.9(d) to § 37.9(f) in order to keep the rules setting forth permissible execution methods in § 37.9 grouped together. In conjunction with re-designating existing § 37.9(d) to § 37.9(f), the Commission is making ministerial edits to correct internal cross references in re-designated § 37.9(f).

[47] *See* IHS Markit at 8.

[48] The Commission will continue to evaluate these categories of package transactions for new developments in execution methods on SEFs and may in the future revise the categories of package transactions in which the swap component is eligible to be executed through flexible means of execution.

[49] *See* ISDA at 1, TP ICAP SEFs 2–3, and IECA 4.

transactions, (i) the swap component serves as the hedging instrument to other instruments in the package transaction, or (ii) the package transaction as a whole may be utilized as part of a market participant's portfolio management program. If the swap component of such package transactions were impractical or unable to be executed due to the required methods of execution, market participants would be prevented from entering or effectively entering into the package transaction, nullifying the package transaction's purpose and benefits as a hedging and portfolio management tool. Based on its experience with the existing no-action relief, the Commission believes that these final rules will allow market participants to utilize flexible methods of execution for the swap component of the relevant package transaction, thereby ensuring that market participants are able to continue to utilize these effective hedging tools.

Further, the Commission agrees with the TP ICAP SEFs that these final rules will advance the SEF statutory goal of promoting trading on SEFs.[50] These final rules provide relief from execution method requirements that are generally intended to help promote trading on SEFs.[51] However, the swap components of the relevant package transactions are not suitable for trading via such required methods of execution, as discussed above. Accordingly, the Commission believes that in this case flexibility with respect to execution methods will better promote trading of such component swaps on SEFs, consistent with the statutory SEF goals. In addition, the Commission agrees with IECA that flexible methods of execution for the swap components of the package transactions in these final rules may encourage SEFs to develop new and innovative methods of executions.[52]

The Commission agrees with Citadel that the transition of the swap components of package transactions from no-action relief to SEF trading has: (i) Improved pricing and liquidity as SEFs offer access to more competitive and transparent trading with a greater number of liquidity providers; (ii) enhanced market stability and integrity given the monitoring and surveillance capabilities of SEFs; and (iii) reduced operational risk through the pre-trade credit check and straight-through-processing requirements that are applicable to SEF trades.[53] Therefore, the Commission agrees with Citadel that the swap components of package transactions not currently subject to existing no-action relief should continue to be subject to the required methods of executions under § 37.9(a).[54]

In response to Citadel and ISDA's comments regarding MAT/Futures, as noted above, the Commission notes that it did not propose any regulations related to MAT/Futures package transactions and is continuing to evaluate the regulatory treatment of MAT/Futures package transactions. Therefore, the Commission declines to adopt any regulations related to MAT/Futures package transactions in this release.[55] IECA asked the Commission to clarify that package transactions are not subject to the pre-arranged trading ban in § 37.203(a).[56] The Commission did not propose to change any requirements related to pre-arranged trading in the Proposal. However, the Commission makes clear that the requirements in § 37.203(a) apply to the swap components of package transactions. While not suitable for swap components of package transactions that have successfully transitioned onto SEF,[57] the Commission does note that for swap components of package transactions subject to this final rule—MAT/Non-MAT Uncleared, MAT/Non-Swap Instrument, and MAT/Non-Exclusive CFTC Swap—the existing pre-arranged trading prohibition already provides an exception by allowing a SEF to adopt trading practices that are certified or approved by the Commission pursuant to part 40 of the Commission's regulations.[58] Accordingly, the Commission anticipates that a SEF would implement final § 37.9(d) by self-certifying or adopting rules subject to Commission review under part 40 that specify the manner in which counterparties may execute the swap components of MAT/Non-MAT Uncleared, MAT/Non-Swap Instrument, and MAT/Non-Exclusive CFTC Swap package transactions.

The Commission acknowledges ISDA's comment regarding amending the MAT Process to allow modification of the swaps that are subject to the trade execution requirement, especially during times of market stress.[59] However, the Commission did not propose any amendments to the MAT Process in the Proposal. Further, the Commission believes that such a substantive change should be subject to notice and comment rulemaking. Therefore, the Commission declines to adopt ISDA's suggested amendment to the MAT process at this time.

Further, the Commission acknowledges the TP ICAP SEFs' request that the Commission evaluate adopting additional no-action relief that was not proposed to be codified in the Proposal.[60] The Commission will evaluate whether there is additional no-action relief that is currently outstanding that should be codified but declines to codify at this time without further notice and comment any no-action relief that was not proposed to be codified in the Proposal.

[50] *See* TP ICAP SEFs at 3. *See also* 7 U.S.C. 7b–3(e).

[51] Further, while the final rules also provide flexibility from the required methods of execution that are otherwise intended to help promote pre-trade transparency on SEFs, the Commission notes that permitting market participants to use flexible methods of execution is consistent with how package transactions are treated within other jurisdictions. For example, in the European Union (''EU''), certain package transactions (including package transactions for which the Commission currently requires the swap component to be executed through the required methods of execution, such as U.S. Dollar Spreadover package transactions) are eligible to be waived from the EU's transparency regime. The Commission believes that these final rules strike an appropriate balance between promoting pre-trade transparency and ensuring that U.S. markets and their participants are not unnecessarily burdened. *See* Regulation (EU) 2016/1033 of the European Parliament and of the Council of 23 June 2016 amending Regulation (EU) No 600/2014 on markets in financial instruments, Regulation (EU) No 596/2014 on market abuse and Regulation (EU) No 909/2014 on improving securities settlement in the European Union and on central securities depositories, Commission Delegated Regulation (EU) 2017/2194 of 14 August 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to package orders, and Commission Delegated Regulation (EU) 2017/583 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on transparency requirements for trading venues and investment firms in respect of bonds, structured finance products, emission allowances and derivatives. The Commission further believes that in this regard, these final rules further the establishment of consistent international standards with respect to the regulation of swaps as directed by Congress in the Dodd-Frank Act. *See* Section 752(a) of the Dodd-Frank Act, *supra.*

[52] *See* IECA at 4.

[53] *See* Citadel at 1–2.

[54] *See id.* In response to Citadel's comment that the scope of package transactions eligible to be executed through flexible methods of execution should not be expanded, such as altering the treatment of block package transactions, the Commission notes that it did not propose any changes related to the treatment of block package transactions. Therefore, the Commission is taking no action related to the treatment of block package transactions in these final rules.

[55] The Commission notes the MAT/Futures package transactions continue to fall within the bounds of current Commission staff relief provided in NAL No. 20–31 for MAT/Futures package transactions.

[56] *See* IECA at 5.

[57] However, such swap components of package transactions may still be executed subject to the requirements of § 37.9(b)(1). 17 CFR 37.9(b)(1).

[58] *See* 17 CFR 37.203(a).

[59] ISDA at 1–2.

[60] *See* TP ICAP SEFs at 4–5.

Therefore, for the reasons stated above, the Commission is adopting the addition of § 37.9(d) and amendment of § 37.9(a)(2) to permit the swap components of certain package transactions to be executed via flexible methods of execution pursuant to § 37.9(c)(2) as proposed.[61]

B. Addition of § 37.3(a)(4)

1. Proposed Rule

In the Proposal, the Commission proposed to add § 37.3(a)(4) to allow SEFs not to offer an Order Book for the swap components of the following package transactions: (i) MAT/Non-MAT Uncleared package transactions; (ii) MAT/Non-Swap Instrument package transactions; and (iii) MAT/Non-Exclusive CFTC Swap package transactions.[62]

An Order Book is one of the two required methods of execution under § 37.9(a). The Commission designated an Order Book as the ''minimum trading functionality'' each SEF must maintain and offer for each swap that it lists for trading. An Order Book is defined under § 37.3(a)(3) as (i) an electronic trading facility;[63] (ii) a trading facility;[64] or (iii) a trading system or platform in which all market participants in the trading system or platform have the ability to enter multiple bids and offers, observe or receive bids and offers entered by other market participants, and transact on such bids and offers.[65]

Generally speaking, it may be complex to apply the existing Order Book requirement in § 37.3(a)(2) to the swap components of the package transactions covered by this proposed amendment. In some situations, § 37.3(a)(2) may require that a SEF maintain separate Order Books for the same type of swap: One Order Book for when the swap is executed as a single transaction (referred to as an ''outright transaction''), and a separate Order Book for when the swap is executed as part of a package transaction. In fact, multiple Order Books could be required for the same type of swap if it were included as part of multiple types of package transactions. The Commission understands that, in part because of the availability of relief under the staff letters described above, SEFs have put in place relatively few Order Books for swaps to be executed as part of the package transactions covered by the Proposal, and any such Order Books in place are not actively used.

2. Public Comment

Citadel, IECA, ISDA, and the TP ICAP SEFs generally support the codification of existing relief for package transactions which includes relief from having to provide an Order Book for (i) MAT/Non-MAT Uncleared package transactions; (ii) MAT/Non-Swap Instrument package transactions; and (iii) MAT/Non-Exclusive CFTC Swap package transactions.[66]

3. Commission Determination

The Commission agrees with commenters and is adopting § 37.3(a)(4) as proposed to allow SEFs not to offer an Order Book for the swap components of the following package transactions: (i) MAT/Non-MAT Uncleared package transactions; (ii) MAT/Non-Swap Instrument package transactions; and (iii) MAT/Non-Exclusive CFTC Swap package transactions.[67] As noted above,[68] executing Required Transaction swap components of certain package transactions through the required methods of execution is operationally complex, and in many instances, impracticable. Given that the Commission continues to believe that it is infeasible or inefficient to facilitate swap components of these package transactions through the required methods of execution, which includes an Order Book under § 37.3(a), it logically follows that requiring SEFs to offer an Order Book for the swap components of package transactions would be superfluous.

Finally, the Commission believes that not requiring SEFs to offer an Order Book for the swap components of the relevant package transactions would help reduce operating costs for SEFs, as they would no longer be required to operate and maintain order book systems that are not suitable for trading the swap components of the relevant package transactions. Instead of employing resources to build (or attempt to build) and support an unused or underutilized Order Book for the swap components of certain package transactions, the final rules will instead provide a SEF with the flexibility to determine how to allocate its resources, particularly as it relates to developing methods of execution that are better suited to trading the relevant package transactions.[69]

Therefore, for the reasons stated above, the Commission is adopting § 37.3(a)(4) as proposed to allow SEFs not to offer an Order Book for the swap components of the following package transactions: (i) MAT/Non-MAT Uncleared package transactions; (ii) MAT/Non-Swap Instrument package transactions; and (iii) MAT/Non-Exclusive CFTC Swap package transactions.[70]

C. Exemption of New Issuance Bond Package Transactions From the Trade Execution Requirement—Addition of § 36.1

1. Proposed Exemption

In the Proposal, the Commission proposed new rules under part 36 of the Commission's regulations to establish an exemption to the trade execution

[61] The Commission notes that upon the effective date of these rules, the addition of § 37.9(d) and amendment of § 37.9(a)(2), as well as the adoption of § 37.3(a)(4) as discussed below, will negate the need for the relief provided in NAL No. 20–31 for MAT/Non-MAT Uncleared, MAT/Non-Swap Instrument, and MAT/Non-Exclusive CFTC Swap package transactions.

[62] However, the Proposal did not alter any requirement applicable to such swap components to the extent they are executed in transactions that were not package transactions covered by the Proposal. The text of proposed § 37.3(a)(4) made clear that § 37.3(a)(2) of the Commission's regulations would continue to apply to such swap components and SEFs would be required to offer Order Books for these Required Transactions as outright transactions.

[63] CEA section 1a(16) defines ''electronic trading facility'' as a trading facility that (i) operates by means of an electronic or telecommunications network; and (ii) maintains an automated audit trail of bids, offers, and the matching of orders or the execution of transactions on the facility. 7 U.S.C. 1a(16).

[64] CEA section 1a(51) defines ''trading facility'' as ''a person or group of persons that constitutes, maintains, or provides a physical or electronic facility or system in which multiple participants have the ability to execute or trade agreements, contracts, or transactions (i) by accepting bids or offers made by other participants that are open to multiple participants in the facility or system; or (ii) through the interaction of multiple bids or multiple offers within a system with a pre-determined non-discretionary automated trade matching and execution algorithm.'' 7 U.S.C. 1a(51)(A).

[65] 17 CFR 37.3(a)(3).

[66] *See* Citadel at 1–2; IHS Markit at 8; IECA at 2–4; ISDA at 1; and TP ICAP SEFs at 1–3. The TP ICAP SEFs based part of their support on the idea that Permitted Transactions ''[do] not require an Order Book under the Commission's regulations.'' TP ICAP SEFs at 3. Out of an abundance of caution, the Commission notes that while Permitted Transactions are not required to be executed through Order Books or RFQ Systems, as part of the § 37.9(a)'s required methods of execution, SEF's are still required to provide Order Books for permitted transactions as part of the minimum trading functionality requirements in § 37.3(a)(2).

[67] However, these final rules do not alter any requirement applicable to such swap components to the extent they are executed in transactions that are not package transactions covered by this amendment. The text of § 37.3(a)(4) makes clear that § 37.3(a)(2) of the Commission's regulations continues to apply to such swap components and SEFs would be required to offer Order Books for these Required Transactions as outright transactions.

[68] *See* section II.A.—Addition of § 37.9(d) and Amendment of § 37.9(a) for the Execution of Certain Package Transactions.

[69] The Commission notes that nothing in these final rules would preclude a SEF from offering an Order Book if it is able to develop an Order Book solution that is effective in trading the swap component of the relevant package transactions.

[70] *See supra* note 61.

requirement for swap transactions that are components of a ''New Issuance Bond'' package transaction. The Commission believes that exempting these types of transactions from the trade execution requirement is authorized by, and would be consistent with the objectives of, CEA section 4(c).[71] The Proposal was consistent with the time-limited no-action relief provided by Commission staff for this category of package transactions.[72]

New Issuance Bond package transactions include at least one individual swap component that is subject to the trade execution requirement and at least one individual component that is a bond issued and sold in the primary market.[73] An underwriter (on behalf of an issuer) arranges the issuance of a bond packaged with a fixed-to-floating interest rate swap (''IRS'') that features the issuer as a counterparty. The terms of the IRS, which include tenor and payment terms, typically match the terms of the bond issuance. By issuing a bond with a fixed-to-floating IRS, issuers are able to effectively turn fixed-rate liabilities into variable-rate liabilities, or vice versa.[74] To match the terms between these two components and facilitate the bond issuance in an efficient and cost-effective manner, the IRS component is customized and negotiated in a manner that closely corresponds to the bond issuance process.

Given the process under which the swap is negotiated,[75] this type of package transaction has not been conducive to execution on a SEF trading system or platform. The Commission notes that the no-action relief that has been provided by Commission staff for these swaps components reflects the ongoing lack of an available execution method on an appropriate trading venue.[76] Based on the integral role of the bond issuance in facilitating the component swap execution, the Commission believes that the IRS component is not suitable for execution on a SEF, even if a SEF were able to offer flexible means of execution, as the Commission proposed for swap components of other package transactions in the Proposal.[77]

Therefore, consistent with current no-action relief provided by Commission staff, the Commission proposed to exempt swap components of a New Issuance Bond package transaction from the trade execution requirement within new § 36.1. The proposed exemption would establish that a ''package transaction'' consists of two or more component transactions executed between two or more counterparties, where (i) at least one component transaction is subject to the trade execution requirement in section 2(h)(8) of the Act; (ii) execution of each component transaction is contingent upon the execution of all other component transactions; and (iii) the component transactions are priced or quoted together as one economic transaction with simultaneous or near-simultaneous execution of all components.[78]

2. Public Comment

Citadel, IECA, ISDA, and the TP ICAP SEFs generally support the codification of existing relief for package transactions which includes relief from the trade execution requirement for the swap components of New Issuance Bond package transactions.[79]

In addition, as noted above, ISDA recommends that MAT/Futures package transactions be exempted from the Trade Execution Requirement.[80]

3. Commission Determination and Discussion of CEA Section 4(c) Authority

Section 4(c) of the CEA grants the Commission the authority to exempt any transaction or class of transactions, including swaps, from certain provisions of the CEA, including the Commission's trade execution requirement, in order to ''promote responsible economic or financial innovation and fair competition.''[81] Section 4(c)(2) of the CEA further provides that the Commission may not grant exemptive relief unless it determines that: (i) The exemption is appropriate for the transaction and consistent with the public interest; (ii) the exemption is consistent with the purposes of the CEA; (iii) the transaction will be entered into solely between ''appropriate persons;'' and (iv) the exemption will not have a material adverse effect on the ability of the Commission or any contract market to discharge its regulatory or self-regulatory responsibilities under the CEA. In enacting section 4(c), Congress noted that the purpose of the provision is to give the Commission a means of providing certainty and stability to existing and emerging markets so that financial innovation and market development can proceed in an effective and competitive manner.[82]

The Commission believes that exempting swap components of New Issuance Bond package transactions from the trade execution requirement is consistent with the objectives of CEA section 4(c).[83] The Commission recognizes the inherent challenges in trading or executing these swap components on a SEF or DCM and, therefore, recognizes the benefits of continuing to allow market participants to maintain established market practices with respect to this type of package transaction.

The Commission recognizes the importance of new bond issuances in helping market participants to raise capital and fund origination loans for businesses and homeowners. The Commission recognizes that allowing the swap components of New Issuance Bond package transactions to be executed away from a SEF or DCM—consistent with current market practice—is integral to facilitating the bond issuance. Further, the Commission

[71] 7 U.S.C. 6(c).

[72] *See supra* note 29 (describing the no-action relief from the trade execution requirement provided by Commission staff for categories of package transactions).

[73] The Commission understands that a bond issued and sold in the primary market that may constitute part of a package transaction is a ''security,'' as defined in section 2(a)(1) of the Securities Act of 1933 or section 3(a)(10) of the Securities Exchange Act of 1934. To the extent that counterparties may be facilitating package transactions that involve a security, or any component agreement, contract, or transaction over which the Commission does not have exclusive jurisdiction, the Commission does not opine on whether such activity complies with other applicable law and regulations.

[74] For example, a bond issuer seeks to pay variable rates on its bonds, but prospective investors may seek a fixed rate of return. By arranging a New Issuance Bond package transaction, the bond issuer can issue a fixed-rate bond and simultaneously enter into an offsetting IRS. The IRS enables the issuer to receive a fixed rate that matches the fixed rate on its bond to be issued, while paying the variable rate that it originally sought. Ultimately, this arrangement may allow the bond issuer to issue the fixed-rate bond at a lower cost.

[75] The Commission notes that these types of package transactions differ from other package transactions that involve the purchase or sale of a security in the secondary market, given that they involve the issuance of a new security.

[76] *See* NAL No. 20–31 at 2–3.

[77] *See* Section II.A.2.

[78] The Commission notes that this definition is consistent with the definition for package transaction in § 37.9(d)(1).

[79] *See* Citadel at 1–2; IHS Markit at 8; IECA at 2–4; ISDA at 1; and TP ICAP SEFs at 1–3.

[80] ISDA at 1–2.

[81] 7 U.S.C. 6(c); *see also* 7 U.S.C. 2(d).

[82] House Conf. Report No. 102–978, 1992 U.S.C.C.A.N. 3179, 3213.

[83] The Commission notes that this exemption would not apply to swap components of package transactions that include sovereign debt, such as U.S. Treasury bonds, notes, and bills.

recognizes that the exemption is limited in nature, *i.e.,* the swap transaction remains subject to all other applicable Commission rules and regulations.

Therefore, the Commission believes that the exemption from the trade execution requirement for swap components of New Issuance Bond package transactions is appropriate and would be consistent with the public interest and purposes of the CEA.

The Commission further believes that the regulation would not have a material adverse effect on the ability of the Commission or any SEF or DCM to discharge its regulatory or self-regulatory duties under the CEA. The Commission notes that the exemption is limited in scope and the swap components subject to this exemption are still required to be reported to a swap data repository pursuant to parts 43 and 45 of the Commission's regulations. Further, the Commission retains its special call, anti-fraud, and anti-evasion authorities, which will enable it to adequately discharge its regulatory responsibilities under the CEA.

The Commission notes that under the exemption, swap transactions would still be entered into solely between eligible contract participants (''ECPs''), whom the Commission determines, for purposes of this exemption, to be appropriate persons within the scope of section 4(c)(3)(K) of the CEA.[84] This determination is consistent with, and rests on the same reasoning of, previous Commission determinations that ECPs are appropriate persons.[85] As the Commission has noted, the elements of the ECP definition (as set forth in section 1a(18)(A) of the CEA and Commission regulation 1.3) generally are more restrictive than the comparable elements of the enumerated ''appropriate person'' definition.[86] Given that only ECPs are permitted to enter into swaps off of a DCM, there is no risk that a non-ECP or a person who does not satisfy the requirements for an ''appropriate person'' could enter into a New Issuance Bond package transaction using this exemption. Therefore, the Commission believes that the class of persons eligible to rely on the exemption for New Bond Issuance package transactions will be limited to ''appropriate persons'' within the scope of section 4(c)(3) of the CEA.

For the reasons stated above, the Commission is finalizing the exemption from the trade execution requirement for New Issuance Bond package transactions with the addition of new § 36.1.[87] In response to ISDA's comment regarding MAT/Futures, as noted above, the Commission notes that it did not propose any regulations related to MAT/Futures package transactions and is continuing to evaluate the regulatory treatment of MAT/Futures package transactions. As such, the Commission declines to adopt any regulations related to MAT/Futures package transactions in this release.

D. Error Trades: Execution of Trades To Correct Operational and Clerical Errors on Swap Execution Facilities—Addition of § 37.9(e)

1. Proposed Rules

In the Proposal, the Commission proposed to amend the SEF regulatory framework by adding subsection (e) to § 37.9 to establish a flexible SEF error trade policy standard that would, among other things, incorporate the intent of the existing no-action relief in NAL No. 17–27 and NAL No. 20–01 for resolving errors in Required Transactions. Proposed § 37.9(e)(2)(i) requires that a SEF must maintain rules and procedures that are fair, transparent, consistent, and allow for timely resolution of an ''error trade,'' as defined under proposed § 37.9(e)(1)(ii).[88] The error trade rules in the Proposal would apply to any error trade that occurs on a SEF, regardless of whether the swap is submitted for clearing or not.

Further, proposed § 37.9(e)(2)(i) would require SEFs to have error trade rules and procedures that require market participants to provide prompt notice to the SEF of an error trade and, as applicable, the corresponding correcting trade and offsetting trade. The Proposal made clear that this notice need not be separate from the error trade correction process.

In the Proposal, for correcting trades associated with an error trade that has been rejected from clearing, proposed § 37.9(e)(2)(i)(A) would require the SEF to submit the correcting trade for clearing to the registered DCO or exempt DCO as soon as technologically practicable, but no later than one hour after notice of the rejection to the relevant clearing members. For an offsetting trade and a correcting trade associated with an error trade that already has been accepted for clearing, proposed § 37.9(e)(2)(i)(B) would require the SEF to submit both types of trades to the registered DCO or exempt DCO as soon as technologically practicable, but no later than three days after the registered DCO or exempt DCO accepted the error trade for clearing. In addition to these proposed timeframes, proposed § 37.9(e)(2)(ii) would prohibit counterparties from executing a second correcting trade to fix an error trade if the initial correcting trade is rejected from clearing.

2. Public Comment

Citadel, IHS Markit, IECA, ISDA, and the TP ICAP SEFs generally supported the Proposal to establish a flexible SEF error trade policy standard in § 37.9(e).[89]

In particular, ISDA commended the Commission for codifying no-action relief, such as the relief granted for error trades, as it ''will reduce operational and compliance uncertainty, enhance efficiency, and improve regulatory oversight.'' [90]

Citadel stated that it supports ''the Proposal's formal codification of the remaining no-action relief that allows . . . the efficient resolution of error trades on SEFs.'' [91] In particular, Citadel supports the codification of the existing error trade no-action relief ''which enables SEFs and market participants to efficiently correct transactions that have an operational or clerical error. This includes permitting SEFs to allow members to quickly correct an error trade on their own, with an *ex post facto* review performed by the SEF.'' [92] Further, Citadel believes it is important that ''error trade cancellations and corrected trades be properly reported pursuant to Parts 43 and 45'' and recommends that the Commission address the reporting of error trades in the final rules.[93]

The TP ICAP SEFs support the Proposal as it would ''establish a principles-based approach for SEF error trade policies that incorporates relief from the required methods of execution under proposed Rule 37.9 for Required Transactions for trades intended to resolve error trades.'' [94] The TP ICAP SEFs believe the principles-based approach provides ''flexibility for SEFs

[84] 7 U.S.C. 6(c)(3)(K).

[85] *See, e.g.,* Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21750, 21754 (Apr. 11, 2013).

[86] *Id.*

[87] The Commission notes that upon the effective date of these rules, exemption from the trade execution requirement for swap components of New Issuance Bond package transactions will negate the need for the relief provided in NAL No. 20–31 for New Issuance Bond package transactions.

[88] As proposed, an ''error trade'' would be defined as any trade executed on or subject to the rules of a swap execution facility that contains an operational or clerical error.

[89] Citadel at 1–2; IHS Markit at 8; IECA at 2; ISDA at 1; and TP ICAP SEFs at 1–4.

[90] ISDA at 1.

[91] Citadel at 1.

[92] *Id.* at 2.

[93] *Id.* at 3.

[94] TP ICAP SEFs at 3.

to determine the most suitable error trade rules for their markets and participants.'' [95] Further, the TP ICAPs SEFs believe that the Proposal's approach in providing flexibility that is consistent with the SEF core principles ''is an appropriate approach to implementing the related statutory provision with the regulatory certainty of a Commission rule, while preserving discretion for SEFs to formulate the specific approach most appropriate for their customers.'' [96]

In addition, on the basis that SEF participants are sophisticated institutions, the TP ICAP SEFs support the proposed requirements in § 37.9(e)(2)(i) ''that SEFs must have error trade rules and procedures that require market participants to provide prompt notice to the SEF of an error trade and, as applicable, the corresponding correcting trade and offsetting trade.'' [97]

While IHS Markit commends the Commission for codifying the error-trade no-action relief in the Proposal, IHS Markit recommended that, especially during periods of market stress, the ''appropriate timeline for submitting correcting trades [should] be five (5) business days.'' [98]

IECA supports flexible methods of execution for error trades.[99] IECA believes that allowing flexible methods of execution for error trades ''will encourage SEFs to develop new and innovative trade execution methods'' for error trades and the development of new and innovative execution methods may result in commercial end-users and their hedging affiliates to execute more transactions on SEF.[100] Further, IECA requested that the Commission clarify that § 37.203(a)'s prohibition of pre-arranged trading does not apply to error trades.[101]

3. Commission Determination

The Commission has determined to adopt § 37.9(e) as proposed. Final § 37.9(e)(2)(i) requires that a SEF must maintain rules and procedures that are fair, transparent, consistent, and allow for timely resolution of an ''error trade,'' as defined under § 37.9(e)(1)(ii).[102] The error trade rules in § 37.9(e) would apply to any error trade that occurs on a SEF, regardless of whether the swap is submitted for clearing or not.

As adopted, final § 37.9(e) would require a SEF to adopt rules to resolve error trades that involve swaps submitted for clearing. For an error trade rejected from clearing and therefore deemed void *ab initio,* final § 37.9(e)(2)(i)(A) would require a SEF to permit the counterparties to subsequently execute a correcting trade, as defined in § 37.9(e)(1)(i), through any method of execution offered by the SEF. For an error trade that has been accepted for clearing, § 37.9(e)(2)(i)(B) would require a SEF to permit the counterparties to subsequently execute both an offsetting trade, as defined in § 37.9(e)(1)(iii), and a correcting trade through any method of execution offered by the SEF. The Commission intends for its principles-based approach to provide SEFs with the flexibility to implement its error trade policy in a manner that is best suited to its trading and trade processing operations.

Under the principles-based approach adopted in this release, the Commission notes that a SEF would not be prohibited from incorporating the conditions contained within NAL No. 17–27, or implementing rules that allow market participants, *sua sponte,* to correct error trades that have been accepted for clearing with an *ex post facto* review by the SEF of the error trade, offsetting trade, and correcting trade on a T+1 basis as is contemplated by NAL No. 20–01. Further, these final rules would not preclude SEFs from deploying error trade rules and procedures which consider whether a transaction cancellation or price adjustment will adversely impact market integrity, facilitate market manipulation or other illegitimate activity, or otherwise violate the CEA, Commission regulations, or the SEF's rules. However, regardless of the error trade rules and procedures that a SEF may adopt, the Commission notes that pursuant to this adopting release such rules must be fair, transparent, and consistent.[103]

Further, these final rules provide flexibility in the execution methods that a SEF may offer to counterparties to execute offsetting and correcting trades that involve swaps that are Required Transactions.[104] The Commission agrees with commenters that this flexibility would promote SEF operational efficiency by allowing SEFs to offer error trade protocols that are tailored to their markets and to allow identification and resolution of operational and clerical errors in a timely manner.[105] Without such flexibility, market participants with an error in Required Transactions would otherwise be prohibited from determining to resolve the error between themselves by entering into an offsetting trade or a new trade with the correct terms due to the execution method requirements under § 37.9(a)(2), which require that all Required Transactions be traded via either an Order Book or RFQ System.

The Commission also believes that the final error trade rules further the SEF statutory goals of promoting trading on SEFs and pre-trade price transparency in the swaps market.[106] These final rules provide flexibility to depart from required execution methods that are otherwise intended to advance those statutory goals; allowing counterparties to correctly and efficiently execute swaps with the intended terms and conditions, however, enhances market integrity on SEFs, which promotes SEF participation. Additionally, the Commission believes these final rules would also help to ensure that trade data, which market participants rely upon to inform their swaps trading decisions, accurately reflects prevailing market pricing at any given time.

The Commission agrees with Citadel that properly reporting error trade cancellations and correcting trades pursuant to parts 43 and 45 is

[95] *Id.*

[96] *Id.* at 3–4.

[97] *Id.* at 4.

[98] IHS Markit at 8.

[99] IECA at 4.

[100] *Id.*

[101] *Id.* at 5.

[102] As adopted, an ''error trade'' would be defined as any trade executed on or subject to the rules of a SEF that contains an operational or clerical error. With respect to ''package transactions,'' as defined under final § 37.9(d)(1), the Commission deems the submission of the component transactions in a sequence that causes a rejection from clearing of an individual component to constitute an operational error that could be resolved through a correcting trade under final § 37.9(e)(2)(i)(A). Market participants had previously informed the Commission that an individual component transaction may be rejected from clearing if prematurely submitted because the risk of that component, in isolation, could cause a trader to exceed its credit limit. Under a different submission sequence of component transactions to the DCO, however, the net risk of all of those transactions may not have exceeded the credit limit, thereby avoiding the rejection. The Commission emphasizes, however, the use of a corrective trade may only apply to the rejected component and otherwise would not apply to the other legs of the package transaction that have been accepted for clearing.

[103] The Commission further reiterates that any SEF offering trading in swaps subject to the post-trade name give up prohibition under existing § 37.9(d) (re-designated to § 37.9(f) in this final rulemaking. *See supra* note 46) must ensure its rules and procedures for error trades allow for error trade remediation without disclosure of the identities of counterparties to one another. *See* Post-Trade Name Give-Up on Swap Execution Facilities, 85 FR 44693, 44701 (July 24, 2020).

[104] The Commission notes that swaps that are Permitted Transactions, including those that are submitted to a DCO for clearing, may already be executed through any method of execution offered by a SEF pursuant to § 37.9(c)(2).

[105] *See* Citadel at 1–3, IECA at 4, ISDA at 1, and TP ICAP SEFs at 3–4.

[106] *See* 7 U.S.C. 7b–3(e).

important.[107] The Commission notes that the reporting requirements for error trade cancellations, correcting trades, and offsetting trades will depend upon the error trade rules that SEFs adopt under this principles-based approach. However, regardless of the error trade rules that are adopted by a SEF, the Commission wants to make clear that SEFs and market participants are responsible for ensuring that they comply with their respective reporting requirements in parts 43 and 45 of the Commission's regulations.

The final rules adopted in § 37.9(e)(2)(i) specify timeframes for executing and submitting correcting and offsetting trades for clearing. In particular, as noted above, for correcting trades associated with an error trade that has been rejected from clearing, § 37.9(e)(2)(i)(A) would require the SEF to submit the correcting trade for clearing to the registered DCO or exempt DCO as soon as technologically practicable, but no later than one hour after notice of the rejection to the relevant clearing members. For an offsetting trade and a correcting trade associated with an error trade that already has been accepted for clearing, final § 37.9(e)(2)(i)(B) requires the SEF to submit both types of trades to the registered DCO or exempt DCO as soon as technologically practicable, but no later than three days after the registered DCO or exempt DCO accepted the error trade for clearing.

IHS Markit recommended that correcting trades have up to five days to be submitted to clearing.[108] IHS Markit thought a five-day submission period was particularly important during times of market stress.[109] The Commission notes that IHS Markit does not provide or offer any support or background on why a five-day submission period is more appropriate then the timeframes proposed by the Commission in the Proposal. The Commission believes that the timeframes adopted in this release are consistent with the goal of promoting straight-through processing. The timing requirements are intended to provide a SEF and the counterparties to an error trade with an appropriate amount of time to identify and resolve error trades, while also minimizing delays to achieving prompt and efficient clearing of transactions. Therefore, the Commission declines to adopt IHS Markit's recommendation that correcting trades have up to five days to be submitted to clearing.

Further, final § 37.9(e)(2)(i) would require SEFs to have error trade rules and procedures that require market participants to provide prompt notice to the SEF of an error trade and, as applicable, the corresponding correcting trade and offsetting trade.[110] Such notice need not be separate from the error trade correction process.

The Commission agrees with the TP ICAP SEFs that SEFs should have error trade rules and procedures that require market participants to provide prompt notice to the SEF of an error trade and, as applicable, the corresponding correcting trade and offsetting trade. The Commission believes that such a requirement is important to facilitate SEFs' fulfillment of their self-regulatory obligations. In particular, the Commission believes that providing a SEF prompt notice that an error trade has occurred on its trading system(s) or platform(s) will further enable it to facilitate direct supervision of its markets in order to determine whether a rule violation has occurred as required under § 37.203(b), as well as enhance its ability to carry out real-time market monitoring of all trading activity on its system(s) or platform(s) to identify disorderly trading and any market or system anomalies pursuant to § 37.203(e).[111]

Final § 37.9(e)(2)(ii) would prohibit counterparties from executing a second correcting trade to fix an error trade if the initial correcting trade is rejected from clearing. The Commission believes that limiting the number of instances in which counterparties may attempt to correct an error trade will help to facilitate prompt and efficient clearing by incentivizing the counterparties to accurately execute their correcting trade as quickly as possible.

IECA requests that the Commission clarify that application of the pre-arranged trading prohibition under Commission regulation 37.203(a).[112] The Commission notes that the existing prohibition already provides an exception to that prohibition by allowing a SEF to adopt trading practices that are certified or approved by the Commission pursuant to part 40 of the Commission's regulations.[113] Accordingly, the Commission anticipates that a SEF would implement final § 37.9(e) by self-certifying or adopting rules subject to Commission review under part 40 that specify the manner in which counterparties may execute offsetting and correcting trades.

Therefore, for the reasons stated above, the Commission is adopting § 37.9(e) as proposed.[114]

III. Effective Date

The Commission proposed an effective date for the Proposal to be 60 days after publication of final regulations in the **Federal Register**. The Commission received no comments regarding the effective date. Therefore, the Commission is adopting an effective date for these rules for 60 days after publication of final regulations in the **Federal Register**. The Commission believes that such an effective date allows SEFs and market participants sufficient time to adapt to the amended and additional rules in an efficient and orderly manner.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'')[115] requires Federal agencies, in promulgating regulations, to consider the impact of those regulations on small businesses. The regulations adopted herein will affect SEFs and their market participants. The Commission has previously established certain definitions of ''small entities'' to be used by the Commission in evaluating the impact of its regulations on small entities in accordance with the RFA.[116] The Commission previously concluded that SEFs are not small entities for the purpose of the RFA.[117] The Commission has also previously stated its belief in the context of relevant rulemakings that SEFs' market participants, which are all required to be ECPs[118] as defined in

[107] *Id.* at 3.

[108] *See* IHS Markit at 8.

[109] *See id.*

[110] To the extent a SEF implements error trade rules and procedures that allow market participants to correct error trades *sua sponte* with an *ex post facto* review by the SEF, that SEF must require that market participants notify it of the subsequent correcting and offsetting trades. Conversely, a SEF that adopts error trade rules and procedures in which the SEF is responsible for correcting the error trade, that SEF would not be required to have market participants notify it of the subsequent correcting and offsetting trades. Regardless of the type of error trade rules and procedures a SEF adopts, it is required to adopt rules and procedures which require its market participants to provide prompt notice to it of an error trade that has occurred on its trading system(s) or platform(s).

[111] *See* 17 CFR 37.203(b); 17 CFR 37.203(e).

[112] *See* IECA at 5.

[113] See 17 CFR 37.203(a).

[114] The Commission notes that upon the effective date of these rules, the adoption of § 37.9(e) will negate the need for the relief provided in NAL No. 17–27 and NAL No. 20–01.

[115] 5 U.S.C. 601 *et seq.*

[116] 47 FR 18618–18621 (Apr. 30, 1982).

[117] SEF Core Principles Final Rule, 78 FR 33476, 33548 (June 4, 2013) (citing 47 FR 18618, 18621 (Apr. 30, 1982) (discussing DCMs); 66 FR 42256, 42268 (Aug. 10, 2001) (discussing derivatives transaction execution facilities, exempt commercial markets, and exempt boards of trade); and 66 FR 45604, 45609 (Aug. 29, 2001) (discussing registered DCOs)).

[118] 17 CFR 37.703.

section 1a(18) of the CEA,[119] are not small entities for purposes of the RFA.[120] The Commission received no comment on whether SEFs and SEF market participants covered by these final rules should be considered small entities for the purpose of the RFA. Therefore, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the regulations will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* (''PRA'') imposes certain requirements on Federal agencies (including the Commission) in connection with conducting or sponsoring any ''collection of information,'' [121] as defined by the PRA. Among its purposes, the PRA is intended to minimize the paperwork burden to the private sector, to ensure that any collection of information by a government agency is put to the greatest possible use, and to minimize duplicative information collections across the government.[122]

The PRA applies to all information, regardless of form or format, whenever the government is obtaining, causing to be obtained, or soliciting information, and includes required disclosure to third parties or the public, of facts or opinions, when the information collection calls for answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons.[123] The PRA requirements have been determined to include not only mandatory, but also voluntary information collections, and include both written and oral communications.[124] The Commission may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (''OMB'') control number.

This final rulemaking contains collections of information for which the Commission has previously received control numbers from OMB. The titles for these collections of information are ''Core Principles and Other Requirements for Swap Execution Facilities, OMB control number 3038–0074'' and ''Part 40, Provisions Common to Registered Entities, OMB control number 3038–0093.'' This final rulemaking would not impose any new information collection requirements from any persons or entities that require approval of OMB under the PRA.

C. Cost-Benefit Considerations

Section 15(a) of the CEA [125] requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

1. Background

The Commission is amending certain rules in parts 36 and 37 of its regulations relating to the execution of the swap components of certain package transactions on SEFs and the resolution of error trades on SEFs.

The baseline against which the Commission considers the costs and benefits of these final rules is the statutory and regulatory requirements of the CEA and Commission regulations now in effect, in particular CEA section 5h and certain rules in part 37 of the Commission's regulations. The Commission, however, notes that as a practical matter SEFs and market participants have adopted some current practices based upon no-action relief provided by Commission staff that is time-limited in nature.[126] As such, to the extent that SEFs and market participants have relied on relevant staff no-action letters, the actual costs and benefits of the final rules as realized in the market may not be as significant.

In some instances, it is not reasonably feasible to quantify the costs and benefits to SEFs and certain market participants with respect to certain factors, for example, market integrity. Notwithstanding these types of limitations, however, the Commission otherwise identifies and considers the costs and benefits of these rules in qualitative terms. The Commission did not receive any comments from commenters which quantified or attempted to quantify the costs and benefits of the Proposal.

The following consideration of costs and benefits is organized according to the rules and rule amendments proposed in this release. For each rule, the Commission summarizes the amendments, identifies and discusses the costs and benefits attributable to such rule, and identifies and discusses alternatives that the Commission considered. The Commission, where applicable, then considers the costs and benefits of the final rules in light of the five public interest considerations set out in section 15(a) of the CEA.

The Commission notes that this consideration of costs and benefits is based on the understanding that the swaps market functions internationally, with many transactions involving U.S. firms taking place across international boundaries, with some Commission registrants being organized outside of the United States, with leading industry members typically conducting operations both within and outside the United States, and with industry members commonly following substantially similar business practices wherever located. Where the Commission does not specifically refer to matters of location, the discussion of costs and benefits below refers to the effects of the final rules on all swaps activity subject to the amended regulations, whether by virtue of the activity's physical location in the United States or by virtue of the activity's connection with activities in, or effect on, U.S. commerce under CEA section 2(i).[127]

[119] 7 U.S.C. 1(a)(18).

[120] 66 FR 20740, 20743 (Apr. 25, 2001) (stating that ECPs by the nature of their definition in the CEA should not be considered small entities).

[121] *See* 44 U.S.C. 3502(3)(A).

[122] *See* 44 U.S.C. 3501.

[123] *See* 44 U.S.C. 3502(3).

[124] *See* 5 CFR 1320.3(c)(1).

[125] 7 U.S.C. 19(a).

[126] In its discussion of cost-benefit considerations, the Commission believes it is also relevant to consider the costs and benefits of the final regulations in comparison to circumstances in which such no-action relief has expired and is no longer available. The Commission further notes that in connection with NAL No. 16–58 and its extension NAL No. 17–27 (relief related to clerical or operational error trade resolution), market participants specifically requested that the Commission undertake rulemakings to establish a permanent solution for addressing these clerical and operational errors, rather than merely extending the previous NAL relief. *See* NAL No. 16–58 and NAL No 17–27. In contrast, previous requests for no-action relief from market participants for the NALs which preceded NAL No.16–58 and NAL No. 17–27 were merely for temporary relief.

[127] Section 2(i)(1) applies the swaps provisions of both the Dodd-Frank Act and Commission regulations promulgated under those provisions to activities outside the United States that have a direct and significant connection with activities in, or effect on, commerce of the United States. 7 U.S.C. 2(i)(1). Section 2(i)(2) makes them applicable to activities outside the United States that contravene Commission rules promulgated to prevent evasion of Dodd-Frank.

2. Package Transactions

The Commission is adding § 37.9(d) and amending § 37.9(a)(2) to permit the swap components of certain package transactions to be executed via flexible methods of execution pursuant to § 37.9(c)(2). The final rules define a ''package transaction'' as a transaction consisting of two or more component transactions executed between two or more counterparties where (i) at least one component transaction is subject to the trade execution requirement in section 2(h)(8) of the Act; [128] (ii) execution of each component transaction is contingent upon the execution of all other component transactions; and (iii) the component transactions are priced or quoted together as one economic transaction with simultaneous or near-simultaneous execution of all components. Based on this definition and consistent with existing no-action relief, the final rule allows the swap component of the following three categories of package transactions to be executed via flexible means of execution pursuant to § 37.9(c)(2): (1) MAT/Non-MAT Uncleared package transactions; (2) MAT/Non-Swap Instrument package transactions; [129] and (3) MAT/Non-Exclusive CFTC Swap package transactions.

In addition, the Commission is relieving the swap components of these three types of package transactions from the requirement in § 37.3 that the SEF offer an Order Book for every swap listed for trading on the SEF, while continuing to require that SEFs offer an Order Book for outright transactions in every swap listed for trading on the SEF. Finally, the Commission is using its exemptive authority pursuant to CEA section 4(c) to exempt swap transactions that are executed as a component of a package transaction that includes a component that is a new issuance bond from the trade execution requirement under section 2(h)(8) of the Act.

Benefits: The final rule will allow market participants to choose the most suitable execution method for each package transaction and will allow SEFs to continue to offer flexible execution methods for these package transactions rather than only offer the required methods of execution for swaps subject to the trade execution requirement. The Commission expects this will reduce execution risks, improve efficiency, and decrease transaction costs as market participants will be able to avoid legging into transactions, that is, entering into each part of the package separately. The Commission notes that these benefits are currently available to market participants through existing no-action relief. The Commission further believes that the final rule will provide the liquidity and transparency benefits of increased trading of component swaps on SEFs, as without this flexibility, market participants would be unable or unwilling to trade such swap components through SEFs' required methods of execution.[130]

The Commission believes that not requiring SEFs to offer an Order Book for the swap components of the three types of relevant package transactions will benefit SEFs by helping them to reduce operating costs, as they will no longer be required to operate and maintain an Order Book for trading those swaps that are components of those package transactions. However, SEFs will need to retain the availability of Order Books for those swaps executed as outright transactions.

Further, as discussed above, given the illiquid and bespoke nature of various components within the relevant package transactions, the Commission acknowledges that the Order Book is not the ideal method of execution for many of such transactions. Therefore, the Commission anticipates that if SEFs are not required to provide an Order Book for the swap components of the relevant package transactions that are not suitable for Order Book trading, SEFs will be able to more effectively employ their resources, and no longer face the prospect of being required to provide Order Books that will not be utilized given the complex, illiquid, and bespoke nature of various components of the relevant package transactions.

The Commission believes that exempting swap transactions that are executed as a component of a package transaction that includes a component that is a new issuance bond from the trade execution requirement will ensure that market participants such as bond underwriters and issuers can continue to execute these packages (where the new-issuance bond is hedged by an interest rate swap with tenor and payment terms that typically match the terms of the bond issuance) off-SEF. As discussed above, this exemption may facilitate new bond issuances, which may benefit capital formation by helping market participants to raise capital and fund origination loans for businesses and homeowners. Moreover, in light of the involvement of the bond issuer and the underwriter in arranging and executing a package transaction in conjunction with a new issuance bond and the unique negotiation and fit-for-purpose nature of these package transactions, the Commission understands that it remains difficult or impossible to trade these package transactions on a SEF. SEFs have not been able to design an execution method suitable for this particular type of package, rendering it impracticable to execute these packages on-SEF. While the swap components of many swap/new-issuance bond packages executed today are not currently subject to the trade execution requirement,[131] the final rule will ensure that those transactions would remain exempt in the event the trade execution requirement is expanded to include more types of swaps.

Costs: The amendments to allow flexible execution methods for certain package transactions and the exemption for package transactions that include a new issuance bond should not impose costs on market participants since they only provide flexibility to market participants and do not require them to change their current trade practices. Moreover, to the extent that market participants are relying on existing no-action relief, they can continue to implement existing industry practice. The Commission believes that current SEF rules typically allow participants to utilize flexible execution methods pursuant to the existing no-action relief, but to the extent that SEFs need to modify their rules to incorporate the amendments, they may incur modest costs.

As noted, not requiring SEFs to offer an Order Book for the swap components of the relevant package transactions may enable SEFs to reduce operating costs. Since any existing Order Books for swap components of the relevant package transactions are not actively used and are not practicable for market participants to use, removing these Order Books (and not requiring SEFs to create such Order Books) should not impose significant costs on market participants.

[128] Note prong (i) of the package transaction definition in § 37.9(d)(1) states ''at least one component transaction is a Required Transaction'' which is substantively the same as prong (i) of the definition used above.

[129] Under final § 37.9(d)(3), consistent with the no-action relief, this category specifically excludes U.S. Dollar Spreadover package transactions; MAT/Futures package transactions, MAT/Agency MBS package transactions; and New Issuance Bond package transactions.

[130] *See supra* note 51.

[131] For example, the swap component may be a forwarding-starting swap whose start date corresponds to the issuance date of the bond. Forward starting swaps are not currently subject to the trade execution requirement.

Section 15(a) Factors

a. Protection of Market Participants and the Public

The Commission believes that the amendments and exemption will protect market participants from the risks associated with legging into the relevant packages by enabling market participants to enter into package transactions using appropriate execution methods. Permitting SEFs to eliminate the Order Book for use when swaps are components of the relevant package transactions should not impact protection of market participants. While protecting market participants also benefits the public, the Commission has not identified any further effect of the final rules on protection of the public.

b. Efficiency, Competitiveness, and Financial Integrity of the Markets

The amendments will enhance efficiency by enabling market participants to continue to execute the swap components of the relevant packages in a single transaction with an appropriate execution method, rather than via the inefficient process of legging into the package one component at a time. The amendments will also enhance financial integrity by enabling market participants to continue to avoid the execution risk associated with potential adverse price movements while attempting to leg into a transaction. The Commission has not identified any likely effects of the final rule amendments on competition in the swap markets. The Commission expects that, since there are few, if any, active Order Books for swaps as components of the relevant package transactions, SEFs will not use final § 37.3(a)(4) to remove active Order Books that are providing competitive markets.

c. Price Discovery

Package transactions are typically executed at a single price for the entire package, rather than at the prices of the individual components. The amendments will continue to allow the relevant package transactions to be executed using the execution methods that are designed to facilitate price discovery in these packages. For packages that include new issuance bonds, the exemption will permit price discovery to occur at the appropriate venue. The Commission believes that § 37.3(a)(4), which exempts swaps that are part of the relevant package transactions from the Order Book requirement, will not materially inhibit price discovery since the Commission anticipates that SEFs would retain Order Books where price discovery is occurring and that currently price discovery is not occurring in Order Books for swap components of the package transactions addressed within this final rule.

d. Sound Risk Management Practices

The Commission believes that the final rules will continue to promote sound risk management by facilitating the execution of package transactions as market participants consider package transactions to often be useful and appropriate instruments for management and transfer of risk and to avoid the execution risks associated with legging of transactions.

e. Other Public Interest Considerations

The exemption from the trade execution requirement for the swap components of packages involving new issuance bonds may help promote capital formation by facilitating the issuance of bonds to raise capital. The Commission has not identified any other effect of the final rules and exemption regarding package transactions on other public interest considerations.

3. Error Trades

The Commission is adding subsection (e) to § 37.9 to establish a flexible SEF error trade policy standard that, among other things, incorporates the intent of the existing no-action relief in NAL No. 17–27 for resolving errors in Required Transactions. Final § 37.9(e)(2)(i) specifies that a SEF must maintain rules and procedures that are ''fair, transparent, consistent'' and ''allow for timely resolution'' of an ''error trade,'' as defined under final § 37.9(e)(1)(ii). This standard applies to any error trade that occurs on a SEF, regardless of whether or not the swap is submitted for clearing. Further, under final § 37.9(e)(2)(i), SEFs must have error trade rules and procedures that require that market participants provide prompt notice to the SEF of an error trade and, as applicable, correcting and offsetting trades.

Final § 37.9(e) also requires a SEF to adopt rules to resolve error trades that involve swaps submitted for clearing. For an error trade rejected from clearing and therefore deemed void *ab initio,* final § 37.9(e)(2)(i)(A) requires a SEF to permit the counterparties to subsequently execute a correcting trade, as defined in § 37.9(e)(1)(i), through any method of execution offered by the SEF. For an error trade that has been accepted for clearing, final § 37.9(e)(2)(i)(B) requires a SEF to permit the counterparties to subsequently execute both an offsetting trade, as defined in final § 37.9(e)(1)(iii), and a correcting trade through any method of execution offered by the SEF.

The final rule includes some limitations that are similar to the existing no-action relief, including specified timeframes for executing and submitting these trades for clearing. For correcting trades associated with an error trade that has been rejected from clearing, final § 37.9(e)(2)(i)(A) requires the SEF to submit the correcting trade for clearing to the registered DCO or exempt DCO as soon as technologically practicable, but no later than one hour after notice of the rejection to the relevant clearing members. For an offsetting trade and a correcting trade associated with an error trade that already has been accepted for clearing, final § 37.9(e)(2)(i)(B) requires the SEF to submit both types of trades to the registered DCO or exempt DCO as soon as technologically practicable, but no later than three days after the registered DCO or exempt DCO accepted the error trade for clearing. In addition to these timeframes, final § 37.9(e)(2)(ii) prohibits counterparties from executing a second correcting trade to fix an error trade if the initial correcting trade is rejected from clearing.

However, the final rule does not include certain additional conditions applicable to SEFs and counterparties that are contained in the no-action relief under NAL No. 17–27 or NAL No. 20–01. For example, the no-action relief in NAL No. 17–27 requires that a SEF must make an affirmative finding that an alleged error trade has occurred and must have rules setting forth the procedures for making such a finding.

Benefits: Absent the adoption of these rules, both SEFs and market participants would need to comply with the existing Commission regulations, notwithstanding the significant procedural and logistical difficulties of doing so. In particular, market participants would have to resolve error trades in Required Transactions using the Order Book or RFQ System, which would likely make it impossible to recreate the trade as originally intended. These difficulties could dissuade SEFs from being actively involved in the error trade resolution process and market participants from executing swaps on a SEF. The Commission believes that the final rule will avoid these potential difficulties.

The Commission believes that, given that the amendments are largely consistent with current industry practice, SEFs and market participants may likely have already realized much of the benefit of final § 37.9(e). The Commission believes, however, that the

final rules additionally will provide a tangible benefit to market participants on a longer-term basis by allowing market participants to continue utilizing policies and protocols which the Commission understands most SEFs adopted in reliance upon the relief provided in existing no-action letters to resolve error trades.

The requirement under § 37.9(e)(2)(i) that market participants provide prompt notice to a SEF of an error trade and, as applicable, the corresponding correcting trade and offsetting trade will benefit SEFs in carrying out their self-regulatory obligations. In particular, the Commission believes that providing SEFs prompt notice that an error trade has occurred on their trading system(s) or platform(s) will enhance their ability to carry out real-time market monitoring of all trading activity on their system(s) or platform(s) to identify disorderly trading and any market or system anomalies or violations of SEF rules.

The Commission also believes that the amendments will facilitate the goal of promoting consistency in the swaps market with respect to how errors are evaluated and resolved. First, the amendments will require all SEFs to adopt such policies. To the extent SEFs have not yet implemented such policies, the amendments will benefit market participants who will now be able to correct error trades and avoid related economic losses. Further, market participants can obtain the benefit of executing a swap transaction that corrects an error trade with the terms originally intended.

Finally, some SEFs have already implemented robust error trade resolution policies pursuant to existing no-action relief, while other SEFs have not implemented robust error trade policies. This inconsistency among SEFs could otherwise cause a ''race to the bottom'' for SEFs' compliance and market oversight, as certain market participants may prefer SEFs with less stringent error trade policies. As a result, SEFs that have implemented robust error trade policies—and the swaps market in general—will benefit by eliminating this potential ''race to the bottom,'' and the Commission will underscore the importance of SEF market oversight by adopting such requirements in Commission regulations.[132]

Costs: Similar to the conditions established by Commission staff in time-limited no-action relief, the amendments would require SEFs to establish rules implementing various policies and procedures for resolving error trades. Under the final rules, SEFs must submit new rules to the Commission pursuant to part 40 of the Commission's regulations. However, the Commission understands that pursuant to the existing no-action relief, most SEFs currently have rules that otherwise comply with the adopted regulations. SEFs may choose to adjust their rules in light of the absence in the final rules of the requirement in the no-action relief that SEFs affirmatively determine that an error trade has occurred.[133] To the extent that SEFs must draft and submit new rules to the Commission, the Commission estimates that the costs will be modest.

The Commission believes that the amendments will not impose significant additional costs on market participants and intermediaries, because resolving error trades is inherently costly regardless of regulations imposed by the Commission, and market participants and intermediaries are currently subject to SEF policies and procedures. The requirement that market participants provide prompt notice to a SEF of an error trade and, as applicable, the correcting trade and offsetting trade will impose modest costs on market participants. In practice, though, market participants have likely needed to report error trades to SEFs in order to facilitate SEF determinations that an error trade has occurred pursuant to NAL No. 17–27, and would have had to report the correcting trade and offsetting trade in order to facilitate the SEF's *ex post facto* review pursuant to NAL No. 20–01. Not requiring that a SEF find that an error trade has occurred either before it has been resolved or via an *ex post facto* review should impose only minor costs on market participants associated with changes in procedures to no longer request that a SEF make such a determination.

The Commission notes that NAL No. 17–27 and NAL No. 20–01 apply to both SEFs and DCMs, but the final rule applies only to SEFs. Therefore, the Commission believes that the final rule will impose no costs on DCMs, and notes that no DCM is currently availing itself of the no-action relief.

Section 15(a) Factors

a. Protection of Market Participants and the Public

The addition of § 37.9(e) regarding error trades will protect market participants and the public by providing SEFs with greater authority under Commission regulations to resolve error trades. Further, by providing SEFs with the authority to permit counterparties to execute correcting trades and offsetting trades, the final rule amendments will protect market stability and transparency by preventing potential losses to market participants in connection with error trades and reducing instances in which market participants rely on inaccurate pricing information to inform their trading decisions. The addition of § 37.9(e) will also promote greater transparency of the error trade resolution process to SEFs' market participants as SEFs will be required to establish policies and procedures for reviewing and determining how to resolve alleged error trades. The adopted requirement under § 37.9(e)(2)(i) that market participants provide prompt notice to a SEF of an error trade and, as applicable, the correcting trade and offsetting trade will promote protection of market participants and the public by enhancing a SEF's ability to carry out its market oversight and monitoring responsibilities. The Commission believes that the absence of a requirement in the final rule that SEFs must affirmatively determine, or determine after an *ex post facto* review, that an error trade has occurred (which are conditions in the existing no-action relief under NAL No. 17–27 and NAL No. 20–01) will not materially impact the protection of market participants and the public.

b. Efficiency, Competitiveness, and Financial Integrity of the Markets

The addition of § 37.9(e) may improve the efficiency and financial integrity of markets by enabling counterparties to correct operational or clerical errors in a swap transaction. In particular, the final rules will help promote greater trading accuracy in the market by allowing counterparties to ultimately carry out transactions as originally intended, and would avoid unexpected trading losses caused by error trades. The requirement under § 37.9(e)(2)(i) that market participants provide prompt notice to a SEF of an error trade and, as applicable, the correcting trade and offsetting trade would enhance a SEF's ability to carry out its market oversight and monitoring responsibilities, which helps promote the financial integrity of

[132] The Commission notes that a robust error trade resolution policy is also consistent with an effective compliance and oversight program because the ability to resolve error trades (i) helps protect market integrity by unwinding certain error trades that otherwise would have an adverse effect on the market and (ii) promotes legal certainty by ensuring that market participants obtain the economic position in the transaction that they intended.

[133] In light of the flexibility of the final rules, SEFs can continue to require such an affirmative declaration if they determine that such requirement provides benefits to market participants or the SEF.

its markets. The Commission believes that the absence of the no-action provision that SEFs must affirmatively determine that an error trade has occurred could enhance the efficiency of the error trade resolution process and would not materially impact the competitiveness or financial integrity of the swap market on SEFs.

Absent these final rules, counterparties would be required in certain circumstances to correct or re-execute swap transactions in a less efficient and effective manner on a SEF, such as through the required methods of execution under § 37.9(a). The final rules, which also require SEFs to adopt certain policies and procedures for addressing error trades, should further promote efficiency in the resolution process by providing market participants that transact on multiple SEFs with a more consistent approach across different platforms for correcting error trades.

c. Price Discovery

The addition of § 37.9(e) regarding error trades will enable SEFs to correct error trades containing a clerical or operational error while maintaining the price discovery benefits associated with the pre-trade transparency requirements of § 37.9. In particular, the final rules will help promote price discovery by allowing counterparties, whose original trade has been cancelled upon rejection from clearing due to a clerical or operational error, to re-execute the trade with the terms as originally intended. For error trades that have been accepted by a registered DCO or exempt DCO for clearing, the final rules promote greater accuracy in the price discovery process by allowing the counterparties to correct the error trade by executing an offsetting swap transaction and a correcting swap transaction with the terms as originally intended.

d. Sound Risk Management Practices

The addition of § 37.9(e) regarding error trades may promote sound risk management practices by providing SEFs with greater authority under Commission regulations to facilitate error trade resolution. The final rules will help to mitigate potential losses to market participants arising out of trade cancellations, where the error trade is rejected from clearing, or arising from maintaining the position of an unintended error trade.

e. Other Public Interest Considerations

The Commission has not identified any effect of § 37.9(e) on other public interest considerations.

Consideration of Alternatives. Commenters were generally supportive of the proposed rules and recommended only one viable alternative.[134] IHS Markit recommended with respect to the error trade rules that, especially during periods of market stress, the ''appropriate timeline for submitting correcting trades [should] be five (5) business days.'' [135] As discussed above, under final § 37.9(e)(2)(i), a SEF must submit a correcting trade for clearing to the registered DCO or exempt DCO as soon as technologically practicable, but no later than one hour (if rejected for clearing) or three days (if accepted for clearing) after notice of the error trade. The Commission notes that the final rule is the same as the requirements of the no-action relief and that SEFs have successfully implemented error trade procedures consistent with the no-action relief and, thus, the final rule. SEFs have not indicated to the Commission that the deadlines are overly costly or burdensome. Moreover, during the recent period of market stress associated with the COVID–19 pandemic, no SEF requested relief from the error trade requirements. The Commission has therefore determined not to adopt the alternative recommended by IHS Markit.

The Commission considered adopting new rules identical to the no-action relief but determined, based on SEFs' and the Commission's experience with the no-action relief, to adopt changes where appropriate relative to the no-action relief. In particular, the final rule does not contain the requirement that a SEF affirmatively determine that an error trade has occurred, either before resolution or via an *ex post facto* review. The Commission believes that such a requirement would impose unnecessary costs on SEFs and market participants, and potentially impair the efficiency of the error trade resolution process. To the extent that SEFs and market participants are currently availing themselves of current no-action relief, they therefore may realize reduced costs under the final rule.

[134] As discussed above, commenters did recommend several other potential Commission actions that are outside the scope of this rulemaking and are therefore not addressed in this consideration of costs and benefits. Further, commenters did not specifically comment on the Commission's consideration of costs and benefits in the Proposal. To the extent that comments addressed issues bearing on the Commission's consideration of costs and benefits, they are discussed above in section II; the cost-benefit considerations discussion incorporates previous discussion of comments relevant to costs and benefits by reference.

[135] IHS Markit at 8.

D. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the objectives of the CEA, in issuing any order or adopting any Commission rule or regulation. The Commission does not anticipate that the amendments to parts 36 and 37 will promote or result in anti-competitive consequences or behavior.

List of Subjects

17 CFR Part 36

Package transactions, Trade execution requirement.

17 CFR Part 37

Error trades, Package transactions, Required methods of execution, Swap execution facilities, Swaps, Trade execution requirement.

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends 17 CFR chapter I as follows:

■ 1. Revise part 36 to read as follows:

PART 36—TRADE EXECUTION REQUIREMENT

Authority: 7 U.S.C. 1a, 2, 5, 6, 6c, 7, 7a–2, and 7b–3, as amended by Titles VII and VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (2010).

§ 36.1 Exemptions to trade execution requirement.

(a) A swap transaction that is executed as a component of a package transaction that also includes a component transaction that is the issuance of a bond in a primary market is exempt from the trade execution requirement in section 2(h)(8) of the Act.

(1) For purposes of paragraph (a) of this section, a package transaction consists of two or more component transactions executed between two or more counterparties where:

(i) At least one component transaction is subject to the trade execution requirement in section 2(h)(8) of the Act;

(ii) Execution of each component transaction is contingent upon the execution of all other component transactions; and

(iii) The component transactions are priced or quoted together as one economic transaction with simultaneous or near-simultaneous execution of all components.

(2) [Reserved]

(b) [Reserved]

PART 37—SWAP EXECUTION FACILITIES

■ 2. The authority citation for part 37 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 5, 6, 6c, 7, 7a–2, 7b–3, and 12a, as amended by Titles VII and VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376.

■ 3. In § 37.3, add paragraph (a)(4) to read as follows:

§ 37.3 Requirements and procedures for registration.

(a) * * *

(4) A swap execution facility is not required to provide an order book under this section for transactions defined in § 37.9(d)(2), (3), and (4), except that a swap execution facility must provide an order book under this section for Required Transactions that are components of transactions defined in § 37.9(d)(2), (3), and (4) of this part when such Required Transactions are not executed as components of transactions defined in § 37.9(d)(2), (3), and (4).

* * * * *

■ 4. Amend § 37.9 by:

■ a. Revising introductory text of paragraph (a)(2)(i);

■ b. Redesignating paragraph (d) as paragraph (f);

■ c. Adding new paragraphs (d) and (e); and

■ c. Revising newly redesignated paragraph (f).

The additions and revisions read as follows:

§ 37.9 Methods of execution for required and permitted transactions.

(a) * * *

(2) * * *

(i) Each Required Transaction that is not a block trade as defined in § 43.2 of this chapter shall be executed on a swap execution facility in accordance with one of the following methods of execution except as provided in paragraph (d) or (e) of this section:

* * * * *

(d) *Exceptions to required methods of execution for package transactions.* (1) For purposes of this paragraph, a package transaction consists of two or more component transactions executed between two or more counterparties where:

(i) At least one component transaction is a Required Transaction;

(ii) Execution of each component transaction is contingent upon the execution of all other component transactions; and

(iii) The component transactions are priced or quoted together as one economic transaction with simultaneous or near-simultaneous execution of all components.

(2) A Required Transaction that is executed as a component of a package transaction that includes a component swap that is subject exclusively to the Commission's jurisdiction, but is not subject to the clearing requirement under section 2(h)(1)(A) of the Act, may be executed on a swap execution facility in accordance with paragraph (c)(2) of this section as if it were a Permitted Transaction;

(3) A Required Transaction that is executed as a component of a package transaction that includes a component that is not a swap, as defined under section 1a(47) of the Act, may be executed on a swap execution facility in accordance with paragraph (c)(2) of this section as if it were a Permitted Transaction. This provision shall not apply to:

(i) A Required Transaction that is executed as a component of a package transaction in which all other non-swap components are U.S. Treasury securities;

(ii) A Required Transaction that is executed as a component of a package transaction in which all other non-swap components are contracts for the purchase or sale of a commodity for future delivery;

(iii) A Required Transaction that is executed as a component of a package transaction in which all other non-swap components are agency mortgage-backed securities; and

(iv) A Required Transaction that is executed as a component of a package transaction that includes a component transaction that is the issuance of a bond in a primary market.

(4) A Required Transaction that is executed as a component of a package transaction that includes a component swap that is not exclusively subject to the Commission's jurisdiction may be executed on a swap execution facility in accordance with paragraph (c)(2) of this section as if it were a Permitted Transaction.

(e) *Resolution of operational and clerical error trades.* (1) As used in this paragraph:

(i) *Correcting trade* means a trade executed and submitted for clearing to a registered derivatives clearing organization, or a derivatives clearing organization that the Commission has determined is exempt from registration, with the same terms and conditions as an error trade other than any corrections to any operational or clerical error and the time of execution.

(ii) *Error trade* means any trade executed on or subject to the rules of a swap execution facility that contains an operational or clerical error.

(iii) *Offsetting trade* means a trade executed and submitted for clearing to a registered derivatives clearing organization, or a derivatives clearing organization that the Commission has determined is exempt from registration, with terms and conditions that economically reverse an error trade that was accepted for clearing.

(2) *Execution of correcting trades and offsetting trades.* (i) A swap execution facility shall maintain rules and procedures that facilitate the resolution of error trades. Such rules shall be fair, transparent, and consistent; allow for timely resolution; require market participants to provide prompt notice of an error trade—and, as applicable, offsetting and correcting trades—to the swap execution facility; and permit market participants to:

(A) Execute a correcting trade, in accordance with paragraph (c)(2) of this section, regardless of whether it is a Required or Permitted Transaction, for an error trade that has been rejected from clearing as soon as technologically practicable, but no later than one hour after a registered derivatives clearing organization, or a derivatives clearing organization that the Commission has determined is exempt from registration, provides notice of the rejection; or

(B) Execute an offsetting trade and a correcting trade, in accordance with paragraph (c)(2) of this section, regardless of whether it is a Required or Permitted Transaction, for an error trade that was accepted for clearing as soon as technologically practicable, but no later than three days after the error trade was accepted for clearing at a derivatives clearing organization or a derivatives clearing organization that the Commission has determined is exempt from registration.

(ii) If a correcting trade is rejected from clearing, then a swap execution facility shall not allow the counterparties to execute another correcting trade.

(f) *Counterparty anonymity.* (1) Except as otherwise required under the Act or the Commission's regulations, a swap execution facility shall not directly or indirectly, including through a third-party service provider, disclose the identity of a counterparty to a swap that is executed anonymously and intended to be cleared.

(2) A swap execution facility shall establish and enforce rules that prohibit any person from directly or indirectly, including through a third-party service provider, disclosing the identity of a

counterparty to a swap that is executed anonymously and intended to be cleared.

(3) For purposes of paragraphs (f)(1) and (2) of this section, ''executed anonymously'' shall include a swap that is pre-arranged or pre-negotiated anonymously, including by a participant of the swap execution facility.

(4) For a package transaction that includes a component transaction that is not a swap intended to be cleared, disclosing the identity of a counterparty shall not violate paragraph (f)(1) or (2) of this section. For purposes of this paragraph, a ''package transaction'' consists of two or more component transactions executed between two or more counterparties where:

(i) Execution of each component transaction is contingent upon the execution of all other component transactions; and

(ii) The component transactions are priced or quoted together as one economic transaction with simultaneous or near-simultaneous execution of all components.

Issued in Washington, DC, on November 27, 2020, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Swap Execution Facility Requirements—Voting Summary and Chairman's and Commissioners' Statements

Appendix 1—Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Supporting Statement of Chairman Heath P. Tarbert

I am pleased to support today's final rule amending Part 36 and Part 37 of the CFTC's regulations relating to swaps. These amendments codify staff no-action letters in two areas: (1) Package transactions and (2) error trades.

Before the 2008 financial crisis, swaps were executed bilaterally ''over the counter,'' rather than on a centralized exchange. When crafting the Dodd-Frank Act in 2010, Congress faced a key decision: Should it require swaps to trade like futures, via a centralized exchange order book visible to the entire market of potential buyers and sellers? Or should it retain the old bilateral, off-exchange trading practices?

This was a difficult decision. After all, the crisis highlighted the need for more effective price discovery in our swaps markets.[1] For more than a century, centralized exchanges have supported price discovery in futures products by providing a liquid, transparent market for buyers (longs) and sellers (shorts) to come together and transact. On the other hand, swaps are not futures. Many swaps products are executed only episodically through the negotiation of bespoke terms. In the 1990s and 2000s, this was done primarily through brokers and dealers providing quotes to one another on the telephone or over email. Hence, anonymous electronic trading via a central limit order book (CLOB) has not been viable for much of the swaps market.[2] Even relatively standardized swaps are not typically as liquid as futures contracts and historically did not trade via the CLOB as futures do.

The Creation of SEFs

Ultimately, Congress sought a golden mean that would balance these competing concerns. The Dodd-Frank Act gave birth to the concept of swap execution facilities (SEFs). SEFs are platforms on which certain standardized swaps are required to trade.[3] They resemble centralized exchanges, but have more flexibility in execution methods to accommodate the unique trading characteristics of swaps. In this regard, Congress took an evolutionary rather than a revolutionary approach, recognizing that mandating too much change too quickly could diminish rather than foster liquidity.

In implementing this portion of the Dodd-Frank Act, the CFTC required swaps that must be executed on a SEF (on-SEF) to trade via the CLOB or a request for quote to at least three SEF participants (Required Execution Methods or Required Methods).[4] By contrast, swaps voluntarily traded on-SEF may be executed by any method the parties choose.[5]

The SEF regulatory regime has generally worked well.[6] But rarely is statutory implementation perfect on the first attempt. Some requirements are suitable for the swaps market as a whole but are not a good fit for particular types of transactions. CFTC staff has addressed such issues through a series of no-action letters, many of which have been in place for over six years. With the benefit of this experience, now is the time to begin codifying these no-action letters, with tweaks and refinements where needed.

Through today's action, we continue to strive for the golden mean that strikes the optimal balance between the features of the old bilateral swaps world and those of the anonymous, exchange-traded futures model. In short, we aim to facilitate a natural progression toward more standardized and liquid products with tighter spreads. At the same time, we recognize that certain products that benefit the market do not lend themselves to the Required Execution Methods.

Package Transactions

A ''package transaction'' typically involves multiple component financial instruments, to be executed simultaneously (or nearly so), with each component transaction contingent on the others. Pricing for certain components of the package is often based on the prices of other components. Some components may hedge other components. Executing these instruments in package form can improve execution pricing and efficiency, reduce execution costs, and mitigate execution risk, as compared with executing each instrument separately (known as ''legging'' into the transaction).

In layman's terms, a package transaction is conceptually similar to booking a flight and hotel for an overnight trip. Each booking's utility is contingent on the other—making concurrent booking desirable—and there are often opportunities to improve cost and efficiency by bundling the bookings through a travel broker. As a practical matter, the derivatives market is no different.

The final rule approved by the Commission today address package transactions that include both (1) one or more swaps that are required to trade on-SEF pursuant to the Required Execution Methods, and (2) one or more instruments that are not. The Required Execution Methods are suitable for swaps required to trade on-SEF, when such swaps are executed as standalone transactions. But when these swaps are executed as part of a package, they often take on the trading characteristics of the less-liquid instruments in the package, thereby making it unfeasible to execute these swaps via the Required Methods.

This is a part of the market that is itself evolving.[7] However, several types of package

[1] *See* Committee on Capital Markets Regulation, *The Global Financial Crisis: A Plan for Regulatory Reform* 55 (May 2009) (With the real-time availability of both pre-trade quotes and post-trade contract prices, an exchange would thus provide an important source of price discovery that would complement the OTC market and enhance its liquidity.); Federal Reserve Bank of Chicago, *Derivatives Overview* in *Understanding Derivatives: Markets and Infrastructure* 9–11 (2013) (OTC markets also exhibit low levels of transparency compared with futures markets . . . . Further, OTC markets provide limited price discovery; indeed, OTC trading relies heavily on price information generated by exchange-traded markets.).

[2] *E.g.,* J. Christopher Giancarlo, Commissioner, CFTC, Pro-Reform Reconsideration of the CFTC Swaps Trading Rules: Return to Dodd-Frank (2015). CLOBs are the modern computerized exchanges that have replaced the open-outcry trading pits of yesteryear.

[3] Specifically, swaps that are required to be centrally cleared must be traded on-SEF unless no SEF makes that swap available to trade. Commodity Exchange Act (CEA) section 2(h)(8), 7 U.S.C. 2(h)(8). The swaps that are required to be cleared are generally the most standardized and liquid classes of swaps.

[4] 17 CFR 37.9(a).

[5] *Id.* section 37.9(c).

[6] *See, e.g.,* Lynn Riggs, et al., CFTC, *Swap Trading after Dodd-Frank: Evidence from Index CDS,* at 6, 52 (Aug. 17, 2019) (finding that SEF-traded index credit default swap markets are working relatively well following the Dodd-Frank swap trading reforms, though there is always room for improvement); Evangelos Benos, Richard Payne & Michalis Vasios, *Centralized Trading, Transparency, and Interest Rate Swap Market Liquidity: Evidence from the Implementation of the Dodd-Frank Act,* Bank of England Staff Working Paper No. 580, at 31 (May 2018) (finding liquidity improvement for swaps subject to the SEF trading mandate).

[7] CFTC staff has allowed the relief for certain package transactions to expire as swaps markets and market infrastructure have progressed such that the swap component of these package transactions

transactions would include swaps that must trade via the Required Methods under CFTC rules, but currently cannot do so as part of a package. And it is not clear that they will be able to do so in the foreseeable future. Accordingly, today's final rule codifies the no-action relief allowing swap components of those packages to trade through any execution method, provided that the trade occurs on-SEF.[8] I support this approach because it recognizes the progress made toward centralized exchange-type trading for swaps without forcing the market too far ahead of its natural evolutionary process. In addition, we must work to ensure our rules reflect actual market practice and functioning.

Error Trades

The CFTC, in accordance with the Commodity Exchange Act, has long taken a principles-based regulatory approach to the futures markets.[9] In granting the CFTC jurisdiction over swaps, the Dodd-Frank Act did not repudiate this principles-based tradition, but instead reinforced it. Section 733 of the Act sets forth core principles for SEFs and expressly affords SEFs ''reasonable discretion'' in determining how to comply.[10]

In this spirit, the amendments set out a principles-based approach to addressing error trades. They give SEFs the flexibility to determine the most suitable error trade rules for their markets and participants. At the same time, as I have said repeatedly, principles-based regulation is not a euphemism for ''deregulation'' or a ''light-touch'' approach.[11] Accordingly, under our amendments a SEF must require its participants to inform it of error trades and correcting trades, so the SEF can maintain orderly markets and guard against false error claims.[12]

Conclusion

Today's action is in keeping with my recent directive on the use of staff letters and guidance, in which I noted that they should supplement rulemakings, rather than themselves function as rules.[13] CFTC staff has provided important relief over the last six years, but we cannot rely on staff no-action relief to bridge the gaps forever. I expect these amendments will provide certainty and clarity to SEFs and their participants, thereby advancing our strategic objective of enhancing the regulatory experience for market participants at home and abroad.

Furthermore, I remain open to dialogue on further fine-tuning of our SEF rules, consistent with Congress's mandate as well as the CFTC's priorities and resources. I therefore will support finalizing additional rules in the near term that have the backing of a broad-based consensus of market participants and stakeholders. Swaps markets will benefit most from evolution, not revolution.

Appendix 3—Supporting Statement of Commissioner Brian Quintenz

I support today's final rule that codifies through rulemaking two issues concerning swap execution facilities (SEFs) currently addressed in staff no-action letters. I am pleased that this final rule will provide market participants with much needed regulatory certainty in the areas of ''package transactions'' (a series of related transactions sometimes including non-swap components) and the correction of erroneous trades. With the benefit of six-plus years of implementation experience, and multiple extensions of each of these no-action letters, it is long overdue for the Commission to codify and clarify its policy on each of these important issues.

With regard to package transactions, the amendments recognize the need to provide flexible means of execution for swaps that are negotiated and executed concurrently with other components of a larger, integrated transaction. This flexibility has proved workable since 2014.[1] In codifying current permissible practices with regard to the resolution of erroneous trades,[2] the final rule similarly permits SEFs to allow market participants to execute offsetting or correcting trades through any method of execution offered by the SEF. These amendments will facilitate the prompt identification and correction of error trades, thereby minimizing market participants' exposure to market, credit, and operational risks.

I have long disagreed with the overly restrictive mandate on permissible SEF methods of execution. While Dodd Frank's amendments to the Commodity Exchange Act define a SEF as a trading system facilitating multiple-to-multiple trading activity ''through any means of interstate commerce,''[3] the CFTC saw fit to only allow for two methods (RFQ and CLOB) to be used in connection with a swap subject to the trade execution requirement (''Required Transactions'').[4] By dictating how Required Transactions are executed, the current regime forecloses any number of alternatives that could create liquidity on SEFs and better address the highly variable, bespoke nature of many swaps. I believe the Commission should follow the law and further expand the allowed methods of execution for Required Transactions to any form that is truly multiple-to-multiple, which would allow SEFs to experiment with new means of execution tailored to the bespoke liquidity of a wide variety of critical risk management products. Similarly, in the area of block trades, I recently expressed concern when the Commission raised the block size threshold, thereby reducing the population of swaps that can be negotiated through alternative means.[5]

Lastly, I hope the Commission promptly finalizes additional provisions of the SEF ruleset that the Commission has proposed revising. These areas include making more practical the SEF financial resources requirement and codifying an exemption from the trade execution requirement for swaps between affiliated counterparties. Resolving these issues through final rules will promote the liquidity and transparency of SEFs.

Appendix 4—Statement of Commissioner Dan M. Berkovitz

I support today's final rule to amend parts 36 and 37 of the Commission's regulations relating to the execution of package transactions and correction of error trades on swap execution facilities (''SEFs''). The final rule will further, in a flexible and cost-effective manner, the Congressional goal of promoting the trading of swaps on SEFs.

Beginning in 2014, the Commission issued a series of no-action letters specifying permissible methods of execution for certain package transactions, which enabled the agency to phase-in the application of the trade execution mandate for these transactions. As market infrastructure has evolved, the Commission has allowed portions of the relief for some package transactions to expire, leaving a narrow set of these transactions that still may be implemented through flexible methods of execution. Based on experience, the Commission has determined that flexible methods of execution are currently more appropriate for packages in which at least one of the components is (1) a swap not subject to the clearing requirement; (2) not a swap; or (3) a swap for which the CFTC does not have exclusive jurisdiction. Requiring that the swap components of these transactions be traded through the required

can be executed through the required methods of execution. *See, e.g.,* CFTC No Action Letter (NAL) No. 14–12; NAL No. 14–62; NAL No. 14–121; NAL No. 14–137; NAL No. 15–55; NAL No. 16–76; NAL No. 17–55.

[8] The final rules would also allow any swap that is part of a package that also includes a new bond issuance to trade off-SEF.

[9] *E.g.,* Remarks of CFTC Chairman Heath P. Tarbert at the 2019 Annual Robert Glauber Lecture at Harvard University's Institute of Politics (Oct. 24, 2019).

[10] CEA section 5b(f), 7 U.S.C. 7b–3(f) (setting forth core principles for SEFs and providing that a SEF ''shall have reasonable discretion in establishing the manner in which [it] complies with the core principles'').

[11] Tarbert, *supra* note 10; Heath P. Tarbert, *Fintech Regulation Needs More Principles, Not More Rules,* Fortune (Nov. 19, 2019), *https://fortune.com/2019/11/19/bitcoin-blockchain-fintech-regulation-ctfc/.*

[12] The final rules reiterate that any SEF offering trading in swaps subject to the post-trade name give-up prohibition must ensure its rules and procedures for error trades allow for error trade remediation without disclosure of the identities of counterparties to one another. *See* Post-Trade Name Give-Up on Swap Execution Facilities, 85 FR 44693, 44701 (July 24, 2020).

[13] *See* Directive of Chairman Heath P. Tarbert on the Use of Staff Letters and Guidance (Oct. 27, 2020), *https://www.cftc.gov/PressRoom/SpeechesTestimony/tarbetstatement102720.*

[1] These amendments address the relief currently provided by CFTC No-Action Letter 17–55 (Oct. 31, 2017).

[2] These amendments address the relief currently provided by CFTC No-Action Letters 17–27 (May 30, 2017) and 20–01 (Jan. 8, 2020).

[3] Definition of SEF in sec. 1a(50) of the Commodity Exchange Act.

[4] Reg. 37.9(a).

[5] Supporting Statement of Commissioner Brian Quintenz Regarding Final Rules Amending the Real-Time Reporting Requirements, available at: *https://www.cftc.gov/PressRoom/SpeechesTestimony/quintenzstatement091720b*

methods of execution (*i.e.,* Order Book or Request-for-Quote to a minimum of 3 counterparties) could force market participants to break up the package into their individual components, which would increase transaction costs and risks, and thereby defeat the economic purpose and efficiency of the package transaction. Commenters supported the rule as proposed. It is therefore appropriate for the Commission to codify that flexible methods of execution may be used for the swap components of this limited set of package transactions.

The final rule also exempts from the trade execution requirement swap transactions that are components of ''new issuance bond'' package transactions, and amends part 37 to provide flexibility in the execution methods a SEF may offer counterparties to correct clerical or operational errors. While providing additional flexibility for resolving error trades, the rule limits the number of instances in which such errors may be corrected, and preserves important protections to guard against abuse. Notably, the Commission requires market participants to provide prompt notice to a SEF of an error trade, enabling the SEF to conduct real-time market monitoring and fulfill other self-regulatory obligations. In addition, the rule makes clear that a SEF must maintain rules and procedures that are fair, transparent, incentivize timely resolution of an error trade, and allow for such resolution without disclosing the identity of counterparties to one another where the swaps trading is subject to the post-trade name give up prohibition.

Given the tailored nature of these amendments and the appropriate safeguards, I support this final rule. I thank the staff of the Division of Market Oversight for their work on this rule and their helpful engagement with my office.

[FR Doc. 2020–26555 Filed 12–17–20; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 102

[Docket No. FDA–2019–D–0892]

The Use of an Alternate Name for Potassium Chloride in Food Labeling; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''The Use of an Alternate Name for Potassium Chloride in Food Labeling.'' This guidance explains our intent to exercise enforcement discretion for the declaration of the name ''potassium salt,'' as an alternative to ''potassium chloride,'' in the ingredient statement on the labels of foods that contain potassium chloride as an ingredient.

DATES: The announcement of the guidance is published in the **Federal Register** on December 18, 2020.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–0892 for ''The Use of an Alternate Name for Potassium Chloride in Food Labeling.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''The Use of an Alternate Name for Potassium Chloride in Food Labeling.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of May 20, 2019 (84 FR 22749), we made available a draft guidance for industry entitled ''The Use of an Alternate Name for Potassium Chloride in Food Labeling'' (''draft guidance''), which was intended to explain to food manufacturers our intent to exercise enforcement discretion for the declaration of the name ''potassium chloride salt'' in the ingredient statement on food labels as an alternative to the common or usual name ''potassium chloride.'' The draft guidance considered, in part, a NuTek Food Science citizen petition requesting that we issue guidance recognizing ''potassium salt'' as an additional common or usual name for potassium chloride (see Citizen Petition from NuTek Food Science, LLC, dated June 27, 2016, FDA–2016–P–1826–0001 at page 1). Additionally, we specifically invited comment on how the use of the name ''potassium chloride salt'' in the ingredient statement as an alternative to ''potassium chloride'' would improve consumer understanding of the ingredient and what alternate names to ''potassium chloride salt'' would better promote consumer understanding of potassium chloride (84 FR 22749 at 22750 through 22751). We gave interested parties until July 19, 2019, to submit comments for us to consider before beginning work on the final version of the guidance.

In response to requests for more time to comment on the draft guidance, we issued a notice in the **Federal Register** of July 10, 2019 (84 FR 32848) extending the comment period to September 17, 2019. We received more than 70 comments on the draft guidance. Many comments expressed concerns that declaration of the alternate name ''potassium chloride salt'' would be confusing or would not achieve the public health goal of reduced sodium consumption, as food manufacturers would likely not use the alternate name. Food manufacturers, public health and consumer advocacy groups provided comments and data supporting ''potassium salt'' as an alternate name to ''potassium chloride.''

After careful review and consideration of the comments to the draft guidance, some of which led us to further review of relevant published literature, we have modified the final guidance. Changes to the guidance include:

- Exercising enforcement discretion for declaration of ''potassium salt,'' rather than ''potassium chloride salt,'' in the ingredient statement on food labels as an alternative to declaration of the common or usual name ''potassium chloride;'' and
- Further explaining potassium chloride's technical role as a partial substitute for sodium chloride in food manufacturing through the inclusion of additional examples and references.

As discussed in the final guidance, we have made these changes with the following considerations in mind: Potential public health benefits to the U.S. population from reduced sodium and increased potassium intake, the recognition that potassium chloride can substitute for sodium chloride in a variety of food manufacturing applications across a number of food categories, and the unlikelihood that the alternate name will mislead consumers.

The guidance announced in this notice finalizes the draft guidance dated May 2019.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 11, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27750 Filed 12–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1318

[Docket No. DEA–506]

RIN 1117–AB54

Controls To Enhance the Cultivation of Marihuana for Research in the United States

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations to facilitate the cultivation of marihuana for research purposes and other licit purposes to enhance compliance with the Controlled Substances Act, including registering cultivators consistent with treaty obligations. This final rule adopts, with minor modifications, the notice of proposed rulemaking published on March 23, 2020, including regulations that govern applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, and regulations related to the purchase and sale of this marihuana by DEA.

DATES: This final rule is effective January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152–2639; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority and Background

The Controlled Substances Act (CSA) requires all persons who seek to manufacture a controlled substance to obtain a DEA registration.[1] 21 U.S.C. 822(a)(1). The CSA defines ''manufacture'' to include the ''production'' of a controlled substance, which in turn includes, among other things, the planting, cultivation, growing, or harvesting of a controlled substance. 21 U.S.C. 802(15), (22). Thus, any person who seeks to plant, cultivate, grow, or harvest marihuana[2][3]

[1] All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b).

[2] This document uses both the CSA spelling ''marihuana'' and the modern spelling ''marijuana'' interchangeably.

[3] As defined in Section 802(16).

to supply researchers or for other uses permissible under the CSA (such as product development) must obtain a DEA manufacturing registration. Because marihuana is a schedule I controlled substance, applications by persons seeking to become registered to manufacture marihuana are governed by 21 U.S.C. 823(a). *See generally* 76 FR 51403 (2011); 74 FR 2101 (2009), *pet. for rev. denied, Craker* v. *DEA,* 714 F.3d 17 (1st Cir. 2013). DEA's Administrator has the authority to grant a registration under section 823(a). To do so, the Administrator must determine that two conditions are satisfied: (1) The registration is consistent with the public interest (based on the enumerated factors in section 823(a)), and (2) the registration is consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (''Single Convention'' or ''Treaty''), 18 U.S.T. 1407.[4]

In 2016, DEA issued a policy statement aimed at expanding the number of manufacturers who could produce marihuana for research purposes. *See* Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). Subsequently, the Department of Justice (DOJ) undertook a review of the CSA, including the requirement of section 823(a) that a registration to bulk manufacture a schedule I or II controlled substance must be consistent with United States obligations under international treaties such as the Single Convention, and determined that certain changes to its 2016 policy were needed. As part of this review, in June 2018, the DOJ Office of Legal Counsel (OLC) prepared an opinion (''OLC Opinion''), now publicly available, examining DEA's policies and practices for granting bulk manufacturing registrations to marihuana growers in light of the CSA's requirement that DEA register manufacturers of schedule I and II controlled substances in a manner consistent with the Single Convention.[5]

This rule is being implemented pursuant to the Administrator's authority under the CSA ''to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances,'' 21 U.S.C. 821, and to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under [the CSA],'' 21 U.S.C. 871(b).

Summary of the Notice of Proposed Rulemaking

On March 23, 2020, DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** to (1) facilitate the cultivation of marihuana for research and licit purposes in compliance with the CSA, including a provision requiring consistency with the Single Convention; (2) amend DEA regulations pertaining to applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers; and (3) establish regulations related to the purchase and sale of this marihuana by DEA. 85 FR 16292. This final rule responds to comments received concerning the proposed rule, and DEA is adopting the proposed rule with minor modifications to the regulations to be codified at 21 CFR 1318.04, as described below.

Discussion of Public Comments

DEA received comments from the general public, DEA registrants, applicants for registration to manufacture marijuana, organizations, associations, and a United States Senator. Some commenters expressed general support of the proposed rule because it will increase the number of DEA-registered bulk manufacturers of marihuana for research. Some commenters expressed general concern about the impact of the proposed rule. Other commenters expressed specific concerns about, among other things, the application process and applicant criteria, quality of marihuana produced, DEA's ability and authority to lead the program, controls for the purchase and sale of marihuana, harvest time, quota, and costs. Other commenters submitted comments that are outside of the scope of this rule.

Application Process and Criteria

Commenters expressed concerns about the application process and the criteria for applicants. The following issues raised by the commenters, and DEA's response to each, fall under this category.

Issue 1: Many commenters stated that the approval process for applications takes too long and needs to be streamlined, suggesting that a timeframe for the approval or denial of applications should be determined, specifically within 30 days, 90 days, or six months of receipt of the application.

Response 1: DEA has a process for receiving, reviewing, and acting on applications for a DEA registration or re-registration, as described in 21 CFR part 1301. The process involves applicants submitting applications online or on paper and DEA evaluating all applications and supporting documentation submitted in accordance with the factors specified in 21 U.S.C. 823. The length of this process varies due to the detailed review performed by DEA, and as explained in the NPRM, a review of pending applications to manufacture marihuana has been delayed due to the need to establish the additional policies reflected in this rule. After receiving an application, DEA will send a questionnaire to the applicant to be completed and returned to DEA within 10 business days. DEA uses the information from the questionnaire and the application to determine whether the application should be granted under the factors specified in 21 U.S.C. 823. After the completed questionnaire is processed, DEA publishes a notice of application in the **Federal Register**, and current registrants and applicants for bulk manufacture of the same class of substance have 60 days to comment on, or object to, the application, as required by 21 CFR 1301.33. During the application process, DEA investigators also complete site visits and submit the appropriate reports to aid in the determination of whether to grant a registration. Because the process of evaluating an application to manufacture a schedule I controlled substance includes a 60-day public comment period, DEA cannot act on the application in a shorter timeframe, such as 30 days. Likewise, DEA must balance limited resources to conduct pre-registration vetting of numerous applicants, which impacts the length of time needed to complete the application process. As a result, DEA declines to adopt a specific approval date applicable to all applications for registration to bulk manufacture marihuana.

However, in accordance with 21 U.S.C. 823(i), for applications to manufacture a schedule I or II controlled substance for use only in a clinical trial, DEA will issue a notice of application not later than 90 days after the application is accepted for filing. Additionally, DEA will register the applicant, or serve an order to show cause upon the applicant in accordance with 21 U.S.C. 824(c), not later than 90 days after the date on which the period

[4] Section 823(a) provides that the registrations to manufacture controlled substances in schedule I or II must be ''consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.'' The Single Convention entered into force for the United States on June 24, 1967. *See* Single Convention, 18 U.S.T. 1407.

[5] That opinion is available at *http://www.justice.gov/olc/opinion/licensing-marijuana-cultivation-compliance-single-convention-narcotic-drugs.*

for comment pursuant to such notice ends, unless DEA has granted a hearing on the application under 21 U.S.C. 958(i). An applicant that believes it qualifies for review under these procedures should identify itself as an 823(i) applicant in its initial application for registration submitted to DEA. DEA will then determine whether the applicant qualifies for the review timeline specified under section 823(i).

Issue 2: Some commenters suggested that when there is a denial, DEA should provide notice and allow a hearing.

Response 2: Pursuant to 21 U.S.C. 824(c) and 21 CFR 1301.37, when DEA proposes to deny an application, DEA must serve the applicant with an order to show cause setting forth the factual and legal basis for the proposed denial. The applicant may file a request for a hearing, in accordance with 21 CFR 1301.43. If a hearing is requested, DEA will hold the hearing in accordance with the provisions for formal adjudications set forth in the Administrative Procedure Act and DEA regulation found at 21 CFR 1316 subpart D.

Issue 3: Another commenter stated that DEA used an internal memorandum to delay approval of applications to bulk manufacture marihuana.

Response 3: As mentioned in the NPRM, after the 2016 marihuana grower policy statement issued by DEA,[6] DOJ reviewed DEA's policies and practices for issuing bulk marihuana manufacturing registrations in light of the CSA and determined that DEA needed to amend its policies.[7] DEA has acted as expeditiously as possible to amend its policies to ensure consistency with the Single Convention as required by the CSA, while increasing the number of marihuana growers for research purposes. DOJ and DEA fully support research into the effects of marihuana and the potential medical utility of its chemical constituents, and DEA is working to expand the number of DEA-registered bulk manufacturers of marijuana, including through the finalization of this rule.

Issue 4: One commenter requested that DEA make the revised Form 225 and updated questionnaire available online for applicants.

Response 4: As required by the Paperwork Reduction Act (PRA), DEA must receive approval from the Office of Management and Budget (OMB) when a rule creates a new information collection or modifies an existing collection. This approval must be granted before an agency can use a revised form. In the NPRM, DEA discussed the modification of the existing information collection which would revise Form 225 and add questionnaires to the registration application process. Within the PRA section of the NPRM, DEA explained that an interested party could contact DEA for a copy of the form and questionnaires. The revision of the collection is awaiting approval; and, as such, DEA cannot yet post the proposed revisions to the form online for applicants. However, after the form has been approved, DEA will post the application to its website, and an applicant can complete and submit it online. DEA will then send the applicable questionnaires to the applicant after the application has been received.

Issue 5: Some commenters believe that DEA's consideration of an applicant's compliance with Federal marihuana law would exclude qualified applicants, specifically those who operate in compliance with State laws that are inconsistent with Federal law.

Response 5: Congress has established by statute the factors that DEA must consider when evaluating whether to grant an application for registration. For an applicant to manufacture a schedule I or II controlled substance, DEA must consider, among other factors, the applicant's ''compliance with applicable State and local law;'' ''prior conviction record . . . under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;'' ''past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;'' and ''such other factors as may be relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(a). An applicant that has manufactured marijuana without obtaining a DEA registration has violated Federal law, *see* 21 U.S.C. 841(a), regardless of whether that manufacturer has violated the laws of the State in which the applicant is located. Such activity is relevant to past experience in the manufacture of a schedule I controlled substance, past experience in preventing diversion of a controlled substance from other than DEA-authorized sources, and the promotion and protection of public health and safety. Moreover, prior conduct in violation of the CSA is relevant to determining whether the applicant can be entrusted with the responsibilities associated with being a DEA registrant. Indeed, DEA registration is a fundamental component of the CSA, and it is wholly appropriate to consider an applicant's past noncompliance with the CSA when deciding whether to grant a registration under the Act. DEA will consider all relevant factors for each individual applicant, on a case-by-case basis, when determining whether to grant registration, as provided for in 21 U.S.C. 823(a) and the regulatory text at 21 CFR 1318.05. While the DEA Administrator has discretion to weigh the statutory factors and any one factor need not be dispositive, an applicant's prior compliance with Federal law is a relevant consideration when determining whether to grant an application for registration.

Issue 6: A commenter suggested that a notice of exemption for a new drug application issued by the Food and Drug Administration (FDA) be an alternative to obtaining a DEA registration.

Response 6: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). Using FDA's authorization of a notice of exemption for a new drug application would not be in compliance with the CSA and therefore cannot be considered an alternative for obtaining a DEA registration.

Issue 7: A commenter opined that applicants should only be required to submit proof of State-issued marihuana licenses to DEA, after DEA approves the application.

Response 7: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). In assessing the application, DEA also weighs the applicant's compliance with applicable State law. 21 U.S.C. 823(a)(2). DEA has always required applicants seeking to manufacture a controlled substance to obtain and submit a valid State pharmaceutical manufacturer's license to demonstrate compliance with State law. Likewise, an applicant seeking to manufacture marihuana must submit evidence that it possesses a valid State manufacturer's license as part of its application, or explain why no such license is required by the State to manufacture marihuana for use in research. This evidence must be submitted to DEA as part of the determination of whether to grant a registration.

Issue 8: Some commenters suggested that the registration requirement be waived for marihuana growers (manufacturers) who will be supplying

[6] Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States,'' 81 FR 53846 (Aug. 12, 2016).

[7] The Attorney General determined that adjustments were necessary after receiving the aforementioned advisory OLC Opinion.

marihuana to researchers under 21 U.S.C. 822(d).

Response 8: DEA-registered researchers are not currently allowed to obtain marihuana from entities that are not registered with DEA. DEA is permitted to waive the registration requirement if it finds that doing so is ''consistent with the public health and safety,'' pursuant to 21 U.S.C. 822(d), and acting under authority delegated by the Attorney General. However, DEA has never previously waived the registration requirement to allow controlled substances to be manufactured outside the closed system of distribution, and doing so would be incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. In addition, waiving the requirement of registration for marihuana growers who supply researchers would be inconsistent with U.S. obligations under the Single Convention.[8] It should also be noted that supplying marihuana to researchers does not demonstrate that the material being supplied has been produced in accordance with other Federal laws. As a result, DEA does not consider such a waiver of registration for a bulk manufacturer to be a legally viable option.

The scope of this rule addresses the registration of manufacturers of marihuana, not researchers of marihuana. To the degree that the commenters were seeking to exempt marihuana researchers, rather than manufacturers, from registration, in addition to the foregoing concerns about adherence to treaty obligations, DEA does not at this time conclude that there is a public health need to exempt schedule I researchers from DEA registration. DEA notes that over the last several years, there has been a 149 percent increase in the number of active researchers registered with DEA to perform bona fide research with marihuana, marihuana extracts, and marihuana derivatives (from 237 in November 2014 to 589 in June 2020). At present, more researchers are registered to conduct research in the United States on marihuana, marihuana extracts, and marihuana derivatives than on any other schedule I substance, and more than 72 percent of DEA's total schedule I research registrant population (589 of 808 as of June 2020) is registered to conduct research on these substances. As a result, DEA concludes that there is not currently a public health need to exempt researchers from the registration requirement.

Issue 9: Other commenters suggested that DEA-registered researchers should be exempt from applying for DEA manufacturer registrations if the researchers are growing marihuana for their own studies and not for distribution.

Response 9: As reflected in this rule, any person lawfully growing marihuana must be registered with DEA to allow DEA to fulfill its obligations under the CSA. For the reasons discussed above, DEA has concluded that this requirement cannot be waived for researchers. Thus, under this final rule, when an applicant, including a researcher growing for his or her own use, is approved to grow marihuana, the applicant is registered as a bulk manufacturer. After the applicant is approved as a bulk manufacturer, the registrant must apply for and be issued an individual manufacturing quota (IMQ) for the amount of marihuana it needs to manufacture to meet the legitimate research and scientific needs of its customers. If the manufacturer plans to use the marihuana grown in bulk for its own research, it will also need to apply for a procurement quota. Under this rule, the DEA registrant must sell their harvest to DEA and then purchase from DEA the amount that they are allowed to procure based on the procurement quota issued to them. As such, DEA cannot exempt a researcher from the requirement of a DEA manufacturing registration even if they plan to use the marihuana grown for their own studies.

Issue 10: A few commenters suggested applicants who applied to be registered to grow marihuana soon after DEA published its 2016 marihuana growers policy should receive priority over more recent applicants. On the other hand, some commenters suggested that DEA should not delay consideration of new marihuana grower applications submitted after this rule is promulgated, as 21 CFR 1318.05(c) provides. In particular, some commenters expressed confusion about the ''limited exception'' to this delay noted in the NPRM and suggested that the limited exception should apply to all applicants.

Response 10: As previously stated in the NPRM, applications received after the date the final rule becomes effective will not be considered until all of the applications currently pending have been approved or denied, unless an application requires action under 21 U.S.C. 823(i). Applications already submitted will receive priority, and as a result, DEA will not have to restart its consideration of the pool of pending applications whenever a new application is submitted.

As described in the NPRM, the ''limited exception'' refers to the review of applications claiming the benefit of the statutory timeline of 21 U.S.C. 823(i). Congress has set the timeline for review of such applications by statute. That timeline will apply in lieu of the provision at 21 CFR 1318.05(c) for applicants that clearly identify themselves as 823(i) applicants in their original application, and for which DEA determines that the applicant qualifies for review under 823(i).

Issue 11: Another commenter suggested that the number of applicants selected to bulk manufacture marihuana should be unlimited and that DEA should consider the bulk manufacture of marihuana as a coincident activity to a researcher registration.

Response 11: The CSA mandates that DEA consider the maintenance of effective controls against diversion by limiting the bulk manufacture to a number of establishments which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 U.S.C. 823(a)(1). By statute, DEA is not allowed to register an unlimited amount of manufacturers, and DEA must perform an analysis of each application to determine whether the addition of the applicant is necessary to provide the adequate and uninterrupted supply of marihuana for research needs or whether the legitimate need will be met by the registration of others.

Currently, researchers are only permitted to manufacture as a coincident activity in limited quantities as set forth in a protocol approved by DEA in the researcher's registration application (or re-registration application), and to the extent that manufacture is not for the purposes of dosage form development. 21 CFR 1301.13(e)(1). A researcher's planting, cultivating, growing, or harvesting of marihuana does not constitute such a coincident activity to research. Rather, the planting, cultivating, growing, or harvesting of marihuana requires a manufacturer registration obtained under 21 U.S.C. 823(a), even when the researcher is growing the marihuana for his or her own research use. *See* 21 CFR 1301.33(d). As described in response to Issue 9, and in the section on quota that follows, international treaties require that DEA control manufacturing of marijuana and other schedule I and II controlled substances by means of quota. Although regulatory provisions allow for the approval of certain small-

[8] *See* OLC Op., *supra* note 5, at 7.

scale manufacturing pursuant to a DEA-approved protocol, significant manufacturing, including for research purposes, must be performed pursuant to a quota to maintain effective controls against diversion. As a result, researchers must register with DEA as manufacturers to engage in significant manufacture of controlled substances, even if the manufactured substances will exclusively be used in the grower's own research.

In addition, the Single Convention obligates a single government agency of the United States to purchase and take possession of all marihuana manufactured, and DEA has concluded this includes marihuana manufactured for research even when manufactured for use in research by the grower. By requiring all planting, cultivating, growing, and harvesting of marihuana be performed by DEA registered manufacturers, DEA can ensure that the controls set forth in the Single Convention are properly applied to all registrations to manufacture marihuana for research.

Issue 12: Other commenters suggested that the criteria for applicants should include the applicant's ability to produce high quality marihuana while another commenter suggested that applicants should have prior experience producing quality cannabis or hemp.

Response 12: The CSA provides that two conditions must be satisfied for an applicant to become a registrant: (1) The registration must be consistent with the public interest, and (2) the registration must be consistent with U.S. obligations under the Single Convention on Narcotic Drugs. Congress defined the factors for DEA to evaluate whether granting a registration is consistent with the public interest in 21 U.S.C. 823(a), and the burden lies with the applicant to demonstrate that the application meets those factors. Under those factors, DEA will consider the applicant's ''past experience in the manufacture of controlled substances'' and its ''promotion of technical advances in the art of manufacturing these substances,'' including the applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition. § 1318.05(b)(2). DEA must also consider the applicant's overall past experience with controlled substances in relation to preventing diversion.

Issue 13: Some commenters suggested DEA establish application requirements or committees that ensure diversity and inclusion of minority applicants. Other commenters suggested DEA provide regulatory provisions that afford economic opportunities to communities that have been disproportionately impacted by substance abuse and illicit drug markets and make application selection inclusive to include rural farmers, racial minorities, and disabled persons.

Response 13: DEA gives all applicants equal treatment regardless of the gender, race, socioeconomic status, or disabled status of the applicant. The only criteria used to evaluate the application for registration are those factors defined by Congress at 21 U.S.C. 823(a). *See* 21 CFR 1318.05.

Issue 14: Another commenter inquired whether manufacturers would be permitted to develop contracts, partnerships, or cooperative agreements with international research and development firms.

Response 14: Registrants are permitted to import and export controlled substances, including marihuana, in accordance with the criteria defined at 21 U.S.C. 952(a) (import) and 21 U.S.C. 953(a) (export), and after obtaining registration in accordance with 21 U.S.C. 958. After obtaining a registration to manufacture marihuana, the applicant may form agreements with international firms, but, if the importation or exportation of marihuana or another controlled substance will be involved as part of the agreement, it must ensure that any such importation or exportation complies with 21 U.S.C. 952, 953, and 958, and the relevant implementing regulations. Moreover, in addition to these general regulatory requirements, § 1318.04(b) of this rule specifically requires prior written notice to DEA of each proposed importation or exportation of marihuana, and DEA's express written authorization for the importation or exportation.

Quality of Marihuana

DEA received a number of comments that expressed concerns about the quality of marihuana that will be produced under this rule.

Issue 1: Some commenters stated that the current quality of marihuana produced for Federal research is of poor quality.

Response 1: The purpose of this rule is to increase the number and variety of marihuana growers in order to diversify the supply available to researchers. As proposed in the NPRM and finalized in this rule, one of the selection criteria for marijuana grower applicants is the ''applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition.'' 21 CFR 1318.05(b)(2).

Issue 2: A few commenters suggested that samples of marihuana should be tested to determine the quality prior to sales transactions and that manufacturers should be allowed to send samples of crops before and after harvest to analytical labs for testing, prior to DEA taking possession.

Response 2: DEA has no objection to DEA-registered marihuana growers and buyers exchanging samples or sending such samples to analytical labs for testing so long as this exchange occurs in a manner consistent with the CSA, and is amending the rule to make this clear. DEA understands that it is necessary for registered growers to engage in sampling and testing prior to harvest or DEA taking possession of the crop for growers to demonstrate compliance with contractual specifications to their researcher customers. Prior to the agency taking possession of the marihuana harvest, a registered grower may collect samples and distribute those samples to a DEA-registered analytical laboratory for analysis. It is consistent with the Single Convention to permit growers to conduct sampling and exclude the samples from the total crop that DEA is required to purchase and possess because the Single Convention plainly contemplates that growers will be able to harvest and sell their marijuana crops, and without sampling, sales would be practically impossible because the final intended purchaser could not know whether the marijuana is acceptable for purchase.

DEA is thus modifying the regulations proposed in the NPRM to add a new section at 21 CFR 1318.04(d). This new section explicitly permits DEA-registered manufacturers of marihuana to collect samples and distribute them to DEA-registered analytical laboratories for chemical analysis prior to DEA taking possession of the marihuana grown. However, to limit the risk of diversion and keep the distribution within the legitimate purposes permitted by the CSA, the quantity of samples collected and distributed must be small.

Issue 3: Some commenters stated that the time it takes DEA to take possession of the marihuana could negatively impact the quality of marihuana.

Response 3: To minimize the risk of diversion and delays that may impact the quality of the crop, DEA intends to take physical possession of the crop after harvest and distribute marihuana to the purchaser as soon as practicable.

Issue 4: Many commenters expressed concerns that DEA is excluded from liability for any damage to crops that may occur while in DEA's possession, and that there are no regulations to ensure the quality of marihuana while

in DEA's possession. Other commenters stated that there is no process or remedy for the damage or loss of crops that could occur while in DEA's possession.

Response 4: DEA assesses the risk of marihuana crops being lost or damaged while in DEA's possession to be low. DEA does not anticipate retaining possession of marihuana crops for long periods of time; in most instances, they will be transferred quickly from the seller to the buyer, with DEA's possession being as brief as possible to effectuate its role in transferring the marihuana from buyer to seller. In addition, crops in DEA's possession are largely expected to be maintained at the manufacturer's registered location, in a secure location designated by DEA. Accordingly, crops are highly unlikely to be damaged or lost in DEA's possession. To avoid costly and unnecessary disputes related to any loss or damage of crops, § 1318.07 makes clear that DEA has no liability with regard to the performance of any of the terms agreed to by a grower and buyer of marihuana, including but not limited to the quality of the marihuana. In effect, this rule makes clear that buyers and sellers should structure their marihuana transactions to minimize the risk of damage or disputes over quality, rather than expecting DEA to mediate or bear the costs of such disputes.

DEA recognizes that some growers and buyers may wish the DEA to assume a greater role in assuring the quality of marihuana supplied to researchers. Doing so, however, could significantly increase DEA's costs for operating the marihuana grower program, which would then be transferred to growers and buyers in the form of increased administrative fees. Thus, given the relatively low risk that crops will be lost or damaged in DEA's possession, DEA has concluded that the program will provide marihuana to researchers most efficiently if DEA does not assume any role in quality assurance and accordingly does not assume liability for such risks.

Issue 5: One commenter inquired how DEA will ensure availability of different strains of marihuana for research.

Response 5: DEA does not have the authority to dictate the strains of marihuana to be produced by growers. Rather, DEA believes that market forces will drive the strains of marihuana materials that growers will produce, and the purchasers will be able to choose which DEA-registered grower they believe will best produce the strains or quality of marihuana that will meet their needs. The factors that the Administrator will consider in granting a registration to grow marihuana will be consistent with the public interest factors set forth in section 21 U.S.C. 823(a), including the applicant's ability to consistently produce and supply high quality marihuana and defined chemical composition and other criteria as specified in 21 CFR 1318.05.

Issue 6: Some commenters suggested that DEA-registered researchers be allowed to obtain marihuana and marihuana products from State-authorized sources for the purpose of Federal research.

Response 6: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). State licenses to manufacture marijuana do not satisfy the requirements of Federal law. *See id.;* 21 U.S.C. 841(a)(1). Therefore, possession of a license to manufacture marijuana issued by a State government or agency does not meet the requirements of the CSA and cannot be accepted in lieu of DEA registration to manufacture or distribute. Registrants, including researchers, are only authorized to possess, manufacture, distribute, or dispense controlled substances ''to the extent authorized by their registration and in conformity with the other provisions'' of the CSA. 21 U.S.C. 822(b).

DEA does not view the receipt of a schedule I substance from a non-registrant, distributed in violation of § 841(a), to be ''in conformity with the other provisions'' of CSA as required of registrants by § 822(b). The receipt of controlled substances from outside the CSA's closed system of distribution is incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. In addition, as discussed above, the CSA—including a provision that requires consistency with the Single Convention—requires DEA to, among other things, register marihuana growers and take possession of all marihuana crops. Thus, authorizing researchers to obtain marihuana from unregistered sources is inconsistent with the Single Convention, and with DEA's CSA enforcement duties. Authorizing such research using marihuana from unregistered sources may also be inconsistent with the requirements of other Federal laws, as well as DEA's broader obligation to authorize controlled substances research in a manner consistent with the public safety.

Moreover, such a change is unnecessary. By registering additional marihuana growers pursuant to this rule, DEA will expand researchers' access to marihuana in accordance with the CSA, and in a manner that supports the public health.

Issue 7: Some commenters suggested that growers should be allowed to perform marihuana-related activities that are State-sanctioned but violate Federal law, such as distributing marihuana to recreational users, in the same facilities as DEA-authorized marihuana-related activities to save costs.

Response 7: As previously explained, DEA cannot authorize marihuana growers to violate the CSA or other Federal laws. Endorsing the production of marihuana outside the CSA's closed system of distribution would be incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. Authorizing such activities would also be inconsistent with the Single Convention, and with DEA's CSA enforcement duties, as well as contrary to other Federal laws.

Federal Agency Obligations Pertaining to Cannabis Controls

DEA received several comments regarding the division of authority between agencies in regulating the growing of marijuana for scientific research.

Issue 1: DEA received comments asserting that scientific or public health-based agencies such as the Department of Health and Human Services (HHS), National Institutes of Health (NIH), FDA, or Department of Agriculture should oversee the marihuana grower program. Some of these commenters also suggested that the CSA be amended by Congress to allow a health-related agency to be in charge of this program. Similarly, a commenter suggested that DEA contract with a private third party and authorize that contractor to carry out the functions described in this rule.

Response 1: DEA agrees that HHS and other Federal agencies can offer valuable insights into how the Federal government can best oversee the provision of marihuana for legitimate scientific research. DEA is committed to collaborating with HHS and other Federal agencies to ensure marihuana is available to meet the research and scientific needs of the United States, and that this rule is implemented with minimal disruption of the National Institute on Drug Abuse (NIDA) Drug Supply Program (DSP). That said, as a matter of current law, any registration and coordination of legitimate marihuana growing in the United States will be overseen solely by DEA, not

other Federal agencies. In other words, even if DEA preferred other Federal agencies to carry out these functions, as DOJ has interpreted the CSA, including a provision requiring that registrations be consistent with U.S. obligations under the Single Convention, it would be unlawful for DEA to transfer these functions to another Federal agency. Commenters' suggestions that the law should be changed are beyond the scope of this rulemaking: This rulemaking must follow the law, as enacted by Congress.[9]

As discussed above and in the NPRM, under the CSA, DEA may only grant a person a registration to grow marihuana if: (1) The registration is consistent with the public interest, and (2) the registration is consistent with U.S. obligations under the Single Convention. *See* 21 U.S.C. 823(a). Accordingly, DEA may only grant marihuana grower registrations which are consistent with U.S. obligations under the Single Convention. Article 23(2) of the Single Convention, which is applicable to the cultivation of marihuana through Article 28, describes five functions related to the distribution, supervision, and licensing of marihuana cultivation [10] that the United States is obligated to fulfill as part of a regulatory scheme that authorizes the growing of marihuana.

The Single Convention requires that these five functions ''be discharged by a single government agency if the constitution of the Party concerned permits it.'' Single Convention art. 23(3).[11] Nothing in the U.S. Constitution precludes the United States from discharging all five of those controls through one government agency, so a single U.S. Federal agency must perform all five of the controls. Further, by requiring that the functions be discharged by a government agency, the Single Convention prohibits the United States from assigning them to a private government contractor.

Through the CSA, Congress assigned the first three of the Single Convention functions to DEA by authorizing DEA—and, at least at the Federal level, DEA alone—to register and regulate marihuana growers: Under the CSA, DEA effectively designates the area in which the marihuana cultivation is permitted, limits marihuana growers to those it licenses, and specifies the extent of the land on which marihuana cultivation is permitted as required by the Single Convention. Thus, to fully comply with the CSA provision requiring consistency with the Single Convention, DEA also must perform the remaining two functions of Article 23: Taking possession of marihuana crops after harvest and maintaining the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marihuana and its resin. Congress granted DEA the power to enforce these provisions by directing DEA to grant registrations if the registrations are consistent with U.S. obligations under the Single Convention. 21 U.S.C. 823(a).[12]

Therefore, Congress has assigned DEA the duty and authority to carry out the five functions the Federal government is required to perform under the Single Convention if it authorizes the production of marihuana. DEA has no authority to assign these functions to another agency or a private contractor outside the government. Rather, DEA must perform the functions itself, and this rule will enable DEA to do so more effectively.

Issue 2: Another commenter suggested that NIDA be completely removed from any role in supplying marihuana to researchers.

Response 2: Marihuana research can be enhanced by allowing other growers to supply marihuana to researchers. However, scientific and medical research is likely to benefit from the NIDA DSP's continued involvement in these efforts. As discussed in the NPRM and further discussed below, the NIDA DSP has long played a fundamental role in supplying marihuana to researchers. In doing so, the NIDA DSP has acquired valuable experience and expertise in the production of marihuana. Moreover, because researchers currently obtain their marihuana though the NIDA DSP, the continued operation of the NIDA DSP will allow researchers who wish to continue to receive such NIDA DSP marihuana to do so with minimal disruption. Ultimately, the purpose of this rule is to expand researchers' options for obtaining marihuana, not eliminate them, a result best achieved by allowing the NIDA DSP to continue to operate, while also registering additional marihuana growers.

Issue 3: Some commenters suggested that DEA and DOJ misinterpreted the Single Convention. Some commenters stated that DEA is inappropriately using the Single Convention requirements as a justification to maintain exclusive control over marihuana sales/purchases. Another commenter suggested that DEA's view of the Single Convention is too narrow and not aligned with other parties to the Single Convention with respect to Article 23. This same commenter suggested that the United States withdraw from the Single Convention and rejoin with a formal reservation opting out of the cannabis related provisions of the Single Convention. Some other commenters suggested DEA initiate the process to amend the treaty to accomplish its intent of allowing robust research to be performed.

Response 3: As a matter of law, the CSA requires that registrations to manufacture schedule I and II controlled substances be consistent with U.S. obligations under the Single Convention, which requires a single government agency to regulate the cultivation of and certain trading in marihuana, including taking possession of marihuana after harvest.[13] The CSA assigns this function to the Attorney General, who has delegated this statutory authority to the DEA Administrator. The CSA therefore requires DEA to grant registrations that are consistent with U.S. obligations under the Single Convention, which includes regulating the cultivation of and certain trading in marihuana. DEA acknowledges some may disagree with these legal conclusions, but DEA is bound by the law as DOJ and DEA understand it. Whether the Single Convention's or the CSA's controls of marihuana should be amended and whether the United States should withdraw from the Single Convention

[9] The relevant law is briefly summarized here but is discussed in greater depth in the aforementioned OLC Opinion.

[10] The five functions of Article 23(2) of the Single Convention are as follows: (1) Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis or cannabis resin shall be permitted; (2) ensure that only cultivators licensed by the agency shall be authorized to engage in such cultivation; (3) ensure that each license shall specify the extent of the land on which the cultivation is permitted; (4) require all cultivators of the cannabis plant to deliver their total crops of cannabis and cannabis resin to the agency and ensure that the agency purchases and takes physical possession of such crops as soon as possible, but not later than four months after the end of the harvest; and (5) have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of cannabis and cannabis resin, except that this exclusive right need not extend to medicinal cannabis, cannabis preparations, or the stocks of cannabis and cannabis resin held by manufacturers of such medicinal cannabis and cannabis preparations.

[11] The Commentary to the Single Convention notes that this is in order to facilitate national planning and coordinated management of the various tasks imposed upon a country by Article 23, and that in countries where more than one agency is needed to perform these tasks on constitutional grounds, administrative arrangements should be made to ensure the required coordination.

[12] These issues are discussed further in the OLC Opinion.

[13] As noted, the relevant legal considerations are explored in greater detail in the aforementioned OLC Opinion.

are beyond the scope of this rulemaking and DEA's authority. This rulemaking must be consistent with DEA's obligations under the CSA, including granting registrations which are consistent with the Single Convention as it currently stands.

Issue 4: Some commenters believe that DEA's increased involvement in the provision of marihuana to researchers would have an adverse impact on clinical research, clinical trials, and the creation of cannabis preparations.

Response 4: As explained elsewhere in this rulemaking, DEA anticipates this rule will increase researchers' access to marihuana for medical and scientific research. At present, researchers must obtain marihuana for researchers through the NIDA DSP, and researchers who wish can continue to do so with minimal disruption. However, this rule will also allow researchers to legally obtain marihuana from other DEA-registered growers. DEA's involvement in that process will be limited, as set forth in these regulations, to those activities required by the CSA.

Issue 5: Another commenter suggested that DEA allow researchers to possess marihuana without restriction and that DEA's role in regulating the growing of marihuana be completely eliminated.

Response 5: As explained above, the CSA requires any person seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). More broadly, marihuana remains a schedule I controlled substance, and as such has a high potential for abuse and no currently accepted medical use in treatment in the United States. *See, e.g.,* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 FR 53687 (Aug. 12, 2016). Allowing the cultivation of marihuana for research without a DEA registration or otherwise regulating this activity would be incompatible with the CSA and its requirement of consistency with the Single Convention; it would also fail to protect public health and safety from the danger of that marihuana being diverted and abused.

Issue 6: One commenter suggested that the NPRM is incompatible with the Administrative Procedure Act (APA) on the grounds that DEA did not sufficiently explain the reasoning underlying the proposed rule.

Response 6: The NPRM satisfied the requirements of the APA, as does this final rule. The NRPM and this rule both set out the legal and practical reasons why DEA is promulgating this rule to increase the availability of marihuana for research consistent with the legal requirements of the CSA, as well as with DEA's duty to protect the public interest by preventing its diversion and abuse.

Issue 7: Two commenters requested that DEA extend the comment period given the current coronavirus disease 2019 public health emergency.

Response 7: DEA recognizes the challenges applicants and registrants may be facing during the public health emergency. However, DEA has decided not to extend the comment period beyond the 60 days generally required under Executive Order 12866 to avoid any further delays in registering additional marihuana growers. DEA, therefore, decided that extending the comment period would have unnecessarily delayed the registering of additional marihuana growers without meaningfully enhancing the rulemaking process.

The Meaning of ''Medicinal Cannabis''

Issue 1: Some commenters expressed concern about the definition of medicinal cannabis. Specifically, they argued that ''medicinal cannabis'' should include any cannabis that State law authorized for use as ''medical marijuana.'' One commenter requested DEA amend the definition of medicinal cannabis to include investigational marihuana for an investigational new drug.

Response 1: Under this rule, DEA will have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of marihuana other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations.[14] The term ''medicinal cannabis'' in this rule is limited to ''a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act,'' and DEA continues to believe this is the most appropriate definition for the term.

Through this rule, DEA is asserting an exclusive right of importing, exporting, wholesale trading and maintaining stocks of marihuana so as to ensure compliance with the CSA, including a provision requiring registrations to be consistent with the Single Convention. The exclusion of medicinal cannabis from this function is based on Single Convention Article 23's exclusion of medicinal opium from parties' obligation to maintain an exclusive right over opium trading (as applied to cannabis through Article 28). The Single Convention does not define medicinal cannabis, but its definition of ''medicinal opium'' is limited to opium that ''has undergone the processes necessary to adapt it for medicinal use.'' Single Convention art. 1(o).

Thus, DEA understands ''medicinal cannabis'' to mean drug products derived from cannabis in a form that the United States has approved for medical use, which is most effectively captured in this rule by requiring that the product be able to be legally marketed under the Food Drug and Cosmetic (FD&C Act). The United States, not State governments, is the relevant party to the Single Convention, and thus ''medicinal cannabis'' should only include cannabis-derived products that the United States has approved for medical use, not products States may have approved.

For similar reasons, this definition excludes an investigational new drug containing cannabis; such products may eventually become approved for full medical use in the United States (as opposed to research), but have not yet obtained such approval. The finished dosage form of such a substance may qualify as a ''cannabis preparation,'' which is outside of DEA's exclusive right to engage in the wholesale trade in cannabis, but remains subject to control under the CSA. It should be emphasized, however, that the bulk material from which any cannabis preparation is manufactured must be obtained from DEA.

Security Costs and Requirements Applicable to the Manufacture of Marihuana

Issue 1: Some commenters inquired about the packaging requirements necessary prior to the transport of purchased marihuana and once that marihuana is sent from a grower to a seller. Many commenters suggested DEA use tracking technology, similar to that used by some States, to monitor the movement of marihuana seeds, marihuana plants, and other marihuana products. Some commenters suggested that the use of such tracking technology would eliminate the need for the security measures proposed in the NPRM and required by DEA regulations more generally.

Response 1: DEA registrants are required to maintain effective controls against diversion. DEA registered manufacturers are responsible for providing proper security during the growing process. The crops must either be delivered and stored in a secure storage mechanism at the manufacturer's registered location, if one is designated by DEA, or delivered

[14] The exception that allows DEA registered manufacturers of medicinal cannabis and cannabis preparations to maintain stocks of cannabis materials for the purpose of producing such drugs or preparations only applies where the raw cannabis material was previously delivered to DEA.

to a location designated by DEA. In either case, the registrant must comply with security requirements specified in 21 CFR part 1301. A DEA registrant is also required to adhere to the recordkeeping and reporting requirements set forth in 21 U.S.C. 827 and 21 CFR part 1304, including the requirement to maintain records of all controlled substances which it manufactures, sells, and delivers. Although this regulation does not specify any special measures imposed on a grower for the packaging of a marihuana crop for purchase by DEA, DEA may develop packaging requirements as part of separate agreements between DEA and individual manufacturers; [15] but in all cases, DEA's general security regulations shall apply.

With regard to tracking technology, DEA recognizes that security technology is always evolving, and that in some circumstances tracking technology may present a useful means of protecting against diversion. In addition to security measures specifically required by DEA regulations, registrants should take the appropriate measures to guard against diversion of their crops, which may include the use of new technologies. At this time, however, DEA has concluded that it is not necessary to update its security regulations in this regard, and has not yet seen evidence that tracking technology can adequately replace security measures required by current regulations.

Issue 2: Other commenters suggested that the procedures for inspection of crops and harvests, and physical security requirements are expensive and would discourage applicants.

Response 2: As noted, DEA requires all applicants and registrants to maintain effective controls against the diversion of controlled substances as set forth in 21 CFR part 1301. The proposed rule and this final rule do not impose new or amended regulations for the security requirements set forth in 21 CFR part 1301. Furthermore, DEA registrants are subject to routine scheduled investigations conducted by DEA diversion investigators and other administrative requirements such as those specified in 21 CFR part 1304. DEA understands there will be costs incurred in meeting these administrative requirements; however, these requirements and costs are comparable to those applicable to bulk manufacturers of other controlled substances. Requiring such security controls is a critical part of DEA's efforts to fulfill its duties under the CSA to reduce the diversion and abuse of controlled substances, including marihuana.

Harvest

Issue: One commenter suggested that DEA expand the amount of time to deliver a harvest to DEA. This commenter also suggested DEA change the time period for providing notice of a harvest to five days, instead of 15 days beforehand, and suggested that the amount of harvests per year should be changed from three to five. Other commenters suggested manufacturers provide DEA with notice more than 15 days prior to harvest. Another commenter agreed that DEA should take possession of the crop no later than four months after harvest to maintain chemical composition of the crop.

Response: DEA understands the importance of taking possession of harvested crops in a timely manner to expedite the re-distribution of those crops to researchers and to reduce any potential for changes in the crops' chemical composition. As stated in the NPRM, and to comply with a CSA provision requiring consistency with the Single Convention, DEA must take physical possession of the crops within four months after the end of harvest. The requirement that a grower notify DEA at least 15 days prior to the commencement of a harvest is intended to provide DEA with sufficient time to make the necessary arrangements for traveling to the grower's registered location and to take possession of the crops. DEA has concluded that a five-day notice period will not provide sufficient time to make the arrangements needed to travel to a grower and attend a harvest.

With respect to this commenter's statement that DEA should change the number of harvests per year from three to five, DEA is not regulating the number of growing cycles that a registered grower may conduct. A grower may conduct as many growing cycles as is necessary to meet customer demand, so long as it does not exceed its IMQ for the year. The NPRM used three harvests per year as the estimated average number of harvests only for the purpose of conducting its regulatory analysis.

Quotas

Issue 1: A commenter stated there is a significant lag time from when quota is issued to harvest time. This same commenter inquired as to whether the cultivation of marihuana can begin prior to the issuance of quota. Another commenter suggested that DEA provide a deadline by which DEA must review or approve bona fide supply agreements and make quota determinations based upon them. A commenter also suggested that each manufacturer should be issued IMQ. One commenter suggested that DEA issue a multi-year license for new bulk manufacturers to meet quota needs.

Response 1: Pursuant to 21 U.S.C. 826, DEA is required to ''determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II . . . to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States [and] for lawful export requirements.'' This figure, which is known as the aggregate production quota (APQ), is then allocated to individual registered manufacturers based on each manufacturer's application for an IMQ as set forth in 21 U.S.C. 826(c). Pursuant to section 826(c), DEA is required to issue IMQ ''[o]n or before December 1 of each year'' for the following year.

While there may be significant lead time between the date on which an IMQ is issued and the date of harvest, a grower's lead time is dependent upon the growing techniques it uses. It should also be noted that non-botanical manufacturers of controlled substances frequently deal with significant lead times and have been able to manage them. In any event, Federal law prohibits the manufacturing of a controlled substance by a registrant which ''is not expressly authorized . . . by a quota assigned to him pursuant to'' 21 U.S.C. 826. 21 U.S.C. 842(b).

Thus, a registered manufacturer cannot commence growing marihuana until it has been granted its IMQ. Furthermore, because the CSA expressly requires that both the APQ and an IMQ be determined on a calendar year basis; DEA is not authorized to issue an IMQ other than on a single year basis.

As stated above, the CSA requires that DEA issue IMQ ''[o]n or before December 1 of each year'' for the following year. Thus, the CSA already sets the deadline by which DEA must review a bona fide supply agreement and make a quota determination. Each registered manufacturer of marijuana who produces evidence that it has entered into a bona fide supply agreement with a researcher will be issued an IMQ. In the event a registered manufacturer enters into additional bona fide supply agreements after receiving its IMQ, which would result in an increase in its estimated net disposal for the calendar year, it may apply for an increase in its IMQ for that calendar year. 21 CFR 1303.25.

[15] DEA routinely enters into memoranda of agreement with certain registrants.

Issue 2: A commenter suggested that the price and quantity of extracts is not based on dried flower weight and that different strains of marihuana will yield different extract weights from the same weight of marihuana. Thus, this commenter argued, DEA should set marihuana quotas based on the amount of marihuana extract produced from a harvested marihuana crop, not the weight of the harvested marihuana itself.

Response 2: Under the CSA, IMQ limits the quantity of controlled substances a manufacturer may produce. *See, e.g.,* 21 U.S.C. 826(c). Marihuana itself, not just its extract, is a schedule I controlled substance. Accordingly, when a marihuana grower cultivates a marihuana crop, that grower has produced a schedule I controlled substance. Thus, under the CSA, marihuana growers require an IMQ for the entire marihuana crop, regardless of the value or quantities of other controlled substances produced from that crop. Setting marihuana quota based solely on the amount of extract eventually produced would also inhibit quota enforcement, as DEA may not be able to determine if a marihuana grower was complying with its IMQ until the grower processed the marihuana into an extract. Finally, not all marihuana grown will necessarily be used to produce extracts—some marihuana research makes use of the plant material itself. Thus, not all marihuana production quotas could be tied to the quantity of extract produced from it, because not all marihuana grown for research is converted into an extract.

Costs, Pricing, and Fees of Marihuana for DEA Registrants

Issue 1: A commenter inquired how the purchase price is established when DEA purchases cannabis from a registrant that the registrant intends to use for his/her own research.

Response 1: This scenario was addressed in the NPRM by proposed 21 CFR 1318.06(b)(4), which this rule promulgates without change. Normally, under the rule, the seller and buyer may negotiate their own purchase price, to which DEA will add its administrative fee. When a registrant grows marihuana for its own use, the purchase price is irrelevant, given that the grower is effectively negotiating the price with itself. Thus, the rule will allow the grower to set any ''nominal price'' it chooses, given that the grower will purchase the marihuana back from DEA at the same price at which it is sold to DEA. In this scenario, the only net cost of the transaction is the per-kilogram administrative fee that grower must pay to DEA.

Issue 2: Several commenters suggested the purchase price of cannabis should be the registrant's average purchase price of the last six months or the average U.S. price for high grade commercial cannabis, plus 20 percent due to its research grade. Another commenter suggested a cap on the wholesale value of cannabis.

Response 2: DEA recognizes that supply and demand for the cultivation of marihuana for research and other licit purposes may fluctuate based on the lawful needs of the U.S. market. As such, DEA believes that allowing the buyer and seller to negotiate the purchase price of the marihuana provides more flexibility in determining appropriate prices driven by market forces. Attempting to set a universal price—or schedule of prices—for cannabis, or limiting a registrants' ability to change its prices in response to new circumstances, would unduly restrict the varieties of marihuana grown and may unduly limit growers' ability to produce marihuana to satisfy new research needs. Similarly, setting a price cap may prevent growers from meeting researchers' need for cannabis that is unusually expensive given its strain or the conditions in which it must be grown.

Issue 3: A commenter inquired whether the administrative fees are paid by the purchasing researchers or the selling growers.

Response 3: Under the rule, the administrative fee is considered part of the price of the cannabis DEA sells to the purchasing researcher. That said, the rule requires the ''parties'' to pay the fee to DEA upon entering into a contract for the provision of cannabis, but before the cannabis is actually delivered to the researcher. In other words, DEA is not charging the administrative fee to either party in particular, but to the parties jointly as part of the transaction. The parties are free to apportion the fee among themselves in any way they choose.

Issue 4: Some commenters suggested that the administrative fee be waived for DEA-registered manufacturers who cultivate and research their own marihuana, and do not sell their marihuana. Similarly, some commenters suggested that the administrative fee would discourage research and thus suggested that the administrative fee be waived for researchers in general.

Response 4: As explained in the NPRM, the purpose of the administrative fee is to allow DEA to recover the operational costs of administering the program, as required under 21 U.S.C. 886a(1)(C). Because DEA anticipates the vast majority of marihuana will be sold to researchers, a waiver of the administrative fee in transactions involving researchers would not allow DEA to properly recover its costs of administering the marihuana growers program under 21 U.S.C. 886a(1)(C).

DEA nonetheless continues to encourage lawful cultivation of marihuana for research and other licit purposes through the administration of this program. As discussed in the NPRM and below, DEA does not expect this administrative fee to be a barrier to research. Nothing in this rule prohibits NIH—or any other third-party funder of research grants—from funding marihuana research by covering the cost of marihuana materials used in research, including these administrative fees, via grants to researchers.

DEA also cannot waive the administrative fee for researchers growing marihuana for their own use because that too would prevent DEA from recovering its operational costs. The provisions of this rule—and the CSA and DEA regulations more broadly—apply not only when a grower is selling to a third party, but also when a grower is producing marihuana for its own use. DEA must still register the grower, and purchase and take possession of the marihuana, even if the marihuana is being used for the grower's own research. Thus, DEA does not anticipate its operational costs to be significantly less when it is regulating a grower's cultivation of marihuana for its own research or for another party's use. Accordingly, DEA will charge the same fees in both situations.

Issue 5: One commenter requested that DEA clarify administrative fees.

Response 5: The nature and purpose of the administrative fee, as well as how it is set, are explained both in the rule itself and throughout the NPRM. In sum, an administrative fee for each transaction will be added to the sales price of the marihuana. The administrative fee is a variable fee based on the quantities, in kilogram (not quality, grade, potency, etc.) of bulk marihuana distributed. The parties to the transaction will pay DEA the administrative fee upon entering into a contract for the provision of the marihuana and prior to the delivery of the marihuana. DEA will set the administrative fee rate at least annually at a level adequate to allow DEA to recover the costs of administrating the marihuana growers program under 21 U.S.C. 886a(1)(C).

Issue 6: One commenter suggested that DEA waive the administrative fee

for any crops that are damaged or lost while in DEA's possession.

Response 6: Such a fee waiver is unnecessary and inconsistent with DEA's obligations under the CSA and this rule. As explained elsewhere, DEA generally does not anticipate retaining possession of crops for significant periods of time; in most instances, they should be transferred quickly to the buyer. Accordingly, crops are unlikely to be damaged or lost in DEA's possession. Moreover, as explained above, the administrative fee must be set at a rate that allows DEA to recover the costs of operating the marihuana growers program under 21 U.S.C. 886a(1)(C). Every marihuana transaction under this rule will impose costs on DEA. Thus, if DEA waived fees for some marihuana buyers and sellers, it would have to increase fees on other buyers and sellers to compensate for the amounts lost due to the waiver. DEA has concluded that it is most equitable to base the administrative fee on the weight of marihuana produced, and not other factors.

Out of Scope

Issue: DEA received comments that are outside the scope of this final rule. Some comments raised general concerns regarding the treatment of marihuana under Federal law. Others raised specific issues regarding, among other things, medical illnesses, medical treatments, the scheduled class of marihuana, marihuana-related activities permitted and prohibited in specific States, and the status of previous congressional inquiries.

DEA Response: DEA acknowledges receipt of these comments; however, such comments are outside the scope of the NPRM and the final rule. These comments ultimately have no bearing on the rule under consideration, or on the regulatory decisions DEA is making as part of this rulemaking.

Section-by-Section Summary of the Final Rule

The purposes and functions of this rule were discussed in the NPRM. Aside from a minor amendment to 21 CFR 1318.04, this rule adopts the proposed rule without change. DEA's reasoning was fully explained in the NPRM. However, in addition to describing the amendment—in particular, the added section at § 1318.04(d)—DEA will summarize this rule's various changes to DEA regulations and the reasoning behind these changes for the sake of clarity and convenience.

§ 1301.33: Applying the Marihuana Grower Regulations to All Marihuana Growers

This rule makes two technical changes to 21 CFR 1301.33 to account for the addition of part 1318, which in turn provides regulations specific to the growing of marihuana in accordance with the CSA.

As discussed above, part 1301 of DEA's regulations governs the registration of manufacturers, distributors, and dispensers of controlled substances. It also includes various sections governing how entities are to apply to become registered with DEA. *See, e.g.,* 21 CFR 1301.13–17. These sections include § 1301.33, which contains certain provisions unique to applications to become registered to manufacture schedule I and II substances in bulk. For example, § 1301.33(a) requires that DEA publish a notice of application after receiving a schedule I and II bulk manufacturer application. Previously, § 1301.33(c) provided that the other provisions of § 1301.33 do not apply when the manufacturing at issue is ''as an incident to research or chemical analysis as authorized in § 1301.13(e)(1),'' *i.e.,* when the bulk manufacture is a coincident activity of a DEA-registered researcher or chemical analyst.

This rule amends § 1301.33(c) to modify this exception in the case of marihuana growing. Specifically, under this rule, § 1301.33(c)'s exclusion applies to manufacturing as an incident to research and chemical analysis, except as provided in the newly added § 1301.33(d). And the new § 1301.33(d) provides that an application to manufacture marihuana ''that involves the planting, cultivating, growing, or harvesting of marihuana'' (as opposed to, for example, marihuana manufacturing that merely involves processing marihuana grown by another party into a new marihuana product) shall be subject both to the general requirements of § 1301.33 as well to the newly added requirements of part 1318.

This change serves two purposes. First, by cross-referencing part 1318 in part 1301, this change ensures that marihuana grower applicants reviewing the general registration and application requirements in part 1301 are made aware of the regulations specific to marihuana growers in part 1318. Second, the Single Convention does not distinguish marihuana grown by a researcher or chemical analyst from that grown by other manufacturers; under the Single Convention, a government agency is required to purchase and take possession of that marihuana and then oversee its distribution. Thus, both to ensure that DEA complies with the CSA, including a provision requiring consistency with obligations under international treaties such as the Single Convention, and to ensure that these applications are treated as equitably as possible, DEA is amending its regulations to ensure that all marihuana growers are subject to the requirements of both § 1301.33 and part 1318.

§ 1318.01: The Scope of the New Marihuana Grower Regulations

New 21 CFR part 1318 adds a series of new provisions to ensure that DEA can register additional marihuana growers in a way consistent with its obligations under the CSA, including a provision requiring consistency with the Single Convention. New § 1318.01 clarifies the scope of these new provisions, stating that they govern ''the registration of manufacturers seeking to plant, grow, cultivate, or harvest marihuana.''

Among other things, this serves to make clear that part 1318 only applies to those manufacturers involved in activities related to the cultivation of marihuana, not all forms of marihuana manufacturing. The CSA defines ''manufacturing'' broadly as ''the production, preparation, propagation, compounding, or processing of a drug or other substance,'' including extraction from plant products and certain forms of packaging. 21 U.S.C. 802(15). Thus, under the CSA, entities involved in a variety of marihuana-related activities, not just marihuana growers, are required to register with DEA as marihuana manufacturers.

Section 1318.01 emphasizes that part 1318 does not apply to all marihuana manufactures, but only to those involved in the planting, growing, cultivating, or harvesting of marihuana.[16] Part 1318 limits itself to marihuana growers, rather than all manufacturers, given the unique obligations the Single Convention places on the United States with regard to the growing of marihuana and the unique diversion risks growing presents.

§ 1318.02: Definitions

Part 1318 contains a number of terms that are not used elsewhere in DEA regulations or have a unique meaning when used in the context of part 1318. Thus, to avoid any ambiguity about the meaning of those terms and the regulations in which they are used,

[16] The rule refers to those ''seeking to plant, grow, cultivate, or harvest marihuana'' rather than just to ''grow'' or ''cultivate,'' to ensure that all activities related to growth and cultivation are included.

§ 1318.02 specifically defines those terms for the purposes of part 1318.

Most of the definitions in § 1318.02 are self-explanatory. For example, ''cannabis'' means any plant of the genus Cannabis (unless otherwise excepted, as discussed below), and ''cannabis resin'' (with one exception discussed below) means the separated resin, whether crude or purified, obtained from the cannabis plant. Similarly, the definition of ''Single Convention'' includes a citation to eliminate any possible confusion about the Single Convention at issue, and the definition of ''bona fide purchase agreement'' specifies the broad type of agreements DEA is seeking to encompass by this term.

Several provisions of § 1318.02, however, warrant further discussion. First, as discussed in the NPRM and above, the Single Convention exempts ''medicinal cannabis'' and ''cannabis preparations'' from certain of its requirements. Following suit, part 1318 likewise exempts these substances from certain of its provisions, and, to facilitate this exemption, § 1318.02 defines ''medicinal cannabis'' and ''cannabis preparations.'' Under § 1318.02, ''medicinal cannabis'' means a drug product made from the cannabis plant, or derivatives thereof that can be legally marketed under the FD&C Act. ''Cannabis preparation'' means cannabis that was delivered to DEA and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis or cannabis resin. These definitions track those of the Single Convention, as adapted to account for Federal law.[17]

Finally, § 1301.02(e) clarifies that, when used in part 1318, none of these cannabis-related terms—cannabis, cannabis preparation, cannabis resin, or medicinal cannabis—include substances that fall outside the CSA's definition of marihuana. Among other things, § 1301.02(e) is intended to reflect the CSA amendments made by the Agriculture Improvement Act of 2018 (AIA), Public Law 115–334. The AIA amended the definition of marihuana to exclude ''hemp,'' defined as the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. 7 U.S.C. 1639*o*(1). Thus, under the AIA, anything that meets this definition of hemp is no longer a controlled substance, and the CSA's requirements no longer apply to it. This rule is designed to regulate marihuana growers, not hemp growers; and thus § 1301.02(e) ensures that part 1318 does not apply to the cultivation of substances do not meet the definition of marihuana under the CSA, such as hemp.

§ 1318.03: Implementation of the CSA's Requirements

This section reiterates the requirements of certain other provisions of the CSA and DEA regulations, both to make clear that these requirements apply to marihuana grower applications and as background for other provisions of part 1318. Specifically, § 1318.03(a) reiterates the requirement of 21 U.S.C. 823(a) that the DEA Administrator may only grant an application to cultivate marihuana if he determines that such registration is both consistent with the public interest and with U.S. obligations under the Single Convention. Section 1318.03(b) states that, in accordance with both 21 U.S.C. 823(a) and 21 CFR 1301.44, the applicant has the burden of demonstrating that these requirements are satisfied.

§ 1318.04: Specific Control Measures Applicable to the Cultivation of Marihuana

This section adds a series of control measures designed to ensure that, once DEA registers additional marihuana growers, their marihuana cultivation occurs in accordance with the CSA, including the provision that requires registrations be granted consistent with the Single Convention. In particular, this section adds regulations that will ensure that DEA is able to purchase and take possession of marihuana crops within four months of harvest, and also that DEA has the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marihuana (other than medicinal cannabis or cannabis preparations)—both functions that the Single Convention expressly requires a single agency of the Federal government to perform. This section also contains provisions describing how DEA will perform these functions, provisions that are designed both to guide DEA's performance of these duties (and growers' expectations) as well as to ensure that these functions are performed in a way that protects against diversion of marihuana without placing an undue burden on growers. These provisions—and how they apply to particular scenarios—are discussed in greater depth both above and in the NPRM.

Finally, this section adds a provision that explicitly provides an allowance for registered bulk manufacturers of marihuana to distribute samples to registered analytical laboratories. Because these samples are small, distributed to the laboratory solely for the purpose of analysis, and consumed in the course of the analysis or destroyed upon completion of the testing, DEA has determined that DEA is not required to take possession of these samples to satisfy U.S. obligations under the Single Convention. This allowance permits registered bulk manufacturers to monitor the cannabinoid content of their crop in order to properly time their harvest and demonstrate compliance with contract specifications to their customers.

§ 1318.05: Applying the CSA's Public Interest Factors to Marihuana Grower Applicants

As indicated above, in addition to ensuring registration is consistent with its Single Convention obligations, DEA may grant a registration to manufacture a schedule I or II controlled substance only where the Administrator determines that the registration is consistent with the public interest, based on the factors listed in 21 U.S.C. 823(a).

This section both reiterates these public interest factors and explains how DEA will evaluate whether a particular marihuana grower application is consistent with them. For example, under 21 U.S.C. 823(a)(1), DEA must weigh, as one of the registration factors, the need to maintain effective controls against diversion by limiting the number of registered bulk marihuana growers to that which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. Section 1318.05 states that, for the purpose of assessing this factor, a bona fide supply agreement between a marihuana grower and a duly registered schedule I researcher or manufacturer provides evidence that an applicant's registration is necessary to produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. An applicant proposing to grow marihuana to supply its own research may also be deemed to have satisfied this aspect of public interest factor 823(a)(1) upon the presentation of evidence that it possesses a registration to conduct

[17] Article 1 of the Single Convention defines ''medicinal opium'' and ''opium preparations.'' These definitions apply to cannabis through Article 28, which, with limited exception, subjects the cultivation of cannabis to the system of controls set forth in Article 23 with regard to the cultivation of opium. DEA adapted the Single Convention's definitions to reflect governing Federal law, including the FD&C Act and the CSA.

research with marihuana under 21 CFR 1301.32.

The rule also provides that, when selecting marihuana grower registrants, the DEA Administrator will place particular emphasis on an applicant's ability to consistently produce and supply marihuana of a high quality and defined chemical composition, and whether the applicant has demonstrated prior compliance with the CSA and DEA regulations. These factors are designed to result in registration of those manufacturers of marihuana that can most efficiently supply the lawful needs of the U.S. market in terms of quantity and quality. These factors are further aimed at selecting applicants that can be entrusted with the responsibility of a DEA registration and complying with the corresponding obligations under the CSA and DEA regulations.

Section 1318.05(c) provides that, aside from any applications governed by 21 U.S.C. 823(i), applications DEA accepts for filing after the date this rule becomes effective will not be considered pending until all applications accepted for filing on or before this effective date have been granted or denied by the Administrator. This is because, as explained above, the CSA requires DEA to consider the need to maintain effective controls against diversion by limiting the total number of registered marihuana growers to that necessary to produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. Thus, DEA must consider all pending applicants together when deciding which applications to grant. Given this requirement, DEA is including this provision to avoid a situation in which the agency is in the midst of evaluating these applications and has to begin its evaluation anew each time it accepts a new marihuana grower application for filing.

§ 1318.06: Factors Affecting Marihuana Prices

As discussed in the NPRM and above, to ensure compliance with the CSA, including a provision requiring consistency with the Single Convention (and as specified in § 1301.04 of this rule), DEA will purchase all lawfully grown marihuana crops within four months of harvest and then sell the marihuana to DEA registrants who seek to acquire it for research, product development, or other lawful purposes under the CSA. To do so, DEA will establish purchasing and selling prices: § 1318.06 describes how DEA will do this—and more broadly explains how certain aspects of these transactions will work, as well as how DEA will fund its expenses from carrying out these duties.

As explained elsewhere in the NPRM and this rule, in purchasing such marihuana, DEA will use the Diversion Control Fee Account established in 21 U.S.C. 886a. Thus, DEA must take into account its obligation under 21 U.S.C. 886a(1)(C) to charge fees under its diversion control program ''at a level that ensures the recovery of the full costs of operating the various aspects of that program.'' There are two potential categories of fees that could be used to recover the costs of carrying out the new aspects of the diversion control program relating to marihuana: (1) Fees charged to persons who apply for, and seek to renew, a DEA registration to manufacture marihuana, and (2) fees charged for the sale of marihuana by DEA. Under this rule, DEA intends to recover its basic operating costs primarily through the latter means, by recovering these costs through an administrative fee set based on these costs. Section 1318.06 describes how this will occur.

Under § 1318.06, DEA will allow market forces to direct prices for marihuana grown by the manufacturer and purchased by DEA, allowing the marihuana grower and ultimate purchaser to negotiate a sales price. Where the grower and the buyer are the same entity (or related entities), § 1318.06 allows the entity to set a nominal price.

In addition to that negotiated price, § 1318.06 provides that DEA will add an administrative fee (per kilogram (kg)) to the sales price of the marihuana it sells to end users. As provided in § 1318.06(a), DEA will calculate this administrative fee no less than annually by taking the preceding fiscal year's cost to operate the program and dividing it by the quantity in kg of the total of the IMQs for marihuana issued during the current quota year. Section 1318.06(c) requires DEA to make the updated administrative fee available on DEA's website.

As discussed elsewhere, DEA does not intend for this rule to interfere with HHS's funding of marihuana for use in research. Thus, to avoid any possibility of confusion, § 1318.06(d) notes that this section does not prohibit HHS from funding the purchase cost or associated administrative fees for marihuana purchased for research.

§ 1318.07: DEA's Disclaimer of Liability

As explained above, DEA generally does not anticipate retaining possession of marihuana crops for significant periods of time: In most instances, they should be transferred quickly from the seller to the buyer, with DEA's possession being as brief as possible to effectuate its role in transferring the marihuana from buyer to seller. Accordingly, crops are highly unlikely to be damaged or lost in DEA's possession. That said, if a buyer concludes that a crop is unacceptable, it is conceivable that a grower could claim that the damage is attributable to DEA, leading to costly and unnecessary disputes. To avoid disputes, § 1318.07 makes clear that DEA has no liability with regard to the performance of any of the terms agreed to by a grower and buyer of marihuana, including but not limited to the quality of the marihuana. In effect, this puts buyers and sellers on notice that it is their obligation to structure their marihuana transactions in such a way as to minimize the risk of damage or disputes over quality, rather than looking to DEA to mediate or bear the costs of such disputes.

Regulatory Analyses

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

This rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs 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, and other advantages; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. Section 3(f) of Executive Order 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of

recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

OMB's Office of Information and Regulatory Affairs (OIRA) has determined that, although this rule is not economically significant, it is a significant regulatory action under section 3(f) of Executive Order 12866, and it therefore has been reviewed by OMB.

I. Need for the Rule

This rule is needed to ensure that DEA complies with the CSA and grants registrations that are consistent with relevant treaty provisions as DEA seeks to increase the number of registered growers of marihuana. Specifically, this rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. These amendments will ensure that DEA carries out all five functions under Article 23 and Article 28 of the Single Convention pertaining to marihuana, thus facilitating the planning and coordinated management of marihuana production necessary as the number of registered marihuana manufacturers increases.

II. Alternative Approaches

This rule amends DEA regulations only to the extent necessary to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana. In areas where DEA has discretion, such as in setting a fee structure to recover the cost of this rule, alternative approaches normally would be discussed. However, because DEA does not have sufficient information at this time to discuss alternatives for either the future registration fees or the fees for the sale of marihuana, the alternative approaches for such provisions are not included in this rule. Consistent with past agency practice, any changes to registration fees will be the subject of a separate rulemaking proceeding, including a discussion of alternative approaches.

III. Analysis of Benefits and Costs

There are two key benefits associated with this rule. First, DEA believes it is possible that the approval of new growers may increase the variety (quality, potency, etc.) of bulk marihuana for research, leading to more effective research and potentially resulting in the development of FDA-approved drug products. Second, this rule ensures that DEA's regulations comply with the requirements of the CSA by granting registrations that are consistent with the Single Convention relating to marihuana. DEA is unable to quantify these benefits at this time.

DEA analyzed the costs of this rule and estimates an annual cost of $651,318.[18] The details of the analysis are below.

This rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. Upon promulgation of this rule, the following key changes are anticipated: More persons will be authorized to grow marihuana, DEA will purchase and take title to the crops of marihuana, and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes mean that authorized purchasers of bulk marihuana to be used for research, product development, and other purposes permitted by the CSA may only purchase from DEA, except that DEA's exclusive rights do not extend to medicinal cannabis or cannabis preparations. The changes described above affect three primary groups of entities: Growers and prospective growers, the authorizing agencies,[19] and purchasers (generally medical and scientific researchers). To examine the impact of the rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the three affected groups.

Current System

To date, DEA has authorized one grower, the National Center for Natural Products Research (National Center), to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana from seeds supplied initially by NIDA for use in research studies.[20] The National Center has designated a secure plot of land or indoor grow facility where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[21] NIDA obligated approximately $1.5 million in Fiscal Year 2015 under this contract.[22] This amount included costs unrelated to growing and cultivating marihuana, such as extracting chemical components and producing marihuana cigarettes and other marihuana-related material. However, based on recent discussion with NIDA,[23] DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 were approximately $2.9 million.[24] The $2.9 million includes compensation for the cultivating and the 2019 manufacturing quota (MQ) of 2,000 kgs for NIDA (National Center) as well as all other duties required in the contract.[25]

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is currently available at no cost to research investigators supported by a NIH grant. Marihuana is also available to research investigators who are funded through non-Federal sources. Although NIDA considered charging for marihuana on a ''cost-reimbursement basis,'' [26] the current policy is to provide the marihuana at no charge.[27]

Changes to Growers

Upon promulgation of this rule, DEA anticipates approving more than one

[18] This is an increase from the estimated cost of $607,644 in the NPRM. The increase is due to change in estimated personnel requirements as described below.

[19] The ''authorizing agency'' refers to federal government agencies, including NIDA and DEA.

[20] Production, Analysis, and Distribution of Cannabis and Related Materials, Federal Business Opportunities (Apr. 12, 2015), *https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N01DA-15-7793/listing.html.*

[21] NIDA's Role in Providing Marijuana for Research, National Institute on Drug Abuse, *https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research.*

[22] Information on Marijuana Farm Contract, National Institute on Drug Abuse, *https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research/information-marijuana-farm-contract.*

[23] Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

[24] Estimated spending for the marihuana DSP for 2019 was $3.3 million to $3.4 million, of which 10%-15% meet the definition of ''hemp'' under the provisions of the AIA. Using the midpoint of these ranges, the estimated spending is $2.9 million for marihuana, excluding hemp. The figures are based on a general discussion, and actual figures may differ.

[25] The 2019 APQ for all marihuana is 2,450 kgs. 2,000 of the 2,450 kgs are for the NIDA (National Center) cultivating and manufacturing quota of bulk marihuana. *See* 83 FR 67348.

[26] Marijuana Plant Material Available from the NIDA Drug Supply Program, National Institute on Drug Abuse, *https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program/marijuana-plant-material-available-nida-drug-supply-program.*

[27] Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

entity to cultivate and harvest bulk marihuana. As explained earlier in this document, the CSA imposes limitations on the number of registrations that DEA may issue to bulk manufacturers of a given schedule I or II controlled substance. In addition, in deciding whether to grant an application for any such registration, the CSA requires DEA to consider the other public interest factors of 21 U.S.C. 823(a), which must be evaluated on an applicant-by-applicant basis. Further, DEA cannot accurately predict in advance which particular applications will be granted, or how many. Accordingly, DEA is unable to accurately estimate the number of registered bulk marihuana growers. As a result, to allow for this analysis, DEA estimated the economic impact of this rule under two different hypothetical scenarios, the first in which the number of growers expands to three growers, and the second in which the number of growers expands to 15 growers. It should be understood that this range of potential registrants is not necessarily reflective of the actual number of applications that DEA will grant.

In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[28] Since the publication of the 2016 policy statement, DEA has received approximately 38 pending applications for registration as bulk manufacturer of marihuana for research. As indicated above, the CSA requires DEA to limit the total number of registered bulk manufacturers of a given schedule I or II controlled substance to that necessary to produce an adequate and uninterrupted supply under adequately competitive conditions. Therefore, DEA believes a range of three to 15 growers is a reasonable estimate for purposes of this economic analysis, with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[29] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and the reimbursement of production cost through sales) is transferred from the single incumbent grower to new growers. This means that there is only a transfer of economic activity rather than any new cost. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[30]

Transitioning from one large grower to multiple growers may introduce inefficiencies, driving up production or facility costs. Some growers may introduce more costly growing techniques to produce certain traits. Alternatively, some growers may introduce more efficient growing methods, driving down costs. Additionally, having more growers may spur more demand in bulk marihuana for research, pushing up the MQ. In particular, one of the goals of this new rule is to enhance marijuana availability for product development, which may have the effect of increasing the MQ. However, DEA does not have a basis to estimate the impact of these possibilities. Therefore, for the purposes of this analysis, DEA estimates that an increase in the number of approved growers does not impact the MQ. In summary, there is no new cost to growers.

Changes to Authorizing Agencies—Cost to DEA

DEA anticipates that there will be a transfer of economic activity from NIDA to DEA as well as several new costs as a result of this rule. This analysis should not be construed as a proposal to modify agency funding or funding sources.

As discussed above, assuming a constant MQ for bulk marihuana of 2,000 kgs, DEA estimates the cost of all the activities the National Center performs under its contract with NIDA and the purchase of the entire aggregate crop, regardless of the number of growers, is $2.9 million. This $2.9 million is not a new cost; it is a transfer. Rather than NIDA paying the current single grower, DEA will pay the multiple new growers. In practice, DEA anticipates crops from multiple growers will be purchased at different times of the year, allowing funds from sales of earlier purchases to pay for subsequent purchases. Therefore, to purchase and distribute $2.9 million in bulk marihuana, a working capital of a lesser amount is likely needed. However, due to many unknowns and to be conservative, for the purposes of this analysis, the estimated transfer and working capital requirement is assumed to be $2.9 million.

DEA anticipates incurring new costs associated with the following activities: Taking title to the crops and employing personnel to administer the program. The growers, purchasers, and DEA will already understand, prior to growing and harvesting, the quantities of marihuana to be distributed and to whom the distribution will be made, because the bona fide supply agreements presented during the registration application process will provide such information. In most instances, DEA is expected to purchase and take title to the crop, then sell and distribute the crop to the purchaser on the same day at the grower's registered location. For the purposes of this analysis, DEA assumes the following process:

1. After marihuana is harvested and prepared for delivery to DEA, the registered manufacturer will contact DEA to inform it that the marihuana is ready for collection.

2. Within a reasonable timeframe, but in no event later than four months after the harvest, DEA will purchase and take title to the marihuana. Two DEA Special Agents from the nearest local DEA field office will drive an estimated 100 miles (200 miles roundtrip) to the registered manufacturer to take title. Any marihuana that is not immediately distributed is stored in a designated secure storage mechanism at the grower's registered location for later distribution. The number of trips by the two DEA Special Agents equals the number of harvests.

3. For marihuana distributed from storage at the grower's registered location, the grower distributes marihuana on DEA's behalf. If DEA deems it necessary to be present at such distribution, the distribution is scheduled to coincide with DEA's visit to take title to the next crop, requiring no additional trips by DEA to the grower.

4. Each grower has three harvests, requiring DEA to collect three times per year per grower.

For each collection, DEA estimates $2,071 of labor cost[31] and $116 of vehicle cost[32] for a total of $2,187 per

[28] Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). This rule supersedes the 2016 policy statement.

[29] 21 CFR 1303.11(a).

[30] The phrase ''multiple growers'' includes the possibility that the current grower is one of ''multiple growers.''

[31] DEA's loaded hourly rate of a Special Agent is $103.54. Assuming 10 hours each (full work-day) for two agents, the total labor cost associated with collection from a registered manufacturer is $2,071. ''Loaded hourly rate'' includes wages, benefits, and ''loading'' of ''non-productive'' hours, *i.e.,* leave, training, travel, etc.

[32] $116 is based on Internal Revenue Service standard mileage rates for 2019 of $0.58 per mile

Continued

collection. DEA understands that some growers, employing certain growing methods, may have more harvests per year. However, DEA does not have a basis to estimate these growers' methods or the number of harvests per year. Therefore, DEA believes three harvests per year is a reasonable estimate. Assuming three collections per year per grower, there would be nine collections with three approved growers and 45 collections with 15 approved growers. Applying the estimated cost of $2,187 per collection, DEA estimates a transport cost of $19,683 and $98,415 for scenarios with three and 15 growers, respectively.

Additionally, DEA anticipates it will need additional personnel resources to operate this program. There are many unknowns and no decisions have been made on hiring. However, for the purposes of this analysis, DEA estimates three full-time-equivalent (FTE) professional staff in the Diversion Control Division will be needed, consisting of two FTE diversion investigator (DI), and one FTE professional/administrative (PA) resources.

Applying the fully loaded annual cost of $211,981 per DI and $168,307 per PA, the estimated total cost of the three FTE employees is $592,269. For the purposes of this analysis, this cost does not vary with the number of growers. Table 1 below summarizes the costs associated with increased staffing.

TABLE 1—COST OF PERSONNEL RESOURCES

Position	Job category	Modular cost/unit cost ($)	Number of FTEs	Cost ($)
Staff Coordinator	DI	211,981	2	423,962
Program Analyst	PA	168,307	1	168,307
Total	N/A	N/A	3	592,269

In summary the estimated cost to DEA is:

- $19,683 or $98,415 per year to purchase and take title to the bulk marihuana for scenarios with 3 or 15 authorized growers, respectively;
- $592,269 per year for three DEA FTE employees;
- The estimated total annual cost is $611,952 with three growers and $690,684 with 15 growers and no offsetting cost savings at NIDA. Using the average of the two values, the estimated cost to DEA is $651,318. Table 2 summarizes the costs.

TABLE 2—DEA COST SUMMARY

	Low ($)	High ($)	Average ($)
Transport Cost	19,683	98,415	N/A
Personnel Cost	592,269	592,269	N/A
Total Cost	611,952	690,684	651,318

Changes Affecting Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that some researchers will acquire the bulk marihuana from DEA, rather than from NIDA. As discussed earlier, the only new cost associated with this regulation is the cost to DEA of $651,318, an average of high and low scenarios, which will be recovered by adding an administrative fee of $326 per kg. The administrative fee was updated from $304 per kg in the NPRM to $326 per kg in this final rule because there is a change in the personnel required to administer the program.[33] As discussed earlier, the administrative fee will be adjusted annually.

While the purchaser will purchase marihuana from DEA, this rule does not in any way affect the purchaser's source of funds to purchase from DEA. If marihuana for research is funded by a third party, the researcher may not experience any cost increase. In particular, NIH has long served as a third-party funder for research through grants, including grants to researchers studying marihuana. Nothing in this rule prohibits NIH from continuing to fund such research by continuing to cover the cost of marihuana materials used in research, via grants to researchers.

Cost Summary

DEA estimates the cost of producing the 2019 MQ for bulk marihuana of 2,000 kgs and operating NIDA's marihuana DSP is $2.9 million per year. Under the rule, DEA anticipates more bulk marihuana producers will be approved. DEA estimates the $2.9 million in economic activity will be transferred across multiple growers, without introducing new costs.

DEA's purchase of bulk marihuana is not a new cost (to the economy); it is a transfer from NIDA to DEA. However, $611,952 to $690,684 in operating costs will be incurred by DEA. DEA will recover the costs of carrying out the new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated

multiplied by the estimated 200 miles driven, roundtrip.

[33] In the NPRM, DEA estimated personnel requirements to administer the program was one DEA Diversion Investigator and two Professional/Administrative personnel. After further review, DEA has estimated in this final rule that two DEA Diversion Investigators and one Professional/Administrative personnel are needed to administer the program. The two Diversion Investigators are needed to provide adequate oversight of reporting and recordkeeping requirements associated with distribution.

sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis.

The net present values (NPV) of the low cost estimate of $611,952 per year over 10 years are $5.2 million and $4.3 million at a three percent discount rate and seven percent discount rate, respectively. The NPVs of the high cost estimate of $690,684 over 10 years are $5.9 million and $4.9 million at a three percent discount rate and seven percent discount rate, respectively. The average of the estimated low and high costs is $651,318. The NPVs of the average of $651,318 over 10 years are $5.6 million and $4.6 million at three percent and seven percent discount rates, respectively. Table 3 summarizes the estimated annual effect and NPVs calculation for each of the transfers and the three scenarios.

TABLE 3—SUMMARY OF ANNUAL EFFECT AND NPVS

	Annual effect ($)	NPVs at 3% ($M)	NPVs at 7% ($M)
Cost (Low)	611,952	5.2	4.3
Cost (Average)	651,318	5.6	4.6
Cost (High)	690,684	5.9	4.9

Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rule is a deregulatory action for the purposes of Executive Order 13771. The rule is an enabling rule which, coincidentally with other provisions, expands the number of authorized bulk marihuana growers.

Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens on regulated parties and the court system.

Executive Order 13132 (Federalism)

This rule does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless the agency can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities and a discussion of its findings is below.

As discussed in the section of this rulemaking relating to Executive Orders 12866, 13565, and 13771, this rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, and adds provisions related to the purchase and sale of this marihuana by DEA. Upon promulgation of this rule, the following key changes are anticipated: More persons will be authorized to grow marihuana; DEA will purchase and take physical possession of crops; and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes, as explained above, mean that authorized purchasers of bulk marihuana may only purchase from DEA, except that DEA's exclusive right will not extend to medicinal cannabis or cannabis preparations as these terms are defined in paragraphs (b) and (c), respectively, of § 1318.02 of this rule.

The changes described above affect three primary groups of entities: Growers and prospective growers, the authorizing agencies (including NIDA and DEA), and purchasers (generally researchers). Because any economic impact on Federal agencies is outside the scope of the RFA, the transfer of economic activity between the agencies is excluded from this discussion. To examine the impact of the rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the two affected non-Federal groups: Growers (bulk manufacturers of marihuana) and researchers.

Current System

To date, DEA has authorized one grower, the National Center, to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana for use in research studies.[34] The National Center designates a secure plot of land where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[35] As explained previously, DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 were approximately $2.9 million.[36] The $2.9 million includes compensation for the cultivating and the 2019 MQ of 2,000 kgs for NIDA as well as all other duties required in the contract.[37]

[34] Production, Analysis, and Distribution of Cannabis and Related Materials, Federal Business Opportunities (Apr. 12, 2015), *https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N01DA-15-7793/listing.html.*

[35] NIDA's Role in Providing Marijuana for Research, National Institute on Drug Abuse, *https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research.*

[36] Estimated spending for the marihuana DSP for 2019 was $3.3 million to $3.4 million, of which 10 percent to 15 percent meet the definition of ''hemp'' under the provisions of the AIA. Using the midpoint of these ranges, the estimated spending is $2.9 million. The figures are based on a general discussion, and actual figures may differ.

[37] The 2019 APQ for all manufacturers of marihuana is 2,450 kgs. 2,000 kgs are for cultivating and manufacturing of bulk marihuana. *See* 83 FR 67348.

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is available at no cost to research investigators who are supported by an NIH grant. Marihuana is also available to research investigators who are funded through non-Federal sources. Although NIDA considered charging for marihuana on a ''cost-reimbursement basis,'' [38] the current policy is to provide the marihuana at no charge.[39]

Impact on Growers

Upon promulgation of this rule, DEA anticipates approving more than one person to cultivate and harvest bulk marihuana. In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[40] Since the publication of the 2016 policy statement, there are approximately 38 pending applications for registration as bulk manufacturer of marihuana for research. Additionally, some applicants may not meet the statutory and regulatory criteria for holding a registration as a bulk manufacture and will be denied. Therefore, for the purposes of this analysis, DEA will estimate the economic impact of this rule at three and 15 growers with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[41] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and reimbursement of their production cost through sales) is transferred from the incumbent grower to new growers. This means that there is no new cost; instead, there is only a transfer of economic activity. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[42]

Transitioning from one large grower to multiple smaller growers may reduce production efficiency, driving up cost. Some growers may introduce more costly growing techniques in order to produce certain traits. Alternatively, some growers may introduce more efficient growing methods, driving down cost. Additionally, having more growers may spur more demand in bulk marihuana for research, pushing up the MQ. However, DEA does not have a basis to estimate the impact of these possibilities.

Impact on Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that the researcher will acquire the bulk marihuana from DEA, rather than from NIDA or the National Center. As discussed earlier, the only new cost associated with this regulation is the cost to DEA of $651,318, which will be recovered by adding an administrative fee of $326 per kg. As discussed earlier, the administrative fee will be adjusted annually. While purchasers will purchase marihuana from DEA, this rule does not in any way affect the purchasers' source of funds to purchase from DEA. If marihuana for research is funded by a third party, the researcher may not experience any cost increase.

Affected Number of Small Entities

This rule affects the current and prospective bulk manufacturers of marihuana for research and researchers. Based on the discussion above, DEA anticipates up to 15 bulk manufacturers are affected by this rule. Additionally, based on a discussion with NIDA,[43] DEA estimates 40 researchers are affected by this rule. The 40 researchers represent the approximate number of researchers that receive marihuana from NIDA's marihuana DSP.

Based on a review of representative North American Industry Classification System (NAICS) codes for bulk manufacturers and researchers, the following number of firms may be affected: [44]

- 421 firms related to 'Medicinal and Botanical Manufacturing' (325411) [45]
- 9,634 firms related to 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712) [46]

The United States Small Business Administration (SBA) sets size standards that determine how large an entity can be and still qualify as a small business for Federal government programs. For the most part, size standards are based on the average annual receipts or the average number of employees of a firm. The SBA size standard for both industries identified by the NAICS codes above is 1,000 employees.[47]

Comparing the SBA size standards to the U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) detailed data on establishment size by NAICS code for each affected industry, DEA estimates the following number of small entities and percent of firms that are small entities by industry:

- 392 (93.1 percent of total) firms in the area of 'Medicinal and Botanical Manufacturing' (325411)
- 9,090 (94.4 percent of total) firms in the area of 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712)

Table 4 details the calculation for the number of small entities by industry.

[38] Marijuana Plant Material Available from the NIDA Drug Supply Program, National Institute on Drug Abuse, *https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program/marijuana-plant-material-available-nida-drug-supply-program.*

[39] *See* note 23.

[40] Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (2016). This rule supersedes the 2016 policy statement.

[41] 21 U.S.C. 826(a).

[42] The phrase ''multiple growers'' includes the possibility that the current grower is one of the ''multiple growers.''

[43] Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

[44] For the purposes of this analysis, the term ''firms'' is synonymous with ''entities.''

[45] 2015 SUSB Annual Datasets by Establishment Industry, U.S. & States, NAICS, Detailed Employment Sizes (U.S., 6-digit and States, NAICS Sectors), United States Census Bureau, *https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html.*

[46] *Ibid.*

[47] Table of Small Business Size Standards Matched to North American Industry Classification System Codes, United States Small Business Association (Oct. 1, 2017). The NAICS code was updated for 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' from 541712 to 541715. The 2015 SUSB data uses 541712 and the 2017 SBA size standard uses 541715 for the same industry.

TABLE 4—NUMBER OF SMALL ENTITIES BY INDUSTRY

NAICS description	Firm size by average employees	Firms	SBA size standard	Small entities	% small entities
325411—Medicinal and Botanical Manufacturing	<500	384	1,000	384	100
	500–749	3		3	100
	750–999	5		5	100
	1,000–1,499	6			0
	1,500–1,999	2			0
	2,000–2,499	1			0
	2,500–4,999	7			0
	5,000+	13			0
	Total	421		392	93.1
541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology).	<500	8,972	1,000	8,972	100
	500–749	68		68	100
	750–999	50		50	100
	1,000–1,499	70			0
	1,500–1,999	40			0
	2,000–2,499	35			0
	2,500–4,999	132			0
	5,000+	267			0
	Total	9,634		9,090	94.4

Applying the calculated respective percentage for small entities to the number of affected bulk manufacturers and researchers, DEA estimates 14 (15 × 93.1 percent) bulk manufacturers and 38 (40 × 94.4 percent) researchers, for a total of 52 small entities, will be affected by this rule. The 14 affected small entity bulk manufacturers represent four percent of the estimated 392 small entities in the 'Medicinal and Botanical Manufacturing' (325412) industry, and the 38 affected small entity researchers represent 0.4 percent of the estimated 9,090 small entities in the 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712) industry. Table 5 summarizes the calculations for the percentage of small entities that are affected by the rule.

TABLE 5—PERCENT OF SMALL ENTITIES AFFECTED BY INDUSTRY

NAICS description	Number of firms	SBA size standard	Estimated number of small entities	Estimated number of affected small entities	Percentage of small entities affected
325411—Medicinal and Botanical Manufacturing	421	1,000	392	14	4
541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)	9,634	1,000	9,090	38	0.4
Total	10,055	N/A	9,482	52	N/A

DEA generally uses a threshold of 30 percent as a ''substantial'' number of affected small entities. Thus, the above analysis reveals that a non-substantial amount of small bulk manufacturer entities (4 percent) and of small researcher entities (0.4 percent) will be affected by this rule.

DEA generally considers impacts that are greater than three percent of annual revenue to be a ''significant economic impact'' on an entity. As discussed earlier, DEA estimates that there will be a new cost to DEA of $611,952 to $690,684 per year, or the average of the high and low estimates of $651,318 per year. DEA will recover the costs of carrying out the new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis. Based on the average of the high and low estimates of $651,318 and MQ of 2,000 kgs, the administrative fee is $326 per kg, adjusted annually.

Furthermore, NIH-funded or other third-party funded researchers are likely to request and receive enough funding for the full price of marihuana, including the administrative fee. There will be no impact to these researchers. However, DEA does not have sufficient information to estimate the number of small entity researchers that will fall under this category. Although DEA is unable to quantify the economic impact for the estimated 14 small entity bulk manufacturers and 38 small entity researchers, the number of affected small entity manufacturers and researchers is not a substantial number of small entities in their respective industries.

Based on the analysis above, and because of these facts, DEA believes this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* DEA has determined that this action will not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' *See* 2 U.S.C. 1532(a). Therefore, neither

a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3521, DEA is revising existing information collection 1117–0012. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *https://www.reginfo.gov/.*

A. Collections of Information Associated With the Rule

Title: Application for Registration (DEA Form 225); Renewal Application for Registration (DEA Form 225A); Affidavit for Chain Renewal (DEA Form 225B).

OMB control number: 1117–0012.

Form numbers: DEA–225, DEA–225A, DEA–225B.

Type of information collection: Revision of a currently approved collection.

Applicable component of the department sponsoring the collection: Department of Justice/Drug Enforcement Administration, Diversion Control Division.

Affected public who will be asked or required to respond: Business or other for-profit.

Abstract: The Controlled Substances Act requires all businesses and individuals who manufacture, distribute, import, export, or conduct research and laboratory analysis with controlled substances to register with DEA. 21 U.S.C. 822; 21 CFR 1301.11, 1301.13. Registration is a necessary control measure that helps to detect and prevent diversion by ensuring that the closed system of distribution of controlled substances can be monitored by DEA, and that the businesses and individuals handling controlled substances are accountable.

This rule amends the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. Persons seeking to become registered with DEA to grow marihuana as bulk manufacturers will still apply for registration using the same DEA Form 225 as other bulk manufacturers, but there will be a new supplemental questionnaire unique to marihuana manufacturers in order to gather additional information about applicants. There will also be new questionnaires used for importer applicants and non-marihuana bulk manufacturer applicants. Forms 225, 225A, and 225B will all receive minor revisions to improve clarity and usability for registrants.

DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 15,919.
- *Frequency of response:* 1 per respondent per year.
- *Number of responses:* 15,919.
- *Burden per response:* 0.1304 hours.
- *Total annual burden in hours:* 2,076.

If you need a copy of the proposed information collection instruments with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152–2639; Telephone: (571) 362–3261.

At this point, any comments related to this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB54/Docket No. DEA–506.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. DEA submitted a copy of the final rule to both Houses of Congress and to the Comptroller General.

National Environmental Policy Act

DEA has analyzed the impacts of this Final Rule on the human environment pursuant to the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* and has determined that it is categorically excluded under 28 CFR part 61, Appendix B. Categorical exclusions are actions identified in an agency's NEPA implementing procedures that normally do not have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant preparation of an EA or EIS. This action is covered by the categorical exclusion for registration of persons authorized to handle controlled substances listed in 28 CFR part 61, Appendix B.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1318

Administrative practice and procedure, Drug traffic control.

For the reasons stated in the preamble, DEA amends 21 CFR chapter II as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

■ 2. In § 1301.33, revise paragraph (c) and add paragraph (d) to read as follows:

§ 1301.33 Application for bulk manufacture of Schedule I and II substances.

* * * * *

(c) Except as provided in paragraph (d) of this section, this section shall not apply to the manufacture of basic classes of controlled substances listed in Schedule I or II as an incident to research or chemical analysis as authorized in § 1301.13(e)(1).

(d) An application for registration to manufacture marihuana that involves the planting, cultivating, growing, or harvesting of marihuana shall be subject to the requirements of this section and the additional requirements set forth in part 1318 of this chapter.

■ 3. Add part 1318 to read as follows:

PART 1318—CONTROLS TO SATISFY THE REQUIREMENTS OF THE ACT APPLICABLE TO THE MANUFACTURING OF MARIHUANA

Sec.

1318.01 Scope of this part.
1318.02 Definitions.
1318.03 Implementation of statutory requirements.
1318.04 Specific control measures applicable to the bulk manufacture of marihuana.

1318.05 Application of the public interest factors.
1318.06 Factors affecting prices for the purchase and sale by the Administration of cannabis.
1318.07 Non-liability of the Drug Enforcement Administration.

Authority: 21 U.S.C. 801(7), 821, 822(a)(1), (b), 823(a), 871(b), 886a.

§ 1318.01 Scope of this part.

Procedures governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest marihuana are set forth by this part.

§ 1318.02 Definitions.

(a) Except as provided in paragraph (e) of this section, the term *cannabis* means any plant of the genus Cannabis.

(b) Except as provided in paragraph (e) of this section, the term *medicinal cannabis* means a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act.

(c) Except as provided in paragraph (e) of this section, the term *cannabis preparation* means cannabis that was delivered to the Administration and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis, cannabis resin, or extracts of cannabis.

(d) Except as provided in paragraph (e) of this section, the term *cannabis resin* means the separated resin, whether crude or purified, obtained from the cannabis plant.

(e) As used in this part, the terms *cannabis, medicinal cannabis,* and *cannabis preparation* do not include any material, compound, mixture, or preparation that falls outside the definition of marihuana in section 102(16) of the Controlled Substances Act (the Act) (21 U.S.C. 802(16)).

(f) The term *Single Convention* means the Single Convention on Narcotic Drugs, 1961 (18 U.S.T. 1407).

(g) The term *bona fide supply agreement* means a letter of intent, purchase order or contract between an applicant and a researcher or manufacturer registered under the Act.

(h) The term *registered researcher or manufacturer* means a person registered under the Act to perform research or manufacture of marihuana in Schedule I.

§ 1318.03 Implementation of statutory requirements.

(a) As provided in section 303(a) of the Act (21 U.S.C. 823(a)), the Administrator may grant an application for a registration to manufacture marihuana, including the cultivation of cannabis, only if he determines that such registration is consistent with the public interest and with United States obligations under the Single Convention.

(b) In accordance with section 303(a) of the Act and § 1301.44(a) of this chapter, the burden shall be on the applicant to demonstrate that the requirements for such registration have been satisfied.

§ 1318.04 Specific control measures applicable to the bulk manufacture of marihuana.

For a registration to manufacture marihuana that involves the cultivation of cannabis, the following provisions must be satisfied:

(a) All registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis to the Administration, except as provided in paragraph (d). The Administration shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest. The Administration may accept delivery and maintain possession of such crops at the registered location of the registered manufacturer authorized to cultivate cannabis consistent with the maintenance of effective controls against diversion. In such cases, the Administration shall designate a secure storage mechanism at the registered location in which the Administration may maintain possession of the cannabis, and the Administration will control access to the stored cannabis. If the Administration determines that no suitable location exists at the registered location of the registered manufacturer authorized to cultivate cannabis, then the Administration shall designate a location for the authorized grower to deliver the crop as soon as possible, but not later than four months after the end of the harvest. However, in all cases the registrant must comply with the security requirements specified in part 1301 of this chapter.

(b) The Administration shall, with respect to cannabis, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. Such exclusive right shall not extend to medicinal cannabis or cannabis preparations. The Administration may exercise its exclusive right by authorizing the performance of such activities by appropriately registered persons. The Administration shall require prior written notice of each proposed importation, exportation, or distribution of cannabis that specifies the quantity of cannabis to be imported, exported, or distributed and the name, address, and registration number of the registered manufacturer or researcher to receive the cannabis before authorizing the importation, exportation, or distribution. All importation and exportation shall be performed in compliance with part 1312 of this chapter, as applicable. Under no circumstance shall a registered manufacturer authorized to grow cannabis import, export, or distribute cannabis without the express written authorization of the Administration.

(c) A registered manufacturer authorized to grow cannabis shall notify in writing the Administration of its proposed date of harvest at least 15 days before the commencement of the harvest.

(d) A registered manufacturer authorized to grow cannabis may distribute small quantities of cannabis to a registered analytical lab for chemical analysis by such analytical lab prior to the Administration purchasing and taking physical possession of the crop. The cannabis delivered to the analytical lab under such circumstances need not be delivered to the Administration pursuant to paragraph (a), provided such cannabis is destroyed by the analytical lab upon completion of the testing. Any such distribution of cannabis by a registered manufacturer to a registered analytical lab must comply with all applicable requirements of the Act and this subchapter, including but not limited to security and recordkeeping requirements.

§ 1318.05 Application of the public interest factors.

(a) In accordance with section 303(a) of the Act (21 U.S.C. 823(a)), the Administrator shall consider the public interest factors set forth in paragraphs (a)(1) through (6) of this section:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these

substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) Such other factors as may be relevant to and consistent with the public health and safety.

(b) The Administrator's determination of which applicants to select will be consistent with the public interest factors set forth in section 303(a), with particular emphasis on the following criteria:

(1) Whether the applicant has demonstrated prior compliance with the Act and this chapter;

(2) The applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition; and

(3)(i) In determining under section 303(a)(1) of the Act (21 U.S.C. 823(a)(1)) the number of qualified applicants necessary to produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions, the Administrator shall place particular emphasis on the extent to which any applicant is able to supply cannabis or its derivatives in quantities and varieties that will satisfy the anticipated demand of researchers and other registrants in the United States who wish to obtain cannabis to conduct activities permissible under the Act, as demonstrated through a bona fide supply agreement with a registered researcher or manufacturer as defined in this subpart.

(ii) If an applicant seeks registration to grow cannabis for its own research or product development, the applicant must possess registration as a schedule I researcher with respect to marihuana under § 1301.32 of this chapter. As specified in § 1301.13 of this chapter, chemical analysis and preclinical research (including quality control analysis) are not coincident activities of a manufacturing registration for schedule I substances, including cannabis. In determining under section 303(a)(1) of the Act (21 U.S.C. 823(a)(1)) the number of qualified applicants necessary to produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions, the Administrator shall consider the holding of an approved marihuana research protocol by a registered schedule I researcher seeking to grow cannabis for its own research or product development as evidence of the necessity of the applicant's registration under this factor.

(c) Applications accepted for filing after January 19, 2021 will not be considered pending for purposes of paragraph (a) of this section until all applications accepted for filing on or before January 19, 2021 have been granted or denied by the Administrator. Where an application is subject to section 303(i) of the Act (21 U.S.C. 823(i)), that section shall apply in lieu of this paragraph (c).

(d) In determining the legitimate demand for cannabis and its derivatives in the United States, the Administrator shall consult with the U.S. Department of Health and Human Services, including its components.

§ 1318.06 Factors affecting prices for the purchase and sale by the Administration of cannabis.

(a) In accordance with section 111(b)(3) of Public Law 102–395 (21 U.S.C. 886a(1)(C)), seeking to recover the full costs of operating the aspects of the diversion control program that are related to issuing registrations that comply with the Controlled Substances Act, the Administration shall assess an administrative fee. To set the administrative fee, the Administration shall annually determine the preceding fiscal year's cost of operating the program to cultivate cannabis and shall divide the prior fiscal year's cost by the number of kgs of cannabis authorized to be manufactured in the current year's quota to arrive at the administrative fee per kg. The administrative fee per kg shall be added to the sale price of cannabis purchased from the Administration. The administrative fee shall be paid to the Diversion Control Fee Account.

(b) As set forth in § 1318.04, the Administration shall have the exclusive right of, among other things, wholesale trading in cannabis that it purchases from registered manufacturers. The Administration will, therefore, buy from such manufacturer, sell cannabis to registered researchers and manufacturers, and establish prices for such purchase and sale. The Administration will set such prices in the following manner:

(1) Bulk growers of cannabis shall negotiate directly with registered researchers and manufacturers authorized to handle cannabis to determine a sale price for their cannabis. Upon entering into a contract for the provision of bulk cannabis and prior to the exchange of cannabis, the parties shall pay to the Administration an administrative fee assessed based on the number of kgs to be supplied. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

(2) The Administration shall sell the cannabis to the buyer at the negotiated sale price plus the administrative fee assessed on a per kg basis. Prior to the purchase of the cannabis by the Administration, the buyer shall pay the negotiated purchase price and administrative fee to the Administration. The Administration shall hold funds equal to the purchase price in escrow until the delivery of the cannabis by the grower to the Administration. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

(3) After receiving the purchase price and administrative fee from the buyer, the Administration shall purchase the cannabis from the grower, on behalf of the buyer, at the negotiated sale price. The Administration shall retain the administrative fee. In the event the buyer fails to pay the purchase price and the administrative fee, the Administration shall have no obligation to purchase the crop and may order the grower to destroy the crop if the grower cannot find an alternative buyer within four months of harvest.

(4) In instances where the grower of the cannabis is the same entity as the buyer of the cannabis, or a related or subsidiary entity, the entity may establish a nominal price for the purchase of the cannabis. The Administration shall then purchase the entity's cannabis at that price and sell the cannabis back to the entity, or a related or subsidiary entity, at the same price with the addition of the administrative fee.

(c) Administrative fees set in accordance with this part will be made available, on an updated basis, on the Administration's website, no later than December 15th of the year preceding the year in which the administrative fee will be collected.

(d) Nothing in this section shall prohibit the U.S. Department of Health and Human Services from continuing to fund the acquisition of cannabis for use in research by paying, directly or indirectly, the purchase cost and administrative fee to the Administration.

§ 1318.07 Non-liability of Drug Enforcement Administration.

The Administration shall have no liability with respect to the performance of any contractual terms agreed to by a grower and buyer of bulk cannabis, including but not limited to the quality of any cannabis delivered to a buyer. In

the event that a buyer deems the delivered cannabis to be defective, the buyer's sole remedy for damages shall be against the grower and not the Administration.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–27999 Filed 12–17–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9925]

RIN 1545–BP23

Meals and Entertainment Expenses Under Section 274; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations; correction.

SUMMARY: This document contains corrections to the final regulations (Treasury Decision 9925) that published in the **Federal Register** on October 9, 2020. The final regulations provide guidance under section 274 of the Internal Revenue Code (Code) regarding certain recent amendments made to that section. Specifically, the final regulations address the elimination of the deduction under section 274 for expenditures related to entertainment, amusement, or recreation activities, and provide guidance to determine whether an activity is of a type generally considered to be entertainment.

DATES: These corrections are effective on December 18, 2020 and applicable for taxable years that begin on or after October 9, 2020.

FOR FURTHER INFORMATION CONTACT: Patrick Clinton of the Office of the Associate Chief Counsel (Income Tax and Accounting), (202) 317–7005 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9925) that are the subject of this correction are issued under section 274 of the Internal Revenue Code.

Need for Correction

As published the final regulations (TD 9925) contain errors that need to be corrected.

Correction of Publication

Accordingly, the final regulations (TD 9925), that are the subject of FR Doc. 2020–21990, published on October 9, 2020 (85 FR 64026), are corrected as follows:

1. On page 64031, third column, the second line, the language ''*in Sutherland Lumber*'' is corrected to read ''in *Sutherland Lumber-Southwest*''.

2. On page 64031, third column, the ninth line of the second full paragraph, the language ''§ 1.274–10(a)(2)(ii)(C)(2)'' is corrected to read ''§ 1.274–10(a)(2)(ii)(C)(*2*)''.

3. On page 64032, second column, the second line, the language ''or gross income is zero, whether zero is'' is corrected to read ''or gross income is zero (other than due to a reimbursement by the recipient), whether zero is''.

4. On page 64032, second column, the thirteenth line from the top of the page, the language ''(e)(9) do not apply.'' is corrected to read ''(e)(9) generally do not apply.''.

5. On page 64032, second column, the thirteenth line from the top of the page, the language ''Similarly, the exceptions in section 274(e)(2) and (e)(9) do not apply if'' is corrected to read ''However, the exceptions in section 274(e)(2) and (e)(9) will apply if the recipient reimburses the taxpayer for a portion of the value of the food or beverages even if the value exceeding the reimbursed amount is properly excluded from the recipient's compensation and wages or gross income. In this case, however, the taxpayer must apply the dollar-for-dollar rule as described in § 1.274–12(c)(2)(i)(D). In cases in which''.

6. On page 64032, second column, the second and last sentence from the bottom of the first partial paragraph, remove the language ''. In that case, however,''.

7. On page 64032, third column, the third line of the second full paragraph, the language ''regulations confirm'' is corrected to read ''regulations confirmed''.

8. On page 64032, third column, the twelfth line of the second full paragraph, the language ''demonstrates'' is corrected to read ''demonstrated''.

Crystal Pemberton,

Senior Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2020–26860 Filed 12–17–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2020–0694]

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Madeira Beach FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Welch Causeway (SR 699) Bridge, mile 122.8 at Madeira Beach, Florida. A request was made to place the drawbridge on a daily operating schedule to alleviate vehicle congestion due to on demand bridge openings. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. The Coast Guard is seeking comments from the public regarding these proposed changes.

DATES: This deviation is effective from 12:01 a.m. on January 1, 2021 through 11:59 p.m. on June 25, 2021.

Comments and relate material must reach the Coast Guard on or before February 25, 2021.

ADDRESSES: You may submit comments identified by docket umber USCG–2020–0694 using Federal eRulemaking Portal at *https://www.regulations.gov.*

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this test deviation, call or email LT Clark W. Sanford, U.S. Coast Guard, Sector Saint Petersburg Waterways Management Division; telephone 727–824–7506, email *Clark.W.Sanford@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Background, Purpose and Legal Basis

The Welch Causeway (SR699) Bridge across the Gulf Intracoastal Waterway, mile 122.8, at Madeira Beach, Florida is a double-leaf bascule bridge with a 25 foot vertical clearance at mean high water in the closed position and an 89 foot horizontal clearance between fenders. The normal operating schedule for the bridge is found in 33 CFR 117.287(h). Navigation on the waterway is commercial and recreational.

The City of Madeira Beach Florida has requested the current operating

schedule be modified due to the increased economic growth, vehicle traffic in the area as well as a school located in close proximity to the bridge. The City of Madeira Beach requested the bridge operation logs from the bridge owner, Florida Department of Transportation (FDOT) to validate the need for a regulation change. The Coast Guard has reviewed these logs as well and determined a test deviation is needed before proceeding with a rule change for the operation of this bridge.

Under this test deviation, from 7 a.m. to 7 p.m., the draw shall open on the hour and half-hour; except Federal Holidays and at all other times, the draw shall operate on demand.

The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

II. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this notification as being available in this docket and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

Dated: December 2, 2020.

Randall D. Overton,

Director, Bridge Administration, Seventh Coast Guard District.

[FR Doc. 2020–27443 Filed 12–17–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2020–0708]

Safety Zones; Annual Firework Displays Within Captain of the Port, Puget Sound Area of Responsibility

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce one safety zone for an annual firework display in the Area of Responsibility of the Captain of the Port Sector Puget Sound. This action is necessary to protect life and property from hazards associated with the firework display. During the enforcement periods, entry into, transit through, mooring, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Sector Puget Sound or a Designated Representative.

DATES: The regulations in 33 CFR 165.1332 will be enforced for Alderbrook Resort & Spa Fireworks display from 5 p.m. on December 31, 2020, through 1 a.m. on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Peter J. McAndrew, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone 206–217–6051, email *SectorPugetSoundWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce regulations in 33 CFR 165.1332 for the safety zone established for Annual Fireworks Displays in Hood Canal. These regulations will be enforced from 5 p.m. on December 31, 2020, through 1 a.m. on January 1, 2021, at the following locations:

Event name	Location	Latitude	Longitude
Alderbrook Resort & Spa Fireworks	Hood Canal	47°21.033′ N	123°04.1′ W.

This action is necessary to provide for the safety of life on navigable waterways during this event. Our annual fireworks displays and other events in the Area of Responsibility of the Captain of the Port Sector Puget Sound (AOR) that require safety zones are listed in 33 CFR 165.1332. During the enforcement periods, as reflected in § 165.1332 (d), no vessel operator may enter, transit, moor, or anchor within this safety zone, except for vessels authorized by the Captain of the Port or Designated Representative.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via a Broadcast Notice to Mariners and a Local Notice to Mariners.

Dated: December 7, 2020.

P.M. Hilbert,

Captain, U.S. Coast Guard, Captain of the Port Sector Puget Sound.

[FR Doc. 2020–27255 Filed 12–17–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0713]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, Natchez, MS

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Lower Mississippi River (LMR), between Mile Marker 368 and 370. The safety zone is needed to protect persons, property, infrastructure, and the marine environment from the potential safety hazards associated with line pulling operations in the vicinity of the Natchez, MS. Entry of persons or vessels into this zone is prohibited unless authorized by the Captain of the Port Sector Lower Mississippi River or a designated representative.

DATES: This rule is effective without actual notice on December 18, 2020. For the purposes of enforcement, actual notice will be used from December 9, 2020 until December 17, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0713 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MSTC Lindsey Swindle, U.S. Coast Guard; telephone 901–521–4813, email *Lindsey.M.Swindle@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. Immediate action is needed to protect persons and property from the potential safety hazards associated with line pulling operations. The NPRM process would delay the establishment of the safety zone until after the date of the event and compromise public safety.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the line pulling operations in the vicinity of Natchez, MS.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP) Sector Lower Mississippi River (LMR) has determined that potential hazards associated with the line pulling operations at Mile Marker (MM) 369.0, scheduled to start on December 9, 2020, would be a safety concern for all persons and vessels on the Lower Mississippi River between MM 368.0 and MM 370.0 through December 18, 2020. This rule is needed to protect persons, property, infrastructure, and the marine environment in all waters of the LMR within the safety zone while line pulling operations are being conducted.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from December 9, 2020 to December 18, 2020. The safety zone will cover all navigable waters of the LMR from MM 368.0 to MM 370.0. The duration of this safety zone is intended to ensure the safety of waterway users on these navigable waters during, the line pulling operations.

Entry of persons or vessels into this safety zone is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Lower Mississippi River. Persons or vessels seeking to enter the safety zones must request permission from the COTP or a designated representative on VHF–FM channel 16 or by telephone at 901–521–4822. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative. The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, and duration of the safety zone. Vessel traffic will be prohibited from entering this safety zone, which will impact a one-mile stretch of Lower Mississippi River for only 6 days. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the safety zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a

significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit entry on a one-mile stretch of the Lower Mississippi River. It is categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of UDHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0713 to read as follows:

§ 165.T08–0713 Safety Zone; Lower Mississippi river, Natchez, MS.

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River from Mile Marker (MM) 368 through MM 370.

(b) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Lower Mississippi River (COTP) or the COTP's designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Lower Mississippi River.

(2) To seek permission to enter, contact the COTP or the COTP's representative via VHF–FM channel 16 or by telephone at 901–521–4822. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(c) *Enforcement period.* This rule is effective without actual notice on December 18, 2020. For the purposes of enforcement, actual notice will be used from December 9, 2020 until December 17, 2020.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts, as appropriate.

Dated: December 8, 2020.

R.S. Rhodes,

Captain, U.S. Coast Guard, Captain of the Port Sector Lower Mississippi River.

[FR Doc. 2020–27418 Filed 12–17–20; 8:45 am]

BILLING CODE 9110–04–P

GENERAL SERVICES ADMINISTRATION

41 CFR 102–34

[Notice-MA–2020–13; Docket No. 2020–0002; Sequence No. 36]

Use of Government-Issued Fleet Charge Cards Guidance

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Availability of GSA Bulletin FMR B–53, Motor Vehicle Management.

SUMMARY: This Federal Management Regulation (FMR) bulletin recommends Federal agencies establish policies addressing Government-issued fleet charge card compliance with Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Pub. L. 115–232) and security risks associated with fleet charge card transactions.

DATES: *Applicability Date:* December 18, 2020.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Mr. James Vogelsinger, Director, Vehicle Policy Division, GSA, at 202–501–1764, or email *vehicle.policy@gsa.gov.* Please cite Notice of FMR Bulletin B–53.

SUPPLEMENTARY INFORMATION:

Background: Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Pub. L. 115–232) prohibits contracting with entities that use certain telecommunications and video surveillance services or equipment. This bulletin makes Federal agencies aware of this prohibition and recommends that agencies establish policies that facilitate compliance when a Government-issued fleet charge card is used to acquire fuel or maintenance services for Government motor vehicles.

This bulletin also recommends policies and practices agencies and charge card users may implement to lessen the security risks associated with fleet charge card transactions.

This bulletin can be viewed at *www.gsa.gov/reference/gsa-bulletins.*

Jessica Salmoiraghi,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2020–26378 Filed 12–17–20; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 5000, 5400, 5420, 5440, 5450, 5460, 5470 and 5500

[LLHQ200000 L63000000 PH0000 21X]

RIN 1004–AE61

Forest Management Decision Protest Process and Timber Sale Administration

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: Through this final rule, the Bureau of Land Management (BLM) is amending its regulations governing protests of forest management decisions and administration of the timber sale process. This final rule will streamline the process for active forest management by the BLM. The BLM has promulgated this final rule to address poorly defined, repetitive, and burdensome regulatory requirements. This final rule will improve the BLM's ability to conduct active forest management, while reducing burdens to the public and the administration of BLM-managed lands.

DATES: This final rule is effective on January 19, 2021.

Information Collection Requirements: If you wish to comment on the information collection requirements in this final rule, please note that the Office of Management and Budget (OMB) is required to make a decision concerning the collection of information contained in this final rule between 30 and 60 days after publication in the **Federal Register**. Therefore, comments should be submitted to OMB by January 19, 2021.

ADDRESSES: *Information Collection Requirements:* Written comments and recommendations for this information collection should be sent within 30 days of publication of this document to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Darrin King, Information Collection Clearance Officer, Attention PRA Office, Bureau of Land Management, 440 W 200 S #500, Salt Lake City, UT 84101 or by email to *BLM_HQ_PRA_Comments@blm.gov.* Please reference OMB Control Number 1004–0058 and RIN 1004–AE61 in the subject line of your comments. Please note that due to COVID–19, electronic submission of comments is recommended.

FOR FURTHER INFORMATION CONTACT: Marlo Draper, Division Chief of Forest, Rangeland, and Vegetation Resources, HQ–220, 208–373–3812. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day,7 days a week, to leave a message or question with the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

I. Background
II. Discussion of the Changes to the Existing Forest Management Rule and Changes From the Proposed Rule to Final Rule
III. Procedural Matters

I. Background

The BLM initiated this rulemaking on June 8, 2020, through publication of a notice of proposed rulemaking in the **Federal Register** seeking public comment for 60 days (85 FR 35049). The comment period closed on August 7, 2020, and the BLM received a total of 2,760 comments. The BLM received comments from individuals, organizations, business, county, state, and Federal entities or representatives. The BLM has provided a summary of substantive comments and its response to the comments in the discussion section of this final rule.

This final rule revises the BLM's regulations addressing its forest management decision process, sales of forest products, preparation for sale, award of contract, contract modifications, and non-sale disposal.

Pursuant to the Oregon and California Grant Lands Act (O&C Act) and the Coos Bay Wagon Road Grant Lands Act (CBWR Act) (43 U.S.C. 2601 *et seq.*), jointly referred to as the O&C Act, the BLM is required to manage approximately 2.4 million acres of lands in Western Oregon for forest production in conformity with the principle of sustained yield. In accordance with the O&C Act, the BLM declares the allowable sale quantity (ASQ) of timber for each sustained yield unit in its Resource Management Plans (RMPs) for western Oregon and then offers for sale a volume of timber equal to the declared ASQ on an annual basis. *See Swanson* v. *Bernhardt,* No. 1:15–cv–01419 (D.D.C.) (September 30, 2019 Order). The O&C Act is a dominant use statute for sustained yield timber production. Under the Materials Act of 1947 (30 U.S.C. 601 *et seq.*); and other legal authorities, the BLM is authorized to convey timber and other vegetative materials on other lands that the BLM

administers. The Federal Land Policy and Management Act (FLPMA) (43 U.S.C. 1701 *et seq.*) charges the BLM with managing public lands on the basis of multiple use and sustained yield, unless otherwise specified by law.

The regulations pertaining to the Administration of Forest Management Decisions (43 CFR part 5000) were promulgated in 1984 (49 FR 28561 (July 13, 1984)), and 43 CFR part 5400 pertaining to the Sale of Forest Products were promulgated beginning in 1970 (35 FR 9785, June 13, 1970). These regulations were adopted to implement the Materials Act and the O&C Act. The BLM has amended these regulations since their original promulgation to expedite implementation of decisions relating to forest management, to improve agency procedures, and to update the regulations for consistency with statutory changes.

In 1984, the BLM proposed to add a 15-day public-protest process to certain forest management decisions, including advertised timber sales. This measure was expected to ''expedite implementation of decisions relating to timber management'' and ''increase the probability that private businesses dependent upon the Bureau of Land Management's timber management contracts would be able to accomplish their regularly scheduled activities'' (49 FR 3884, Jan. 31, 1984). The BLM issued a final rule adopting a 15-day protest period and establishing that filing a notice of appeal with the Interior Board of Land Appeals under 43 CFR part 4 does not automatically suspend the effect of forest management decisions that are posted and protested as described under 43 CFR 5003.2 and 5003.3 later that year. The BLM has not revised the protest process since the final rule was issued in 1984, although the way that the BLM plans forest management projects and completes the environmental review of these projects has changed significantly since that time.

When the forest management rules were promulgated in 1984, the BLM designed individual timber sales that were based on the location and extent of the forest management activity. Over time, the BLM has changed the way it designs its timber sales and other forest management projects and often conducts its environmental review on multiple projects in a single watershed or on a biologically relevant scale, such as wildlife habitat for a particular species. Moreover, the BLM promotes collaboration and information-sharing during the National Environmental Policy Act (NEPA) process and concurrent RMP process, and today more interested individuals and parties participate in the public involvement opportunities during the decision-making process when their input is most helpful. While the protest process was originally proposed to ''expedite implementation of decisions relating to timber management,'' in some cases today individuals and organizations that are not satisfied with the final forest management decision are using the protest process to delay implementation by filing lengthy protests with the same comments that were previously raised during the NEPA process and with no explanation of how the BLM failed to address these previously submitted comments. Responding to these protests can be costly to the BLM in terms of time and other resources, and in many cases may not improve the agency decision or reduce appeals and litigation.

The final rule eliminates the current administrative protest process after a forest management decision is issued. This change will facilitate expeditious development and implementation of forest management decisions while encouraging the BLM to consider relevant information earlier in its decision-making process, including in comments on any RMP or NEPA documents that the BLM circulates for public review. Under the existing regulations, the BLM regularly issued forest management decisions that could not be protested until the BLM issued a notice of an advertised timber sale, which, in many cases, occurred long after the completion of environmental review. The final rule streamlines the procedures governing forest management decisions by allowing a single forest management decision to cover all forest management activities covered in an environmental review document. This change allows the public to identify any resource conflicts or other issues of concern earlier in the BLM's forest management process and enhances the BLM's ability to resolve those issues before it advertises a timber sale or implements other forest management activities. The final rule also improves administrative efficiencies by allowing the BLM to simultaneously address issues associated with multiple individual sales and other forest management activities in a single decision. In addition, many of the BLM's decisions are time sensitive in nature, such as fire resilience thinning, thinning for insect and disease resilience, or post-fire salvage sales. The changes will help the BLM be more responsive to developing forest health issues and identified wildfire risks. In western Oregon, the final rule will help the BLM to more expeditiously offer timber sales on O&C lands in order to achieve the declared ASQ in accordance with the O&C Act.

The final rule will facilitate the BLM's use of communications technology by requiring the BLM to make decisions available online on a designated agency website, in addition to other means of notification. These changes will increase efficiency for both the public and the BLM.

Additionally, the final rule contains multiple updates and revisions to part 5400 Sale of Forest Products. This rule amends the regulations to conform to statutes prohibiting the export of unprocessed Federal timber and makes changes that will allow the BLM to be more innovative and more effectively administer scale sales. In general, the final rule provides better clarity of the terms and conditions the BLM may include in future sale contracts and gives the BLM greater flexibility to conduct sales efficiently.

II. Discussion of the Final Rule and Comments on the Proposed Rule

Part 5000 Administration of Forest Management Decisions

While a protest process for forest management decisions is not required by statute, the BLM's existing regulations at 43 CFR 5003.3 included a discretionary protest process available for certain authorizations relating to forest management. This discretionary protest process was largely duplicative of other opportunities for public involvement, including through the NEPA process. In general, the best opportunity to influence management of resources is during the early stages of decision-making and not after the issuance of a decision or the publication of a notice of decision. At least in some instances, the protest process added time and expense to the decision-making process, contrary to the express purpose of the 1984 rulemaking; did not avert administrative appeals and judicial litigation as evidenced by the numerous appeals and multiple lawsuits since 1984; and, most importantly, cannot be shown to have produced better BLM decisions and resource management outcomes than could have otherwise occurred. For example, the BLM reviewed 1,560 timber sale decisions from 2002 to 2017 that showed that 26 percent of the total volume those sales represented was protested. The average time between advertisement (also the beginning of the protest period) and award of those protested sales was 251 days. In

addition, a significant number of timber sales are developed to reduce the potential for high-severity wildfire. Prolonged decision-making processes under the existing regulations delayed implementation of critical wildfire mitigation treatments that often had the objective of protecting human health and safety, and which may need to be implemented during a narrow window to take advantage of favorable weather. To address these issues, the BLM's final rule eliminates the protest process. The final rule maintains the public's ability to appeal those decisions to the Interior Board of Land Appeals (IBLA) or challenge them in Federal court.

The final rule adds a definition of ''forest management activity,'' and specifies how the BLM must provide notice of forest management decisions.

Section 5003.1 Effect of Decisions; General

The revision to 43 CFR 5003.1(a) clarifies that forest management decisions issued under § 5003.2 may, at the discretion of the authorized officer, be implemented immediately or at a different date specified in the decision. Under existing regulations, the BLM could make decisions effective immediately after denial of protest in § 5003.3(f). The revision also clarifies that forest management decisions are not automatically stayed under 43 CFR 4.21(a) if notice of appeal or a petition for a stay pending appeal is filed with the IBLA which is the same as in the existing rule. The BLM did not make changes to § 5003.1 between the proposed and final rule.

Comment: The BLM received comments suggesting that removal of the administrative protest process, allowing the BLM to implement a forest management decision immediately, and specifying that filing a notice of appeal and a petition for a stay pending appeal under 43 CFR part 4 does not automatically suspend the effect of a forest management decision, would not allow for an effective administrative review process for decisions and may result in increased litigation in Federal district court.

Response: The final rule eliminates the administrative protest process because the BLM found it to be redundant considering that under the existing rule the BLM allows for public comment on most proposed forest management decisions during the NEPA and RMP process. The final rule does not eliminate the public's opportunity to seek administrative appeal to the IBLA, nor does it prevent the IBLA from issuing a stay pending appeal where appropriate. Additionally, parties can continue to challenge forest management decisions in Federal court.

In general, the best opportunity to influence management of resources is during the early stages of public comment periods provided during the NEPA process and prior to the formulation of a decision. The final rule does not require the BLM to issue all forest management decisions in full force and effect when forest management decisions are issued. Instead, under the final rule the BLM authorized officer has discretion to determine, on a case-by-case basis, whether to identify a period of time before a decision can be implemented or whether the decision can be implemented immediately, which may be appropriate when authorizing critical wildfire mitigation treatments or help the BLM to more expeditiously offer timber sales on O&C lands in order to achieve the declared ASQ in accordance with the O&C Act. Moreover, under the final rule, once the BLM issues a forest management decision, there are typically additional processes that must occur before any actual on-the-ground work begins, such as advertising and conducting a timber sale auction and awarding a contract. The final rule does not change the ability of the IBLA to issue a stay and does not change any IBLA procedures. Changes to IBLA procedures to expedite cases are outside the scope of this rulemaking.

The final rule revises § 5003.2(a) to include a reference to a new definition for a forest management activity in § 5003.4 and clarifies that the BLM authorizes certain forest management activities by issuing forest management decisions. The BLM added text to § 5003.2 to clarify that to be effective under § 5003.1, the BLM must publish notice of a forest management decision and post the decision on the BLM's website.

The BLM received multiple comments that it does not have authority under the existing regulations to issue forest management decisions in full force and effect. The final rule clarifies the BLM's authority in this regard. The comments also indicated the changes in the proposed rule were not clear.

Under existing § 5003.1(a), the BLM may make those forest management decisions where the BLM provided a protest process effective immediately upon issuance of the protest response. Filing an appeal under 43 CFR part 4, including an appeal with a stay request does not suspend the effectiveness of the decision under the existing regulations. Currently the BLM determines on a case-by-case basis whether to implement the decision immediately.

The final rule retains the BLM's ability in § 5003.1(a) to make certain decisions effective immediately. The BLM also retains the discretion that currently exists whether to go full force and effect on a case-by-case basis. Moreover, to ensure the public has adequate notice that the BLM may use its full force and effect authority under § 5003.1, the BLM has made changes in the final rule to § 5003.2(a) that require the BLM to post all forest management decisions that it may make effective immediately to ensure the public has notice of the activity. Only those decisions that are to be effective under § 5003.1 are required to be posted as described by § 5003.2.

Section 5003.2 Notice of Forest Management Decisions

Revisions in the final rule to § 5003.2(a) change the primary medium of public notice from publication in a newspaper of general circulation in the area where the lands affected by the decision are located to posting the decision on a designated agency website. In general, web-based communication is now more convenient and accessible than print newspapers. In many areas, print newspapers have transitioned to news websites, which makes the notice requirements in the existing regulations impractical in areas that lack print newspapers.

The final rule adopts those changes proposed to § 5003.2(a), which require the authorized officer to post forest management decisions on an agency website and provide notice of a forest management decision by publishing notice in a newspaper of general circulation in the area, sending notice to interested parties directly, or notifying the general public through various means, such as social media, email, or other mass-media. This change is intended to further facilitate notice reaching interested parties, including those who may not have internet access. Section 5003.2(b) also clarifies that the posting and publication of a forest management decision establishes the official date of the decision and not the notice of an advertised timber sale, as is the case under the existing regulations.

Section 5003.3 Reserved

The proposed rule proposed removing the public protest process in existing § 5003.3. The proposed rule, also indicated the BLM was considering replacing the public protest process with a 10-day public comment period, requesting comments on this potential change and other opportunities to foster

public involvement in forest management decisions, such as through the NEPA process. The BLM has elected not to include a 10-day public comment process and is continuing with the elimination of the protest process in the final rule. The protest process is duplicative of the IBLA appeals process and most forest management decisions undergo a NEPA scoping and comment process that allow the public to participate. The original protest period was created administratively to expedite the timber sale process. It has not met its intent as established. As such, the BLM is removing this administratively-created provision to improve the expediency of the process.

Comment: The BLM received comments claiming that eliminating the protest process would violate section 309(e) of FLPMA, and that eliminating the protest process is arbitrary and capricious under the Administrative Procedure Act (5 U.S.C. 706(2)(A)) because the BLM failed to adequately explain the reasons for this change.

Response: The commenters describe how the timber sale protest process is an opportunity for public involvement and suggest that removal of the protest process would be contrary to Section 309(e) of FLPMA. The BLM disagrees.

Section 309(e) of FLPMA states that the Secretary, by regulation, shall establish procedures, including public hearings where appropriate, to give the Federal, State, and local governments and the public adequate notice and an opportunity to comment upon the formulation of standards and criteria for, and to participate in, the preparation and execution of plans and programs for, and the management of, the public lands.

This rule does not change this process. This section vests the Secretary with broad discretion to identify appropriate public participation procedures when promulgating rules relating to the management of public lands. When exercising this authority, the Secretary accounts for the degree to which public participation is appropriate for the preparation and execution of specific BLM plans and programs. Section 309(e) of FLPMA, however, does not require public participation for every BLM implementation decision. Instead, it authorizes the Secretary to identify, through regulation, the appropriate public participation procedures, if any, that should apply to each type of BLM plan, program, and implementation decision.

This final rule does not change in any way the ability for public comment in the resource management process. BLM decisions to conduct timber sales often have their beginnings in an RMP that sets the general governance of the land-use over a specified area, in accordance with the Federal Land Policy and Management Act of 1976 (FLPMA).

In developing a viable resource management plan, the BLM starts first with a notice of intent, which begins a formal public scoping period during which time the public may submit input on issues that should be considered in the land management plan. At this time, the public may submit their input on forest management, or any number of issues that the resource management plan will address.

After the scoping process, the BLM next will issue a Draft RMP and draft Environmental Impact Statement (EIS), which initiates a 90-day public comment period. After all comments have been reviewed and evaluated, the BLM then revises the draft RMP as necessary and publishes a proposed RMP and final EIS. This publication initiates a 30-day protest period during which time the public may again protest resource management decisions included in the RMP. Concurrently, the BLM provides the proposed plan to the Governor's of those states included in the RMP, at which time a 60-day Governor's Consistency Review is initiated. The BLM may use this time to consider inconsistences with state and local plans and has the discretion to resolve them to the extent practical. After this period is up, the BLM then may issue a Record of Decision which acts as a final management direction, and may include any changes resulting from protests, the Governor's Consistency Reviews, or other considerations.

From this RMP, the BLM then tiers subsequent decision making on smaller parcels of the land from the RMP in order to conduct a timber sale. For instance, the BLM Grants Pass Interagency Office issued a Decision Record for hazardous fuels reduction maintenance treatments for the Picket West Forest Management Project—which included in its decision record citations to several resource management plans and their associated NEPA documents, all of which included several of the public comment opportunities outlined above. For this particular project, these forest management projects, which included timber sales, also tiered from a subsequent Environmental Assessment document, which re-analyzed smaller portions of the same acreage included in the relevant RMPs, and provided another public comment period (in this case, 48 days).

This rulemaking does not adjust in any material way BLM's regulations that establish procedures for preparation, revision, or amendment of land use plans pursuant to FLPMA, and the important opportunities for continued public comment contained therein. Instead, this rule removes an administratively burdensome process that has been found to not meet its original intent to expedite timber management decisions.

Individual forest management decisions are generally localized projects that concern local impacts and the advisability of uses for particular parcels of land; they tend not to be major management decisions that involve sweeping policy decisions affecting vast tracts of land.

Moreover, the existing Forest Management regulations provide an opportunity to protest some, but not all, forest management decisions. For forest management decisions that are not subject to protest, it has long been the BLM's practice to provide for public participation through a combination of land use planning, project-specific NEPA documents, opportunities for administrative appeal to the IBLA, and other public involvement opportunities. The final rule continues this approach. In addition to public participation opportunities during the planning process, most individual forest management projects would still have opportunities for public participation during the project-specific NEPA process, which may include scoping, public meetings, an opportunity for comment on draft analysis, and other opportunities that the BLM may provide.

Additionally, for those BLM lands in western Oregon managed under the O&C Act, the BLM develops annual timber sale plans that generally indicate the various tracts of timber that will be offered for sale. In the case of the lands that fall under the specific management of the O&C Act, the underlying RMPs for those areas must be guided by the statutory mandate under the O&C Act which states that: ''[t]he annual productive capacity for [O&C] lands shall be determined and declared . . . [and] timber from said lands in an amount not less than one-half billion feet board measure, or not less than the annual sustained yield capacity when the same has been determined and declared, shall be sold annually, or so much thereof as can be sold at reasonable prices on a normal market.'' [43 U.S.C. 2601]. This textual direction has been determined by the courts to ''[convey] a clear requirement.'' *Swanson Group Mfg, LLC* v. *Salazar,*

951.F. Supp.2d 75, 81 (D.D.C. 2013), *vacated on other grounds Swanson Group Mfg., LLC* v. *Jewell,* 790 F.3d 235 (D.C. Cir. 2015). These plans are typically posted on the BLM's website and suggestions from prospective purchasers may be received to assist in the development of the plan. See 43 CFR 5410.0–6.

Finally, the final rule preserves the public's ability to appeal forest management decisions to the IBLA.

Comment: The BLM received comments suggesting the protest process delays BLM timber sales on O&C lands which contributes to the BLM not meeting its obligations under the O&C Act, and therefore the process should be eliminated.

Response: The BLM acknowledges that the protest process is one of many factors that affect workloads and BLM's capacity to fulfill its obligations under the O&C Act in western Oregon. As discussed above, eliminating the process will help the BLM achieve the declared ASQ in accordance with the O&C Act with more certainty.

Comment: The BLM received comments that support eliminating the protest process and not replacing it with a comment period. Commenters pointed out that the public already has multiple opportunities to provide input on the management of BLM-managed public lands during the Land Use Planning process and its associated NEPA process and the public would still have an opportunity to challenge BLM forest management decisions through available IBLA and judicial review if the protest process is eliminated. These commenters also noted that it would allow the BLM to more efficiently implement RMPs, prevent delay of certain forest thinning projects to reduce fire hazard, reduce delays of county payments derived from timber sale revenues; remove a duplicative process, and improve certainty to the forest products sector and local economy by reducing long delays. Some commenters stated the protest process was being abused to cause multi-year delays of projects that clearly conformed to activities described in RMPs and met the requirements of the O&C Act.

Response: The BLM citied similar justification for this rule and considers these comments as supportive of changes in the final rule to eliminate the protest process. As the BLM has explained, eliminating the protest process will help reduce delays on all BLM lands in the implementation of forest resilience treatments to mitigate the effects of wildfire, insect, disease, and drought and help fulfill BLM's statutory obligations for sustained yield timber harvest under the O&C Act on BLM's O&C lands in western Oregon. The impacts of the existing protest process on the BLM's implementation of forest management is well known. The 2020 Interior Appropriations committee report provided the following direction:

> the Committee continues to be troubled by the disparity in timber targets compared with timber awarded and harvested on some districts. The Bureau is once again directed to prioritize response to administrative protests on timber sales in a timely manner and to report timber sale accomplishments in volume of timber sold and awarded, rather than merely the volume offered for sale, and shall report to the Committee on its progress.

The BLM has prioritized responding to protests but responding to lengthy protests that are often similar to comments received during the NEPA process, comments unrelated to the project at issue, or are arguments against implementation, are still causing delays. The BLM has concluded that eliminating the protest process would help address the Committee's concerns.

Comment: The BLM received comments that claim only IBLA can establish when a decision becomes effective and what the effects of a stay petition involve.

Response: The BLM disagrees. 43 CFR 4.21, which governs the effective date of decisions subject to appeal, explicitly provides that another ''pertinent regulation'' may provide otherwise. This final rule is such a regulation. Indeed, the existing regulations allowed the BLM to implement a forest management decision immediately after resolving applicable protests, without waiting an additional 30 days as required for other kinds of BLM decisions under 43 CFR part 4. The existing regulations further provided that the filing of a notice of appeal to the IBLA did not automatically suspend the effect of a forest management decision. The final rule maintains the BLM's ability to issue forest management decisions in full force and effect while clarifying that the effect of any such decision would be suspended if the IBLA or a court issues a stay or other applicable injunctive relief, which is the current practice.

Comment: Some comments requested the BLM include changes to adopt a public review process similar to the U.S. Forest Service pre-decisional objection process.

Response: The proposed rule discussed how the BLM considered requiring a public comment period on a proposed decision for proposed forest management decisions, which is similar to the U.S. Forest Service objection process. The BLM has determined, however, that public participation can otherwise be integrated into the BLM's decision-making process, including into the project-specific NEPA process for most forest management decisions, and that an additional comment period would be redundant and unlikely to raise new issues or lead to different outcomes.

Comment: One commenter suggested that if the BLM replaces the existing protest process with a comment process, then the comment process should be for 15 days instead of 10 days, so it is the same duration as the existing protest process. Other commenters supported removing the protest process and opposed replacing that process with a 10-day public comment period because the comment process would be redundant of the NEPA comment period.

Response: In the final rule, the BLM has elected to eliminate the protest process without requiring a comment period as discussed in the proposed rule. As explained, this change does not diminish the BLM's obligations to comply with NEPA, including the need to provide opportunities for public involvement through the NEPA process, nor does this change the BLM's discretion to offer other opportunities for public involvement on a case-by-case basis. These changes allow the Authorized Officer, who is most familiar with the local circumstances surrounding each decision, to determine if offering additional public participation opportunities would be beneficial for a particular project. The BLM expects a significant proportion of forest management decisions will be supported by an EA with public review and comment. The BLM also agrees that in instances where the public has an opportunity to comment on a proposed forest management action through the NEPA process, a separate public comment period would generally be redundant and has determined not to include a 10-day public comment period in the final rule.

Comment: The BLM received comments that the protest process and IBLA appeals process are often duplicative, addressing objections and issues already considered during NEPA review. The comments supported eliminating the protest process and maintaining an appeal to IBLA for forest management decisions.

Response: The BLM agrees with these commenters that the purpose of a post-decision review process is to provide an opportunity for the affected and interested parties to request review when a decision allegedly violates law, regulation, or policy, and that both the protest process under the existing

regulations and the IBLA appeal process provide this opportunity. The BLM also agrees that over time these processes have become duplicative, and that the BLM receives protests that identify issues that the BLM has already addressed during the NEPA process for the decision. The BLM has also found that protests generally result only in minimal changes to a small number of the total decisions that are protested. As such, the final rule amends section 5003.3 to remove the existing protest process.

Section 5003.4 Definitions: General

The existing regulations address forest management decisions for forest management activities, but they do not define a forest management activity. Section 5003.4 of the proposed rule included a definition of forest management activity. The final rule adopts the definition in the proposed rule. This change clarifies the type of activities that will fall under the scope of this section of the regulations. The definition emphasizes that a forest management activity has a silvicultural or forest-protection objective. These activities result in changes to forest or forest adjacent vegetation that have an explicit forest output or ecological condition as the outcome of the activity and may include other activities that facilitate or complement the forest management activity. Examples of forest management activities may include: Cutting of trees and vegetation; harvesting; tree planting; seedling protection; vegetation type conversions; fuels reduction; fire pre-suppression; and road construction and maintenance, when these activities are intended to provide, for example, a commercial forest product, improve tree and forest heath, reduce fire risk, increase forest resiliency to environmental stressors, or address insect or disease infestations. A forest management activity would not include, for example, clearing trees for the construction of a power line in a right of way.

Comment: The BLM received a comment that the definition of Forest Management Activity should add the terms fuel reduction, non-commercial thinning, prescribed burning, vegetation reduction, and wildfire hazard reduction.

Response: The BLM did not make any changes in the final rule to address this comment because it believes the terms silviculture and forest protection in the rule encompass these described activities. The BLM considered providing an exhaustive list of terms in the regulations that silviculture and forest protection encompass, but determined it unnecessary since these terms are already defined in the professional Dictionary of Forestry published by the Society of American Foresters, and scientific literature and are well understood.

Section 5003.5 Severability

This new section would describe the legal principle of ''severability'' and apply it to the regulations in Group 5000. Under severability, if any portion of these regulations were found invalid or unenforceable as to a particular set of circumstances or particular people, the remaining portions of the regulations would remain valid and BLM could enforce them separately and legitimately. This principle has always applied to the regulations but is stated here for information and clarity.

Other Comments Related to Part 5000

The BLM received other comments related to aspects of the rule text in prior sections but which are more general and address the BLM's or the DOI's administrative processes, NEPA, other statutes, and other issues related to forest management. Those comments are addressed below.

Comment: The BLM received a comment that participation in the protest process is the only way to be a party for the purposes of an appeal to IBLA and removing the process from the regulations will eliminate a party's ability to appeal a forest management decision.

Response: It is not the intent of these changes to eliminate the ability to appeal forest management decisions to the IBLA. Separate regulations governing IBLA appeals, which are not amended by this final rule, provide that ''any party to a case who is adversely affected by a decision of the Bureau'' may appeal to the IBLA (see 43 CFR 4.410(a)). This includes any party ''that is the subject of the decision on appeal, is the object of that decision, or has otherwise participated in the process leading to the decision under appeal,'' (43 CFR 4.410(b)), including by commenting on an environmental document. As discussed, in most cases a party would still have the opportunity to comment about a proposed forest management decision during the NEPA process, which is unaffected by the final rule.

Comment: The BLM received a comment asking whether the commenter must file an appeal to IBLA challenging the promulgation of this rule to exhaust administrative remedies before challenging this rule in Federal district court.

Response: This rulemaking is not appealable to the IBLA.

Comment: The BLM received a comment that the BLM failed to conduct adequate NEPA analysis on the environmental effects of the proposed rule.

Response: The BLM's adoption of the final rule complies with NEPA. The BLM does not believe this rule constitutes a major Federal action significantly affecting the quality of the human environment, and has prepared documentation to this effect, explaining that a detailed statement under the National Environmental Policy Act (NEPA) is not required because the rule is categorically excluded from NEPA review. Specifically, the BLM relied on 43 CFR 46.210(i), which provides for use of a Categorical Exclusion for policies, directives, regulations, and guidelines that are of an administrative, financial, legal, technical, or procedural nature; or whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis and will later be subject to the NEPA process, either collectively or case-by-case. The final rule changes the BLM's administrative procedures for forest management activities as well as some of the procedures to administer a timber sale. The rule does not authorize any on-the-ground actions or constrain the BLM's ability to exercise its substantive discretion when making future forest management decisions. Future forest management decisions will be subject to the NEPA process, as appropriate. The BLM has also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. Documentation of the reliance upon a categorical exclusion has been prepared with other supporting documents for this final rule.

Comment: The BLM received comments suggesting that the existing protest process ensures the BLM uses best available science in decision making.

Response: The protest process in the existing regulations is an administrative review process and does not address the use of science in the decision-making process. The final rule does not change the existing obligations under law, regulation or policy that address the use of science, including the BLM's obligations under the Information Quality Act, section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554, H.R. 5658), and

implementing guidelines of OMB,[1] DOI,[2] and the BLM[3] for '' ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies'' and direction in Secretary's Order 3369 *Promoting Open Science.*[4] The BLM will also continue to adhere to NEPA requirements for using ''high quality'' information and ''[a]ccurate scientific analysis'' (40 CFR 1500.1(b)), and for ensuring the ''professional integrity including scientific integrity of the discussions and analysis in [EISs]'' (40 CFR 1502.24).

Comment: The BLM received comments that the proposed rule affects the NEPA process and the ability of the BLM to conduct environmental analysis on forest management activities.

Response: The changes amend the administrative processes in the BLM's forest management regulations and do not change the laws, regulations or policies applicable to the BLM's NEPA compliance for forest management decisions. Over time, since the existing rule was promulgated, the BLM has changed the way it designs its timber sales and other forest management decisions and now often conducts environmental review on multiple projects in a single watershed or on a biologically relevant scale, such as wildlife habitat for a particular species. Additionally, the BLM promotes collaboration and information-sharing during the NEPA process, and today more interested individuals and parties participate in the public opportunities during the decision-making process when their input is most helpful. The amendments update the administrative process in the forestry management regulations to reflect these changes in forest management projects, but they do not authorize any forest management activities or change the BLM's NEPA obligations for future activities.

Comment: The BLM received comments related to the consolidation of sale decisions stating that this does not allow an opportunity for site specific comment.

Response: The final rule does not change how the BLM complies with NEPA for forest management activities. The BLM conducts site specific NEPA on timber sales and the final rule does not change the BLM's obligations to comply with NEPA for these and other forest management activities. Currently, multiple sales are often related in terms of geography, *e.g.,* watershed or on a biologically relevant scale, such as wildlife habitat for a particular species, and the BLM evaluates these sales in one environmental document, which in many cases can lead to better informed decision-making. While the final rule removes the protest process for individual sales in 5003.3, the final rule does not change the public's ability to comment on or otherwise be involved in these sales during the NEPA process.

Comment: The BLM received comments that suggested the proposed rule would affect resources such as water quality, wildlife habitat, carbon storage, potential wildfire behavior, older trees, and other resources due to an increase in logging.

Response: The final rule addresses the BLM's administrative procedures for forest management decisions. It does not authorize any on-the-ground actions or constrain the BLM's substantive decision-making discretion with respect to harvest methods or the amount of timber harvest that will occur on public lands. Decisions on harvest levels, methods and prescriptions, and areas open to or reserved from harvest, are generally made through land use planning decisions consistent with the BLM's planning process provided in its planning regulations at 43 CFR part 1600, subpart 1610. These planning and forest resource decisions are made through a separate decision-making process and must comply with NEPA as appropriate.

Part 5400 Sales of Forest Products; General

Section 5400.0–3 Authority

Section 5400.0–3 contains the authority for part 5400. Section 5400.0–3(a) updates the O&C Act citation due to renumbering that took place in the U.S. Code. Section 5400.0–3(c) references a law related to the prohibition of exporting unprocessed timber from Federal lands that was superseded by 16 U.S.C. 620. The final rule contains these updated references to the BLM's current statutory requirements. The BLM did not receive any substantive comments on this section and did not make changes to this section between the proposed and final rule.

Section 5400.0–5 Definitions

Section 5400.0–5 contains the definitions for part 5400. The final rule adds new definitions for ''lump sum sale'' and ''scale sale,'' which are used, but not defined, in the existing regulations. These two sale types are the only sale types the BLM uses. These definitions will ensure a common understanding of the key difference between these sale types, which relates to how the volume of the forest product is determined. The BLM did not make changes to this section between the proposed and final rules. The BLM did not receive substantive comments related to the change.

In the final rule, the Fair Market Value definition is updated by deleting the second sentence referencing a BLM Manual that is no longer effective. This change will have no effect because appraisal guidance was updated in 1996 to address this change. Changes in § 5400.0–5 add the terms ''export'' and ''sourcing area'' to provide a basis for determining a violation of the export prohibition. The substitution definition is also changed to update the time period from 12 months to 24 months to conform to 16 U.S.C. 620, and a reference to a substitution exception for rights-of-way that is not included in the statute is deleted in the final rule. The BLM did not make changes to this section between the proposed and final rule.

Comment: The BLM received a comment on the definition of Fair Market Value suggesting that the definition should define the extent as well as methods for determining the fair market value.

Response: The definition for Fair Market Value reflects BLM's obligation to sell forest products to the highest bidder after advertisement (30 U.S.C. 601) with limited exception for small quantities (30 U.S.C. 602). It is generally accepted in commodity markets that the true value is determined through open competitive bidding. This is reflected in the changes and no additional changes are necessary.

Changes to § 5402.0–6(d) delete an exception to substitution restrictions that is not provided by the Forest Resources Conservation and Shortage Relief Act of 1990 (16 U.S.C. 620) as amended. This exception was established in the BLM's regulations

[1] Office of Management and Budget, ''OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication,'' (67 FR 8452, February 22, 2002).

[2] U.S. Department of the Interior, ''Information Quality Guidelines Pursuant To Section 515 Of The Treasury And General Government Appropriations Act For Fiscal Year 2001,' *https://www.doi.gov/sites/doi.gov/files/migrated/ocio/information_management/upload/515Guides.pdf.*

[3] Bureau of Land Management, ''Information Quality Guidelines—Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Bureau of Land Management,'' (April 2, 2018) *https://www.blm.gov/documents/national-office/public-room/guidebook/blm-information-quality-guidelines.*

[4] Secretarial Order 3369 A1 ''Promoting Open Science'' *https://www.doi.gov/sites/doi.gov/files/elips/documents/so_3369a1_-_promoting_open_science.pdf.*

prior to the passage of the statute. The BLM did not make changes to this section between the proposed and final rules. The BLM did not receive substantive comments related to the change.

Section 5402.0–6 Policy

The final rule amends § 5402.0–6(e) to clarify how special forest product prices will be determined. The BLM sells permits to the public for special forest products, which include fuelwood, Christmas trees, edibles, pine nuts, cones, seedlings, and other forest products other than sawtimber. BLM State Offices generally publish a price list based on estimated values within a State. The existing § 5420.0–6 requires that all vegetative resources be appraised and in no case sold at less than appraised value. BLM offices are concerned that selling products at the published price for the State is not consistent with subpart 5420, because the value of products across a State can vary. The addition of § 5402.0–6(e) in the final rule clarifies that vegetative products can be sold by permit without appraisal after payment of adequate compensation, which is the standard in the authorizing statute. This means that price lists developed by the BLM for special forest product permits can be used, and that individual appraisals for each permit will not be required. The BLM did not receive substantive comments related to the change. The BLM did not make changes to this section between the proposed and final rule.

Part 5420—Preparation for Sale

Section 5420.0–6 Policy

The existing § 5420.0–6 requires appraisal of all timber and vegetative resources that are sold, and in no case sold for less than the appraised value. The final rule adds an exemption from appraisal for special forest products in § 5402.0–6(e) as described in the previous section. The final rule removes the phrase ''prohibiting the sale of products at less than appraised value'' to allow the BLM to award timber sale contracts or vegetative material permits if bids come in below the appraised value. The Materials Act of 1947 (30 U.S.C. 601) requires the BLM to advertise timber sales and to award sales to the highest bidder. The BLM is not required by law to sell timber at or above the appraised value. Producing highly accurate appraisals is costly due to factors such as acquiring log price data, labor costs, and equipment costs, including fuel, maintenance, and depreciation. This has two potentially negative consequences. First, the BLM could incur a high cost to produce an appraisal, which is particularly counterproductive for lower value products. Second, an appraisal could over-price a sale and result in no bids. No-bid sales result in increased costs associated with reappraising and reoffering a sale and are particularly costly for salvage sales where the timber quality rapidly deteriorates. The changes to this section are intended to continue the practice of appraising timber as a guide to determining a reasonable price, but also to allow the BLM to sell products to the highest bidder at a price below the appraised price if the authorized officer receives a reasonable bid. This provision recognizes that an appraisal is an estimate of the market price, but that competitive bidding through an auction or a sealed bid is generally superior at identifying the true market price. The BLM anticipates these changes will decrease costs, increase efficiency and result a reduction in no bid sales. The BLM did not make changes to this section between the proposed and final rules.

Comment: The BLM received comments indicating that the removal of the prohibition on selling a product at less than appraised value (43 CFR part 5420) would lead to the public not receiving fair compensation for the use of public resources. The BLM also received comments in support of the changes to use the competitive bidding process to determine the sale price regardless of the appraisal in order to avoid no-bid sales.

Response: Accurately appraising forest products can be technically challenging and costly. The BLM has had many instances where forest product sales receive no bids because of inaccurate appraisals or the inability to forecast market changes and the expense of contract requirements. For example, in 2018 there was a significant and rapid change in market conditions that led to over 25 percent of western Oregon timber sales receiving no-bid. Even with the best data and professional appraisers, appraisals have limitations in determining the market value and expenses because appraisals are based on retrospective analysis and markets and expenses can change rapidly. In addition, the BLM's current sale process does not allow for price adjustments once the sale is advertised which is a minimum of two weeks before receiving bids. The final rule will allow the BLM to avoid having to delay sales and incur additional administrative costs of reappraising and reoffering sales if no bids are received by allowing the Authorized Officer the discretion to select a high bid that is below the appraised value when it is determined that the appraisal overestimated the market price. This discretion is particularly important for salvage timber where appraisal accuracy is even more difficult and the effect of a delay due to a sale going no-bid could result in the need to abandon the sale due to wood deterioration.

Part 5400—Sales of Forest Products; General

Section 5422.1 Lump-Sum Sales

This final rule changes the title of § 5422.1 from ''Cruise Sales'' to ''Lump-Sum Sales.'' This section is also revised to say that a lump-sum sale is most often estimated using a tree cruise method. The BLM does not use the term ''cruise sale,'' though it is generally understood to mean lump sum. This revision is intended to clarify that both sale types are acceptable and may be used by an authorized officer. The BLM did not make changes to this section between the proposed and final rule. The BLM did not receive substantive comments related to the change.

Section 5422.2 Scale Sales

Changes to § 5422.2 revise some of the rules for the use of scale sales and reorganize the section for clarity. The existing regulations limit the use of scale sales to events such as timber disasters or imminent resource loss. Currently other circumstances in which its use is permitted are ambiguous. Implementation of this section in the existing rule has generally discouraged scale sales, despite the fact that it is a standard practice in the logging industry and its use is common among other sellers of timber, such as State governments and the U.S. Forest Service. The final rule removes the existing limitations and permits the use of scale sales at the discretion of the authorized officer. In the final rule the term ''scale sales'' includes the use of weight scales, including third party weight scales that are certified by a State government for timber sold on a per-ton basis. Section 5422.2 in the existing rule does not mention weight scales, which can lead to the incorrect conclusion that the term scale sale in the existing rule is only referring to log scaling using a log rule. The BLM did not make changes to this section between the proposed and final rule. The BLM did not receive substantive comments related to the change.

Section 5424.0–6 Policy

A minor change in § 5424.0–6(d) corrects a typographical error by replacing the word ''from'' with ''form''.

Section 5424.1 Reporting Provisions for Substitution Determination

Section 5424.1 relates to the enforcement of the export prohibition. Timber export laws are designed to not only prohibit the timber cut from Federal land from being exported, but also to prohibit Federal timber from being used as a substitute for other timber the purchaser owns and exports. The final rule updates the time period for tracking and reporting the export of private timber for a purchaser or an affiliate of a purchaser of Federal timber from 1 year to 2 years. This revision is intended to bring the rule into conformance with the Forest Resources Conservation and Shortage Relief Act of 1990, as amended. The BLM did not receive substantive comments related to these changes and did not make changes to this section between the proposed and final rules.

Part 5430—Advertisement

Subpart 5430—Advertisement; General

Section 5430.0–6 Policy

Section 5430.0–6 of the final rule gives the BLM the option to advertise competitive timber sales on an agency website. The BLM did not make changes to this section between the proposed and final rules. The BLM did not receive substantive comments related to these changes.

Part 5440—Conduct of Sales

Section 5441.1 Qualification of Bidders

Section 5441.1 of the final rule establishes the qualifications for bidders on BLM timber sales. Revisions to this section pertain to the debarment regulations at 2 CFR part 180. Under proposed § 5441.1(c), an individual or entity could be disqualified as a bidder on a BLM timber sale if that individual or entity is debarred in the Federal Government-wide debarment list. In accordance with 2 CFR part 180, there is a process for petitioning for an exception from debarment which is noted in the proposed § 5441.1(c)(1). The revision to this section brings it into conformance with 2 CFR part 180. The BLM did not make changes to this section between the proposed and final rules. The BLM did not receive substantive comments related to these changes and did not make changes to this section between the proposed and final rules.

Section 5441.1–1 Bid Deposits

Section 5441.1–1 sets forth the requirements for a bid deposit that must accompany a bid on a timber sale. The final rule allows the BLM to refund up to half of the bid deposit if the award of the sale is delayed for more than 90 days. This change is to address current instances in which a sale is conducted, a high bidder is announced, and then before award of the contract, circumstances, such as a court injunction, delay the award of the timber sale contract. Given that bid deposits are 10 percent of the appraised value, a deposit can be substantial. The BLM recognizes that delays in the award of timber sale contracts is a burden for purchasers; thus, this revision helps reduce that burden. The BLM did not receive substantive comments related to these changes and did not make changes to this section between the proposed and final rules.

Section 5441.1–2 Special Considerations

Section 5441.1–2 refers to a Small Business Administration road construction loan program that no longer exists. This section is deleted because it is obsolete. The BLM did not receive substantive comments related to these changes and did not make changes to this section between the proposed and final rules.

Part 5450—Award of Contract

Section 5451.1 Minimum Performance Bond Requirements; Types

Section 5451.1 pertains to performance bonds for timber sale contracts, which function to protect the government's interest in Federal lands and resources by helping to ensure the fulfillment of a purchaser's contract obligations and the BLM's resource objectives. Performance bonds may be held by the BLM when a purchaser is not in compliance with contract terms and conditions. The bond can be forfeited to the BLM to cover costs of remedying unfinished contract obligations. Currently, a performance bond is required for all contracts for the sale of products greater than or equal to $2,500, and for installment contracts of less than $2,500. For cash sales of less than $2,500, bond requirements are at the discretion of the authorized officer. The final rule requires a performance bond for all contracts for the sale of products greater than or equal to $10,000, and impose a minimum performance bond of not less than $500 or 20 percent of the contract price, whichever is greater, for all installment contracts of less than $10,000. For all cash sales less than $10,000, bond requirements will be at the discretion of the authorized officer. Under the final rule, the BLM retains discretion to require performance bonds within the specific limits established in the regulations and determines the amount of bond required on a case-by-case basis after site-specific analysis. These changes account for estimated inflation, since the existing rule was established in 1970 when the amount of material covered by the bond was four to five times the amount of material covered at current prices. For example, three to five truckloads of timber might have been sold for $2,500 in 1970, whereas, at current dollar valuation, a single truckload of the same quality timber might exceed the threshold for the bonding requirement. This change adjusts the BLM's risk exposure to a level that is similar to when the bond threshold in the existing regulations was originally published. The BLM did not receive substantive comments related to these changes and did not make changes to this section between the proposed and final rules.

Part 5460—Sales Administration

Section 5461.3 Total Payment

The BLM changed the term ''cruise sale'' to ''lump sum sale'' consistent with other changes in the rule. The BLM did not receive substantive comments related to these changes and did not make changes to this section between the proposed and final rules.

Section 5463.1 Time for Cutting and Removal

The BLM changed the maximum time for cutting and removal to 48 months in the final rule.

Comment: The BLM received comments requesting additional time for cutting and removal stating that the current maximum of 36 months (43 CFR 5463.1) is not adequate to complete sales with limited operating seasons and an increasing number of project design features that are required in BLM timber sale contracts.

Response: In response to comments on the proposed rule recommending that the BLM consider opportunities to provide greater flexibility in the amount of time to complete cutting and removal, the BLM's final rule revises § 5463.1 to increase the maximum amount of time allowed for cutting and removal of timber in BLM timber sale contracts. In the existing rule, the maximum time for the cutting and removal of timber is 36 months and in the final rule this period is increased to up to 48 months. Although the BLM did not specifically

propose this change in the proposed rule, the BLM raised the issue of contract performance timing in its proposed rule and specifically proposed changes in § 5473.3 to identify additional circumstances in which the BLM could extend the period of performance in BLM contracts. The BLM received no comments opposed to this specific proposed change, with all comments addressing this section expressing support. Commenters recommended that the BLM further address this issue by providing greater flexibility for the BLM to issue contracts with a longer performance term at the outset. These comments stated that the existing maximum of 36 months in § 5463.1 is no longer adequate to complete sales with limited operating seasons and an increasing number of project design features intended to limit environmental impacts.

The BLM's review of comments it received on the proposed rule to address the period of performance issue, coupled with a second look from the BLM at the causes of increased need for contract extensions, led the BLM to make this change in the final rule. The BLM recognizes that the 36-month maximum contract term is no longer enough time to perform the terms of some contracts due to changed conditions since the existing rule was finalized, including an increasing number of contracts with additional restrictions to limit environmental impacts, seasonal restrictions, events such as weather, fire closure and other related conditions that interrupt operating time. Changed conditions was the basis for proposing changes to allow additional contract extensions, and this change has the same effect as the changes to § 5463.1.

Part 5470—Contract Modification—Extension—Assignment

Section 5473.4 Approval of Request

The final rule also changed § 5473.4 to allow the authorized officer to grant a purchaser's request to extend the amount of operating time on a timber sale contract without reappraisal in certain circumstances. The revision to § 5473.4(c) adds unusual weather conditions and national, state, or local government emergency declaration such as a pandemic or natural disaster to the list of reasons the BLM may grant a request for a contract extension. It is the BLM's experience that some pause in operations occurs due to normal weather, such as a halt in log hauling during heavy rain events or a shutdown of yarding due to wet soils during spring melt, which would not amount to unusual weather conditions. Unusual weather conditions could be record drought leading to prolonged fire hazard or record rainfall leading to prolonged wet soil conditions. Although allowing contract extension for national, state, or local emergency declarations was not specifically proposed, the BLM did receive a request from the timber industry to grant blanket contracts extensions to BLM contracts due to operational disruptions as the result of Federal state and local restrictions responding to the COVID–19 pandemic. The BLM received multiple individual requests for extensions for these reasons during the public comment period for the proposed rule and has decided to include this additional circumstance as one where the BLM may grant contract extensions. Neither of these changes to § 5473.4 allow the BLM to grant blanket extensions for all BLM contracts. The BLM will continue to evaluate extension requests on a case-by-case basis.

Section 5473.4(d) also contains criteria for contract extension related to fire and other natural and man-made disasters. The purpose of this extension is to allow the BLM to extend contracts when a disaster results in significant salvage timber that needs to be harvested elsewhere. Timber impacted by a disaster often deteriorates rapidly and attracts insects and pathogens, and it is prudent that those sales be prioritized over sales that harvest live timber. The final revisions to this section expand the BLM's existing authority and allow the BLM to extend BLM timber contracts in response to disasters on both Federal and non-Federal lands. The revision also puts a 36-month limit on the amount of time that a contract can be extended, which is not in the existing regulations. The BLM recognizes that disasters can pose a serious hardship on local communities. The changes allow the BLM to extend the contract terms and provide additional time for a purchaser to harvest green timber in areas not impacted by the disaster, which could benefit businesses and land owners by allowing them to focus their resources on areas impacted by the disaster, including salvage removal.

Part 5500—Nonsale Disposals; General

Section 5500.0–5 Definitions

Section 5500.0–5(e) revises the definition of public lands to make it consistent with the definition in FLPMA at 43 U.S.C. 1702(e), and to clarify that for this part of the regulations, O&C grant lands are considered public lands. Moreover, this section clarifies that there are conditions for the free use of vegetative and mineral materials on O&C grant lands. The BLM did not make changes to this section between the proposed and final rules. The BLM did not receive substantive comments related to these changes.

Miscellaneous

Technical Note: The BLM is changing the authority sections to reflect that the O&C Act, which was previously codified at Title 43, Chapter 28, Subchapter V, (43 U.S.C. 1181a–j), was transferred to Title 43, Chapter 44, (43 U.S.C. 2601–2634) on July 1, 2017. In the final rule the BLM also removes the Statute at Large citations that have already been codified.

TABLE 1—ABBREVIATED DESCRIPTIONS OF THE MAJOR CHANGES MADE TO 43 CFR PARTS 5000, 5400, AND 5500 BY THIS RULE

Subchapter E—Forest Management		
43 CFR reference and description	Change between proposed rule and existing regulation	Changes between final rule and proposed rule
Part 5000 Adminstration of Forest Management Decisions		
5003.1 Effect of Decisions	Clarifies that decisions may be effective immediately when issued rather than after a protest process.	no changes.

TABLE 1—ABBREVIATED DESCRIPTIONS OF THE MAJOR CHANGES MADE TO 43 CFR PARTS 5000, 5400, AND 5500 BY THIS RULE—Continued

Subchapter E—Forest Management		
43 CFR reference and description	Change between proposed rule and existing regulation	Changes between final rule and proposed rule
5003.2 Notice of forest management decisions.	Provides that the BLM authorizes forest management activities by issuing forest management decisions. The Issuance of a decision authorizing forest management activities, including timber sales, is the decision for timber sales instead of advertisement of the timber sale under current regulations. The changes also allow web-based posting of decisions and that the posting date of the decision is the effective date for the decision for purposes of appeal under 43 CFR part 4.	In addition to changes in the proposed rule, the BLM added text to clarify that forest management decisions that may be effective immediately under § 5003.1 must be posted.
5003.3 Protests	Eliminates the protest process	no changes.
5003.4 Definition of Forest Management Activity.	Provides a definition for decisions that could be made under § 5003.2.	no changes.
5003.5 Severability		Adds a new section of severability for sections in Group 5000.
Part 5400 Sales of Forest Products General		
5400.0–3(a) and (c) Authority	Updates references to BLMs forest management authorities resulting from changes to the U.S. Code and passage of the Forest Resources Conservation and Shortage Relief Act.	no changes.
5400.0–5 Definitions	Added various definitions for terms used in the part 5400 rule	no changes.
5402.0–6(d) and (e) Other than Advertised Sales.	Deleted export exemption for right-of-way timber to conform with law and clarified that special forest product permits do not require individual appraisals.	no changes.
5410.0–6 Annual Timber Sale Plan.	Adds agency website to the ways BLM plans can be published	no changes.
5420.0–6 Preparation for Sale	Removes prohibition of selling products at less than appraised value.	no changes.
5422.1 Lump-sum sales	Changes title from ''Cruise sales'' to ''Lump-sum sales'' to match contract name and common use of Lump-sum and revise to indicate that Lump-sum and Scale are both approved sale types.	no changes.
5422.2 Scale sales	Expands the discretion to use scale sales and clarifies that sale by weight is an approved method.	no changes.
5424.1 Reporting provisions for substitution determination.	Updates the reporting requirement to conform with the Forest Resources Conservation and Shortage Relief Act.	no changes.
5430.0–6 Advertisement	Allows BLM to advertise sales on an agency website	no changes.
5441.1 Qualification of Bidders	Updates the qualification of bidders to conform with Department of the Interior regulation pertaining to debarment 2 CFR part 180.	no changes.
5441.1–1 Bid Deposits	Allows BLM to refund a portion of the bid deposit if award of the sale is delayed.	no changes.
5441.1–2 Small business administration road loans.	Removes the existing section text which was no longer valid and redesignates § 5441.1–3 as § 5441.1–2.	no changes.
5451.1 Minimum performance bond requirements.	Changes the sale value threshold that triggers a requirement for a performance bond from sales that are $2,500 and greater to $10,000 and greater.	no changes.
5461.3 Total Payments	Replaces the term ''cruise sale'' with ''lump-sum sale'' to be consistent with changes to § 5422.1.	no changes.
5463.1 Time for cutting and removal.	Not in the proposed rule but addresses an underlying issue related to the purposes for changes to § 5473.4.	A change was added in § 5463.1 to address issues with increased use of extensions to deal with circumstances that interrupt sales as well as effects from increasingly complex sales.
5473.4 Approval of Requests	Expands the reasons for approving contract extension requests	Adds emergency declarations or public orders as allowable extension reasons based on recent government mandated COVID–19 restrictions and related issues.
Part 5500 Nonsale Disposals, General		
5500.0–5 Definitions	Updates the public lands definition to match the Federal Lands Policy Management Act definition.	no changes.

III. Procedural Matters

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rule making process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

The BLM reviewed the requirements of the final rule and determined that it will not adversely affect in a material

way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. For more detailed information, see the Regulatory Impact Analysis (''Economic and Threshold Analysis for Proposed Forest Management Rule'') (RIA) prepared for this rule. The RIA has been posted in the docket for the proposed rule on the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Searchbox, enter ''RIN 1004–AE61,'' click the ''Search'' button, open the Docket Folder, and look under Supporting Documents.

Reducing Regulation and Controlling Regulatory Costs (E.O. 13771)

The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action as defined in E.O. 12866. Therefore, the rule is not an ''E.O. 13771 regulatory action'' as defined by Office of Management and Budget (OMB) guidance implementing E.O. 13771. As such, the rule is not subject to the requirement for ''regulatory actions'' under E.O. 13771.[5]

Regulatory Flexibility Act

This final rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA). The RFA generally requires that Federal agencies prepare a regulatory flexibility analysis for rules subject to the notice-and-comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 500 *et seq.*), if the rule would have a significant economic impact, whether detrimental or beneficial, on a substantial number of small entities. *See* 5 U.S.C. 601–612. Congress enacted the RFA to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. Small entities include small businesses, small governmental jurisdictions, and small not-for-profit enterprises.

The Small Business Administration (SBA) has developed size standards to carry out the purposes of the Small Business Act, which can be found in 13 CFR 121.201. For a specific industry identified by the North American Industry Classification System (NAICS), small entities are defined by the SBA as an individual, limited partnership, or small company considered at ''arm's length'' from the control of any parent company, which meet certain size standards. The size standards are expressed either in number of employees or annual receipts. This rule will most likely affect entities that participate in timber sales or the related protest process. The industries most likely to be directly affected are listed in the table below along with the relevant SBA size standards.

Industry	Size standards in millions of dollars	Size standards in number of employees
Timber Tract Operations	$11.0	
Forest Nurseries and Gathering of Forest Products	11.0	
Logging		500
Support Activities for Forestry	7.5	
Environmental Consulting Services	15.0	
Environment, Conservation and Wildlife Organizations	15.0	

BLM timber sales are commonly bid on by, and awarded to, small businesses. The BLM is also required by the SBA regulations (13 CFR part 121) to set aside a proportion of BLM timber sales for small businesses. This final rule does not change this process. Four changes in the rule to subparts 5422, 5441, 5451, and 5463 will have small beneficial economic effects to small businesses by lowering financial requirements to enter into a sale contract and by providing more flexibility in the timber sale contract. Section 5441.1–2 refers to a SBA road construction loan program that has expired, and therefore the deletion of this section will have no effect. The revisions to the forest management decision process should benefit small entities that elect to submit comments by more clearly defining the process.

Based on the available information, we conclude that this rule will not have a ''significant economic impact on a substantial number of small entities,'' as that phrase is used in 5 U.S.C. 605. Therefore, a final regulatory flexibility analysis is not required.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more. The total appraised value of all timber offered by the BLM over the last five years is approximately $48 million per year. To the extent that the BLM can become more efficient and meet the increased timber volume offered when authorized in RMPs, this rule could have positive effects to the economy. Additional details can be found in the RIA for this rule.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The primary commodity affected by this rule is lumber. The BLM does not anticipate that a reduction in timber production will occur due to this final rule.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. The BLM believes this rule will result in positive effects in each of these areas. This rule could have a small positive effect on competition by lowering the financial requirements for entering into a small sale contract. To the extent that the BLM can become more efficient and meet the increased timber volume authorized in RMPs, this rule could have positive effects on employment, investment, and productivity.

Unfunded Mandates Reform Act

This rule will not impose an unfunded mandate on State, local, tribal governments, or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments, or the private sector. This rule will only affect the BLM's

[5] Executive Office of the President, OMB Memorandum No. M–17–21, Guidance Implementing Executive Order 13771, Titled ''Reducing Regulation and Controlling Regulatory Costs,'' April 5, 2017.

administrative process for protest of forest management decisions and provide minor revisions to enhance flexibility in developing and administering timber sales. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under E.O. 12630. Section 2(a) of E.O. 12630 identifies policies that do not have takings implications, such as those that abolish regulations, discontinue governmental programs, or modify regulations in a manner that lessens interference with the use of private property. There are no cases where a BLM timber sale or forest management decision has affected private property rights. The rule will revise the timber sale and decision protest processes and will not affect private property rights. A takings implication assessment is not required.

Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. It does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The rule revises processes that have been implemented numerous times over decades and which have not been found to have effects on the relationship or distribution of power between the national government and the States.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government relationships with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in E.O. 13175 and have determined that it has no substantial direct effects on federally recognized Indian tribes, and that consultation under the Department's tribal consultation policy is not required. The BLM consults with tribes at multiple decision support stages, including the development of RMPs, NEPA scoping, consultation under the National Historic Preservation Act, as well as in other circumstances identified in the BLM Tribal Consultation policy. Decisions affected by this rule are included in all these decision support stages. The rule does not affect these tribal consultation processes.

Paperwork Reduction Act (44 U.S.C. 3501 et seq.)

This rule contains existing and revised information collections. All information collections require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The BLM may not conduct or sponsor and, notwithstanding any other provision of law, you are not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. OMB previously reviewed and approved information collection requirements contained in 43 CFR 5003.3 and 43 CFR 5424.1 under OMB control number 1004–0058. Revisions to these previously approved requirements contained in this final rule are explained below. The following proposed revisions to OMB Control Number 1004–0058 require OMB approval:

Final revisions to § 5003.3 eliminate the protest process, thereby eliminating a currently approved but now obsolete requirement for information collection. Revisions to § 5424.1 update the regulation in accordance with the Forest Resources Conservation and Shortage Relief Act of 1990, as amended. The revisions to §§ 5003.3 and 5424.1, explained in more detail below require approval by OMB:

(1) Revisions to § 5003.3 remove the existing protest process:

(a) Section 5003.3(a) currently authorizes protests of a forest management decision to be filed within 15 days of the publication of a notice of decision or notice of sale in a newspaper of general circulation. This discretionary protest process was largely duplicative of other opportunities for public involvement, including through the NEPA process. The final rule eliminates the protest process for activities under § 5003.2 prior to issuing a decision. The elimination of the protest process results in an estimated reduction of 25 responses and 250 burden hours as currently approved by OMB. The total burden currently approved by OMB for this OMB control number is 325 annual responses and 550 annual burden hours. As a result of the final rule, the BLM estimates that there will be 300 annual responses and 300 annual burden hours.

(2) Revisions to § 5424.1(a)(1) and (2) update the reporting requirement for purchasers and affiliates to report the export of private timber from within 1 year to 2 years. The final rule makes no changes to the information collected pursuant to this reporting requirement nor is there a change to the reporting burden associated with collection of information.

Title: Forest Management Log Export and Substitution.

OMB Control Number: 1004–0058.

Form Numbers: 5450–17, 5460–15, and 5460–17.

Type of Review: Revision of a currently approved collection.

Description of Respondents: Purchasers of Federal timber and their affiliates.

Estimated Number of Annual Respondents: 300.

Estimated Number of Responses: 300.

Estimated Completion Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 300.

Respondents' Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Estimated Total Non-Hour Cost: $0.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on any aspect of this information collection, including:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of response.

On June 8, 2020, the BLM published a proposed regulation (RIN 1004–AE61, ''Forest Management Decision Protest Process and Timber Sale Administration'' 85 FR 35049). The proposed rule solicited comments on the proposed changes to the information collections for a period of 30 days, ending on July 8, 2020. The BLM did not receive any comments related to information collection in response to the proposed rule.

Written comments and recommendations for this information collection should be sent within 30 days of publication of this document to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Darrin King, Information Collection Clearance Officer, Attention PRA Office, Bureau of Land Management, 440 W 200 S #500, Salt Lake City, UT 84101 or by email to *BLM_HQ_PRA_Comments@blm.gov.* Please reference OMB Control Number 1004–0058 and RIN 1004–AE61 in the subject line of your comments. Please note that due to COVID–19, electronic submission of comments is recommended.

National Environmental Policy Act

The BLM has determined that the changes made by this final rule are administrative or procedural in nature in accordance with 43 CFR 46.210(i), which provides that policies, directives, regulations, and guidelines: That are of an administrative, financial, legal, technical, or procedural nature; or whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis and will later be subject to the NEPA process, either collectively or case-by-case. Further, the final rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. Therefore, this action is categorically excluded from environmental review under NEPA. Documentation of the reliance upon a categorical exclusion has been prepared and is available for public review with the other supporting documents for this rule.

Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

Author

The principal authors of this rule are: Wade Salverson and Christian Schumacher, Division of Forest, Rangeland, and Vegetation Resources; Jennifer Noe, Division of Regulatory Affairs.

List of Subjects

43 CFR Part 5000

Administrative practice and procedure, Forests and forest products, Public lands.

43 CFR Part 5400

Administrative practice and procedure, Forests and forest products, Public lands, Reporting and recordkeeping requirements.

43 CFR Part 5420

Forests and forest products, Government contracts, Public lands, Reporting and recordkeeping requirements.

43 CFR Part 5440

Forests and forest products, Government contracts, Public lands, Reporting and recordkeeping requirements.

43 CFR Part 5450

Forests and forest products, Government contracts, Public lands, Reporting and recordkeeping requirements.

Surety bonds.

43 CFR Part 5460

Forests and forest products, Government contracts, Public lands.

43 CFR Part 5470

Forests and forest products, Government contracts, Public lands, Reporting and recordkeeping requirements.

43 CFR Part 5500

Forests and forest products, Public lands.

Katharine MacGregor,

Deputy Secretary, U.S. Department of the Interior.

43 CFR Chapter II

For the reasons set out in the preamble, the Bureau of Land Management amends 43 CFR parts 5000, 5400, 5420, 5440, 5450, 5460, 5470, and 5500 as follows:

■ 1. Revise part 5000 to read as follows:

PART 5000—ADMINISTRATION OF FOREST MANAGEMENT DECISIONS

Subpart 5003—Administrative Remedies

Sec.
5003.1 Effect of decisions; general.
5003.2 Notice of forest management decisions.
5003.3 [Reserved]
5003.4 Definitions: General.
5003.5 Severability.
Subpart 5004 [Reserved]

Authority: 43 U.S.C. 2601; 30 U.S.C. 601 *et seq.;* 43 U.S.C. 1701.

Subpart 5003—Administrative Remedies

§ 5003.1 Effect of decisions; general.

Notwithstanding the provisions of 43 CFR 4.21(a):

(a) The authorized officer may make a forest management decision, as described in § 5003.2, effective immediately or on a date established in the decision. The filing of a petition for a stay pending appeal under 43 CFR part 4 shall not automatically suspend the effect of a forest management decision issued under § 5003.2.

(b) Where the Bureau of Land Management (BLM) determines that vegetation, soil, or other resources on the public lands are at substantial risk of wildfire due to drought, fuels buildup, or other reasons, or at immediate risk of erosion or other damage due to wildfire, BLM may make a wildfire management decision made under this part and parts 5400 through 5510 of this subchapter effective immediately or on a date established in the decision. Wildfire management includes but is not limited to:

(1) Fuel reduction or fuel treatment such as prescribed burns and mechanical, chemical, and biological thinning methods (with or without removal of thinned materials); and

(2) Projects to stabilize and rehabilitate lands affected by wildfire.

(c) The Interior Board of Land Appeals will issue a decision on the merits of an appeal of a wildfire management decision under paragraph (b) of this section within the time limits prescribed in 43 CFR 4.416.

§ 5003.2 Notice of forest management decisions.

(a) The BLM authorizes forest management activities, which are defined in § 5003.4, by issuing forest management decisions. Forest management decisions that the BLM may make effective immediately pursuant to § 5003.1(a) shall be posted on a designated agency website while also:

(1) Publishing a notice in a newspaper of general circulation in the area;

(2) Sending a notice by direct or electronic mail to a list of parties requesting direct notification; or

(3) Broadcasting a notice on one or more mass-media platforms.

(b) The posting date of the forest management decision on the agency website establishes the effective date of the decision for purposes of an appeal under 43 CFR part 4.

§ 5003.3 [Reserved]

§ 5003.4 Definitions: General.

Forest management activity generally means activities with a silvicultural or forest protection objective including associated actions needed to carry out the silvicultural or forest protection objective, such as construction and maintenance of roads and improvements.

§ 5003.5 Severability.

If a court holds any provisions of the regulations in this subpart or their applicability to any person or circumstances invalid, the remainder of this subpart and its applicability to other people or circumstances will not be affected.

Subpart 5004 [Reserved]

PART 5400—SALES OF FOREST PRODUCTS; GENERAL

■ 2. The authority citation for part 5400 is revised to read as follows:

Authority: 30 U.S.C. 601 *et seq.,* 43 U.S.C. 315, 2601, 16 U.S.C. 607a, and 43 U.S.C. 1701 *et seq.*

Subpart 5400—Sales of Forest Products; General

■ 3. Amend § 5400.0–3 by revising paragraphs (a) and (c) to read as follows:

§ 5400.0–3 Authority.

(a) The Act of August 28, 1937 (43 U.S.C. 2601) authorizes the sale of timber from the Revested Oregon and California Railroad and Reconveyed Coos Bay Wagon Road Grant Lands and directs that such lands shall be managed for permanent forest production and the timber thereon sold, cut, and removed in conformity with the principle of sustained yield for the purpose of providing a permanent source of timber supply, protecting watersheds, regulating streamflow and contributing to the economic stability of local communities and industries, and providing recreational facilities.

* * * * *

(c) Public Law 101–382 (104 Stat. 714) Forest Resources Conservation and Shortage Relief Act of 1990 (16 U.S.C. 620) restrictions on exports of unprocessed timber originating from Federal lands.

* * * * *

■ 4. Amend § 5400.0–5 by:

■ a. Adding the definition for ''Export'' in alphabetical order;

■ b. Revising the definition of ''Fair Market value;''

■ c. Adding the definitions for ''Lump-sum,'' ''Scale sale,'' and ''Sourcing area'' in alphabetical order; and

■ d. Revising the definitions of ''Substitution'' and ''Third party scaling.''

The additions and revisions read as follows:

§ 5400.0–5 Definitions.

* * * * *

Export means the transporting or causing to be transported, either directly or through another party, unprocessed timber to a foreign country. Export occurs on the date that a person enters into an agreement to sell, trade, or otherwise convey such timber to a person for delivery to a foreign country. If the date in the preceding sentence cannot be established, export occurs when unprocessed timber is placed in an export facility for preparation, including but not limited to, sorting or bundling, and container loading, for shipment outside the United States, or when unprocessed timber is placed on board an oceangoing vessel, rail car, or other conveyance destined for a foreign country, port, or facility.

Fair Market value means the price forest products will return when offered for competitive sale on the open market.

* * * * *

Lump-sum means a sale where the total quantity of forest product that is designated for removal is estimated and established prior to the sale.

* * * * *

Scale sale means a sale where the total quantity of forest product that is designated for removal is determined after cutting, but before its conversion or end use.

* * * * *

Sourcing area means a geographic area approved by the Secretary of the Interior where prohibitions for direct and indirect substitution shall not apply with respect to the acquisition of unprocessed timber originating from Federal lands west of the 100th meridian in the contiguous 48 States by a person who, in the previous 24 months, has not exported unprocessed timber originating from private lands within the sourcing area; and during the period in which such approval is in effect, does not export unprocessed timber originating from private lands within the sourcing area.

Substitution means:

(1) The purchase of a greater volume of Federal timber by an individual purchaser than has been his historic pattern within twenty-four (24) months of the sale of export by the same purchaser of a greater volume of his private timber than has been his historic pattern during the preceding twenty-four (24) months; and

(2) The increase of both the purchase of Federal timber and export of timber from private lands tributary to the plant for which Bureau of Land Management timber covered by a specific contract is delivered or expected to be delivered.

Third party scaling means the measurement of logs by a scaling organization or weight scale certified by a State, other than a Government agency, approved by the Bureau.

* * * * *

Subpart 5402—Other Than Advertised Sales; General

■ 5. Amend § 5402.0–6 by revising paragraph (d), adding paragraph (e), and removing the parenthetical authority citation at the end of the section to read as follows:

§ 5402.0–6 Policy.

* * * * *

(d) All negotiated sales shall be subject to the restrictions relating to the export and substitution from the United States of unprocessed timber.

(e) Special forest products, including firewood, Christmas trees, boughs, greenery, mushrooms, and other similar vegetative resources, may be sold by permit, without appraisal, after payment to the Government of adequate compensation for the material and may include the expense of issuance of the permit.

■ 6. Revised part 5410 to read as follows:

PART 5410—ANNUAL TIMBER SALE PLAN

Subpart 5410—Annual Timber Sale Plan; General

Sec.

5410.0–6 Policy.

Subpart 5411 [Reserved]

Authority: 30 U.S.C. 601 *et seq.;* 43 U.S.C. 2604.

Subpart 5410—Annual Timber Sale Plan; General

§ 5410.0–6 Policy.

Plans for the sale of timber from the O. and C. and public lands (as defined in § 5400.0–5 of this chapter) will be developed annually. Suggestions from prospective purchasers of such timber may be received to assist in the development of a sound annual timber sale plan. Such plan may be advertised in a newspaper of general circulation in the area in which the timber is located or an agency website. Such advertisement shall indicate generally the probable time when the various tracts of timber included in the plan will be offered for sale, set-asides if any, and the probable location and anticipated volumes of such tracts. The authorized officer may subsequently change, alter or amend the annual timber sale plan.

Subpart 5411 [Reserved]

PART 5420—PREPARATION FOR SALE

■ 8. The authority citation for part 5420 is revised to read as follows:

Authority: 30 U.S.C. 601 *et seq.;* 43 U.S.C. 2604.

Subpart 5420—Preparation for Sale; General

■ 9. Revise § 5420.0–6 to read as follows:

§ 5420.0–6 Policy.

All timber or other vegetative resources to be sold, except materials that qualify under § 5402.0–6(e) of this chapter, will be appraised to estimate fair market value. Measurement shall be by tree cruise, log scale, weight, or such other form of measurement as may be determined to be in the public interest.

Subpart 5422—Volume Measurements

■ 10. Revise § 5422.1 to read as follows:

§ 5422.1 Lump-sum sales.

As the general practice, the Bureau of Land Management (BLM) will estimate volume for a lump-sum sale using a tree cruise basis.

■ 11. Revise § 5422.2 to read as follows:

§ 5422.2 Scale sales.

(a) Scaling will be performed by the BLM or third-party scaling organization approved by the BLM or any operator of a State-certified weight scale.

(b) The BLM may also order third-party scaling for administrative reasons. Such reasons would include, but are not limited to, the following: to improve cruising standards, to check accuracy of cruising practices, and for volumetric analysis.

Subpart 5424—Preparation of Contract

■ 12. Amend § 5424.0–6 by revising paragraph (d) to read as follows:

§ 5424.0–6 Policy.

* * * * *

(d) The contract or permit form and any additional provisions shall be made available for inspection by prospective bidders during the advertising period. When sales are negotiated, all additional provisions shall be made part of the contract or permit.

* * * * *

■ 13. Amend § 5424.1 by revising paragraphs (a)(1) and (2) to read as follows:

§ 5424.1 Reporting provisions for substitution determination.

(a) * * *

(1) A purchaser who has exported private timber within two years preceding the purchase date of Federal timber; and/or

(2) An affiliate of a timber purchaser who exported private timber within two years before the acquisition of Federal timber from the purchaser.

* * * * *

PART 5430—ADVERTISEMENT

Subpart 5430—Advertisement; General

■ 14. The authority citation for part 54030, subpart 5430, is revised to read as follows:

Authority: 43 U.S.C. 2604, 30 U.S.C. 601 *et seq.*

■ 15. Revise § 5430.0–6 to read as follows:

§ 5430.0–6 Policy.

Competitive timber sales shall be advertised in a newspaper of general circulation or agency website in the area in which the timber or other vegetative resources are located and a notice of the sale shall be posted in a conspicuous place in the office where bids are to be submitted. Such advertisement shall be published on the same day once a week for two consecutive weeks, except that sales amounting to less than 500 M board feet, need be published once only. When in the discretion of the authorized officer longer advertising periods are desired, such longer periods are permitted.

PART 5440—CONDUCT OF SALES

■ 16. The authority citation for part 5440 is revised to read as follows:

Authority: 43 U.S.C. 2604, 30 U.S.C. 601 *et seq.*

Subpart 5441—Advertised Sales

■ 17. Amend § 5441.1 by revising paragraph (c) to read as follows:

§ 5441.1 Qualification of bidders.

* * * * *

(c) Timber sale contracts are ''covered transactions'' under the suspension and debarment rules for discretionary assistance, loan, and benefit award programs at 2 CFR part 180, implemented as a regulation by the Department of the Interior (the Department) at 2 CFR part 1400. See 2 CFR 180.200, 180.210, and 1400.970.

(1) A bidder or purchaser that has been suspended, debarred, or otherwise determined to be ineligible for award is prohibited from bidding on a timber sale unless an award specific written compelling reasons exception determination pursuant to 2 CFR 180.135 and 1400.137 is issued by the Department's Director of the Office of Acquisition and Property Management to permit an excluded party to participate in the covered transaction.

(2) A bidder or purchaser suspended, debarred, or otherwise award ineligible may continue to bid on timber purchase contracts; however, absent issuance of a written compelling reasons determination under paragraph (c)(1) of this section, no award shall be made during the period of award ineligibility.

(3) As required by 2 CFR 180.335, prior to awarding a timber sale contract, a bidder or purchaser (*i.e.,* a nonprocurement award participant) shall certify to the Bureau of Land Management (BLM) that neither the entity nor any of its principals, as defined at 2 CFR 180.995, is suspended, debarred, or otherwise disqualified.

(4) If a participant enters into a covered transaction with another person at the next lower tier, the participant must verify that the person with whom they intend to enter into that transaction is not suspended, debarred, or otherwise award disqualified. See 2 CFR 180.300 and 1400.220.

■ 18. Revise § 5441.1–1 to read as follows:

§ 5441.1–1 Bid deposits.

Sealed bids shall be accompanied by a deposit of not less than 10 percent of the appraised value of the timber or other vegetative resources. For offerings at oral auction, bidders shall make a deposit of not less than 10 percent of the appraised value prior to the opening of the bidding. The authorized officer may, in his or her discretion, require larger

deposits. Deposits may be in the form of cash, money orders, bank drafts, cashiers or certified checks made payable to BLM, or bid bonds of a corporate surety shown on the approved list of the United States Treasury Department or any guaranteed remittance approved by the authorized officer. Upon conclusion of the bidding, the bid deposits of all bidders, except the high bidder, will be returned. The deposit of the successful bidder will be applied to the purchase price at the time the contract is signed by the authorized officer unless the deposit is a corporate surety bid bond, in which case the surety bond will be returned to the purchaser. If BLM fails to award the timber sale within 90 days of the determination of the high bidder, a portion of the bid deposit may be refunded to the high bidder upon written request to the authorized officer, such that BLM retains a deposit of at least 5% of the appraised value. The remainder of the full bid deposit must be resubmitted to BLM once the high bidder is notified in writing that the delay of award has been remedied and the authorized officer is prepared to issue the contract. If the high bidder is unable to provide the full amount of the bid deposit within 30 days of the written notification, the sale will be re-auctioned and the high bidder will be barred from participating in any subsequent auctions for the same tracts.

§ 5441.1–2 [Removed]

■ 19. Remove § 5441.1–2.

§ 5441.1–3 [Redesignated as § 5441.1–2]

■ 20. Redesignate § 5441.1–3 as § 5441.1–2.

PART 5450—AWARD OF CONTRACT

■ 21. The authority citation for part 5450 is revised to read as follows:

Authority: 43 U.S.C. 2604; 30 U.S.C. 601 *et seq.*

Subpart 5451—Bonds

■ 22. Amend § 5451.1 by revising paragraph (a) introductory text to read as follows:

§ 5451.1 Minimum performance bond requirements; types.

(a) A minimum performance bond of not less than 20 percent of the total contract price shall be required for all contracts of $10,000 or more, but the amount of the bond shall not be in excess of $500,000, except when the purchaser opts to increase the minimum bond as provided in § 5451.2. A minimum performance bond of not less than $500 or 20% of the contract price, whichever is greater, will be required for all installment contracts less than $10,000. For cash sales less than $10,000, bond requirements, if any, will be at the discretion of the authorized officer. The performance bond may be:

* * * * *

PART 5460—SALES ADMINISTRATION

■ 23. The authority citation for part 5460 is revised to read as follows:

Authority: 30 U.S.C. 601 *et seq.,* 43 U.S.C. 2604.

Subpart 5461—Contract Payments

■ 24. Revise § 5461.3 to read as follows:

§ 5461.3 Total payment.

The total amount of the contract purchase price must be paid prior to expiration of the time for cutting and removal under the contract. For a lump sum sale, the purchaser shall not be entitled to a refund even though the amount of timber cut, removed, or designated for cutting may be less than the estimated total volume shown in the contract. For a scale sale, if it is determined after all designated timber has been cut and measured that the total payments made under the contract exceed the total sale value of the timber measured, such excess shall be refunded to the purchaser within 60 days after such determination is made.

Subpart 5463—Expiration of Time for Cutting and Removal

■ 25. Revise § 5463.1 to read as follows:

§ 5463.1 Time for cutting and removal.

Time for cutting and removal of timber or other vegetative resources sold shall not exceed a period of forty-eight months such time for cutting and removal may be extended as provided in 43 CFR part 5470, subpart 5473.

PART 5470—CONTRACT MODIFICATION—EXTENSION—ASSIGNMENT

■ 26. The authority citation for part 5470 is revised to read as follows:

Authority: 30 U.S.C. 601; 43 U.S.C. 2604 and 1740.

Subpart 5473—Extension of Time for Cutting and Removal

■ 27. Amend § 5473.4 by:

■ a. Removing the word ''or'' at the end of paragraph (c)(4);

■ b. Revising paragraph (c)(5);

■ c. Adding paragraphs (c)(6) and (7); and

■ d. Revising paragraph (d).

The revisions and additions read as follows:

§ 5473.4 Approval of request.

* * * * *

(c) * * *

(5) Closure of operations by Bureau of Land Management (BLM) or State fire protection agencies due to fire danger;

(6) Closure of operations due to unusual weather, where BLM restricted operations during periods with specific environmental conditions, including but not limited to restrictions for low soil moisture, sustained dry periods, frozen soils, or operations requiring snow cover of specific depth; or

(7) County, State, or Federal government issuance of an emergency declaration or public order affecting a purchaser's ability to conduct operations in a contract area, along a designated haul route or proximate processing facilities.

(d) Upon written request of the purchaser, the State Director may extend a contract to harvest green timber to allow that purchaser to harvest timber as salvage from other Federal or non-Federal lands that have been damaged by fire or other natural or man-made disaster. The duration of the extension shall not exceed the time necessary to meet the salvage objectives, or a maximum of 36 months. The State Director may also waive reappraisal for such extension.

PART 5500—NONSALE DISPOSALS; GENERAL

Subpart 5500—Nonsale Disposals; General

■ 28. The authority citation for part 5500, subpart 5500, is revised to read as follows:

Authority: 30 U.S.C. 601 *et seq.,* 43 U.S.C. 315, 423.

■ 29. Amend § 5500.0–5 by revising paragraph (e) to read as follows:

§ 5500.0–5 Definitions.

* * * * *

(e) *Public Lands* means any land and interest in land owned by the United States within the several States and administered by the Secretary of the Interior through the Bureau of Land Management, including O. and C. Lands, without regard to how the United States acquired ownership, except:

(1) Lands located on the Outer Continental Shelf; and

(2) Lands held for the benefit of Indians, Aleuts, and Eskimos.

* * * * *

[FR Doc. 2020–27580 Filed 12–17–20; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–ES–2019–0115; FF09E23000 FXES1111090FEDR 212]

RIN 1018–BD84

Endangered and Threatened Wildlife and Plants; Regulations for Designating Critical Habitat

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS or Service), amend portions of our regulations that implement section 4 of the Endangered Species Act of 1973, as amended (Act). The revisions set forth a process for excluding areas of critical habitat under section 4(b)(2) of the Act, which mandates our consideration of the impacts of designating critical habitat and permits exclusions of particular areas following a discretionary exclusion analysis. These regulations outline when and how the Service will undertake an exclusion analysis, including identifying a non-exhaustive list of categories of potential impacts that we will consider. This rule, reflects agency experience, codifies some current agency practices, makes some modifications to current agency practice, and responds to applicable Supreme Court case law. The intended effect of this rule is to provide greater transparency and certainty for the public and stakeholders.

DATES:

Effective date: This final regulation is effective on January 19, 2021.

Applicability date: This revised regulation applies to critical habitat rules for which a proposed rule is published after January 19, 2021.

ADDRESSES: Public comments and materials received, as well as supporting documentation used in the preparation of this final regulation, are available on the internet at *http://www.regulations.gov* in Docket No. FWS–HQ–ES–2019–0115.

FOR FURTHER INFORMATION CONTACT: Gary Frazer, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240, telephone 202/208–4646. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS) at 800/877–8339.

SUPPLEMENTARY INFORMATION:

Background

On September 8, 2020, we proposed to amend portions of our regulations that implement section 4 of the Endangered Species Act of 1973, as amended (hereafter ''Act''; 16 U.S.C. 1531 *et seq.*). In that proposed rule (85 FR 55398), we provided the background for our proposed revisions in terms of the statute, legislative history, and case law; a brief description of the proposed rule follows:

The implementing regulations for the designation of critical habitat for listed species are located in part 424 of title 50 of the Code of Federal Regulations. Relevant definitions are at 50 CFR 424.02, and the standards and procedures for identifying critical habitat are at 50 CFR 424.12. These regulations are jointly administered between the Service and the National Marine Fisheries Service (NMFS) (referred to hereafter as the ''Services''). On February 11, 2016, the Services issued a joint policy describing how we implement the authority to exclude areas from critical habitat designations (''Policy Regarding Implementation of Section 4(b)(2) of the Endangered Species Act,'' 81 FR 7226; hereafter the ''2016 Policy'').

The proposed revisions in our September 8, 2020, proposed rule (85 FR 55398) set forth a process for excluding areas of critical habitat under section 4(b)(2) of the Act, which mandates our consideration of the impacts of designating critical habitat. Section 4(b)(2) of the Act requires us first to consider the relevant impacts of designating critical habitat and authorizes us then to exclude particular areas from the designation based on our discretionary exclusion analysis. We wanted to articulate clearly when and how we will undertake an exclusion analysis, including identifying a non-exhaustive list of categories of potential impacts for us to consider.

In the proposed rule, we revisited certain language in the preamble of the 2016 Policy, as well as certain statements in the preamble to a 2013 rule that revised the regulations on the timing of our economic analyses at 50 CFR 424.19 (August 28, 2013, 78 FR 53058). This 2013 rule is discussed below in this document and is referred to hereafter as the ''Final 424.19 Rule.'' Our goal in the proposed rule was to provide clarity to the Service and the public in light of agency experience and current practices, and to respond to the Supreme Court's recent decision in *Weyerhaeuser Co.* v. *U.S. FWS,* 139 S. Ct. 361 (2018).

In this final rule, we focus our discussion on the comments we received during the comment period and our consideration of the issues raised. For background on the statutory and legislative history and case law relevant to this regulation, we refer the reader to the proposed rule (85 FR 55398, September 8, 2020).

Effects of the Final Rule

After consideration of the information provided through the public comment process, we are finalizing this rule as proposed, but have provided clarification to questions and concerns below in the responses to public comments.

In finalizing the specific changes to the current regulations in the rule portion of this document and setting out the accompanying clarifying discussion in this preamble, we are establishing prospective standards only. Although this regulation is effective 30 days from the date of publication as indicated in **DATES** above, it will apply only to relevant rulemakings for which the proposed rule is published after that date. Thus, the Service will continue to apply the 2016 Policy and the regulations at 50 CFR part 424 to any rulemakings for which a proposed rule was published before the effective date of this rule. Nothing in this final revised regulation is intended to require that any previously completed critical habitat designation be reevaluated on the basis of this final regulation.

For critical habitat designations or revisions that FWS proposes after the effective date of this rulemaking action, we will not apply the 2016 Policy or the Final 424.19 Rule. These regulations primarily adopt and deepen the provisions in the 2016 Policy and Final 424.19 Rule, and, therefore, supersede the 2016 Policy and Final 424.19 Rule with respect to FWS. However, NMFS will continue to implement the 2016 Policy and Final 424.19 Rule for purposes of their critical habitat rulemaking actions. For critical habitat designations or revisions that FWS proposed prior to the effective date of these regulations, FWS will apply the 2016 Policy and the Final 424.19 Rule.

Summary of Comments and Responses

In our proposed rule published on September 8, 2020 (85 FR 55398), we requested public comments on the provisions of the proposed rule. During the public comment period, we received several requests for public hearings. Public hearings are not required for regulation revisions of this type, and we elected not to hold public hearings. After considering several requests for

extensions of the public comment period beyond the original 30-day public comment period, we also decided not to extent the public comment period.

The APA does not specify a minimum number of days for a comment period, but the comment period must be long enough to afford the public a meaningful opportunity to comment, which usually leads agencies to allow a comment period of at least 60 days. Consistent with this principle, courts give broad discretion to agencies in determining the reasonableness of a comment period. Courts have frequently upheld comment periods that were shorter than 60 days. *See, e.g., Connecticut Light & Power Co.* v. *Nuclear Regulatory Comm'n,* 673 F.2d 525, 534 (D.C. Cir. 1982) (upholding a 30-day comment period and stating that ''neither statute nor regulation mandates that the agency do more''). In addition to the length of a comment period, courts consider the number of comments received and whether comments had an effect on an agency's final rule, in assessing whether the public had a meaningful opportunity to comment. Although the comment period here was shorter than 60 days, the public had a meaningful opportunity to comment on the proposed rule. The Services received more than 28,600 public submissions representing more than 107,600 individual commenters. Among the submissions were multiple letters from organizations signed by thousands of individuals expressing general opposition to the rule. Although many of the other individual comments were non-substantive in nature, expressing either general support for, or opposition to, the proposed rule with no supporting information or analysis, we also received many detailed substantive comments with specific rationale for support of, or opposition to, specific portions of the proposed rule. Below, we summarize the substantive public comments sent by the October 8, 2020, deadline.

Comment 1: Some commenters supported adding a requirement that the Service always exclude areas from critical habitat when the costs of designation outweigh the benefits of critical habitat, while others said that the proposed process would prioritize economic gains over species protection. Some were concerned the proposed process for analyzing potential exclusions would base critical habitat exclusions on analyses of incomparable ecological and economic costs and benefits. Additionally, others requested that we determine the monetary value of species and habitats according to the ecosystem services they provide as a way to directly compare the economic costs of designation with biological benefits.

Response: When identifying the areas that meet the definition of ''critical habitat,'' Congress expressly prohibited the Secretaries from using anything other than the best scientific data available. However, Congress also expressly required the Secretaries to consider economic impacts, national-security impacts, and other relevant impacts before finalizing the critical habitat designation. Thus, Congress intended us to consider both the biological needs of a species and economic considerations when designating critical habitat.

As described in the proposed rule, once the Secretary has identified and considered economic and other relevant impacts, he has discretion in how to determine whether the benefits of excluding a particular area from the designation outweigh the benefits of including that area in the designation (see also M–37016,''The Secretary's Authority to Exclude Areas from a Critical Habitat Designation under Section 4(b)(2) of the Endangered Species Act'', October 3, 2008). The regulation states that the Secretary shall exclude any area where the benefits of exclusion outweigh those of inclusion; benefits of exclusion may include avoidance of economic, national security, and other relevant impacts while benefits of inclusion may include ecological or conservation benefits.

When the Service undertakes the mandatory consideration of economic costs and benefits of each critical habitat designation, we are guided by the Final 424.19 Rule. That rule codified the approach of evaluating the incremental impacts when conducting impact analyses, including economic analyses, for critical habitat designations. The preamble to the Final 424.19 Rule provided the numerous legal authorities that support the use of an incremental-impacts analysis, including the Office of Management and Budget's (OMB's) Circular A–4, which provides guidance and best practices for consideration of impacts of regulatory actions. Additionally, this final rule incorporates the incremental-impacts language from the Final 424.19 Rule without change, including the first two sentences of paragraph (a) and all of paragraph (b). As part of this process, we consider the best available information regarding the anticipated impacts of exclusion, either positive or negative, and may include valuation or monetization of ecosystem services provided by species and ecosystems if the information is available.

Comment 2: Several commenters requested that we include all economic impacts of a listing in our economic assessment following the coextensive approach, rather than limiting it to the incremental effects of critical habitat designation. Commenters also requested that the regulation include a definition of ''meaningful'' economic impacts and a description of their scope, along with a requirement to use a quantitative economic assessment whenever possible. Additionally, some commenters requested that only economic impacts in a defined area and only those tied to Federal actions should be considered.

Response: Our Final 424.19 Rule codified the use of the incremental method for conducting impact analyses, including economic analyses, for critical habitat designations. That final rule contains responses to public comments that clearly lay out the Services' rationale for using the incremental method. Evaluating incremental impacts that result from a regulation being promulgated, rather than considering coextensive impacts that may be ascribed to various previous regulations, is further supported by Executive Order 12866, as applied by OMB Circular A–4. In addition, a recent court decision addressing this question confirmed the validity of evaluating incremental impacts of critical habitat designations even in the Tenth Circuit, which used to require coextensive analysis. *Northern N.M. Stockman's Ass'n* v. *U.S.F.W.S.,* No. 18–1138 JB/JFR, slip op. 136–37, 140–78 (D.N.M. Oct. 13, 2020) (concluding that the Service's incremental impacts approach was permissible in light of regulatory changes that post-dated Tenth Circuit decision that had required coextensive approach).

We do not define ''meaningful,'' as we intend it to have its plain-language meaning. We included the word to indicate that evidence of de minimis economic impacts of a proposed designation will not trigger an exclusion analysis. Our consideration of economic impacts includes an assessment of the probable economic impacts of a designation. We evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. In conducting economic analyses, we follow the guidance and best practices set out in Executive Orders (E.O.s) 12866 and 13563, as well as OMB's Circular A–4. Those guidelines direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent

feasible, including monetization) and qualitative terms. As part of our analysis, we consider the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation.

Comment 3: Many commenters support inclusion of a non-exhaustive list of categories of potential impacts described in the proposed rule. Commenters stated that lists would provide clarity and would allow focused public comments while being adaptable to the needs of affected areas. Additionally, many commenters suggested that we add to or elaborate on the potential impacts listed in the proposed regulations, including that we add both direct and indirect impacts to the list.

Response: The text of the regulation is clear that the examples or categories provided in the regulation are not exhaustive. Based on the specific facts in particular critical habitat designations, there may be other impacts identified, and we would consider those impacts. We develop and share a draft economic analysis that considers categories of potential economic impacts at the time we propose critical habitat for a species. When available, we also describe exclusions we are considering and solicit public comments on specific information that may inform those potential exclusions and other potential impacts not known to us at the time of the proposed designation. We are required to evaluate the direct and indirect costs of the designation of critical habitat under the provisions of Executive Order 12866, and we do so through the draft economic analyses of the designation.

Comment 4: Some commenters stated that the Service should engage with appropriate State and other authorities while developing a non-exhaustive list of categories of potential impacts prior to publishing a draft critical habitat designation. Regulations should include a process for consulting with and considering input of State fish and wildlife agencies, local governments, and Tribal governments to identify economic and other relevant impacts.

Response: We routinely coordinate with State and Federal partners during the development of a species status assessment for evaluation of whether to list a species, and with Federal agencies during the development of the draft economic analysis of a proposed critical habitat rule. Through these coordination efforts, we typically receive information from State and Federal agencies regarding potentially relevant impacts of a designation of critical habitat early in our development of a critical habitat designation. Additionally, during the public comment period for a proposed critical habitat designation, we receive information regarding other potentially relevant economic or other impacts from State agencies, local governments, and Tribal governments that we consider when finalizing the designation. We conclude that our current process provides for coordination with States and other authorities, and it is unnecessary to codify our process in regulation.

Comment 5: Some commenters indicated that the list of economic impacts and ''other relevant impacts'' is unlawfully broad, such as including ''community impacts.'' They believed such items were far-reaching and speculative, and definitions could conceivably apply to all but the least substantiated information submissions and to nearly every proposed critical habitat designation, rendering what was a discretionary analysis mandatory under the proposed rule. Such broad lists would place a heavy burden on the Service to evaluate claims of impacts even if evidence is weak. Some commenters suggested we clarify terms such as ''community impacts.''

Response: The phrase ''other relevant impacts'' in the statute gives the Secretary broad discretion to determine what those other relevant impacts might be. This discretion is thoroughly described in Solicitor's Memorandum Opinion M–37016, ''The Secretary's Authority to Exclude Areas from a Critical Habitat Designation under Section 4(b)(2) of the Endangered Species Act,'' (October 3, 2008, p. 12), and the list provided in the proposed rule and in this final rule illustrates the types of information we may consider. We do not agree with comments that state that the elaboration of the types of other relevant impacts is overly broad and therefore would lead us to conduct exclusion analyses for every designation, thereby rendering those analyses ''mandatory.'' The credible-information threshold states that an economic or other relevant impact must be meaningful to support a benefit of exclusion. Therefore, with the application of the credible-information threshold, we anticipate that we will not be in a position where every submission by a proponent of an exclusion would meet the standard of having a meaningful impact and thereby trigger an exclusion analysis. Regarding the phrase ''community impacts,'' the proposed rule provides a few examples of this phrase; however, we will evaluate on a case-by-case basis any information that is submitted by a proponent of an exclusion to determine whether credible information regarding whether there is an impact to a community is presented.

Comment 6: Commenters stated that the proposed rule does not address the impacts of excluding an area necessary to the recovery of a species, nor does it address the mechanisms through which benefits will accrue for the species if critical habitat were to be designated. Impacts on recovery should be addressed, because the goal of the Act is ultimately to recover and delist the species. Additionally, we should consider all relevant factors—including how designating critical habitat is likely to affect the species' risk of extinction and how potential exclusion of areas would affect the recovery of the species—before granting exclusions.

Response: We consider the potential effects to species' recovery when we enter into an exclusion analysis under section 4(b)(2) of the Act. In giving weights to the benefits of including and excluding particular areas, we evaluate the conservation value of the area, including the current function of the area for the species and the future recovery value of the area to the species. Benefits of including or excluding an area from critical habitat are considered for each designation and are fact-specific to each species. We note that critical habitat is one of many tools available to recover species, and the exclusion of an area from a critical habitat designation does not mean that it no longer contributes to recovery. In fact, FWS has excluded many areas because they are already being managed for the conservation of the species thereby reducing the benefits of including those areas within a critical habitat designation. Further, many areas that are excluded from critical habitat designation but are not being managed for conservation of the species still contribute to the recovery of the species.

Comment 7: Some commenters stated that we should allow comment on the draft economic analysis and on our evaluation of any relevant impact of including or excluding areas from the critical habitat. The public may have significant non-economic concerns. Therefore, commenters recommended we expand this rule to allow the public to comment on any relevant factor regarding a designation, not just the economic analysis. The commenters opined that doing so is consistent with congressional intent and would minimize judicial challenge.

Response: We routinely seek comment on proposed designations of critical habitat regarding a wide range of issues, including biological factors that

support the proposed designation and non-biological considerations that may inform potential exclusions from the final designation. We do not limit the scope of public comment to non-economic considerations; all relevant substantive comments are considered when developing a final designation of critical habitat. We make the draft economic analysis of the proposed designation of critical habitat available concurrent with publication of the proposed rule to designate critical habitat. During the public comment period for a proposed designation, the public has ample opportunity to review and comment on the economic analysis, as well as on any other relevant impacts from the designation of critical habitat. Because we already request public comment on all areas of the rulemaking whenever we propose to designate critical habitat, modifying this regulation to require the Service to request comments on non-economic impacts is duplicative and unnecessary.

Comment 8: Commenters stated that the proposed rule's non-exhaustive list of ''other relevant impacts'' and economic impacts is heavily weighted toward negative impacts of designating critical habitat on the community and other stakeholders. It does not consider the potential economic and community benefits (*e.g.,* socio-economic benefits), or cultural or other ecological benefits or co-benefits (such as protection of other species), that may be distinct from the ''conservation value of the area.'' Historically, the Service considered a broad array of direct and indirect economic benefits from critical habitat designations. The list of categories of potential impacts largely focuses on costs and fails to provide transparency about benefits that the Service should consider.

Response: We are not limited to considering the relevant impact examples included in this rule. If the specific facts indicate that there are economic benefits from including a particular area in the designation, we would consider those benefits, where appropriate. In situations where economic benefits are relevant, we generally describe two broad categories of benefits of inclusion of particular areas of critical habitat: (1) Those associated with the primary goal of species conservation and recovery, and (2) those that derive from the habitat conservation measures to achieve this primary goal. In the rare cases where there are incremental impacts beyond administrative impacts from designating critical habitat, we may lack specific information to quantify the use or non-use benefits associated with critical habitat designations such as recreation, wildlife viewing, or ecosystem services that may result from critical habitat designations, but discuss them qualitatively, as permitted by OMB Circular A–4. As a result, we focus our analysis of benefits of inclusion qualitatively to describe the conservation value of the particular area of critical habitat as weighed against the benefits of exclusion.

Comment 9: Commenters stated that it is not clear how the text in proposed § 17.90(a) differs from the ''consider[ation of] probable economic, national security, and other relevant impacts'' referred to in § 17.90(b).

Response: The difference in these two paragraphs is procedural; in § 17.90, paragraph (a) describes the information we will provide in the proposed rule, while paragraph (b) describes our considerations in finalizing the rule. Paragraph (a) explains that the proposed critical habitat designation will identify known national security and other relevant impacts of the proposed designation and identify areas that the Secretary has reason to consider for exclusion and explain why. Additionally, we explain that at the proposed rule stage the Secretary will identify, to the extent known, the categories of potential impacts. We noted in the proposed rule that these impacts are the same as those that the Secretary will consider, as appropriate, when conducting the mandatory consideration of any other relevant impacts as expressed in the first sentence of section 4(b)(2) of the Act and in § 17.90(b). Including this list of categories as described in § 17.90(a) for consideration provides greater transparency and clarity to the public and stakeholders by providing information at the proposed rule stage to better inform public comment.

Comment 10: Commenters cite the statutory requirement that the appropriate scale of analysis is of the ''particular area'' of a proposed critical habitat designation and note that this is in conflict with the proposed rule allowing the Secretary to determine the appropriate scale for the consideration of impacts from a critical habitat designation. The commenters ask the Service to establish a consistent scale of analysis for all designations, or specify in the regulation that the scale of analysis applies to the ''particular area'' or otherwise clarify that the exclusion analysis will only evaluate impacts at a scale that considers the ''particular areas'' of a designation. Commenters state that the proposed rule, as written, would allow the Secretary to select the scale used in the exclusion analysis and assess impacts without regard to the ''particular areas'' of a proposed designation. Other commenters suggest that the Secretary should retain the discretion to determine exclusions at whatever scale he deems to be appropriate, to specifically state what that scale is in the proposed rule when making a critical habitat designation, and to take into full consideration the economic impacts at that scale. Another commenter suggested that the scale of the analysis should be tied to the probability of a Federal nexus.

Response: Each critical habitat designation is different in terms of determining the area that meets the definition of critical habitat, the scope of the applicable Federal actions, economic activity, and the scales for which data are available, and each is very fact-specific. Therefore, the Service must have flexibility to evaluate these ''particular areas'' of critical habitat in whatever way is most meaningful and at whatever scale is appropriate in each situation. For example, for a narrowly distributed endemic species, a critical habitat proposal may cover a small area; in contrast, for a wide-ranging species, a critical habitat proposal may cover an area that is orders of magnitude greater. The appropriate scale of the impact analysis for these two species may not be the same. For the endemic species, it may be possible to conduct an impact analysis at a very fine scale with a great level of detail. In contrast, an impact analysis for the wide-ranging species, which may cover wide expanses of land or water, may use a coarser scale of analysis, due to the sheer size of the proposed designation. Each critical habitat proposal includes a description of the scope of the area being proposed and the ''particular areas'' that are being considered for exclusion, and uses the scale of analysis appropriate to that situation. Furthermore, while we will evaluate the likely effects of designating critical habitat upon the need to engage in, or outcomes of, consultations under section 7 of the Act, the scale of the analysis will be at the appropriate scale as determined by the Secretary. Because the scale is dependent on the data available and is very fact-specific, it will not be necessarily determined by the potential for section 7 consultations.

Comment 11: Commenters requested that the rule clarify or provide a definition for ''credible information'' and outline a clear process for soliciting this information. They suggested clarifying what information should be submitted, when to submit, and how the Service will evaluate the information to determine whether it constitutes credible information.

Response: As stated in the proposed rule, ''credible information'' refers to information that constitutes a reasonably reliable indication regarding the existence of a meaningful economic or other relevant impact supporting a benefit of exclusion for a particular area. In each proposed designation of critical habitat, we solicit information regarding the biological basis for the designation, as well as any probable impact resulting from it. In addition to soliciting public comments on the proposed designation, we also share a draft economic analysis of the designation and solicit comments on that analysis. In determining what constitutes ''credible information,'' we will look at whether the proponent has provided factual information in support of the claimed impacts. We will typically use our economic analysis of the proposed critical habitat designation to help identify any information that does not meet the credible information standard or to confirm or rebut information that is provided by a proponent of an exclusion. Whether the claimed impacts support a benefit of exclusion that could potentially outweigh the benefits of inclusion may therefore be meaningful for the purposes of an exclusion analysis.

Comment 12: Some commenters asserted that their information, such as from the States or other regulated entities, should always be considered credible, whereas other commenters stated that assuming information is credible unless the Service has rebutting information allows non-FWS entities to drive exclusions of critical habitat.

Response: We will evaluate any information provided from outside entities on a case-by-case basis and will decide whether to conduct an exclusion analysis based on whether the proponent of an exclusion has presented credible information regarding a meaningful impact supporting a benefit of exclusion. We decline to institute a list of entities whose information automatically qualifies as credible information. All information submitted to us in support of exclusion will be subject to the credible-information standard.

Comment 13: One commenter asserts that the credible-information standard would prioritize non-biological impacts when considering whether to conduct an exclusion analysis because the commenter anticipates that the most common credible information the Service is likely to receive will be information about non-biological impacts of designations of critical habitat.

Response: As stated in the proposed rule, the credible-information standard applies equally to biological and non-biological information, and the number of either category of comments that we receive that meet the ''credible-information standard'' is likely to differ from one designation to another. It is unknown if the Service will receive more comments about non-biological impacts or whether comments about non-biological impacts are more likely to meet the credible-information standard; we stress that each analysis will be done on a case-by-case basis. However, because the Act mandates our consideration of the impact to three broad categories of non-biological impacts prior to designating critical habitat, we conclude the inclusion of the broad array of non-biological considerations detailed in this rule is consistent with the Act.

Comment 14: Commenters provided both support for and opposition to the provision to assign weights of benefits of inclusion or exclusion based on who has the expertise. Commenters stated that it is unclear how the Service will determine if someone is an expert or what constitutes firsthand knowledge. They suggested that the Service should provide more clarity on how the expertise will be determined and how the weights will be assigned. They further stated that, without this information, the rule would establish a process that is less transparent and vague, would lead to inconsistent application, and is contrary to the conservation goals of the Act. Commenters expressed concern that this provision would inappropriately presume the validity of such information, which could include speculative economic analyses because the rule incentivizes inclusion of impacts provided by self-interested parties, and thereby allow non-FWS entities to drive critical habitat designations. Commenters expressed concern that deferring to information from outside experts would inappropriately delegate expert judgment and authority to third parties who are not statutorily authorized to perform these duties.

Alternatively, other commenters provided support for this provision because it allows for engagement from the public and stakeholders that will allow them to be part of the process and provide their firsthand knowledge. Commenters anticipated that allowing this stakeholder involvement will increase trust and would ensure we receive the best information. Some commenters supported the provision to weigh non-biological impacts in accordance with information provided by State or local governments because these entities have special expertise that should be included in an exclusion analysis. Further, some commenters suggested that the rule include a mandatory consultation process for States to ensure that the correct weights of benefits of exclusion are incorporated in the exclusion analysis, because States have had the responsibility of managing these species before FWS. Other commenters expressed support for allowing outside entities to provide information on economic impacts of the designation of critical habitat because the information from outside entities would improve FWS's economic analyses, which do not provide enough granularity to allow the public to understand the impacts.

Response: As stated in the proposed rule, we will give weight to benefits of inclusion or exclusion based on who has the relevant expertise. We will base critical habitat designations on the best available information, evaluate the information provided from outside entities on a case-by-case basis, and give weights of the benefits of inclusion or exclusion consistent with the available information from experts, firsthand knowledge, and the best available information that the Secretary may have to rebut that information. We do not consider speculative or unsupported information to be the best available information and will use our best professional judgment to evaluate all information critically before incorporating it into any exclusion analysis. Further, the list of categories included in paragraph (d)(1) is non-exhaustive, and if we receive information that is credible and outside the scope of our expertise, we will consider that information on a case-by-case basis as appropriate. We routinely coordinate with outside entities, such as State fish and wildlife agencies, during the development of a species status assessment for evaluation of whether to list a species and when necessary, we continue this coordination during the development of a designation of critical habitat. We conclude that our current process is sufficient to coordinate with States and other authorities, and it is unnecessary to codify any additional consultation process in regulation.

Comment 15: Some commenters stated that the Service should expand § 17.90(d)(1)(i) to include assigning weights consistent with expert or firsthand information from Tribes regarding economic impacts.

Response: We consider any economic impact information submitted by a Tribe when we undertake exclusion analyses. The weights we give to economic impacts identified by Tribes will be

consistent with the information the Tribes provide unless we have knowledge or material evidence information that rebuts that information. Thus, no changes were needed to address the intent of these comments.

Comment 16: A number of commenters stated that the regulation should include provisions requiring the Service to invite Tribal participation in the process for designating critical habitat or in establishing standards for designating Tribal lands as critical habitat. For example, some commenters stated that the regulations should require the Service to consult with affected Indian Tribes when designating critical habitat, while others stated that the regulations should establish a rebuttable presumption that Tribal lands either would be excluded from designations of critical habitat, or would not be considered for designations.

Response: We are committed to honoring and strengthening our unique legal relationship with Indian Tribal governments. When we designate critical habitat, we follow the applicable laws and policies setting out principles and requirements for ensuring meaningful and timely input by Tribal entities. This includes consulting with affected Tribes in accordance with both Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' 65 FR 67249 (Nov. 9, 2000), and Secretarial Order 3206, ''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act'' (June 5, 1997) (S.O. 3206), among other authorities. Because we are already required to consult with affected Tribes under these authorities when we designate critical habitat, we did not make any changes to the regulation in response to these comments.

We do not have the authority to establish a standard making all Tribal lands ineligible for designation as critical habitat, or to establish a rebuttable presumption that Tribal lands would be excluded. The Act requires that critical habitat be designated on the basis of the best scientific data available; therefore, if Tribal lands meet the definition of critical habitat, those areas will be proposed as critical habitat. Our authority to exclude areas from critical habitat is limited to situations in which the benefits of excluding an area outweigh the benefits of including the area in the critical habitat designation where exclusion will not result in extinction of the species. We will give weight to the benefits of excluding Tribal areas consistent with Tribes' firsthand or expert knowledge, in accordance with economic and other information provided by affected Tribes. However, there may be times when we determine the benefits of including Tribal lands outweigh the benefits of excluding those areas. Therefore, we cannot establish a rebuttable presumption that Tribal lands will be excluded from critical habitat designations. In this regulation, we do not make a determination about whether Tribal lands meet the definition of ''critical habitat'' in the first instance because that would fall within the first step in designating critical habitat and is therefore outside the scope of this rulemaking.

Comment 17: Some commenters stated that § 17.90(d)(1)(i) specifying that the Service will assign weights consistent with non-biological impacts of inclusion or exclusion identified by federally recognized Indian Tribes is too narrow. For example, the provision should include assigning weights consistent with expert or firsthand information from Tribes regarding biological impacts or impacts on natural resources, including traditional ecological knowledge.

Response: As stated in the proposed rule, whenever we undertake a discretionary exclusion analysis, we comply with Secretarial Order 3206, ''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act'' (June 5, 1997) (S.O. 3206), prior to finalizing the designation of critical habitat. The exclusion analysis therefore includes consideration of the impacts to any Tribal lands included in, or resources affected by, a potential designation, and we would consider all relevant available information (whether non-biological or biological), including Tribal expertise, firsthand information, and traditional ecological knowledge.

Comment 18: We received comments stating that the regulation should include impacts on Alaska Native-owned lands in the list of ''other relevant impacts'' that the Service must consider. Some commenters also stated that the Service should assign weights consistent with impacts identified by Alaska Native Corporations and other Alaska Native organizations, because those entities also have expert and firsthand knowledge about impacts of critical habitat designations to Tribes, their natural resources, and their economies.

Response: Impacts on Alaska Native-owned lands qualify as ''other relevant impacts'' under section 4(b)(2), and we intend to address those impacts when we designate critical habitat. Similarly, non-biological impacts identified by any Tribal organizations, including Alaska Native Corporations and Alaska Native organizations, are outside the scope of the Service's expertise; therefore, we would give weights to those impacts in accordance with the firsthand information or expert knowledge those organizations provide. We conclude that it is not necessary to change the text of the final rule because both of the lists that the comment references are expressly non-exhaustive. Section 17.90(a) states that '' '[o]ther relevant impacts' may include, *but are not limited to,* impacts to'' a variety of entities and values. Similarly, § 17.90(d)(1) states, ''Impacts that are outside the scope of the Service's expertise include, *but are not limited to*'' several categories of impacts (emphasis added).

Comment 19: Some commenters pointed to Tribal treaties that give Tribes property or other rights with regard to their fisheries; these commenters stated that the proposed rule would put these Tribal rights further at risk by broadening the scope of critical habitat exclusions.

Response: We do not anticipate that the proposed rule would increase risks to any land or resources. To the extent an Indian Tribe is concerned that designating an area as critical habitat or excluding an area from a critical habitat designation could affect their treaty or other rights, under § 17.90(d)(1)(i) of these final regulations, those concerns would be an important part of the discretionary exclusion analysis. Impacts to Tribal rights concerning their land and fisheries fall within the category of impacts that are outside the scope of the Service's expertise. As a result, if any Tribe provides information indicating that its rights would be adversely affected by either including or excluding a particular area from a critical habitat designation, the Service would give a weight to those impacts in accordance with the Tribe's information.

Comment 20: Several commenters requested a clear definition for ''national security'' and ''homeland security'' with predetermined activities to avoid the use of open-ended terms. Other commenters made the case that water projects and related infrastructure and domestic petroleum production should be considered for exclusion due to homeland-security and national-security implications.

Response: As we stated in the proposed rule, we will rely on the expertise of the Department of Defense, Department of Homeland Security, or affiliated agencies to make a determination as to what constitutes an impact to national or homeland

security. The Service is not an expert agency in determining all the activities or projects that may have national-security implications; therefore, we decline to produce a list or further define ''national security'' or ''homeland security'' in these regulations. We will continue to rely on the expert judgment of the agencies responsible for national security and homeland security and any reasonably detailed justification of the potential impacts that they provide regarding a designation of critical habitat to inform our discretionary exclusion analysis.

Comment 21: One commenter suggested project developers and private contractors who work for the Federal Government should be contributors toward the analysis of non-biological impacts to critical habitat.

Response: As captured in the proposed rule and explained in the preamble, § 17.90(d)(1) provides a list of entities that may have specific knowledge that is outside the scope of the Service's expertise and would therefore be considered in an exclusion analysis if deemed to meet the credible information standard. That list is expressly non-exhaustive. Regarding submissions from project developers or private contractors working for another Federal agency, we would anticipate submissions of information to be made ''on behalf of'' or in their ''official capacity representing'' a Federal agency. Therefore, it is unnecessary to add categories of experts or sources to that list.

Comment 22: Commenters both supported and opposed the provision clarifying when the Service will consider excluding Federal lands. Those that expressed opposition to the proposed provision cited the statutory provision of sections 2(c) and 7 of the Act, which both generally state that Federal agencies shall seek to conserve listed species and use their authorities to further the purposes of the Act. Furthermore, commenters stated that, because section 7 of the Act requires consultation by Federal agencies to ensure their actions do not jeopardize listed species or destroy or adversely modify their critical habitat, Federal lands are important locations for species recovery, especially in light of ongoing habitat fragmentation and climate-change effects. Other commenters noted that the potential increase in exclusions of Federal lands could be a negative signal to private landowners regarding the commitment of Federal land managers to species recovery and section 7 consultation. Commenters stated that the change in position from the 2016 Policy to this proposed rule was not adequately explained, there were no changes in circumstances that apparently prompted this change, and they therefore believe this provision is arbitrary and capricious. Commenters also noted that, combined with national-security exclusions and exemptions, additional exclusion of Federal lands could skew critical habitat designations to State and private lands and in turn could potentially pose an economic disadvantage to State and private lands, especially in Western States. Commenters further stated that administrative or transactional costs tend to be minor and should not be a basis for exclusion.

Other commenters expressed support for the approach to Federal lands in the proposed rule and asked that additional provisions be added to the final rule, such as specifically including consideration of more than section 7 transactional costs (for example, considering impacts on the private property of a lessee or permittee). Commenters asked for additional specificity in the types of Federal lands, minerals, and oil and gas activities to be considered for exclusion; whether federally withdrawn lands on which non-Federal entities are conducting activities could be considered; and whether exclusion could apply only with the project footprint or would extend to adjacent areas on Federal land where there may be an effect from the project.

Response: The Act is clear in section 2(c)(1) and section 7(a)(1) that Federal agencies shall use their authorities to further the purposes of the Act and carry out programs for the conservation of endangered and threatened species, and in section 7(a)(2) that Federal agencies must ensure their actions do not jeopardize the continued existence of listed species or result in destruction or adverse modification of their critical habitat. However, section 4(b)(2) of the Act does not provide for a different standard for exclusions on Federal lands relative to other lands. This final regulation does not change the obligations of Federal agencies or our implementation of those provisions of the Act.

Our change in consideration of exclusions of Federal lands from the 2016 Policy recognizes that Federal agencies are required to avoid jeopardy of listed species and destruction or adverse modification of critical habitat through section 7 consultation. While the standards for evaluating Federal and non-Federal lands are the same, we will consider the extent to which consultation would produce an outcome that has economic or other impacts, such as by requiring project modifications and additional conservation measures by the Federal agency or other affected parties, on a case-by-case basis. Additionally, we expect to evaluate the types of activities that are being permitted or the types of leases and activities being conducted on Federal land, any economic benefits associated with those leases and activities, any potential impacts that designating the lands as critical habitat could have on those economic benefits, and the conservation value of the areas that qualify as critical habitat, including whether the areas are occupied or unoccupied. Regardless of inclusion or exclusion of Federal lands from a designation of critical habitat, we consider Federal lands an important piece of species recovery efforts.

In any exclusion analysis for Federal lands, we will consider not only the transactional costs associated with consultation with a Federal agency, but also any potential costs to affected parties, including applicants for Federal authorizations (*e.g.,* permits, licenses, leases, contracts), that would stem from any project modifications that may be required to avoid destruction or adverse modification of critical habitat. While we agree that the transactional costs of consultation with Federal agencies tend to be a relatively minor cost, we do not wish to foreclose the potential to exclude areas under Federal ownership in cases where the benefits of exclusion outweigh the benefits of inclusion. Consideration of other Federal agency transactional costs and other costs, including those to a permittee or lessee, will be considered on a case-by-case basis.

Comment 23: Several commenters shared concerns over the exclusion of lands under an agreement through section 10 of the Act. Comments included concern over the non-binding nature of habitat conservation plans (HCPs), changing conservation measures over time, the finite nature of the agreements, the question of whether the lands are in a currently acceptable state for the listed entity, the lack of protective measures compared to a designation, and an overall concern regarding the durability of agreements compared to a critical habitat designation.

Response: As stated in the proposed rule in paragraph (d)(3) and associated preamble text, we place great value on the partnerships that are developed during the preparation and implementation of plans, agreements, or partnerships that have been permitted under section 10 of the Act. We anticipate consistently excluding areas

covered by plans, agreements, or partnerships as long as the conditions in paragraphs (d)(3)(i)–(iii) are met. Because section 10 permits authorize take of covered species that would otherwise be unlawful, permittees are incentivized to continue the implementation of the measures contained in the conservation plan and required by the associated permit following the exclusion of the covered area. Therefore, the benefits of inclusion are generally less than the benefits of exclusion. We further noted in the proposed rule that this is not the same fact pattern for draft plans or agreements, and we thus would generally give little weight to these draft agreements or unrealized promises of future conservation actions in a discretionary section 4(b)(2) exclusion analysis. The Service will always consider the plans, agreements, or partnerships that have been permitted under section 10 of the Act on a case-by-case basis to determine whether the benefits of exclusion outweigh the benefits of inclusion. We have been applying these concepts formally following the finalization of the 2016 Policy, and our experience is that they work well and provide the clarity needed for landowners and partners to meet the exclusion requirements.

Comment 24: Commenters requested that the Service provide a clear and simple set of metrics for section 10 permitted plans to meet the requirements for areas covered by the plans to be excluded from critical habitat. Commenters stated that setting out these metrics would bolster the confidence of landowners, as well as incentivize participation in permitted plans. Some commenters suggested that the language in the final rule should include a presumption that areas covered by such plans would be excluded, and others suggested that the Service automatically exclude lands under section 10 agreements, or undertake a single comprehensive analysis to cover all section 10 agreements, similar to State wildlife plans, and thereby reduce workload of private landowners and Service employees.

Response: When we undertake a discretionary section 4(b)(2) exclusion analysis, we will always consider whether to exclude areas covered by a permitted HCP or candidate conservation agreement with assurances (CCAA) or safe harbor agreement (SHA), and we anticipate consistently excluding such areas from a designation of critical habitat if incidental take caused by the activities in those areas is covered by the permit under section 10 of the Act and the CCAA, SHA, or HCP meets all of the conditions set forth in the final regulation. We have been applying these concepts formally following the finalization of the 2016 Policy, and our experience is that they work well and provide the clarity needed for landowners and partners to meet the exclusion requirements. Additionally, since finalization of the 2016 Policy, we are aware of at least one instance where a landowner holding a section 10 permit requested not to be excluded from a designation of critical habitat; this experience underscores that exclusion should not be an automatic conclusion for permitted plans such as CCAAs, SHAs, or HCPs so as not to negatively impact our relationship with permittees conducting voluntary conservation. Because every plan is unique, as are the specific needs of every species, it is difficult to offer an automatic exclusion and/or a single comprehensive analysis to cover all conservation agreements. For this reason, the Service has set out general conditions in the final regulation and conducts case-by-case analyses to determine whether to exclude areas covered by permitted plans.

Comment 25: Commenters stated concerns that the Service would provide little weight to draft voluntary agreements and emphasized that analysis of each agreement should be based on the past successes, on the strength of existing relationships, and on the stage of the process (*e.g.,* whether the draft is an early version or a late version). Commenters agreed that a party must demonstrate that the voluntary conservation plan is being implemented consistent with its terms. However, the requirement to demonstrate ''success'' of the chosen mechanism is overbroad and would place an unreasonable threshold for appropriate recognition of voluntary conservation measures. Instead of attempting to measure ''success,'' the Service should instead consider whether the party is meeting or exceeding the metrics or goals identified within the applicable plan.

Commenters stated that non-permitted plans should receive a heavier weight than the regulation implies. In the view of some commenters, the regulations make it too difficult to exclude areas covered by non-permitted plans because the proposed regulation requires the Service's involvement in developing the plans and the factors set out in paragraphs (d)(4)(i)–(viii) that the Service considers in evaluating whether to exclude areas covered by non-permitted plans are too onerous. Commenters stated that the regulation should also provide clear and simple procedures to meet the exclusion threshold. The Service should take the necessary steps to promote conservation plans and bring more attention to them, not disincentivize their use. Additionally, some commenters stated that the presumption of exclusion should extend to agreements not permitted under section 10 of the Act. They stated that the language is only found in the preamble and should be restated in the regulation.

Response: Adding this provision (which was also in our section 4(b)(2) policy) to our regulations is intended to incentivize and recognize voluntary conservation efforts that provide conservation benefits to listed species and other species at risk. When we consider plans, agreements, or partnerships that have not been authorized by a permit under section 10 of the Act, we evaluate a variety of factors. Paragraphs (d)(4)(i)–(viii) of the rule provide a non-exhaustive list of these factors. We use these factors to determine how the benefits of exclusion and the benefits of inclusion of a particular area are affected by the existence of private or other non-Federal conservation plans or agreements and their attendant partnerships when we undertake a discretionary section 4(b)(2) exclusion analysis. The considerations that commenters suggested are already included within the factors that the Service will consider when evaluating plans that have not been authorized by a permit under section 10 of the Act; therefore, no changes are necessary.

We have been applying these concepts formally following the finalization of the 2016 Policy, and our experience is that they work well. Further, as described in the preamble to the proposed rule, the Service is not required to be part of a non-permitted plan or agreement in order to consider the area for exclusion based on that plan. Evaluation of the success of a non-permitted plan or agreement directly relates to the benefits of exclusion of specific areas. We value the collaboration and conservation value provided by voluntary private or non-Federal conservation plans or agreements. It is in that context that we included in paragraphs (d)(4)(i)–(viii) descriptions of how we will consider these plans in a discretionary section 4(b)(2) exclusion analysis. Exclusions are not automatic and are determined on a case-by-case basis in light of the particular facts of each situation.

Comment 26: Commenters stated that the requirement of public participation, agency review, and review under the

National Environmental Policy Act (NEPA) for plans, agreements, or partnerships that have not been authorized by a permit under section 10 of the Act will unnecessarily hinder meaningful and qualified private voluntary conservation measures or programs. While public review and comment are appropriate procedures for governmental programs, it is inappropriate to obligate private entities to meet these standards as a prerequisite for exclusion. They stated that to the extent that the Service believes public review and comment is necessary for the application of an exclusion, such process of review and comment can be addressed through the notice-and-comment process on the critical habitat designation. Specifically, as part of its development of a draft critical-habitat proposal, it is within our discretion to solicit public comments on areas that should be excluded from the critical habitat. Further, concurrent with the issuance of the proposed critical-habitat designation, we can likewise identify any areas that we already anticipate excluding and request public comment on whether we should exclude those or any other areas. Such a process allows for public participation in the exclusion process, as well as providing for an open and transparent process.

Response: As stated in the preamble to the proposed rule, a non-permitted plan or agreement is not required to go through agency review, NEPA review, or similar processes for lands covered by the plan or agreement to qualify for exclusion. However, completion of those processes in development of a plan or agreement does indicate that the plan or agreement has already received a high degree of critical analysis and further bolster the case for exclusion. Additionally, as stated in paragraph (a) of the proposed rule, we will identify areas in the proposed critical-habitat designation that the Secretary has reason to consider for exclusion. As part of the normal critical-habitat designation, the Service requests public input and comment on specific areas considered for exclusion and any other areas that should be considered for exclusion.

Comment 27: Some commenters interpreted the proposed rule as creating a provision that requires the Secretary to waive his discretion on whether to conduct the exclusion analysis given the presence of the ''credible information'' trigger to enter into an exclusion analysis.

Response: Under this rule, the Secretary will conduct an exclusion analysis when credible information triggers that analysis. The rule does not waive the Secretary's discretion; instead, the regulation constitutes the Secretary's decision on how to exercise his discretion under the statute on a consistent comprehensive basis instead of a case-by-case basis.

Comment 28: Some commenters expressed concern that the proposed rule would reduce the Secretary's discretion as to whether to conduct an exclusion analysis because it would collapse the second step (the discretionary exclusion analysis) of the critical habitat designation process into the first step (the requirement to take into consideration economic and other relevant impacts). Other commenters took the contrary view, stating for example that the rule should narrow the Secretary's discretion to undertake an exclusion analysis by specifying when and how he will exercise that discretion. Some of the commenters went so far as to request that the rule should eliminate the Secretary's discretion on this issue by requiring the Secretary to always conduct an exclusion analysis to determine if the benefits of exclusion outweigh the benefits of inclusion. The commenters disagreed that the Secretary has discretion as to whether to undertake an exclusion analysis, because section 4(b)(2) requires the Secretary to take economic and other relevant impacts into consideration and the balancing of impacts in the exclusion analysis is part of that consideration. Therefore, in the view of these commenters, the Secretary's discretion is much narrower—the only part of section 4(b)(2) that is left to the Secretary's discretion is the ultimate decision whether or not to exclude areas.

Response: The structure of section 4(b)(2) makes clear that the exclusion analysis is discretionary. The authorities in section 4(b)(2) are split between two sentences: The first sentence is framed in mandatory terms (''*shall* designate critical habitat . . . after taking into consideration . . . relevant impacts''), and the second sentence is framed in discretionary terms (''*may* exclude any area . . . if the benefits of such exclusion outweigh'') (emphasis added). Consideration of relevant impacts appears in the first sentence, which is the sentence framed in mandatory terms. The decision to enter into the exclusion analysis and the weighing of benefits of exclusion and inclusion appear in the second sentence, which is the sentence framed in discretionary terms. The proposed rule neither alters this structure of section 4(b)(2) nor collapses the two sentences together—it just describes how and when the Secretary will exercise the discretion to undertake an exclusion analysis and to exclude a particular area from the critical habitat designation. This framework facilitates the transparent and consistent implementation of the statute.

Comment 29: Some commenters stated that the proposed rule would give too much discretion to the Secretary in assigning weights and deciding on exclusions in certain outcomes, which would contradict congressional intent to afford imperiled species ''the highest of priorities.'' Some commenters were concerned that the broad discretion that the proposed rule gives to the Secretary in assigning weights to experts in non-biological fields of knowledge runs the risk of placing disproportionate weight on the expertise of entities with private interests whose ultimate goal may not be conservation. Other commenters took the opposite view, stating that the proposed rule would cede the Secretary's discretion as to whether to undertake an exclusion analysis by deferring to regulated entities, lessees, and private landowners on the weighing of costs. Some commenters found it reasonable for experts to provide information about what costs and benefits are, but wanted to make sure that the Service ultimately retained the discretion to reject questionable claims by critical habitat opponents, as well as to ''assign the weights'' that result in the balance achieved by a particular decision meeting legal requirements. Some commenters went further and stated that only the Service has the expertise to determine the weights of costs and benefits.

Response: Rather than ceding the Secretary's discretion, the proposed rule enhances implementation by establishing a transparent and balanced approach in exercising it. Congress gave the authority to undertake exclusion analyses to the Secretary, and the Secretary delegated that authority to the Director of the Service, because the Service has the expertise to evaluate the impact that excluding particular areas from a critical habitat designation would have on an endangered or threatened species. Other relevant impacts of excluding or including particular areas in a critical habitat designation may not be within the Service's expertise. As some of the commenters pointed out, it is reasonable for the Secretary to seek input from experts regarding those other relevant impacts that are outside the scope of the Service's expertise. The proposed rule strikes that balance by providing for the Service to seek that input from experts and give weights to particular impacts in accordance with that input, while

also making clear that the Service ultimately retains the discretion to reject or adjust that input to the extent it is rebutted by the best information available to the Service. By retaining that discretion for the Service, the rule avoids putting disproportionate weight on the expertise of entities whose ultimate goal may not be conservation.

Comment 30: Some commenters requested that the rule clarify whether the Secretary intends to delegate his authority to undertake an exclusion analysis to the Director of the Service.

Response: The Departmental Manual provides that the Secretary has delegated his authority to undertake leadership and coordination responsibilities under the Act to the Assistant Secretary for Fish and Wildlife and Parks and has further delegated those responsibilities, in part, to the Director of the Fish and Wildlife Service (632 DM 1). This includes responsibilities for all aspects of designating critical habitat for endangered species and threatened species.

Comment 31: We received comments that both supported and opposed the inclusion of the phrase ''shall exclude'' in § 17.90(e). Specifically, commenters supported the conclusion that the Service will always exclude the areas where the benefits of exclusion outweigh the benefits of inclusion, as long as exclusion will not result in the extinction of the listed species. Commenters stated that the proposed provision would create a clear standard and encourage consistent and transparent application of section 4(b)(2) of the Act. In addition, in the view of some commenters, once the exclusion analysis is completed, there are no further considerations because if the benefits of exclusion outweighed the benefits of inclusion, including that area in the designation of critical habitat would be arbitrary and capricious, lack a rational basis, and run counter to the evidence evaluated by the Service.

Alternatively, other commenters opposed using the words ''shall exclude'' in § 17.90(e) because those words would be more restrictive and would require us to automatically exclude an area from critical habitat if we determine that the benefits of exclusion outweigh the benefits of inclusion, regardless of the circumstances. Some commenters expressed concern that use of the word ''shall'' constituted an arbitrary and capricious change in agency practice without justification, citing the language in the 2016 Policy (*i.e.,* that ''the decision to exclude is always discretionary,'' and, ''[u]nder no circumstances is exclusion required under the second sentence of section 4(b)(2)'') (81 FR 7226, 7229; Feb. 11, 2016). Commenters expressed concern that this approach would result in more exclusions and contradict the purpose of the Act and Congress's intent that the Secretary retain discretion in determining whether to exclude particular areas from critical habitat. Commenters also expressed concern that requiring that the Secretary exclude areas whenever the benefits of exclusion outweigh the benefits of inclusion would allow for detrimental impacts to a listed species' habitat as long as the species does not go completely extinct.

Response: As described in the proposed rule, this rulemaking directly adopts some aspects of the 2016 Policy and alters other aspects. Using the phrase ''shall exclude'' in this rulemaking is not inconsistent with the statements that the commenters cite from the 2016 Policy. The commenters' excerpts from the 2016 Policy make clear that decisions to exclude areas from critical habitat are discretionary under the structure and language of the statute. The regulation does not change or contravene that fact. Rather, this rulemaking is an exercise of the discretion referenced in those excerpts. As we discussed in the proposed rule, the Secretary is choosing to exercise his discretion in this way to provide for transparency and certainty. Under the statute, the Secretary could have elected to undertake exclusion analyses on a case-by-case basis and exclude areas every time the benefits of exclusion outweigh the benefits of inclusion. However, the approach finalized here would provide greater transparency and certainty because it creates an advance understanding of how the Secretary will proceed when the benefits of exclusion outweigh the benefits of inclusion.

As we explained in the proposed rule, section 4(b)(2) of the Act gives the Secretary the discretion to exclude areas from critical habitat designations when certain criteria have been met. Using the phrase ''shall exclude'' in the regulation indicates how the Secretary is choosing to exercise his discretion, and making this choice is neither unlawful nor contrary to the purposes of the Act. Even with the words ''shall exclude'' in the regulation, under the statute the Secretary could exclude areas only if the Secretary determines that the benefits of exclusion outweigh the benefits of inclusion after considering the conservation value or benefit of inclusion of the area weighed against the impacts of the designation or benefits of exclusion, and the Secretary determines that exclusion will not lead to extinction of the species.

Comment 32: Some commenters identified circumstances in which the Secretary should retain the discretion to include a particular area in a designation even though the benefits of exclusion outweigh the benefits of inclusion. These included where the benefits of exclusion are equal or very near to the benefits of inclusion; or where permittees in areas covered by conservation plans, agreements, or partnerships may prefer to have the area included in the critical habitat designation.

Response: These circumstances are already addressed within the process that the regulation describes for analyzing potential exclusions. In determining whether the benefits of excluding an area outweigh the benefits of including it in the critical habitat designation, we take into consideration numerous factors, perspectives, and impacts, including, for example, the views of permittees. As part of the exclusion analysis, we thoroughly evaluate the impacts based on credible information and Service knowledge and give weight to the various impacts based on the relevant expertise and best available information. Further, the regulation requires exclusion of particular areas only if the benefits of exclusion outweigh those of inclusion; if they are equal, it would not require (and the statute would not allow) exclusion.

Comment 33: Many commenters stated that the proposed regulation violates the Administrative Procedure Act because we failed to provide a reasoned explanation or rational basis for the proposed changes in process for conducting a discretionary section 4(b)(2) exclusion analysis. Commenters stated that referring to the need to address the Supreme Court's decision in *Weyerhaeuser* is not a reasoned explanation because nothing in that decision required that the Service promulgate a regulation on the procedure for exclusion analyses under section 4(b)(2) of the Act. Further, they state that the U.S. Supreme Court did not, and, indeed, could not, authorize the Service to abdicate its statutory authority and discretion regarding whether and how to conduct a critical habitat exclusion analysis under section 4(b)(2) of the Act in the first instance. Additionally, they stated that we failed to explain departure from our 2016 Policy.

Response: To provide transparency, clarity, and certainty to the public and other stakeholders about how the Secretary intends to exercise his

discretion regarding exclusions under section 4(b)(2), we are finalizing this regulation, which would supersede the regulations at 50 CFR 424.19 and the 2016 Policy with respect to the Service's implementation of the Act. In the proposed rule, we explained our rationale for the amendments and changes from the 2016 Policy. The proposed rule also sought comments from the public on the provisions of the regulation, and our comment responses above provide a detailed and reasoned explanation of why the specific terminology in the definition accomplishes the purposes of the definition and the conservation goals of the Act. Therefore, we have provided a reasoned explanation and rational basis for our action as required by the APA.

In addition, regarding *Weyerhaeuser,* although the Supreme Court's opinion did not require promulgation of regulations on the procedure for exclusion analyses under section 4(b)(2) of the Act, it did establish that decisions not to exclude a particular area of critical habitat are judicially reviewable. *Weyerhaeuser,* 139 S. Ct. at 371 (noting that the challenge to the Service's decision not to exclude a particular area was a ''familiar one in administrative law that the agency did not appropriately consider all of the relevant factors that the statute sets forth to guide the agency in the exercise of its discretion''). In light of the Court's holding that decisions not to exclude may be reviewed by courts for abuse of discretion under section 706(2) of the Administrative Procedure Act (APA, 5 U.S.C 706(2)), the Service is of the view that the Court's decision underscores the importance of being deliberate and transparent about how the Service goes about making decisions about whether to exclude areas from designations of critical habitat.

Comment 34: The Service received comments stating that invoking the NEPA categorical exclusion at 43 CFR 46.210(i) is contrary to the requirements of NEPA and its implementing regulations, further asserting that the regulation would have significant, adverse environmental impacts on endangered and threatened species. That categorical exclusions applies to ''[p]olicies, directives, regulations, and guidelines: That are of an administrative, financial, legal, technical, or procedural nature'' under the Service's NEPA implementing regulations. Commenters stated that we violate NEPA by failing to consider the impacts of this proposed rule in combination with the August 5, 2020, proposal that would add a new definition of ''habitat'' to our regulations for making critical habitat designations under section 4 of the Act (see 85 FR 47333, Aug. 5, 2020) (Endangered and Threatened Wildlife and Plants; Regulations for Listing Endangered and Threatened Species and Designating Critical Habitat; Proposed Rule). They state that if we proceed with this rulemaking, an environmental impact statement should be prepared and circulated for public review and comment that considers the cumulative environmental impacts of both the proposed rule and the proposed definition of ''habitat.''

Response: We conclude that the categorical exclusion for ''[p]olicies, directives, regulations, and guidelines: That are of an administrative, financial, legal, technical, or procedural nature'' (43 CFR 46.210(i)) applies to this rulemaking. As we made clear in the proposed rule, the objective of this rulemaking is to ''provide greater transparency and certainty for the public and stakeholders'' because the *Weyerhaeuser* decision may raise questions about the process the Service will use when conducting an exclusion analysis for particular areas of critical habitat. The result of promulgating this regulation is to inform the public and the Service's employees of the mechanics of how the process for excluding areas from critical habitat will work, so that the process of designating critical habitat is more straightforward, more efficient, and more transparent. Accordingly, this rulemaking is of a technical nature.

Comment 35: Commenters requested that we coordinate with NMFS to assist in the development of corresponding regulations implementing section 4(b)(2) of the Act for species under NMFS's jurisdiction.

Response: NMFS will continue to implement the 2016 Policy for exclusions from critical habitat for species in their jurisdiction. The Service and NMFS will continue to comply with requirements of the Act and applicable regulations and policies when designating critical habitat for species in their respective jurisdictions.

Required Determinations

Regulatory Planning and Review—Executive Orders 12866 and 13563

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements. This rule is consistent with Executive Order 13563, and in particular with the requirement of retrospective analysis of existing rules, designed ''to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.''

Executive Order 13771

This final rule is an Executive Order 13771 ''other'' action.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency, or his designee, certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act (RFA) to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. The following discussion explains our rationale.

This rulemaking responds to applicable Supreme Court case law regarding designating critical habitat under the Endangered Species Act and provides transparency, clarity, and consistency for stakeholders. The changes to these regulations do not alter the reach of designations of critical habitat.

The Service is the only entity that is directly affected by this rule because we are the only entity that will designate critical habitat under this regulation. Small entities are not directly regulated by this rulemaking, as it only imposes requirements on the Service. No external entities, including any small businesses, small organizations, or small governments, will experience any direct economic impacts from this rule. There is no requirement under the RFA to evaluate the potential impacts to entities that are not directly regulated. At the proposed rule stage, we certified that this rule would not have a significant economic effect on a substantial number of small entities. Nothing in this final rule changes that conclusion. Therefore the Service once again certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) On the basis of information contained in the Regulatory Flexibility Act section above, this final rule would not ''significantly or uniquely'' affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502, that this rule would not impose a cost of $100 million or more in any given year on local or State governments or private entities (IEc 2020). A Small Government Agency Plan is not required. As explained above, small governments would not be affected because this final rule would not place additional requirements on any city, county, or other local municipality.

(b) This rule would not produce a Federal mandate on State, local, or Tribal governments or the private sector of $100 million or greater in any year; that is, this final rule is not a ''significant regulatory action''' under the Unfunded Mandates Reform Act. This rule would impose no obligations on State, local, or Tribal governments.

Takings (E.O. 12630)

In accordance with Executive Order 12630, this rule would not have significant takings implications. This rule would not directly affect private property, nor would it cause a physical or regulatory taking. It would not result in a physical taking because it would not effectively compel a property owner to suffer a physical invasion of property. Further, the rule would not result in a regulatory taking because it would not deny all economically beneficial or productive use of any land or aquatic resources and it would not present a barrier to all reasonable and expected beneficial use of private property.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, we have considered whether this rule would have significant federalism effects and have determined that a federalism summary impact statement is not required. This rule pertains only to designations of critical habitat under the Endangered Species Act, and would not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Civil Justice Reform (E.O. 12988)

This rule does not unduly burden the judicial system and meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988. This rule pertains only to designations of critical habitat under the Endangered Species Act.

Government-to-Government Relationship With Tribes

In accordance with Executive Order 13175 ''Consultation and Coordination with Indian Tribal Governments,'' the Department of the Interior's manual at 512 DM 2 (December 1, 1995), we have considered possible effects of this final rule on federally recognized Indian Tribes. The following Tribes and Tribal entities stated that Government-to-Government consultation is required or requested Government-to-Government consultation: Southern Ute Indian Tribe; Swinomish Indian Tribe; National Congress of American Indians; and Northwest Indian Fisheries Commission member Tribes including the Lummi, Nooksack, Swinomish, Upper Skagit, Sauk-Suiattle, Stillaguamish, Tulalip, Muckleshoot, Puyallup, Nisqually, Squaxin Island, Skokomish, Suquamish, Port Gamble S'Klallam, Jamestown S'Klallam, Lower Elwha Klallam, Makah, Quileute, Quinault, and Hoh.

The Service has reviewed the comments from these Tribes and concludes that the changes to these implementing regulations make general changes to the Act's implementing regulations and do not directly affect specific species or Tribal lands or interest. This regulation describes how we undertake our mandatory consideration of the impacts of designating critical habitat and our discretionary authority to exclude particular areas following a discretionary exclusion analysis as it is applied to designating critical habitat. Therefore, this rule directly affects only the Service. With or without these regulatory revisions, the Service must continue to list species and to designate critical habitat based on the best available data. Therefore, we conclude that this regulation does not have ''tribal implications'' under section 1(a) of E.O. 13175, and formal government-to-government consultation is not required by the Executive order and related policies of the Department of the Interior. We will continue to collaborate with Tribes on issues related to federally listed species and their habitats and will work with Tribes as we implement the provisions of the Act. *See* Joint Secretarial Order 3206 (''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act,'' June 5, 1997).

We recognize that some commenters stated that government-to-government consultation is necessary because in their view the changes that the proposed rule would make would have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' However, these regulations primarily adopt and deepen the provisions in the 2016 Policy, so they do not have any substantial direct effects of that nature. The 2016 Policy stated that the Service would always consider excluding Tribal lands and would give great weight to Tribal concerns in analyzing the benefits of exclusion. Because the final regulation provides for consideration of any exclusions for which proponents provide credible information, Tribes have the ability to ensure that the Service always considers excluding their lands if that is what they want. In addition, the 2016 Policy already stated that the Service would give great weight to Tribes' concerns when it undertakes exclusion analyses. This regulation essentially does the same thing by stating that the weights the Service gives to the benefits of excluding or including areas that affect Tribal lands or resources will be consistent with the information provided by the affected Tribes. Therefore, this rule does not trigger the requirement to undertake government-to-government consultation because the provisions of the rule merely codify and strengthen the provisions of the 2016 Policy, and this regulation therefore does not ''have substantial direct effects on one or more

Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.''

Paperwork Reduction Act

This rule does not contain any new collections of information that require approval by the OMB under the Paperwork Reduction Act and does not alter the existing collections of information approved under OMB Control Numbers 1018–0093 and 1018–0094. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We analyzed this final rule in accordance with the criteria of the National Environmental Policy Act (NEPA), the Department of the Interior regulations on Implementation of the National Environmental Policy Act (43 CFR 46.10–46.450), and the Department of the Interior Manual (516 DM 8). This rulemaking responds to recent Supreme Court case law.

As a result, we conclude that the categorical exclusion found at 43 CFR 46.210(i) applies to this regulation. At 43 CFR 46.210(i), the Department of the Interior has found that the following category of actions would not have a significant effect on the human environment and are, therefore, categorically excluded from the requirement for completion of an environmental assessment or environmental impact statement: ''Policies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature.''

We have considered the extent to which this regulation has a significant impact on the human environment and determined it falls within one of the categorical exclusions for actions that have no effect on the quality of the human environment.

Energy Supply, Distribution or Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This regulation is not expected to have a significant adverse effect on the supply, distribution, or use of energy, and it has not been otherwise designated by the Administrator of OIRA as a significant energy action. Therefore, this action is a not a significant energy action, and no Statement of Energy Effects is required.

Authority

We issue this final rule under the authority of the Endangered Species Act, as amended (16 U.S.C. 1531 *et seq.*).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

For the reasons discussed in the preamble, the U.S. Fish and Wildlife Service amends part 17 of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

Subpart J—[Redesignated as Subpart K]

■ 2. Subpart J, consisting of §§ 17.100 through 17.199, is redesignated as subpart K.

Subpart I—[Redesignated as Subpart J]

■ 3. Subpart I, consisting of §§ 17.94 through 17.99, is redesignated as subpart J.

■ 4. New subpart I, consisting of § 17.90, is added to read as follows:

Subpart I—Considerations of Impacts and Exclusions From Critical Habitat

§ 17.90 Impact analysis and exclusions from critical habitat.

(a) At the time of publication of a proposed rule to designate critical habitat, the Secretary will make available for public comment the draft economic analysis of the designation. The draft economic analysis will be summarized in the **Federal Register** notice of the proposed designation of critical habitat. The Secretary will also identify any national security or other relevant impacts that the Secretary determines are contained in a particular area of proposed designation. Based on the best information available regarding economic, national security, and other relevant impacts, the proposed designation of critical habitat will identify the areas that the Secretary has reason to consider for exclusion and explain why. The identification of areas in the proposed rule that the Secretary has reason to consider for exclusion is neither binding nor exhaustive. ''Economic impacts'' may include, but are not limited to, the economy of a particular area, productivity, jobs, and any opportunity costs arising from the critical habitat designation (such as those anticipated from reasonable and prudent alternatives that may be identified through a section 7 consultation) as well as possible benefits and transfers (such as outdoor recreation and ecosystem services). ''Other relevant impacts'' may include, but are not limited to, impacts to Tribes, States, local governments, public health and safety, community interests, the environment (such as increased risk of wildfire or pest and invasive species management), Federal lands, and conservation plans, agreements, or partnerships. The Secretary will consider impacts at a scale that the Secretary determines to be appropriate and will compare the impacts with and without the designation. Impacts may be qualitatively or quantitatively described.

(b) Prior to finalizing the designation of critical habitat, the Secretary will consider the probable economic, national security, and other relevant impacts of the designation upon proposed or ongoing activities.

(c)(1) Subject to paragraph (c)(2) of this section, the Secretary has discretion as to whether to conduct an exclusion analysis under 16 U.S.C. 1533(b)(2).

(2) The Secretary will conduct an exclusion analysis when:

(i) The proponent of excluding a particular area (including but not limited to permittees, lessees or others with a permit, lease, or contract on federally managed lands) has presented credible information regarding the existence of a meaningful economic or other relevant impact supporting a benefit of exclusion for that particular area; or

(ii) The Secretary otherwise decides to exercise discretion to evaluate any particular area for possible exclusion.

(d) When the Secretary conducts a discretionary exclusion analysis pursuant to paragraph (c) of this section, the Secretary shall weigh the benefits of including or excluding particular areas in the designation of critical habitat, according to the following principles:

(1) When analyzing the benefits of including or excluding any particular area based on impacts identified by experts in, or by sources with firsthand knowledge of, areas that are outside the scope of the Service's expertise, the Secretary will give weight to those benefits consistent with the expert or firsthand information, unless the Secretary has knowledge or material

evidence that rebuts that information. Impacts that are outside the scope of the Service's expertise include, but are not limited to:

(i) Nonbiological impacts identified by federally recognized Indian Tribes, consistent with all applicable Executive and Secretarial orders;

(ii) Nonbiological impacts identified by State or local governments;

(iii) Impacts based on national security or homeland security implications identified by the Department of Defense, Department of Homeland Security, or any other Federal agency responsible for national security or homeland security; and

(iv) Nonbiological impacts identified by a permittee, lessee, or contractor applicant for a permit, lease, or contract on Federal lands.

(2) When analyzing the benefit of including or excluding any particular area based on economic impacts or other relevant impacts described in paragraph (b) of this section, the Secretary will weigh such impacts relative to the conservation value of that particular area. For benefits of inclusion or exclusion based on impacts that fall within the scope of the Service's expertise, the Secretary will give weight to those benefits in light of the Service's expertise.

(3) When analyzing the benefits of including or excluding particular areas covered by conservation plans, agreements, or partnerships that have been authorized by a permit under section 10 of the Act, the Secretary will consider the following factors:

(i) Whether the permittee is properly implementing the conservation plan or agreement;

(ii) Whether the species for which critical habitat is being designated is a covered species in the conservation plan or agreement; and

(iii) Whether the conservation plan or agreement specifically addresses the habitat of the species for which critical habitat is being designated and meets the conservation needs of the species in the planning area.

(4) When analyzing the benefits of including or excluding particular areas covered by conservation plans, agreements, or partnerships that have not been authorized by a permit under section 10 of the Act, factors that the Secretary may consider include, but are not limited to:

(i) The degree to which the record of the plan, or information provided by proponents of an exclusion, supports a conclusion that a critical habitat designation would impair the realization of the benefits expected from the plan, agreement, or partnership.

(ii) The extent of public participation in the development of the conservation plan.

(iii) The degree to which agency review and required determinations (*e.g.,* State regulatory requirements) have been completed, as necessary and appropriate.

(iv) Whether National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) reviews or similar reviews occurred, and the nature of any such reviews.

(v) The demonstrated implementation and success of the chosen mechanism.

(vi) The degree to which the plan or agreement provides for the conservation of the physical or biological features that are essential to the conservation of the species.

(vii) Whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan or agreement will be implemented.

(viii) Whether the plan or agreement contains a monitoring program and adaptive management to ensure that the conservation measures are effective and can be modified in the future in response to new information.

(e) If the Secretary conducts an exclusion analysis under paragraph (c) of this section, and if the Secretary determines that the benefits of excluding a particular area from critical habitat outweigh the benefits of specifying that area as part of the critical habitat, then the Secretary shall exclude that area, unless the Secretary determines, based on the best scientific and commercial data available, that the failure to designate that area as critical habitat will result in the extinction of the species concerned.

George Wallace,

Assistant Secretary for Fish and Wildlife and Parks, Department of the Interior.

[FR Doc. 2020–28033 Filed 12–17–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 200227–0066]

RTID 0648–XA724

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the Bering Sea Subarea of the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch in the Bering Sea subarea of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2020 Pacific Ocean perch total allowable catch (TAC) in the Bering Sea subarea of the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), December 16, 2020, through 2400 hrs, A.l.t., December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2020 Pacific ocean perch TAC in the Bering Sea subarea of the BSAI is 12,043 metric tons (mt) as established by the final 2020 and 2021 harvest specifications for groundfish in the BSAI and groundfish reserve release (85 FR 13553, March 9, 2020).

The Regional Administrator has determined that the 2020 TAC for Pacific Ocean perch in the Bering Sea subarea of the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 12,003 mt, and is setting aside the remaining 40 mt as bycatch to support other anticipated groundfish fisheries. Consequently, in accordance with § 679.20(d)(1)(iii),

NMFS is prohibiting directed fishing for Pacific ocean perch in the Bering Sea subarea of the BSAI. While this closure remains in effect the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Pacific ocean perch Bering Sea subarea in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of December 14, 2020.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 15, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–27918 Filed 12–15–20; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 85, No. 244
Friday, December 18, 2020

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

[Docket No. PRM–26–6; NRC–2010–0310]

Erik Erb—Minimum Day Off Requirement for Security Officers

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; withdrawal by petitioner.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is announcing the withdrawal, without prejudice to a future filing, of a petition for rulemaking (PRM), PRM–26–6, ''Minimum Day Off Requirement for Security Officers,'' submitted to the NRC by Erik Erb and 91 co-signers (the petitioners) on August 17, 2010. The petitioners requested that the NRC amend its regulations to decrease the minimum days off requirement for security officers working 12-hour shifts from an average of 3 days per week to 2.5 or 2 days per week. The petitioner withdrew PRM–26–6 by email dated December 10, 2019.

DATES: PRM–26–6 was withdrawn on December 10, 2019.

ADDRESSES: Please refer to Docket ID NRC–2010–0310 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2010–0310. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Yanely Malave, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1519, email: *Yanely.Malave-Velez@nrc.gov.*

SUPPLEMENTARY INFORMATION: On August 17, 2010, the petitioner submitted PRM–26–6 to the NRC requesting that it amend its fitness-for-duty regulations to decrease the minimum days off requirement from an average of 3 days per week to 2.5 or 2 days per week for security officers working 12-hour shifts (ADAMS Accession No. ML102630127). On November 23, 2010, the NRC published a notice of receipt of, and request for public comment on PRM–26–6 in the **Federal Register** (75 FR 71368). The NRC received 5 comment letters from corporations, professional organizations, and private citizens. The NRC initially determined that the issues raised in PRM–26–6 would be considered in the ''Quality Control/Quality Verification'' rulemaking (Docket ID: NRC–2009–0090) and published a **Federal Register** notice (76 FR 28191) on May 16, 2011, to this effect. On December 9, 2015, the NRC published a notice in the **Federal Register** discontinuing the QC/QV rulemaking (80 FR 76394). By email dated December 10, 2019, the petitioner withdrew PRM–26–6 (ADAMS Accession No. ML20006D919).

Dated December 3, 2020.

For the Nuclear Regulatory Commission.

John R. Tappert,

Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Materials Safety and Safeguards.

[FR Doc. 2020–27124 Filed 12–17–20; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL TRADE COMMISSION

16 CFR Part 432

Trade Regulation Rule Relating to Power Output Claims for Amplifiers Utilized in Home Entertainment Products

AGENCY: Federal Trade Commission.

ACTION: Advance notice of proposed rulemaking; request for public comment.

SUMMARY: As part of the Commission's systematic review of all current FTC rules and guides, the Federal Trade Commission (''FTC'' or ''Commission'') requests public comment on the overall costs, benefits, necessity, and regulatory and economic impact of the FTC's Trade Regulation Rule Relating to Power Output Claims for Amplifiers Utilized in Home Entertainment Products (the ''Amplifier Rule'' or ''Rule'').

DATES: Comments must be received on or before February 16, 2021.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Amplifier Rule Review, 16 CFR part 432, Project No. P974222'' on your comment, and file your comment online through *https://www.regulations.gov.* If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex A), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex A), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jock Chung (202–326–2984), Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

In response to misleading or confusing power, distortion, and other performance claims, the Commission issued the Amplifier Rule in 1974 to standardize the measurement and disclosure of various amplifier performance characteristics. 39 FR 15387 (May 3, 1974). The Rule establishes uniform test standards and disclosures so consumers can easily compare amplifier characteristics.

Prior to enactment of the Amplifier Rule, manufacturers used at least seven different systems to measure amplifier output, including two incompatible measurement systems with broad industry support, the EIA Standard Methods of Measurement and the IHF Standard.[1] At that time, the same amplifier might have been advertised with different power ratings when incorporated into different products.[2]

Moreover, prior to enactment of the Rule, some manufacturers advertised the maximum power output of a single channel of a stereo amplifier. The Commission found that this practice deceptively indicated a stereo amplifier powered both stereo channels at that level simultaneously, which was not necessarily true.[3] Manufacturers also measured power outputs over short periods of time, which did not account for heat buildup that prevented the amplifiers from being used at the measured output power for longer periods. Additionally, some manufacturers inflated power outputs by measuring amplifier outputs over limited frequency ranges or with excessive distortion, with unrealistic speaker loads, or when operating on battery power.[4]

To address these issues, the Rule requires uniform measurements and disclosures for home entertainment amplifiers. Specifically, it requires manufacturers to fully drive all associated channels when measuring the power output of sound amplification equipment designed to amplify two or more channels simultaneously. The Rule further sets requirements for measuring and disclosing frequency ranges, distortion levels, and speaker loads; requires manufacturers to conduct measurements in still air at a specified temperature to prevent the use of fans or cooling equipment; and requires manufacturers to use outlet power to test amplifiers that can run on either batteries or outlet power.

In 2000, in response to improvements in amplifier design that enabled manufacturers to make inexpensive amplifiers with inaudible levels of harmonic distortion, the Commission exempted certain advertising from the Rule's Total Harmonic Distortion (THD) disclosure requirement. 65 FR 81232 (Dec. 22, 2000). Additionally, to address the development of self-powered subwoofer-satellite combination speaker systems, the Commission clarified the manner in which the Rule's testing procedures apply to those systems.

II. Regulatory Review Program

The Commission reviews its rules and guides periodically to seek information about their costs and benefits, regulatory and economic impact, and general effectiveness in protecting consumers and helping industry avoid deceptive claims or unfair practices. These reviews assist the Commission in identifying rules and guides that warrant modification or rescission.

With the present document, the Commission initiates a review of its Amplifier Rule. The Commission solicits comments on, among other things, the economic impact of, and the continuing need for, the Rule; the Rule's benefits to consumers; and the burdens it places on industry members subject to the requirements, including small businesses.

III. Issues for Comments

To aid commenters in submitting information, the Commission has prepared the following questions related to the Amplifier Rule. The Commission seeks comments on these and any other issues related to the Rule's current requirements. In their replies, commenters should provide any available evidence, including empirical analysis, that supports their position.

(1) *Need:* Is there a continuing need for the Rule? Why or why not?

(2) *Benefits and Costs to Consumers:* What benefits has the Rule provided to consumers, and does the Rule impose any significant costs on consumers? Please quantify these benefits and costs wherever possible.

(3) *Benefits and Costs to Industry Members:* What benefits, if any, has the Rule provided to businesses, and does the Rule impose any significant costs, including costs of compliance, on businesses, including small businesses? Please quantify these benefits and costs wherever possible.

(4) *Recommended Changes:* What modifications, if any, should the Commission make to the Rule to increase its benefits or reduce its costs? How would these modifications affect the costs and benefits of the Rule for consumers? How would these modifications affect the costs and benefits of the Rule for businesses, particularly small businesses?

(5) *Impact on Information:* What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers?

(6) *Compliance:* Provide any evidence concerning the degree of industry compliance with the Rule. Does this evidence indicate that the Rule should be modified? If so, why, and how? If not, why not?

(7) *Unnecessary Provisions:* Provide any evidence concerning whether any of the Rule's provisions are no longer necessary. Explain why these provisions are unnecessary.

(8) *Additional Unfair or Deceptive Practices:* What potentially unfair or deceptive practices, not covered by the Rule, related to amplifiers utilized in home entertainment products are occurring in the marketplace? Are such practices prevalent in the market? If so, please describe such practices, including their impact on consumers. Provide any evidence, such as empirical data, consumer perception studies, or consumer complaints, that demonstrates the extent of such practices. Provide any evidence that demonstrates whether such practices cause consumer injury, and quantify or estimate that injury if possible. With reference to such practices, should the Rule be modified? If so, why, and how? If not, why not?

(9) *Product Coverage:* Should the Commission broaden the Rule to include products not currently covered? Provide any evidence that supports your position. What potentially unfair or deceptive practices related to products not covered by the Rule are occurring in the marketplace? Are such practices prevalent in the market? If so, please describe such practices, including their impact on consumers. Provide any evidence, such as empirical data,

[1] The Electronics Industries Association, an industry group with approximately 240 member companies in 1974, created the EIA Standard Methods of Measurement. The IHF, an industry group with 37 member companies, created the IHF Standard. 39 FR at 15388.

[2] The Commission found that one amplifier was reported as advertised with 3 power ratings based on continuous power output and 1 percent distortion when included in a component system, and with a peak power rating with 5 percent distortion when included in a console system.

[3] The Commission found that ''a stereo having, for example, 20-watts per channel, both channels driven, will give less total power output than a single channel 40-watt amplifier.'' 39 FR at 15390.

[4] Amplifiers running on batteries might have less distortion than the same amplifier running on power from an electric outlet, so tests driving the amplifier to a rated distortion level under battery power might measure a higher power output than measurements for the same amplifier driven to the same distortion level under outlet power. 39 FR at 15393.

consumer perception studies, or consumer complaints, that demonstrates the extent of such practices. Provide any evidence that demonstrates whether such practices cause consumer injury, and quantify or estimate that injury if possible.

(10) *Technological or Economic Changes:* What modifications, if any, should be made to the Rule to account for current or impending changes in technology or economic conditions? How would these modifications affect the costs and benefits of the Rule for consumers and businesses, particularly small businesses?

(11) *Conflicts With Other Requirements:* Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how? Provide any evidence that supports your position. With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not? Are there any Rule changes necessary to help state law enforcement agencies combat deceptive practices in the market for amplifiers utilized in home entertainment products? Provide any evidence concerning whether the Rule has assisted in promoting national consistency with respect to the advertising of amplifiers utilized in home entertainment products.

IV. Comment Submissions

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 16, 2021. Include ''Amplifier Rule Review, 16 CFR part 432, Project No. P974222'' on your comment. Your comment, including your name and your state, will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the public health emergency in response to the COVID–19 outbreak and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comment online through the *https://www.regulations.gov* website. To ensure the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write ''Amplifier Rule Review, 16 CFR part 432, Project No. P974222'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex A), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610, Washington, DC 20024. If possible, please submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website, *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information such as your or anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential''—as provided in section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this request for comment and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 16, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2020–27569 Filed 12–17–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2014–N–0053]

RIN 0910–AI44

Requirements for Additional Traceability Records for Certain Foods; Extension of Comment Period; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is extending the comment period for the proposed rule and reopening the comment period for the information collection related to the proposed rule entitled ''Requirements for Additional Traceability Records for Certain Foods'' that appeared in the **Federal Register** of September 23, 2020. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested persons to submit comments on the proposed rule. We also are taking this action to keep the comment period for the information collection provisions associated with the rule consistent with the comment period for the proposed rule.

DATES: FDA is extending the comment period on the proposed rule published September 23, 2020 (85 FR 59984). Submit either electronic or written comments on the proposed rule by February 22, 2021. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) by February 22, 2021.

ADDRESSES: You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. Electronic comments must be submitted on or before February 22, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 22, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0560. Also include the FDA docket number found in brackets in the heading of this document.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–N–0053 for ''Requirements for Additional Traceability Records for Certain Foods.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

Regarding the proposed rule: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4614, *Brian.Pendleton@fda.hhs.gov.*

Regarding the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 2020 (85 FR 59984), we published a proposed rule entitled ''Requirements for Additional Traceability Records for Certain Foods'' with a 120-day comment period on the provisions of the proposed rule and a 60-day comment period on the information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

FDA has received a request for a 60-day extension of the comment period for the provisions of the proposed rule and an extension of the comment period for the information collection provisions to align with the end of the comment period for the provisions of the proposed rule. The request conveyed concern that the current 120-day comment period does not allow stakeholders time to thoroughly analyze the rule due to its complexity and competing priorities. The request also noted that stakeholders cannot provide meaningful feedback on the information collection burden of the proposed rule without first having given the entire proposed rule thorough consideration, and therefore asked that the comment period for the information collection provisions be extended to align with the comment period for the provisions of the proposed rule. We have concluded that it is reasonable to extend for 30 days the comment period for the provisions of the proposed rule. The Agency believes that this extension allows adequate time for any interested persons to submit comments on the proposed rule. We also are extending the comment period for the information collection provisions to February 22, 2021, to align the comment period for the information collection provisions with the comment period for the provisions of the proposed rule.

Dated: December 2, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

Dated: December 11, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–27829 Filed 12–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 152

[Docket No. FDA–2020–N–1690]

RIN 0910–AI17

Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) proposes to revoke the standard of identity and the standard of quality for frozen cherry pie. This action, in part, responds to a citizen petition submitted by the American Bakers Association (ABA). We tentatively conclude that these standards are no longer necessary to promote honesty and fair dealing in the interest of consumers. We also tentatively conclude that revoking the standards of identity and quality for frozen cherry pie would provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

DATES: Submit either electronic or written comments on the proposed rule by March 18, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 18, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 18, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1690 for ''Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–3719.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule, if finalized, would revoke the standards of identity and quality for frozen cherry pie. This action, in part, responds to a citizen petition submitted by the American

Bakers Association (ABA). We tentatively conclude that the standards of identity and quality for frozen cherry pie are no longer necessary to promote honesty and fair dealing in the interest of consumers and revoking these standards will provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule, if finalized, would revoke the standards of identity and quality for frozen cherry pie.

C. Legal Authority

We are issuing this proposed rule to revoke the standards of identity and quality for frozen cherry pie consistent with our authority under section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341), which directs the Secretary of Health and Human Services (Secretary) to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever, in the Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers.

D. Costs and Benefits

The proposed rule would affect manufacturers of frozen cherry pie and would not require firms within the frozen cherry pie industry to change their manufacturing practices. Our analysis of current food manufacturing practices and the proposal to revoke the standards indicate that the proposed rule would provide benefits in terms of additional flexibility and the opportunity for innovation to the manufacturers. Therefore, we tentatively conclude that the proposed rule to revoke the standards for frozen cherry pie would, if finalized, provide social benefits at no cost to the respective industries.

II. Background

Section 401 of the FD&C Act directs the Secretary to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever, in the Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers. The purpose of these standards is to protect consumers against economic adulteration and reflect consumers' expectations about food.

We proposed the standards of identity and quality for frozen cherry pie in the **Federal Register** of November 1, 1967 (32 FR 15116), and finalized them in the **Federal Register** of February 23, 1971 (36 FR 3364); the requirements were codified at 21 CFR 28.1 (''Frozen cherry pie; identity; label statement of optional ingredients'') and 21 CFR 28.2 (''Frozen cherry pie; quality; label statement of substandard quality''). We later amended the standards of identity and quality in the **Federal Register** of June 13, 1973 (38 FR 15504), by removing minimum frozen cherry pie weight requirements, aligning the definition of blemished cherries with that in the United States Department of Agriculture's U.S. Standards for Grades of Frozen Red Tart Pitted Cherries, and adding clarifying language. We renumbered the two sections in the **Federal Register** of March 15, 1977 (42 FR 14302 at 14449), and combined them into § 152.126 (21 CFR 152.126), with the new section covering both the standards of identity and quality.

FDA received a citizen petition from the ABA asking us, in part, to revoke the frozen cherry pie standards of identity and quality (Citizen Petition from the American Bakers Association, dated August 18, 2005, Docket No. FDA–2005–P–0435 (''petition'')). We propose to grant this request; our proposed action is to revoke part 152 (21 CFR part 152 (''Fruit pies'')) in its entirety because the standards for frozen cherry pie are the only standards in part 152.

III. ABA Citizen Petition and Grounds

The petition asks us, in part, to revoke the standards of identity and quality for frozen cherry pie in 21 CFR 152.126 (petition at page 10).

The petition claims that the essential elements of § 152.126 are the requirements that the drained cherry content of frozen cherry pies cannot be less than 25 percent of the weight of the pie and that no more than 15 percent by count of the cherries in the pie can be blemished (id. at page 9). The petition asserts that the sole purpose of § 152.126 is to establish a standard of quality, and not a standard of identity, for frozen cherry pie products (id.). The petition also opposes the use of any food standards to establish quality characteristics of foods and asserts that food manufacturers and consumers should determine food quality (id.). Consumers would decide whether they wish to spend more money on higher-quality products or less money on lower-quality products. The petition further states that a product of unacceptably low quality will not survive in the marketplace (id.).

The petition also states that there is no basis for singling out frozen cherry pie for the imposition of standards of identity and quality (id. at page 10). The petition observes that there are no standards of identity and quality for any other types of frozen fruit pies, or for any non-frozen fruit pies, including those filled with cherries (id.). The petition further asserts that nonstandardized fruit pies have been sold throughout the country for many years without any evidence of public confusion (id.).

IV. Description of the Proposed Rule

We disagree with the petition's opposition to using standards to establish quality characteristics of foods. Congress has given us the authority to promulgate regulations establishing a reasonable standard of quality for any food. We may exercise this authority to promote honesty and fair dealing in the interest of consumers. Congress has placed few limitations on the foods for which standards of quality may be established, excluding only fresh or dried fruits, fresh or dried vegetables, and butter. Frozen cherry pie is not among these foods, and therefore, we have the authority to establish a standard of quality for frozen cherry pie if doing so promotes honesty and fair dealing in the interest of consumers.

However, we tentatively conclude that the frozen cherry pie standards of identity and quality are no longer needed to promote honesty and fair dealing in the interest of consumers. Consequently, the proposed rule would revoke part 152 (''Fruit pies'') in its entirety because the standards for frozen cherry pie are the only standards in part 152.

As the petition notes, frozen cherry pie is the only fruit pie, either frozen or non-frozen, that is subject to standards of identity and quality. This means that:

- Other cherry pies (*i.e.,* baked, frozen cherry pie, which § 152.126(a)(1) expressly excludes from the standards, and baked, non-frozen cherry pie) are not subject to standards of identity or quality and
- other fruit pies are not subject to standards of identity or quality.

We are not aware of any evidence suggesting that consumers have different expectations for unbaked, frozen cherry pies than for other cherry pies. At the same time, no other cherry pies are subject to a standard of identity or a standard of quality, and we are aware of no evidence indicating that such standards are necessary to promote honesty and fair dealing in the interest of consumers or to ensure that those cherry pies meet consumer expectations. Similarly, other fruit pies are not subject to standards of identity or quality, and we are aware of no

evidence indicating that such standards are necessary to promote honesty and fair dealing in the interest of consumers or to ensure that the pies meet consumer expectations.

Additionally, we tentatively conclude that the prohibition of artificial sweeteners in § 152.126(a)(2) does not promote honesty and fair dealing in the interest of consumers. Baked, frozen cherry pie and baked, non-frozen cherry pie may be made with artificial sweeteners to produce reduced-sugar varieties to accommodate consumer preferences and dietary restrictions. Other types of fruit pies are manufactured with artificial sweeteners to produce reduced-sugar varieties. These varieties appear to cater to consumer preferences and needs, and we are aware of no evidence that they create confusion or circumvent consumer expectations. If the standard of identity for frozen cherry pie is revoked, manufacturers could use artificial sweeteners to make unbaked, frozen cherry pie products, consistent with other reduced-sugar fruit pies available in the marketplace.

Therefore, after considering the petition and related information, we tentatively conclude that the standards of identity and quality for frozen cherry pie are no longer needed to promote honesty and fair dealing in the interest of consumers consistent with section 401 of the FD&C Act. We are interested in any information, including data and studies, on consumer expectations regarding unbaked, frozen cherry pies and whether the specifications in § 152.126 are necessary to ensure that frozen cherry pie meets these expectations.

In addition, our proposal to revoke the standards of identity and quality for frozen cherry pie is consistent with Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs'' (January 30, 2017), and Executive Order 13777, ''Enforcing the Regulatory Reform Agenda'' (February 24, 2017). Executive Order 13771 and Executive Order 13777, taken together, direct agencies to offset the number and cost of new regulations by identifying prior regulations that can be eliminated because, for example, they are outdated, unnecessary, or ineffective. Our proposed revocation also is consistent with section 6 of Executive Order 13563, ''Improving Regulation and Regulatory Review'' (January 18, 2011), which requires agencies to periodically conduct retrospective analyses of existing regulations to identify those ''that might be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them'' accordingly.

V. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 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.'' We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have tentatively concluded, as set forth below, that this rule would not generate significant compliance costs, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule would affect manufacturers of unbaked, frozen cherry pie. Our review of supermarket scanner data for the year 2018 shows that a total of 40 distinct frozen cherry pie products sold that year were manufactured by 20 firms. The proposed rule would not require any firms within the frozen cherry pie industry to change their manufacturing practices. Our analysis of current food manufacturing practices and the proposal to revoke the standards indicate that the proposed rule would provide benefits in terms of additional flexibility to the manufacturers of frozen cherry pie products. The proposed rule would promote innovation and the introduction of new unbaked, frozen cherry pie products, providing benefits to both consumers and industry. Therefore, we tentatively conclude that the proposed rule to revoke the standards for frozen cherry pie would, if finalized, provide social benefits at little to no cost to the respective industries (table 1).

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate	Period covered	
Benefits:							
Annualized Monetized $millions/year.	$0	$0	$0	2018	7% 3% 7%		
Annualized Quantified					3%		

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate	Period covered	
Qualitative							Benefits to manufacturers would be from additional flexibility for, and the opportunity for innovation regarding, frozen cherry pie products.
Costs:							
Annualized Monetized $millions/year.	$0	$0	$0	2018	7% 3%		
Annualized Quantified					7% 3%		
Qualitative.							
Transfers:							
Federal Annualized Monetized $millions/year.					7% 3%		
From/To	From:			To:			
Other Annualized Monetized $millions/year.					7% 3%		
From/To	From:			To:			

Effects:
State, Local or Tribal Government:
Small Business:
Wages:
Growth:

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these cost savings, this proposed rule, if finalized, would be considered a deregulatory action under E.O. 13771.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY

[In $ millions 2016 dollars, over an infinite time horizon]

Item	Primary estimate (7%)	Lower estimate (7%)	Upper estimate (7%)
Present Value of Costs	$0	$0	$0
Present Value of Cost Savings	0	0	0
Present Value of Net Costs	0	0	0
Annualized Costs	0	0	0
Annualized Cost Savings	0	0	0
Annualized Net Costs	0	0	0

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 1) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VI. Analysis of Environmental Impact

We have tentatively determined under 21 CFR part 25.32(a) that this action, if finalized, is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively concluded that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we tentatively conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule

does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis. Available at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 152

Bakery products, Food grades and standards, Frozen foods, Fruits.

PART 152—[REMOVED]

■ Therefore, consistent with our authority under 21 U.S.C. 321, 341, 343, 348, 371, and 379e, under the Federal Food, Drug, and Cosmetic Act, it is proposed that 21 CFR part 152 be removed.

Dated: December 2, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

Dated: December 14, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–27823 Filed 12–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 38

RIN 2900–AR03

Referral for VA Administrative Decision for Character of Discharge Determinations

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend title 38 of the Code of Federal Regulations (CFR) to clarify that, when determining eligibility for interment or memorialization benefits, the National Cemetery Administration (NCA) will refer cases involving other than honorable (OTH) discharges, certain other discharges, or potential statutory or regulatory bars to benefits, to the Veterans Benefits Administration (VBA) for character of discharge determinations. VA is merely updating its regulations to conform with statute and current practice.

DATES: Comments must be received by VA on or before February 16, 2021.

ADDRESSES: Written comments may be submitted through *www.regulations.gov;* or by mail to Director, Legislative and Regulatory Service (42E), Department of Veterans Affairs, 810 Vermont Ave. NW, Washington, DC 20420. Comments should indicate that they are submitted in response to ''RIN 2900–AR03—Referral for VA Administrative Decision for Character of Discharge Determinations.'' Comments received will be available for public inspection at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jerry Sowders, Division Chief, Eligibility Verification Division, National Cemetery Administration (NCA), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone: (314) 416–6369 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: VA proposes to amend § 38.620 to clarify that, when determining eligibility for interment or memorialization benefits, NCA will refer cases involving other than honorable (OTH) discharges or other character of discharge issues to VBA for an administrative decision.

Eligibility for NCA-administered benefits, including interment in national cemeteries, is tied to an individual establishing veteran status or meeting other specified conditions. See, *e.g.,* 38 U.S.C. 2402(a)(1) (stating any ''veteran'' may be buried in any open national cemetery); 112 (allowing VA to provide Presidential Memorial Certificates to those eligible for national cemetery burial); 2306(a) (authorizing VA to provide a government-furnished headstone or marker to those buried in a national cemetery or who meet other specified conditions); 2306(b)(2) (tying eligibility for memorial headstones or markers to ''veteran'' status); 2306(f) (authorizing caskets or urns for burial of deceased ''veterans''). Congress has defined a veteran as ''a person who served in the active military, naval, or air service, and who was discharged or released therefrom under conditions other than dishonorable.'' 38 U.S.C. 101(2).

Applying the ''veteran'' definition to the sections governing NCA-administered benefits, it is thus clear that, unless other specified conditions are met, a deceased individual must have been discharged or released from active service under conditions other than dishonorable; and an adjudication must sometimes be made as to an individual's ''veteran'' status in order to determine eligibility for NCA-administered benefits. Some characterizations of service on a DD–214 (such as honorable and general under honorable conditions) allow for relatively straightforward determinations that the character of discharge was other than dishonorable; however, other types of characterizations can be somewhat complex and require in-depth examination. For example, bad conduct discharges, OTH discharges, discharges upgraded from bad conduct or OTH, and uncharacterized administrative separations may require more extensive character of discharge determinations, including a review to determine whether any of the statutory bars to benefits contained in 38 U.S.C. 5303(a) apply.

In this rulemaking, NCA clarifies that cases involving potential character of discharge bars will be referred to VBA for an administrative decision under 38 CFR 3.12 (Character of discharge) or other applicable sections. NCA makes efficient use of VBA's existing expertise and established procedures to adjudicate character of discharge and other complex eligibility issues when needed. Coordination with VBA for adjudication on such issues helps to ensure consistency in benefits determinations and minimizes confusion for claimants and beneficiaries that would likely result from VBA and NCA having differing protocols. NCA provides funding resources, equivalent to the amount necessary for two full time employees, to VBA to offset the additional workload

created by case referrals. NCA proposes this rule to solidify the continuation of this effective partnership and provide public information regarding adjudication of character of discharge determinations involving potential statutory and regulatory bars to benefits.

Paperwork Reduction Act

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), no new or proposed revised collections of information are associated with this proposed rule.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. There are no small entities involved with the process for determining eligibility for interment or memorialization benefits. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its Regulatory Impact Analysis (RIA) are available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published from FY 2004 Through Fiscal Year to Date.''

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

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.201, National Cemeteries; 64.202, Procurement of Headstones and Markers and/or Presidential Memorial Certificates; and 64.203, State Cemetery Grants.

List of Subjects in 38 CFR Part 38

Administrative practice and procedure, Cemeteries, Claims, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Brooks D. Tucker, Assistant Secretary for Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, Department of Veterans Affairs, approved this document on December 4, 2020, for publication.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set forth in the preamble, VA proposes to amend 38 CFR part 38 as follows:

PART 38—NATIONAL CEMETERIES OF THE DEPARTMENT OF VETERANS AFFAIRS

■ 1. The authority citation for part 38 is revised to read as follows:

Authority: 38 U.S.C. 101, 107, 112, 501, 512, 2306, 2402, 2403, 2404, 2407, 2408, 2411, 5303, 7105.

38.620 [AMENDED]

■ 2. Amend § 38.620 by adding a Note following paragraph (i)(4) to read as follows:

* * * * *

Note to § 38.620: A benefit request pertaining to a decedent whose character of discharge may potentially bar eligibility to that benefit may be referred to the Veterans Benefits Administration for review in accordance with 38 CFR 3.12 (Character of discharge) or other applicable sections.

[FR Doc. 2020–27106 Filed 12–17–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 236

[Docket No. FRA–2019–0075]

RIN 2130–AC75

Positive Train Control Systems

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: FRA is proposing to revise its regulations governing changes to positive train control (PTC) systems and reporting on PTC system functioning. First, recognizing that the railroad industry intends to enhance further FRA-certified PTC systems to continue improving rail safety and PTC technology's reliability and operability, FRA proposes to modify the process by which a host railroad must submit a request for amendment (RFA) to FRA before making certain changes to its PTC Safety Plan (PTCSP) and FRA-certified PTC system. Second, to enable more effective FRA oversight, FRA proposes to: Expand an existing reporting requirement by increasing the frequency from annual to biannual; broaden the reporting requirement to encompass positive performance-related information, not just failure-related information; and require host railroads to utilize a new, standardized Biannual Report of PTC System Performance (Form FRA F 6180.152). Overall, the proposed amendments would benefit the railroad industry, the public, and FRA, by reducing unnecessary costs, facilitating innovation, and improving FRA's ability to oversee PTC system performance and reliability, while not negatively affecting rail safety.

DATES: Written comments must be received by February 16, 2021. FRA believes a 60-day comment period is appropriate to allow the public to comment on this proposed rule. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to Docket No. FRA–2019–0075 may be submitted by going to *http://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name, docket number (FRA–2019–0075), and Regulation Identifier Number (RIN) for this rulemaking (2130–AC75). All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Acting Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov;* or Stephanie Anderson, Attorney Adviser, telephone: 202–493–0445, email: *Stephanie.Anderson@dot.gov.*

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I. Executive Summary

Section 20157 of title 49 of the United States Code (U.S.C.) mandates each Class I railroad, and each entity providing regularly scheduled intercity or commuter rail passenger transportation, to implement an FRA-certified PTC system fully on: (1) Its main lines over which poison- or toxic-by-inhalation hazardous materials are transported, if the line carries five million or more gross tons of any annual traffic; (2) its main lines over which intercity or commuter rail passenger transportation is regularly provided; and (3) any other tracks the Secretary of Transportation (Secretary) prescribes by regulation or order.[1] By law, PTC systems must be designed to prevent certain accidents or incidents, including train-to-train collisions, over-speed derailments, incursions into established work zones, and movements of trains through switches left in the wrong position.[2]

In general, the statutory mandate requires that by December 31, 2020, FRA-certified and interoperable PTC systems must govern operations on all PTC-mandated main lines, currently encompassing nearly 58,000 route miles nationwide.[3] *See* 49 U.S.C. 20157(a); 49 CFR 236.1005(b)(6)–(7). Currently, 35 host railroads[4]—including 7 Class I railroads, 23 intercity passenger railroads or commuter railroads, and 5 Class II or III, short line, or terminal railroads—are directly subject to the statutory mandate to implement an FRA-certified and interoperable PTC system on their PTC-mandated main lines by December 31, 2020. For purposes of FRA's PTC regulations, a host railroad is ''a railroad that has effective operating control over a segment of track,'' and a tenant railroad is ''a railroad, other than a host railroad, operating on track upon which a PTC system is required.'' *See* 49 CFR 236.1003(b).

For context, under the statutory mandate, ''interoperability'' is the general requirement that the controlling locomotives and cab cars of any host railroad and tenant railroad operating on the same main line must communicate with and respond to the PTC system, including uninterrupted movements over property boundaries, except as otherwise permitted by law.[5] As of September 2020, according to host railroads' PTC Implementation Plans (PTCIP), approximately 93 distinct PTC-required tenant railroads operate on main lines subject to the statutory mandate. Because many railroads operate on multiple host railroads' PTC-mandated main lines, there are approximately 219 host-tenant railroad relationships in which PTC system interoperability must be achieved by December 31, 2020.

From 2018 through 2020, FRA held three PTC Symposia and Collaboration Sessions per year to underscore the importance of the mandate, ensure the industry understands the statutory and regulatory requirements, and facilitate timely compliance. In addition, the six Collaboration Sessions during 2019 and 2020 provided the opportunity for FRA to convene the industry's technical experts to share best practices and jointly resolve common technical problems.

Through these meetings and regular coordination with all railroads implementing PTC systems, PTC system vendors and suppliers, and other stakeholders, FRA began proactively identifying aspects of FRA's existing PTC regulations that could impede either PTC-related innovation or FRA's oversight, following the December 31, 2020, statutory deadline for full PTC system implementation. Specifically, FRA identified two existing regulatory provisions, 49 CFR 236.1021 and 236.1029(h), which, if not revised, could impede the industry's ability to advance PTC technology efficiently and FRA's ability to oversee the performance and reliability of PTC systems effectively.

First, understanding that the railroad industry intends to update FRA-certified PTC systems continually to ensure safe operations (*e.g.,* through ongoing, necessary maintenance) and to enhance further the technology (*e.g.,* by adding new functionality or improving a PTC system's reliability and operability), FRA is proposing to modify the process under 49 CFR 236.1021 for

[1] *See* Rail Safety Improvement Act of 2008, Public Law 110–432, 104(a), 122 Stat. 4848 (Oct. 16, 2008), as amended by the Positive Train Control Enforcement and Implementation Act of 2015, Public Law 114–73, 129 Stat. 568, 576–82 (Oct. 29, 2015), and the Fixing America's Surface Transportation Act, Public Law 114–94, section 11315(d), 129 Stat. 1312, 1675 (Dec. 4, 2015), codified as amended at 49 U.S.C. 20157. *See also* Title 49 Code of Federal Regulations (CFR) part 236, subpart I.

[2] *See, e.g.,* 49 U.S.C. 20157(g)(1), (i)(5); 49 CFR 236.1005 (setting forth the technical specifications).

[3] Except a railroad's controlling locomotives or cab cars that are subject to either a temporary or permanent exception under 49 U.S.C. 20157(j)–(k) or 49 CFR 236.1006(b), *Equipping locomotives operating in PTC territory.*

[4] The infographics on FRA's PTC website (*https://railroads.dot.gov/train-control/ptc/positive-train-control-ptc*) identify 41 railroads currently subject to the statutory mandate, but six of those 41 railroads are tenant-only commuter railroads, not host railroads. As this proposed rule primarily focuses on requirements specific to host railroads, FRA will reference the current number of PTC-mandated *host* railroads (35) and any host railroads that may become subject to the statutory mandate in the future.

[5] *See* 49 U.S.C. 20157(a)(2)(A)(i)(I), (a)(2)(D), (i)(3), (j)–(k); 49 CFR 236.1003, 236.1006, 236.1011(a)(3).

RFAs to PTCSPs for FRA-certified systems. The improved process will enable the industry to deploy upgrades and technological enhancements more efficiently, and ensure FRA's review of changes or modifications to FRA-certified systems is more predictable and consistent going forward. The proposed process will apply only to PTC systems FRA has already certified under 49 U.S.C. 20157(h). The statutory mandate generally requires FRA to certify that a host railroad's PTC system complies with 49 CFR part 236, subpart I, before it operates in revenue service, and this proposed rule will not amend the existing certification process FRA developed to comply with this mandate (*i.e.,* this proposed rule would not amend 49 CFR 236.1009 or 236.1015 regarding PTCSPs and the PTC System Certification process). To be clear, FRA's proposal to modify the process that currently requires a host railroad to submit, and obtain FRA's approval of, an RFA to a PTCSP under 49 CFR 236.1021 will not apply to any existing or new PTC system, unless and until FRA has certified that PTC system under 49 U.S.C. 20157(h).

Instead of the existing RFA approval process with an indefinite decision timeline, FRA proposes to require railroads to comply with a streamlined RFA process, which includes providing certain documentation, analysis, and safety assurances. This proposed rule would establish a 45-day deadline for FRA to review and approve or deny railroads' RFAs to their FRA-approved PTCSPs or FRA-certified PTC systems. In addition, FRA proposes to permit host railroads utilizing the same type of PTC system to submit joint RFAs to their PTCSPs and PTC Development Plans (PTCDP)—an option which, if exercised, would efficiently leverage industry's resources, help ensure coordination among railroads operating the same types of PTC systems, and reduce the number of similar or identical RFA filings host railroads submit to FRA for review and approval.

Second, FRA proposes to expand an existing reporting requirement—49 CFR 236.1029(h), *Annual report of system failures*—by increasing the frequency of the reporting requirement from annual to biannual; broadening the reporting requirement to encompass positive performance-related information, not just failure-related information; and requiring host railroads to utilize a new, standardized Biannual Report of PTC System Performance (Form FRA F 6180.152) [6] to enable more effective FRA oversight. In addition, FRA proposes to amend § 236.1029(h) by updating the provision to use certain statutory terminology for consistency; clarifying the ambiguous filing obligation by specifying that only host railroads directly submit these reports to FRA; and explicitly requiring tenant railroads to provide the necessary data to their applicable host railroads by a specific date before the biannual filing deadlines.

FRA analyzed the economic impact of this proposed rule over a ten-year period and estimated its costs and cost savings, which are shown in the table below. The cost savings associated with FRA's proposal to amend § 236.1021—*i.e.,* to simplify the process for all RFAs to PTCSPs and authorize host railroads to file joint RFAs to PTCSPs and PTCDPs—would outweigh the costs associated with FRA's proposal to expand the reporting requirement under paragraph (h) of § 236.1029.

NET COST SAVINGS IN MILLIONS
[2019 Dollars]

	Present value 7%	Present value 3%	Annualized 7%	Annualized 3%
Industry Costs	$324,158	$379,231	$46,153	$44,457
Industry Cost Savings	6,116,671	7,202,273	870,876	844,326
Government Cost Savings	17,978,594	21,188,896	2,559,747	2,483,985
Net Cost Savings	23,771,107	28,011,938	3,384,471	3,283,854

II. Background and Summary of the Main Proposals in the NPRM

A. Legal Authority To Prescribe PTC Regulations

Section 104(a) of the Rail Safety Improvement Act of 2008 required the Secretary to prescribe PTC regulations necessary to implement the statutory mandate, including regulations specifying the essential technical functionalities of PTC systems and the means by which FRA will certify PTC systems.[7] The Secretary delegated to the Federal Railroad Administrator the authority to carry out the functions and exercise the authority vested in the Secretary by the Rail Safety Improvement Act of 2008. 49 CFR 1.89(b).

In accordance with its authority under 49 U.S.C. 20157(g) and 49 CFR 1.89(b), FRA issued its first final PTC rule on January 15, 2010, which is set forth, as amended, under 49 CFR part 236, subpart I, *Positive Train Control Systems.*[8] FRA's PTC regulations under 49 CFR part 236, subpart I, prescribe ''minimum, performance-based safety standards for PTC systems . . . including requirements to ensure that the development, functionality, architecture, installation, implementation, inspection, testing, operation, maintenance, repair, and modification of those PTC systems will achieve and maintain an acceptable level of safety.'' 49 CFR 236.1001(a). FRA subsequently amended its PTC regulations via final rules issued in 2010, 2012, 2014, and 2016.[9]

Most recently, on February 29, 2016, as required, FRA amended its PTC regulations to revise the regulations' date-specific deadlines for conformity with the Positive Train Control Enforcement and Implementation Act of 2015 (PTCEI Act).[10] Specifically, the PTCEI Act extended the original statutory deadline for full implementation of PTC systems from December 31, 2015, to at least December 31, 2018.[11] In addition, the PTCEI Act permits railroads to utilize an

[6] The proposed Biannual Report of PTC System Performance (Form FRA F 6180.152) will be placed in the docket (Docket No. FRA–2019–0075) for review when this NPRM is published.

[7] Public Law 110–432, 122 Stat. 4848 (Oct. 16, 2008), codified as amended at 49 U.S.C. 20157(g).

[8] 75 FR 2598 (Jan. 15, 2010).

[9] *See* 75 FR 59108 (Sept. 27, 2010); 77 FR 28285 (May 14, 2012); 79 FR 49693 (Aug. 22, 2014); 81 FR 10126 (Feb. 29, 2016).

[10] Public Law 114–73, 129 Stat. 568, 576–82 (Oct. 29, 2015), as amended by the Fixing America's Surface Transportation Act, Public Law 114–94, section 11315(d), 129 Stat. 1312, 1675 (Dec. 4, 2015). *See also* 81 FR 10126 (Feb. 29, 2016), amending 49 CFR part 236, subpart I.

[11] 49 U.S.C. 20157(a). Please note that the PTCEI Act also required FRA to extend each deadline under 49 CFR 236.1006(b)(4)(iii)(B) by three years, related to certain Class II and Class III railroads that operate in PTC territory. *See* 49 U.S.C. 20157(k); 81 FR 10126 (Feb. 29, 2016).

''alternative schedule and sequence'' with a full implementation deadline beyond December 31, 2018, but not later than December 31, 2020. Further, the legislation required FRA to approve a railroad's alternative schedule and sequence if the railroad demonstrated it met the six statutory criteria necessary to qualify for an alternative schedule and sequence.[12]

In this proposed rule, FRA proposes to revise three sections, 49 CFR 236.1003, 236.1021, and 236.1029, of FRA's existing PTC regulations pursuant to its specific authority under 49 CFR 1.89 and 49 U.S.C. 20157(g), and its general authority under 49 U.S.C. 20103 to prescribe regulations and issue orders for every area of railroad safety.

B. Public Participation Prior to the Issuance of the NPRM

As referenced above, FRA regularly engages with host railroads, tenant railroads, and PTC system vendors and suppliers, as part of FRA's oversight of railroads' implementation of PTC systems on the mandated main lines under 49 U.S.C. 20157 and the other lines where railroads are voluntarily implementing PTC technology. The purpose of this section is to summarize FRA's pertinent meetings prior to the issuance of this NPRM, pursuant to 49 CFR 5.19.

During two of FRA's PTC Collaboration Sessions in 2019 and 2020, FRA generally discussed its intention to propose to modify the RFA process under § 236.1021, specifically as it relates to FRA-approved PTCSPs and FRA-certified PTC systems. One of these two Collaboration Sessions was held on February 6, 2019 at DOT's Headquarters in Washington, DC, and the other was hosted via teleconference on June 10, 2020.

Specifically, during the Collaboration Session on February 6, 2019, FRA noted it was considering simplifying the formal process for railroads to modify their PTCSPs and PTC systems under § 236.1021, after FRA certifies a railroad's PTC system as required under the statutory mandate. FRA raised questions for the industry to consider, including how host railroads plan to maintain their PTCSPs, as required, acknowledging that PTC technology will continue evolving given, for example, ongoing software modifications necessary for safe operations and voluntary enhancements to improve further the reliability or operability of PTC systems.[13] FRA understands that, over time, new software releases may become necessary to: Fix certain bugs or defects; eliminate newly discovered hazards; or add new functionality to continue to improve rail safety, or the reliability and operability of the technology. In addition, FRA acknowledged that certain changes to PTC systems will likely impact multiple PTCSPs, as the industry is currently implementing five main types of PTC systems.[14] During the Collaboration Session on June 10, 2020, FRA discussed its intention to issue this NPRM and described the high-level objectives of this proposed rule.

In addition, on October 2, 2019, during FRA's PTC Collaboration Session hosted at the National Housing Center in Washington, DC, one Class I railroad suggested that FRA should consider amending the permanent reporting requirement under 49 CFR 236.1029(h) to make it consistent with the temporary statutory reporting requirement under 49 U.S.C. 20157(j)(4), because existing paragraph (h) of § 236.1029 uses different terminology to describe PTC-related failures. In addition, during this meeting, one commuter railroad requested that FRA create a standardized form for railroads to utilize under § 236.1029(h). FRA made no commitments at any of its PTC Collaboration Sessions, but FRA internally considered this industry input as it developed this proposed rule. Please note that all presentations from FRA's PTC Symposia and Collaboration Sessions are available in FRA's eLibrary, including direct links on FRA's PTC website at *https://railroads.dot.gov/train-control/ptc/positive-train-control-ptc.*

As information, representatives from all 35 host railroads currently subject to the statutory mandate attended at least two of the three above PTC Collaboration Sessions, and 89 percent of the PTC-mandated host railroads attended *all* three of the PTC Collaboration Sessions where FRA discussed either 49 CFR 236.1021 or 236.1029(h).[15] Specifically, 97 percent of the 35 applicable host railroads attended the PTC Collaboration Sessions on February 6, 2019 and October 2, 2019, and 94 percent attended the session on June 10, 2020. Furthermore, representatives from the American Public Transportation Association (APTA), the American Short Line and Regional Railroad Association (ASLRRA), and the Association of American Railroads (AAR) participated in all three of these pertinent PTC Collaboration Sessions. In addition, a representative from the Commuter Rail Coalition attended the PTC Collaboration Sessions on October 2, 2019 and June 10, 2020.

Furthermore, on the following dates, FRA met with AAR and several of its member railroads to discuss various PTC-related issues and topics, including FRA's previously stated intention to propose modifications to the RFA process under § 236.1021, specifically as it applies to FRA-certified PTC systems: September 6, 2019; March 3, 2020; April 2, 2020; June 11, 2020; June 25, 2020; July 9, 2020; and August 27, 2020. During the meetings on September 6, 2019 and July 9, 2020, representatives from AAR and its member railroads indicated that FRA should consider amending other provisions under FRA's PTC regulations, in addition to § 236.1021, but those provisions are not the focus of this proposed rule. As noted above, at this time, FRA considers it necessary to amend §§ 236.1021 and 236.1029(h) because those provisions, if not revised, could impede the industry's ability to enhance PTC technology and FRA's ability to oversee the performance and reliability of PTC systems effectively. If FRA finds that any other amendments to 49 CFR part 236, subpart I, are necessary or justified in the future, FRA will address them in a separate NPRM.

Representatives from the following Class I railroads and passenger railroads, listed alphabetically, attended

[12] 49 U.S.C. 20157(a)(3)(C) (using the term ''shall''). As background, four PTC-mandated host railroads reported that they fully implemented an FRA-certified and interoperable PTC system on all their required main lines by December 31, 2018. Every other host railroad subject to the statutory mandate in 2018 formally requested an alternative schedule and sequence under 49 U.S.C. 20157(a)(3). By March 5, 2019, FRA approved all applicable requests for an alternative schedule and sequence, as each railroad sufficiently demonstrated it, at a minimum, met the six statutory criteria necessary to qualify for an alternative schedule and sequence, under the statutory mandate.

[13] *See, e.g.,* 49 CFR 236.1009(d) (requiring a PTC system to be implemented in accordance with the host railroad's PTCSP).

[14] Currently, railroads are primarily implementing the following PTC systems in the United States: (1) The Interoperable Electronic Train Management System (I–ETMS), which Class I railroads and many commuter railroads are implementing; (2) the Advanced Civil Speed Enforcement System II (ACSES II) or the Advanced Speed Enforcement System II (ASES II), which most railroads operating on the Northeast Corridor (NEC) are implementing; (3) Enhanced Automatic Train Control (E–ATC), which five host railroads are implementing; (4) the Incremental Train Control System, which the National Railroad Passenger Corporation (Amtrak) is implementing in parts of Michigan; and (5) the Communication Based Train Control (CBTC) system, which one commuter railroad has fully implemented on its PTC-mandated main lines.

[15] In addition to the 35 host railroads subject to the statutory mandate, representatives from multiple other railroads attended these PTC Collaboration Sessions, including eight tenant-only passenger railroads that operate on PTC-mandated main lines.

the AAR meetings referenced immediately above: Amtrak, BNSF Railway, Canadian National Railway, Canadian Pacific Railway, CSX Transportation, Inc., Kansas City Southern Railway, Norfolk Southern Railway, the Northeast Illinois Regional Commuter Railroad Corporation (Metra), the Southern California Regional Rail Authority (Metrolink), and Union Pacific Railroad. The railroads' main comments during these meetings involved their concerns that the existing process under § 236.1021 would stifle innovation and create significant delays in deploying improvements to PTC technology. In general, they supported revising the existing RFA process under § 236.1021 to help enable technological advancements and ensure FRA is not an impediment to the industry's ability to enhance PTC technology. FRA's statements during these meetings were consistent with FRA's statements to all PTC-mandated host railroads at multiple PTC Collaboration Sessions. The proposals in this NPRM are based on FRA's own review and analysis and, in part, on industry's feedback during the meetings in 2019 and 2020, specified above. FRA seeks comments on all proposals made in this NPRM.

C. Proposal To Establish a New Process for Modifying FRA-Certified PTC Systems and the Associated PTCSPs

FRA's PTC regulations have always acknowledged that after ''implementation of a train control system, the subject railroad may have legitimate reasons for making changes in the system design,'' among other changes, including to a PTC system's functionality.[16] Accordingly, under 49 CFR 236.1015(d)(7), FRA requires host railroads' PTCSPs to include, among other relevant information, a ''complete description of the specific procedures and test equipment necessary to ensure the safe and proper . . . operation, maintenance, repair, inspection, testing, and modification of the PTC system on the railroad.''

Recognizing that PTC technology must be actively maintained throughout its lifecycle and beyond, FRA's regulations also require each railroad to ''catalog and maintain all documents as specified in the PTCDP and PTCSP for . . . maintenance, repair, modification, inspection, and testing of the PTC system.'' [17] Specifically, 49 CFR 236.1039(a) requires railroads to retain these documents in a PTC Operations and Maintenance Manual, which must be ''readily available to persons required to perform such tasks and for inspection by FRA and FRA-certified state inspectors.'' For example, a railroad's Operations and Maintenance Manual must document all ''[h]ardware, software, and firmware revisions . . . according to the railroad's configuration management control plan and any additional configuration/revision control measures specified in the [host railroad's] PTCSP.'' [18]

FRA is aware that host railroads will need to deploy new PTC software releases, among other changes, to ensure their PTC systems are performing properly—for example, to fix certain bugs or defects or eliminate newly discovered hazards. In addition to incremental changes to PTC systems that are necessary for the continued safe and proper functioning of the technology, FRA understands that several railroads and PTC system vendors and suppliers have chosen to design and develop their PTC systems to perform safety-related functions in addition to the minimum, performance-based functions specified under the statutory mandate and FRA's regulations.

Currently, FRA's PTC regulations, in relevant part, prohibit a railroad from making certain changes to its FRA-approved PTCSP or FRA-certified PTC system unless the railroad files an RFA to its PTCSP and obtains approval from FRA's Associate Administrator for Railroad Safety. 49 CFR 236.1021. This proposed rule does not envision revising the types of changes that currently require a host railroad to file an RFA under § 236.1021(h)(1)–(4) (often referred to as ''material modifications'') or the exceptions currently set forth under § 236.1021(i)–(k).

For example, FRA's regulations require a railroad to submit, for FRA review and approval, an RFA to the railroad's PTCSP for any proposed modification of a safety-critical element of a PTC system or any proposed modification of a PTC system that affects the safety-critical functionality of any other PTC system with which it interoperates. *See* 49 CFR 236.1021(h)(3)–(4). Though FRA's existing regulations specify that FRA will, to the extent practicable, review and issue a decision regarding a host railroad's initially filed PTCSP within 180 days of the date it was filed, FRA's regulations do not currently specify an estimated timeline for reviewing and approving or denying railroads' subsequent RFAs to their PTCSPs.[19] In practice, as of September 2020, it has taken FRA 127 days, on average, to review and approve recent RFAs to PTCSPs for FRA-certified PTC systems, which is, in part, due to the complex content requirements currently under paragraphs (d)(1) to (7) of § 236.1021.

Instead of the existing RFA approval process with an indefinite decision timeline, FRA proposes to: (1) Require railroads to comply with a streamlined RFA process, including providing certain documentation, analysis, and safety assurances; and (2) establish a 45-day deadline for FRA's review and issuance of a decision. In new proposed paragraph (m) of § 236.1021, FRA outlines the proposed content requirements for RFAs to PTCSPs for FRA-certified PTC systems—focusing on the core information and analysis FRA would need to review to ensure the PTC system, including any proposed changes, will provide an equivalent or greater level of safety than the existing PTC system. The improved process would enable the industry to implement technological enhancements more efficiently, and the clear timeline would help ensure a more predictable and transparent FRA review process going forward.

In addition, this proposed rule envisions permitting host railroads utilizing the same type of PTC system to submit joint RFAs to their PTCSPs and PTCDPs—an option which, if exercised, will efficiently leverage industry's resources, help ensure coordination among railroads operating the same types of PTC systems, and reduce the number of similar or identical RFA filings host railroads submit to FRA for review. As noted above, currently, the 35 PTC-mandated host railroads are implementing five types of PTC systems, though FRA acknowledges that, in several cases, railroads are implementing PTC systems of the same type in different manners (*e.g.,* variances in design, functionality, and operation), requiring railroads to conduct additional testing and gap analyses to achieve and sustain interoperability, including configuration management.

Appreciating that changes to safety-critical elements, including software or system architecture, of a certain PTC system will likely impact multiple, if not most, railroads implementing that same type of PTC system, FRA's proposed rule outlines a path for such

[16] *See* 75 FR 2598, 2660 (Jan. 15, 2010).

[17] 49 CFR 236.1039(a).

[18] 49 CFR 236.1039(c). *See also Federal Railroad Administration,* Revised PTC Guidance Regarding Interoperability Testing, Operations and Maintenance Manuals, and Certification Responsibilities (July 24, 2018), *available at https://www.fra.dot.gov/eLib/details/L19583#p1_z5_gD_lPO.*

[19] *See* 49 CFR 236.1009(j)(2).

host railroads to submit joint RFAs to their PTCSPs, with specific instructions under new proposed paragraphs (l) and (m) of § 236.1021. The proposed rule would specify that while most types of information required under proposed paragraph (m) of § 236.1021 may be submitted jointly in the RFA, the joint RFA would need to include certain written confirmations or statements [20] from each host railroad that is a signatory to the joint RFA. In addition, FRA's proposed rule specifies that only host railroads with the same PTC System Certification classification under paragraph (e) of § 236.1015 may jointly file an RFA to their PTCSPs.

Though this proposed rule would generally authorize host railroads utilizing the same type of PTC system to file RFAs to their PTCSPs jointly, FRA expects this aspect of the proposal, in the short term, primarily to impact host railroads implementing I–ETMS and E–ATC because each respective I–ETMS and E–ATC system is similar to others of the same type, with a baseline functionality. Conversely, there is not a uniform standard or specification currently underlying the ACSES II or ASES II PTC systems that host railroads are implementing on the NEC. In addition, there is an array of ACSES II suppliers, including for the onboard, wayside, and communications subsystems. In the future, however, as the ACSES II railroads finish establishing the Interoperable Change Management Plan they are currently developing, it is possible that at least some of the host railroads utilizing ACSES II or ASES II will elect to submit joint RFAs to their respective PTCSPs for certain system-wide changes, consistent with the option under proposed paragraphs (l) and (m) of § 236.1021.

FRA recognizes that modifying and simplifying the process for host railroads to submit RFAs to PTCSPs for FRA-certified PTC systems is necessary to facilitate required maintenance and upgrades to PTC technology and encourage railroads to enhance their PTC systems to continue to improve rail safety.

[20] For example, confirmation that: (1) Each host railroad notified any applicable tenant railroads of the proposed changes, any associated effect on the tenant railroads' operations, and any actions the tenant railroads must take in accordance with the configuration control measures set forth in the host railroad's PTCSP; and (2) the PTC system, if modified, would meet all technical requirements under 49 CFR part 236, subpart I, provide an equivalent or greater level of safety than the existing PTC system, and not adversely impact interoperability with any tenant railroads.

D. Proposal To Expand the Performance-Related Reporting Requirements

Following the applicable deadline for full PTC system implementation under 49 U.S.C. 20157, FRA's regulations currently require a railroad to submit an annual report by April 16th each year regarding the number of PTC system failures, ''including but not limited to locomotive, wayside, communications, and back office system failures,'' that occurred during the previous calendar year. *See* 49 CFR 236.1029(h). The first failure-related annual reports pursuant to § 236.1029(h) were due on April 16, 2019 from the four host railroads whose statutory deadline was December 31, 2018 for the full implementation of a PTC system on their required main lines. FRA has found that all annual reports railroads submitted to date have been brief (*e.g.,* as short as half of a page) and included minimal information, but still technically satisfied the existing content requirements under § 236.1029(h).

Because the minimal information currently required under § 236.1029(h) does not permit FRA to monitor adequately the rate at which PTC system failures occur or evaluate improvements over time, FRA is proposing to revise § 236.1029(h) to enable FRA to perform its oversight functions effectively. Specifically, FRA proposes to increase the frequency of this reporting requirement from annual to biannual, with proposed filing deadlines on July 31 (covering the period from January 1 to June 30) and January 31 (covering the period from July 1 to December 31 of the prior calendar year), instead of an annual filing deadline on April 16, as § 236.1029(h) currently provides. Under the existing framework, pursuant to § 236.1029(h), FRA must wait until April 16th each year to receive railroads' failure-related data from the prior calendar year—data which is quite outdated by the time it is filed. FRA's proposed biannual frequency would enable FRA to monitor closely trends in PTC system reliability with more up-to-date data, covering two intervals per year. In addition, FRA notes that the proposed biannual frequency is reasonable, given that railroads must currently submit certain failure-related data quarterly or monthly, pursuant to a temporary reporting requirement under the statutory mandate, as discussed below.

In addition, to ensure the data railroads submit under § 236.1029(h) are uniform, comparable, and objective, FRA proposes to revise this existing reporting requirement by specifying the exact types of statistics and information the reports must include; broadening the reporting requirement to encompass positive performance-related information, not just failure-related information; and requiring host railroads to utilize a new, standardized Biannual Report of PTC System Performance (Form FRA F 6180.152) to enable more effective FRA oversight.

Furthermore, FRA proposes to amend § 236.1029(h) to make it consistent with the temporary reporting requirement under 49 U.S.C. 20157(j)(4) because the existing statutory and regulatory provisions use different terminology to describe PTC-related failures. As background, the PTCEI Act established a reporting requirement that applies only temporarily—from October 29, 2015, to approximately December 31, 2021 [21]—and only to PTC systems that FRA has certified and have been implemented, including on a subset of a railroad's main lines.[22] 49 U.S.C. 20157(j)(4). As a default, the reporting requirement under 49 U.S.C. 20157(j)(4) specifies that when an FRA-certified PTC system ''fails to initialize, cuts out, or malfunctions,'' the railroad must submit a notification to the appropriate FRA regional office within 7 days of the failure, and the notification must include a description of the safety measures the railroad has in place.

However, as the PTCEI Act authorized, FRA established an alternative reporting deadline (instead of within 7 days of each occurrence) and an alternative reporting location (instead of submitting the notifications to the appropriate FRA region).[23] Specifically, on December 30, 2019 and March 16, 2020, FRA published a proposed framework for host railroads operating FRA-certified PTC systems to submit a Statutory Notification of PTC System Failures (Form FRA F 6180.177) to fulfill this temporary reporting requirement under the PTCEI Act.[24] On June 5, 2020, following the required

[21] By law, the temporary reporting requirement under 49 U.S.C. 20157(j)(4) sunsets on approximately December 31, 2021—or more specifically, one year after the last Class I railroad obtains PTC System Certification from FRA and finishes fully implementing an FRA-certified and interoperable PTC system on all its required main lines. *See* 49 U.S.C. 20157(j).

[22] For example, acknowledging the incremental nature of implementation, the PTCEI Act required Class I railroads and Amtrak to demonstrate they ''implemented a [PTC] system or initiated revenue service demonstration on the *majority* of [PTC-mandated] territories . . . or route miles that are owned or controlled by such carrier[s],'' to qualify for an alternative schedule and sequence by law. 49 U.S.C. 20157(a)(3)(B)(vi) (emphasis added).

[23] *See* 49 U.S.C. 20157(j)(4); 49 CFR 1.89.

[24] *See* 84 FR 72121, 72123–26 (Dec. 30, 2019); 85 FR 15022, 15025–27 (Mar. 16, 2020).

notice-and-comment periods, the Office of Management and Budget (OMB) approved the Statutory Notification of PTC System Failures (Form FRA F 6180.177, OMB Control No. 2130–0553),[25] as revised based on feedback from AAR and APTA. Host railroads must utilize that mandatory form and adhere to its instructions, including the two-tiered reporting frequency [26] and the centralized reporting location, to comply with 49 U.S.C. 20157(j)(4) until that temporary reporting requirement expires on approximately December 31, 2021.[27]

In this NPRM, FRA proposes to revise the permanent reporting requirement under § 236.1029(h) to utilize the statutory failure-related terms under 49 U.S.C. 20157(j)—initialization failures, cut outs, and malfunctions—instead of the broad, imprecise term currently used in § 236.1029(h) (''failures''). Also, to ensure uniform interpretation of these terms, FRA proposes to add definitions of these three terms to the definitions section of FRA's PTC regulations, 49 CFR 236.1003, retaining the definitions that FRA adopted during its development of the Statutory Notification of PTC System Failures (Form FRA F 6180.177), based on industry's feedback.

FRA's proposed Biannual Report of PTC System Performance (Form FRA F 6180.152) under proposed § 236.1029(h) will incorporate both: (1) The information currently required under § 236.1029(h); and (2) the corresponding types of data railroads must submit until approximately December 31, 2021 in their Statutory Notifications of PTC System Failures (Form FRA F 6180.177). For example, the proposed Biannual Report of PTC System Performance would require certain geographical information and contextual data to help demonstrate how the occurrences of PTC system initialization failures, cut outs, and malfunctions compare to all operations on that host railroad's PTC-governed main lines.[28]

Furthermore, railroads have previously observed that, under existing § 236.1029(h), it is unclear whether a host railroad, a tenant railroad, or both must submit the required reports to FRA. In this proposed rule, FRA proposes to resolve this ambiguity by specifying that only host railroads must directly submit these reports to FRA. This approach is consistent with the existing regulatory requirement directing a tenant railroad to report any PTC system failures or cut outs to ''a designated railroad officer of the *host railroad* as soon as safe and practicable.'' *See* 49 CFR 236.1029(b)(4) (emphasis added). To ensure that host railroads receive the necessary information from their tenant railroads to compile the proposed Biannual Report of PTC System Performance (Form FRA F 6180.152) under § 236.1029(h), FRA proposes to require explicitly tenant railroads to provide the necessary data to their applicable host railroads by a specific date before the biannual filing deadlines, as set forth under new proposed paragraph (h)(4) of § 236.1029.

FRA considers its proposed changes to § 236.1029(h), as described below, necessary to enable FRA to monitor the performance and reliability of railroads' PTC systems effectively throughout the country.

III. Section-by-Section Analysis

Section 236.1003 Definitions

FRA proposes to add three definitions to paragraph (b) of this section to help ensure that FRA and the railroad industry consistently interpret the statutory failure-related terms under 49 U.S.C. 20157(j)—initialization failures, cut outs, and malfunctions—as FRA now proposes to use these corresponding terms in § 236.1029(h) and the associated Biannual Report of PTC System Performance (Form FRA F 6180.152). Specifically, FRA proposes to adopt the definitions of these three terms that FRA currently utilizes in the Statutory Notification of PTC System Failures (Form FRA F 6180.177), which were, in part, revised and refined based on industry's feedback during the development of that corresponding form and the definitions therein.[29]

Section 236.1021 Discontinuances, Material Modifications, and Amendments

The purpose of existing paragraphs (a) through (d) is to prohibit a railroad from making ''changes, as defined by this section, to a PTC system, PTCIP, PTCDP, or PTCSP,'' unless the railroad submits an RFA, with the content requirements under existing paragraphs (d)(1) through (7), and obtains approval from FRA's Associate Administrator for Railroad Safety.

To be clear, this proposed rule will not revise the *types* of changes that currently require a host railroad to file an RFA under § 236.1021(h)(1)–(4) (often referred to as ''material modifications'') or the exceptions currently set forth under § 236.1021(i)–(k). For example, FRA's regulations currently require a railroad to submit an RFA, subject to FRA's review and approval, before making the following types of changes listed under existing paragraphs (h)(1) through (4): (1) A discontinuance of a PTC system; (2) a decrease of the PTC system's limits; (3) a modification of a safety-critical element of a PTC system; or (4) a modification of a PTC system that affects the safety-critical functionality of any other PTC system with which it interoperates. For context, existing § 236.1009(a)(2)(ii) additionally requires a railroad to submit an RFA—specifically to its FRA-approved PTCIP—if the railroad intends to initiate a new category of service (*i.e.,* passenger or freight) or ''[a]dd, subtract, or otherwise materially modify one or more lines of railroad for which installation of a PTC system is required.''

In general, FRA's proposed revisions to § 236.1021 are primarily intended to streamline the *process* by which host railroads must submit RFAs to their FRA-approved PTCSPs and FRA-certified systems, based on FRA's recognition that the railroad industry intends to update and enhance FRA-certified PTC systems to advance rail

[25] Available at *https://safetydata.fra.dot.gov/PTCSystemFailuresFRAForm177/.*

[26] A host railroad must submit *monthly* failure-related notifications if it has fully implemented a PTC system on all required main lines. However, if a host railroad is operating an FRA-certified PTC system but is still in the process of fully implementing the PTC system, the railroad must submit failure-related notifications on a *quarterly* basis. Host railroads must transition from submitting Form FRA F 6180.177 quarterly to monthly, when they finish fully implementing their FRA-certified and interoperable PTC systems on their required main lines. For simplicity, in general, this two-tiered framework means that most host railroads that have obtained PTC System Certification must submit quarterly Statutory Notifications of PTC System Failures throughout 2020, and monthly notifications throughout 2021 until the reporting requirement expires. For additional detail, please see 85 FR 15022, 15025–27 (Mar. 16, 2020).

[27] *See* 49 U.S.C. 20157(j)(4) and (e)(1) (authorizing DOT to assess civil penalties for any violation of the statutory mandate).

[28] Several railroads previously commented that, without such a percentage or context, the frequency of PTC system failures might otherwise seem high, and additional data would help convey the actual rate of such failures. In addition, in AAR's comments, dated February 28, 2020, associated with Form FRA F 6180.177 (under Docket Nos. FRA 2019–0004–N–20 and FRA 2020–0004–N–3), AAR specifically suggested that to ''keep the report of PTC system initialization failures, cut outs, and malfunctions in perspective, particularly if comparing individual railroads, it would be useful to normalize results between railroads.'' Similarly, in APTA's letter dated February 28, 2020, APTA requested that FRA identify the applicable denominator(s) to utilize when calculating the rate of PTC system initialization failures, cut outs, and malfunctions. *See also* 85 FR 15022, 15026 (Mar. 16, 2020).

[29] *See* 84 FR 72121, 72125 (Dec. 30, 2019); 85 FR 15022, 15025–26 (Mar. 16, 2020).

safety.[30] Accordingly, FRA's proposed revisions to the process under existing paragraphs (a) through (d) are limited to removing any references to PTCSPs from those paragraphs, as FRA is proposing in this proposed rule to establish a new, streamlined process for RFAs associated with PTCSPs under proposed paragraphs (l) and (m). In addition to FRA's proposal to remove references to PTCSPs from existing paragraphs (a) through (d), FRA proposes to remove paragraph (d)(7) in its entirety, and to incorporate the general principle of paragraph (d)(7) into a new proposed paragraph, (m)(2)(i), as discussed below.

Consistent with the existing requirements under § 236.1021, railroads would still need to submit, and obtain FRA's approval of, RFAs for certain changes to their PTCIPs and PTCDPs, including the types of changes enumerated above under 49 CFR 236.1021(h)(1) through (2) and 236.1009(a)(2)(ii)—*e.g.,* a proposed discontinuance of a PTC system or a proposed addition or removal of track segments from a railroad's PTCIP.

New proposed paragraph (l) would permit host railroads utilizing the same type of PTC system to submit joint RFAs to their PTCSPs and PTCDPs, as those are system-based documents, albeit with some railroad-specific variances. FRA expects that host railroads would utilize this joint RFA option to the extent practicable, and it would efficiently leverage industry's resources, help ensure coordination among railroads operating the same types of PTC systems, and reduce the number of similar or identical RFA filings host railroads submit to FRA for review and approval. Because changes to safety-critical elements, including software or system architecture, of a certain PTC system would likely impact multiple, if not most, railroads implementing that same type of PTC system, FRA proposes to outline a path for such host railroads to submit joint RFAs to their PTCSPs, with specific instructions under proposed paragraphs (l) and (m). FRA notes that it would consider it acceptable for an association to submit a joint RFA under proposed paragraph (l), but it would need to be explicitly on behalf of two or more host railroads, and each host railroad would need to sign the filing.

Proposed paragraph (l) would also specify that only host railroads with the same PTC System Certification classification under 49 CFR 236.1015(e) would be able to file a joint RFA to their PTCSPs. For example, when an RFA is necessary under § 236.1021 to account for certain proposed changes to railroads' I–ETMS PTCSPs, or I–ETMS itself, FRA would expect a joint RFA from the set of host railroads whose I–ETMS is certified as a non-vital, overlay PTC system under § 236.1015(e)(1), and a joint RFA from the set of host railroads whose I–ETMS is certified as a mixed PTC system under § 236.1015(e)(4). Two distinct RFAs would be necessary under these circumstances, as the impact of the proposed change(s) would need to be analyzed in the context of the underlying safety analysis in the FRA-approved PTCSPs—a safety analysis that is structured differently based on whether FRA has certified the PTC system as a non-vital, overlay system; a vital, overlay system; a standalone system; or a mixed system.

Furthermore, with respect to joint RFAs, paragraph (l) would specify that, though most types of information required under proposed paragraph (m)(2) may be submitted jointly in the RFA, a joint RFA would need to include the written confirmation and statement specified under proposed paragraphs (m)(2)(iii) and (iv), as described below, from each host railroad that is a signatory to the joint RFA.

New proposed paragraph (m) would outline the mandatory, three-step process a host railroad would need to follow to make changes to its FRA-certified PTC system and the associated FRA-approved PTCSP. FRA intends the process under proposed paragraph (m) to apply to *all* changes necessitating an RFA under existing paragraphs (h)(3) and (4) of this section—*i.e.,* proposed changes to safety-critical elements of PTC systems and proposed changes to a PTC system that affect the safety-critical functionality of any other PTC system with which it interoperates. For brevity, FRA will refer to these changes as changes to safety-critical elements of PTC systems, as that is sufficiently broad for purposes of paragraph (m).

Proposed paragraph (m)(1) would require a host railroad to revise its PTCSP to account for each proposed change to its PTC system, and summarize such changes in a chronological table of revisions at the beginning of its PTCSP. FRA retains its authority to request a copy of a host railroad's governing PTCSP in accordance with 49 CFR 236.1009(h), *FRA access,* and 49 CFR 236.1037, *Records retention.*

Proposed paragraph (m)(2) would specifically require a host railroad to file an RFA pursuant to paragraph (m) electronically, which could include electronic filing on FRA's Secure Information Repository (*https://sir.fra.dot.gov*), where railroads currently file other PTC-related documents, or another designated location. If a host railroad wishes to seek confidential treatment of any part of its RFA, the railroad would need to comply with the existing process and requirements under 49 CFR 209.11, *Request for confidential treatment,* which include marking the document properly with the necessary labels and redactions, and providing a statement justifying nondisclosure and referring to the specific legal authority claimed. FRA would post a host railroad's RFA (the public, redacted version, if applicable) and FRA's final decision letter in the respective railroad's PTC docket on *http://www.regulations.gov.*[31]

In proposed paragraphs (m)(2)(i) through (v), FRA outlines the proposed content requirements for an RFA to an FRA-certified PTC system and the associated PTCSP—focusing on the core information and analysis FRA would need to review to ensure the PTC system, including any proposed changes, would provide an equivalent or greater level of safety than the existing PTC system. Importantly, proposed paragraph (m)(2)(i) would require the RFA to include a summary of the proposed changes to any safety-critical elements of a PTC system, including a summary of how the changes to the PTC system would affect its safety-critical functionality, how any new hazards have been addressed and mitigated, whether each change is a planned change[32] that was previously included in all required analysis under § 236.1015, or an unplanned change, and the reason for the proposed changes, including whether the changes are necessary to address or resolve an emergency or urgent issue.

FRA's existing paragraphs (d)(7)(i) through (v) of § 236.1021 explain the distinction between an unplanned change and a planned change and impose certain additional requirements, including conducting suitable regression testing to FRA's satisfaction and filing a new PTCDP and PTCSP, under certain circumstances. As noted

[30] For additional detail and background, please see Section I (*Executive Summary*) and Subsection II–C (*Proposal to Establish a New Process for Modifying FRA-certified PTC Systems and the Associated PTCSPs*) of this NPRM.

[31] Railroads' applicable PTC docket numbers are available on FRA's website at *https://railroads.dot.gov/train-control/ptc/ptc-annual-and-quarterly-reports.*

[32] *See, e.g.,* 75 FR 2598, 2661 (Jan. 15, 2010) (stating that planned changes ''are those that the system developer and the railroad have included in the safety analysis associated with the PTC system, but have not yet implemented. These changes provide enhanced functionality to the system, and FRA strongly encourages railroads to include PTC system improvements that further increase safety.'').

above, FRA proposes to remove paragraph (d)(7) and instead require a host railroad to identify in its RFA under paragraph (m)(2)(i) only whether the change is a planned change or an unplanned change. That basic information would be valuable to include in the abbreviated RFA under paragraph (m) because several railroads have already accounted for long-term, planned changes to their PTC systems and proactively integrated those assumptions into the corresponding analyses in their PTCSPs.

Proposed paragraph (m)(2)(ii) would require the RFA to include a copy of any associated software release notes, which would be critical for FRA to review and evaluate before one or more railroads deploy the upgraded software. A copy of the release notes would be integral in conveying the actual changes to the PTC system, including any corrections, enhancements, or new features or functionality.

Proposed paragraph (m)(2)(iii) would require the RFA to contain a confirmation that the host railroad has notified any applicable tenant railroads of the proposed changes, any associated effect on the tenant railroads' operations, and any actions the tenant railroads must take in accordance with the configuration control measures set forth in the host railroad's PTCSP. In addition, proposed paragraph (m)(2)(iv) would require the RFA to include a statement from the host railroad's Chief Engineer and Chief Operating Officer, or executive officers of similar qualifications, verifying that the modified PTC system would meet all technical requirements under 49 CFR part 236, subpart I, provide an equivalent or greater level of safety than the existing PTC system, and not adversely impact interoperability with any tenant railroads. This would be consistent with existing regulatory provisions that require PTC systems to achieve and maintain a level of safety, for each system modification, that is equal to or greater than the level of safety provided by the previous PTC system.[33]

Proposed paragraph (m)(2)(v) would require a host railroad to submit any other information that FRA requests on a case-by-case basis, during FRA's review of the RFA. If FRA were to require a host railroad, or a set of host railroads, to provide additional information in support of the RFA, FRA's request would identify a deadline by which to submit the information. Also, this would be generally consistent with the existing provision under 49 CFR 236.1015(f), which provides that in any case where a PTCSP, or an RFA in this scenario, ''lacks adequate data regarding [the] safety impacts of the proposed changes, the Associate Administrator may request the necessary data from the applicant.''

Proposed paragraph (m)(3) would outline a definite, predictable timeline associated with FRA's review of an RFA to a host railroad's PTCSP or FRA-certified PTC system under proposed paragraph (m). Specifically, proposed paragraph (m)(3) would prohibit a host railroad from making any changes, as defined under 49 CFR 236.1021(h)(3) or (4),[34] to its PTC system until the Director of FRA's Office of Railroad Systems, Technology, and Automation approves the RFA. Under proposed paragraph (m)(3)(i), FRA would review the RFA and issue a decision—*i.e.,* an approval, conditional approval, or denial of the RFA—within 45 days of the date on which the RFA was filed under paragraph (m)(2). FRA's decision would be in the form of a letter from the Director of FRA's Office of Railroad Systems, Technology, and Automation. As noted above, FRA would post each final decision letter in the respective railroad's PTC docket on *http://www.regulations.gov.* FRA, however, may send interim correspondence—including any notices requiring a railroad to provide additional information under proposed paragraph (m)(2)(v)—via email.

Proposed paragraph (m)(3)(ii) would explicitly acknowledge that FRA reserves the right to notify a railroad that it may proceed with making its proposed changes prior to the 45-day mark, including in an emergency or under other circumstances necessitating a railroad's immediate implementation of the proposed changes to its PTC system.

Proposed paragraph (m)(3)(iii) would specify that FRA may require a railroad to modify its RFA and/or its PTC system, but only to the extent necessary to ensure safety or compliance with the requirements under FRA's PTC regulations.

If FRA denies an RFA under proposed paragraph (m), proposed paragraph (m)(3)(iv) would specify that each applicable railroad would be prohibited from making the proposed changes to its PTC system until the railroad both sufficiently addresses FRA's questions, comments, and concerns and obtains FRA's approval. Consistent with proposed paragraph (l) of this section, any host railroads utilizing the same type of PTC system, including the same certification classification under paragraph (e) of § 236.1015, would be permitted to submit information jointly to address FRA's questions, comments, and concerns following any denial of an RFA under this section.

FRA expects that its proposed paragraphs (l) and (m) would help establish an improved process that would entail a reasonable level of predictability and transparency in FRA's review process and enable the industry to make technological advancements more efficiently.

Section 236.1029 PTC System Use and Failures

Currently, paragraph (h) of this section requires railroads to report annually to FRA the number of PTC system failures that occurred during the previous calendar year. FRA is proposing to revise this existing paragraph to clarify and expand the reporting requirement and require host railroads to submit the information in a Biannual Report of PTC System Performance (Form FRA F 6180.152). FRA's proposed Excel-based[35] Form FRA F 6180.152 has been placed in the docket for this NPRM (Docket No. FRA–2019–0075) for reference and review. Proposed paragraph (h)(1) would specify this reporting requirement applies to each host railroad subject to 49 U.S.C. 20157 or 49 CFR part 236, subpart I, which would include any new host railroads that become subject to the statutory mandate in the future and any host railroads that voluntarily implement a PTC system under subpart I.[36]

For clarification and simplicity, FRA is proposing to remove the phrase ''following the date of required PTC system implementation established by section 20157 of title 49 of the United States Code'' from paragraph (h) because that phrase would be unnecessary after the final statutory deadline of December 31, 2020 and retaining that phrase may cause confusion about the applicability of this reporting requirement to new railroads that become subject to the statutory mandate after 2020 or railroads

[33] *See, e.g.,* 49 CFR 236.1001(a), 236.1015(d)(11), 236.1015(e)(1)(iii), and 236.1015(g).

[34] That is, proposed changes to safety-critical elements of PTC systems or proposed changes to a PTC system that affect the safety-critical functionality of any other PTC system with which it interoperates.

[35] Excel is a registered trademark of Microsoft Corporation. All third-party trademarks belong to their respective owners.

[36] *See, e.g.,* 49 CFR 236.1011(d) (stating that a ''railroad that elects to install a PTC system when not required to do so may elect to proceed under this subpart [subpart I] or under subpart H of this part,'' including the associated filing and reporting requirements).

voluntarily implementing PTC systems on non-mandated lines.

In addition, proposed paragraph (h)(1) would require a host railroad to file its Biannual Report of PTC System Performance (Form FRA F 6180.152) *electronically,* which could include electronic filing on FRA's Secure Information Repository (*https://sir.fra.dot.gov*), where railroads file other PTC-related documents, or another designated location. To the extent a railroad would seek confidential treatment of any part of its Biannual Report of PTC System Performance (Form FRA F 6180.152), the railroad would need to comply with the existing process and requirements under 49 CFR 209.11, including proper labeling and redacting and providing a statement justifying nondisclosure and referring to the specific legal authority claimed. FRA's proposed Form FRA F 6180.152 would contain fields for a host railroad to identify its request for partial or full confidentiality and provide the required statement under § 209.11(c), if applicable.

Also, proposed paragraph (h)(1) would require a host railroad to include in its Biannual Report of PTC System Performance (Form FRA F 6180.152) the figures itemized under proposed paragraphs (h)(1)(i) through (vii) for the host railroad, each of its applicable tenant railroads (as explained in proposed paragraph (h)(4)), and each of its PTC-governed track segments. In this proposed paragraph, FRA acknowledges that a host railroad's PTCIP may identify or designate its specific track segments as territories, subdivisions, districts, main lines, branches, or corridors, based on a railroad's own naming conventions. FRA expects that requiring this relatively high-level geographical information (*e.g.,* by subdivision, not by milepost location) would still enable FRA to monitor closely trends in PTC system reliability throughout the country and focus its resources, for example, on any areas where PTC system failures are occurring at a high rate.

Consistent with existing paragraph (h), proposed paragraphs (h)(1)(i) through (iii) would require a railroad's biannual report to include the number of PTC-related failures that occurred during the applicable reporting period, in addition to a numerical breakdown of the ''failures by category, including but not limited to locomotive, wayside, communications, and back office system failures,'' quoting existing 49 CFR 236.1029(h). In proposed paragraphs (h)(1)(i) through (iii), however, FRA acknowledges that the source or cause of a PTC system failure might not necessarily involve, in every instance, the PTC system itself, so FRA proposes to include an additional category for railroads to select in the applicable drop-down menu in Form FRA F 6180.152—*i.e.,* ''a non-PTC component.''

Another difference between the existing paragraph (h) and FRA's proposed paragraphs (h)(1)(i) through (iii) is that FRA's proposed language utilizes the statutory terminology under 49 U.S.C. 20157(j)(4) as referenced above—initialization failures, cut outs, and malfunctions—which would be defined under paragraph (b) of § 236.1003. FRA is aware that railroads track their PTC system failures in this manner (by type of failure), given the existing temporary reporting requirement under 49 U.S.C. 20157(j)(4) and FRA's associated mandatory form, the Statutory Notification of PTC System Failures (Form FRA F 6180.177).

In proposed paragraph (h)(1)(iv), FRA is proposing to expand the existing reporting requirement under paragraph (h) to encompass certain positive, performance-related information, as otherwise the information FRA receives would be about PTC system failures only. FRA proposes to require railroads' Biannual Reports of PTC System Performance to include data about PTC technology's positive impact on rail safety and the extent to which PTC systems are functioning as designed—to prevent train-to-train collisions, over-speed derailments, incursions into established work zones, and movements of trains through switches left in the wrong position.[37] Specifically, proposed paragraph (h)(1)(iv) would require a host railroad to identify the number of intended enforcements by the PTC system and any other instances in which the PTC system prevented an accident or incident on the host railroad's PTC-governed main lines, during the applicable reporting period. This type of statistic would be valuable and help demonstrate the extent to which PTC systems are meeting their desired objectives. FRA would interpret the term ''intended enforcement'' in this proposed paragraph consistently with how the term ''enforce'' is applied in FRA's existing PTC regulations, which include references to how a PTC system shall enforce speeds, movement authorities, signal indications, and so forth. *See, e.g.,* 49 CFR 236.1005, 236.1013, 236.1015, and 236.1047(a)(3).

In proposed paragraphs (h)(1)(v) through (vii), FRA would require a railroad's Biannual Report of PTC System Performance to include certain contextual data to help FRA understand how the occurrences of PTC system initialization failures, cut outs, and malfunctions compare to all operations on that host railroad's PTC-governed main lines.[38] Specifically, proposed paragraph (h)(1)(v) would require a railroad's biannual report to include the number of scheduled attempts at initialization of the PTC system during the applicable reporting period, which would help FRA calculate the actual rate of that railroad's PTC system initialization failures. Respectively, proposed paragraphs (h)(1)(vi) and (vii) would require the railroad to provide the number of trains and the number of train miles governed by the PTC system during the applicable reporting period. FRA's proposed paragraphs (h)(1)(v) through (vii) would generally encompass the same types of denominators currently set forth in the Statutory Notification of PTC System Failures (Form FRA F 6180.177) with one notable difference.

In FRA's proposed paragraphs (h)(1)(v) through (vii), unlike Form FRA F 6180.177, FRA would be uniformly requiring those three data points from a host railroad and its applicable tenant railroads. In practice, FRA has found that host railroads providing certain denominators for tenant railroads (*i.e.,* PTC-governed trains) and other denominators for the host railroad itself (*i.e.,* scheduled attempts at initialization and PTC-governed train miles) makes it difficult for FRA to evaluate the rate at which failures are occurring system-wide. FRA expects that requiring uniform figures would help the agency derive more accurate, objective, and comparable statistics. Furthermore, FRA understands that host railroads collect the type of data under proposed paragraphs (h)(1)(v) through (vii) for their own operations and their tenant railroads' operations because several host railroads have provided those additional data points in their Statutory Notifications of PTC System Failures (Form FRA F 6180.177) to date.

Proposed paragraph (h)(2) would require a host railroad's Biannual Report of PTC System Performance (Form FRA F 6180.152) to include a summary of

[37] *See* 49 U.S.C. 20157(g)(1), (i)(5); 49 CFR 236.1005.

[38] FRA's proposed Biannual Report of PTC System Performance (Form FRA F 6180.152) would include fields for host railroads to provide the raw denominators set forth under proposed paragraphs (h)(1)(v) through (vii), and FRA would calculate the rate of failures, utilizing those raw denominators. FRA has found that providing fields for railroads to enter such raw denominators, instead of percentages or rates, helps FRA accurately interpret railroads' data, especially when comparing multiple railroads' data or a single railroad's data to its own prior reports.

any actions the host railroad and its tenant railroads are taking to improve the performance and reliability of the PTC system continually. This narrative section would provide railroads an opportunity to explain briefly the steps they are taking to improve their PTC system's performance, which could also help put the biannual statistics into perspective. FRA did not propose including this content requirement under proposed paragraph (h)(1) because that paragraph would be track segment-specific, and FRA acknowledges that railroads generally take a system-wide approach to improving their PTC systems. Accordingly, FRA proposes to categorize this content requirement in the separate, proposed paragraph (h)(2), and FRA's proposed, Excel-based Form FRA F 6180.152 would contain a field for railroads to enter this summary.

Proposed paragraph (h)(3) outlines the dates by which host railroads would submit their Biannual Reports of PTC System Performance (Form FRA F 6180.152) to FRA—*i.e.,* by July 31 (covering the period from January 1 to June 30), and by January 31 (covering the period from July 1 to December 31 of the prior calendar year). FRA expects that providing railroads one full month (from the end of the half-year period) to complete Form FRA 6180.152 would be sufficient and reasonable, given railroads' experience, since 2016, in submitting their Quarterly PTC Progress Reports (Form FRA F 6180.165) one month after the end of the quarter. Furthermore, under the *temporary* Statutory Notification of PTC System Failures (Form FRA F 6180.177), the due date for any monthly notification is currently the 15th of the following month—so, for example, the notification regarding initialization failures, cut outs, and malfunctions during November 2020 is due by December 15, 2020 for the subset of host railroads that have fully implemented an FRA-certified PTC system. Accordingly, FRA expects that allowing one full month for railroads to prepare and submit their Biannual Reports of PTC System Performance (Form FRA F 6180.152) under proposed paragraph (h)(3) would be a reasonable timeframe for this permanent reporting requirement.

Proposed paragraph (h)(4) would explicitly require any applicable tenant railroads that operate on a host railroad's PTC-governed main line(s) to provide the necessary data to their applicable host railroads by a specific date before the biannual filing deadlines—*i.e.,* by July 15 (for the biannual report covering the period from January 1 to June 30) and by January 15 (for the biannual report covering the period from July 1 to December 31 of the prior calendar year). The text in proposed paragraph (h)(4) clarifies, however, that a host railroad would not need to include data in Form FRA F 6180.152 regarding a tenant railroad that is subject to an exception under 49 CFR 236.1006(b)(4) or (5) during the applicable reporting period because such a tenant railroad's movements would not be governed by PTC technology in that case and there would not be any pertinent, performance-related data to submit.

In general, FRA's proposed paragraph (h)(4) regarding tenant railroad responsibilities is based, in part, on comments AAR and APTA previously submitted during the comment period associated with the Statutory Notification of PTC System Failures (Form FRA F 6180.177). Specifically, on February 28, 2020, AAR commented, ''[i]f FRA is going to require hosts to report tenant data, the agency must impose a clear and direct requirement on tenants to report the desired information to their host railroad.'' [39] In APTA's comments, also dated February 28, 2020, APTA observed that a host railroad would need to obtain ''all necessary logs to complete the analyses'' from its tenant railroads to complete Form FRA F 6180.177 accurately.[40] FRA acknowledges that an existing regulatory provision, 49 CFR 236.1029(b)(4), already requires a tenant railroad to report a PTC system failure or cut out to ''a designated railroad officer of the host railroad as soon as safe and practicable.'' In addition, FRA is aware that several host railroads, including Class I railroads and passenger railroads, already regularly monitor and track tenant railroads' PTC system initialization failures, cut outs, and malfunctions via automatically generated reports and/or via connected PTC system back offices.

FRA expects that the language in proposed paragraph (h)(4) would help clarify the existing obligation on tenant railroads to provide certain data to their host railroads. Also, proposed paragraph (h)(4) would help ensure that host railroads receive tenant railroads' necessary data for purposes of the reporting requirement under paragraph (h) in a timely manner. Specifically, in proposed paragraph (h)(4), FRA proposes to require each applicable tenant railroad to submit the information required under proposed paragraphs (h)(1) and (2) to each applicable host railroad by July 15 (for the report covering the period from January 1 to June 30) and by January 15 (for the report covering the period from July 1 to December 31 of the prior calendar year). FRA expects that adding proposed paragraph (h)(4) to its regulations would offer more clarity and certainty about the timeframe under which tenant railroads would provide host railroads the information necessary to prepare and submit their Biannual Reports of PTC System Performance (Form FRA F 6180.152). In addition, this proposed paragraph would help ensure that host railroads receive such data at least 15 days before the biannual filing deadlines under proposed paragraph (h)(3), *i.e.,* July 31 and January 31.

IV. Regulatory Impact and Notices

A. Executive Orders 12866 and 13771 and DOT Regulatory Policies and Procedures

This proposed rule is a nonsignificant regulatory action under Executive Order 12866, ''Regulatory Planning and Review,'' [41] and DOT's Administrative Rulemaking, Guidance, and Enforcement Procedures in 49 CFR part 5. FRA made this determination by finding that the economic effects of this proposed regulatory action would not exceed the $100 million annual threshold defined by Executive Order 12866. This proposed rule is considered a deregulatory action under Executive Order 13771.[42] FRA estimates this proposed rule would result in cost savings for the industry over a ten-year period.

This proposed rule would reduce the burden on railroads while not adversely affecting railroad safety. To enable FRA to oversee the performance and reliability of railroads' PTC systems effectively, FRA is proposing to change the reporting requirement under 49 CFR 236.1029(h). FRA's proposed changes include, but are not limited to, increasing the reporting frequency from annual to biannual, clarifying the types of statistics and information the reports must include, and expanding the reporting requirement to encompass positive performance-related information, not just failure-related information. The amended provision would require host railroads to submit additional information. Accordingly, FRA estimates that the number of hours it would take a host railroad to report the required information under

[39] *See* Docket Nos. FRA 2019–0004–N–20 and FRA 2020–0004–N–3; 85 FR 15022, 15027 (Mar. 16, 2020).

[40] *See id.*

[41] *See* 58 FR 51735 (Sep. 30, 1993).

[42] *See* 82 FR 9339 (Feb. 3, 2017).

§ 236.1029(h) would increase under the proposed rule. To provide clarity and precision regarding the reporting requirement under § 236.1029(h), FRA has developed a proposed, Excel-based Biannual Report of PTC System Performance (Form FRA F 6180.152) that railroads would utilize to satisfy this reporting requirement.

While FRA is proposing to expand this existing reporting requirement, the regulatory and administrative burden on host railroads would be reduced under § 236.1021. Specifically, FRA is proposing to establish a streamlined process to enable the railroad industry to make technological advancements to FRA-certified PTC systems more efficiently and with FRA's continued oversight. Instead of the existing RFA approval process under § 236.1021, FRA proposes to: (1) Require host railroads to comply with a streamlined process, which would include providing certain safety assurances and analysis in a concise RFA; and (2) establish a 45-day FRA decision deadline. This more efficient process is expected to result in cost savings for both the host railroads and the government. FRA's proposed simplification of the content requirements associated with an RFA to a PTCSP under § 236.1021 would reduce the number of burden hours per RFA. In addition, FRA is proposing to permit host railroads utilizing the same type of PTC system to submit joint RFAs to their PTCDPs and PTCSPs, thus reducing the number of RFAs railroads would need to submit in the future.

Currently, 35 host railroads are required to submit RFAs before making certain changes to their PTCSPs under § 236.1021, with many host railroads projected to submit one RFA to a PTCSP per year. Over the next ten years, FRA expects there will be an average increase of 1.5 new PTC-governed host railroads per year, beginning in the second year, for a total of approximately 14 additional host railroads. Table A summarizes the types of PTC systems the 35 host railroads currently subject to the statutory mandate are implementing as of 2020 and the approximate number of RFAs host railroads would file to their PTCSPs under existing regulations.

TABLE A—ESTIMATED NUMBER OF REQUIRED RFAS TO PTCSPS BY TYPE OF PTC SYSTEM

Type of PTC system	PTC systems being implemented by host railroads (as of 2020) [43]	Annual Number of RFAs per PTC system	Total number of RFAs
ACSES II	8	1	8
CBTC	1	1	1
E–ATC	5	1	5
ITCS	1	1	1
I–ETMS	26	2	52
Total	41		67

Currently, without the proposed rule, FRA estimates the 35 host railroads would need to submit approximately 67 RFAs annually given the types of changes the industry intends to make to their PTC systems each year under 49 CFR 236.1021(h)(3)–(4) in the future.[44] FRA has estimated that the current hourly burden is 160 hours per RFA, based on previously approved PTC Information Collection Requests (ICRs).

Table B below provides the current hourly burden and costs that host railroads face when submitting RFAs to their PTCSPs under the existing § 236.1021.

TABLE B—CURRENT HOST RAILROAD HOURLY BURDEN AND COST FOR RFAS TO PTCSPS

Year	Submissions	Hour burden per submission	Total annual cost	7-Percent	3-Percent
1	67	160	$830,505	$830,505	$830,505
2	69	160	855,296	799,342	830,385
3	70	160	867,692	757,876	817,883
4	72	160	892,483	728,532	816,749
5	73	160	904,879	690,328	803,973
6	75	160	929,670	662,842	801,942
7	76	160	942,066	627,738	788,965
8	78	160	966,857	602,110	786,143
9	79	160	979,252	569,934	773,031
10	81	160	1,004,044	546,133	769,516
Total	740		9,172,744	6,815,340	8,019,091

Costs

As described above, FRA is also proposing to amend a reporting requirement by increasing the frequency from annual to biannual, clarifying the types of statistics and information the reports must include, and expanding the reporting requirement to encompass positive performance-related

[43] Several host railroads are implementing multiple types of PTC systems.

[44] Previously, FRA estimated it would receive, on average, approximately 10 RFAs to railroads' PTCIPs, PTCDPs, and PTCSPs each year. However, from discussions with PTC-mandated railroads, FRA found the estimate did not account adequately for the number of RFAs host railroads intend to submit to their PTCSPs annually under § 236.1021(h)(3)–(4) without the proposed rule. Tables A, B, and F in this proposed rule estimate more accurately the approximate average number of RFAs host railroads would submit to their PTCSPs each year under the existing regulations and under the proposed rule. *See* 84 FR 72121, 72127 (Dec. 30, 2019).

information. Though FRA's proposed rule will increase the number of required submissions, as well as the hourly burden per submission, FRA estimates any new costs will be minimal and offset by the cost savings derived from the proposed changes as presented in the Cost Savings section below.

To clarify the information FRA is requesting from host railroads, FRA created an Excel-based form for the Biannual Report of PTC System Performance (Form FRA F 6180.152). This form will incorporate the information currently required under 49 CFR 236.1029(h) and the additional types of information specified in this NPRM.[45] Host railroads with FRA-certified PTC systems are experienced in compiling this type of information, given the corresponding reporting requirements under the temporary Statutory Notification of PTC System Failures (Form FRA F 6180.177, OMB Control No. 2130–0553).

The hourly burden associated with submitting the required information will increase initially from 8 hours to 12 hours per report on average. FRA estimates that, over time, railroads will develop procedures that decrease the reporting burden from 12 hours per submission to 10 hours per submission. FRA assumes this decrease will begin in the fourth year of the analysis as host railroads become familiar with the Excel-based form and as they develop processes to improve their data collection and reporting.

In addition to the increase in hourly burden, FRA estimates an increased burden will result from the additional annual report this proposed rule will require. Consistent with the previously stated estimates, FRA assumes that 35 host railroads will submit these biannual reports, and the number of applicable host railroads will increase by 1.5 on average each year.

This analysis accounts for the marginal increase of four hours for the first three years of a host railroad reporting and two hours for each subsequent year. Table C below shows the marginal hourly burden increase associated with railroads' reporting under the proposed rule.

TABLE C—TEN-YEAR HOST RAILROAD MARGINAL BURDEN INCREASE

Year	Number of host railroad submissions with marginal 4-hour burden	Number of host railroad submissions with marginal 2-hour burden	Total marginal hourly burden
1	35	0	140
2	37	0	146
3	38	0	152
4	2	38	84
5	3	38	88
6	5	38	96
7	4	40	96
8	4	42	100
9	4	43	102
10	4	45	106
Total	136	284	1,110

In addition to the marginal increase, host railroads will face an additional reporting burden due to the proposed change from annual to biannual reporting. This analysis accounts for the new burden of 12 hours for the first three years of a host railroad's reporting and 10 hours for each subsequent year to account for the proposed change from annual to biannual reporting. Table D below shows the new hourly burden under this proposed rule for the ten-year period of this analysis.

TABLE D—TEN-YEAR HOST RAILROAD NEW SUBMISSIONS

Year	Number of host railroad submissions with new 12-hour burden	Number of host railroad submissions with new 10-hour burden	Total new hourly burden
1	35	0	420
2	37	0	438
3	38	0	456
4	2	38	404
5	3	38	416
6	5	38	440
7	4	40	448
8	4	42	468
9	4	43	478
10	4	45	498
Total	136	284	4,466

[45] The proposed Biannual Report of PTC System Performance (Form FRA F 6180.152) will be placed in the docket (Docket No. FRA–2019–0075) for review when this NPRM is published.

FRA calculated the total additional burden hours for submissions by multiplying the respective number of submissions with their associated annual burden for each individual year. The summation of the hourly burden is multiplied by the fully burdened wage rate of a Professional and Administrative employee. For purposes of this analysis, FRA uses the fully burdened rate of $77.47 to calculate both the costs and cost savings throughout this analysis.[46] Table E provides the ten-year cost to the railroad industry associated with the expanded reporting requirement, as proposed.

TABLE E—TEN-YEAR TOTAL COSTS

Year	Total marginal hour burden	Total new submission hour burden	Total new complete hour burden	Total annual host railroad submissions cost[47]	7-Percent	3-Percent
1	140	420	560	$43,385	$43,385	$43,385
2	146	438	584	45,244	42,284	43,926
3	152	456	608	47,103	41,142	44,399
4	84	404	488	37,807	30,861	34,598
5	88	416	504	39,046	29,788	34,692
6	96	440	536	41,525	29,607	35,820
7	96	448	544	42,145	28,083	35,296
8	100	468	568	44,004	27,404	35,780
9	102	478	580	44,934	26,152	35,471
10	106	498	604	46,793	25,453	35,863
Total	1,110	4,466	5,576	431,987	324,158	379,231

* **Note:** Table may not sum due to rounding.

FRA estimates that the total cost to the railroad industry will be $324,158, discounted at 7 percent, or $379,231, discounted at 3 percent. In terms of governmental costs associated with the expanded reporting requirement, including the proposed increase from annual to biannual reporting, FRA expects it will cost approximately $10,000, over the ten-year period, to review the additional data railroads will submit in the proposed Biannual Reports of PTC System Performance (Form FRA F 6180.152). As FRA considers these additional governmental costs to be *de minimis,* they are not included in the economic analysis.

Cost Savings

There are currently 35 host railroads that are required to submit an RFA before changing safety-critical elements of their PTC systems and their PTCSPs. FRA estimates that over the next ten years, the number of PTC-governed host railroads will increase by approximately 14, for a total of 49 host railroads. For purposes of this analysis, FRA estimates that approximately 1.5 new host railroads are added each year, beginning in year two.

Currently, under FRA's existing regulations, FRA estimates that host railroads will submit 67 annual RFAs to their PTCSPs that FRA must review and approve before those host railroads change and improve their PTC systems. Under this proposed rule, FRA is proposing to permit host railroads utilizing the same type of PTC system to submit joint RFAs to their PTCDPs and PTCSPs.[48]

Table F below shows the number of RFAs to PTCSPs that would be submitted under the existing regulation and the proposed rule. Over a ten-year period, FRA estimates that the changes described in this proposed rule will result in railroads submitting approximately 590 fewer RFAs.

TABLE F—ESTIMATED NUMBER OF RFAS TO PTCSPS

Current types of PTC systems	Approximate number of RFAs to PTCSPs per year under existing regulations	Approximate number of RFAs to PTCSPs per year under proposal	Total number of reduction of RFAs to PTCSPs
ACSES II	8	8	0
CBTC	1	1	0
E–ATC	5	1	4
ITCS	1	1	0
I–ETMS	52	[49] 4	48
Subtotal in Year 1	67	15	52

[46] 2019 Composite Surface Transportation Board (STB) Professional and Administrative hourly wage rate of $44.27 burdened by 75-percent ($44.27 × 1.75 = $77.47).

[47] Total Annual Host Railroad Submissions Cost = Total New Complete Hour Burden × $77.47.

[48] FRA expects its proposal to allow host railroads to submit joint RFAs to impact primarily host railroads implementing I–ETMS and E–ATC because each I–ETMS system is relatively similar and manufactured by the same set of suppliers, and each E–ATC system is relatively similar and manufactured by the same set of suppliers.

FRA estimates the current burden is 160 hours per RFA to a PTCSP based on the existing RFA content requirements. FRA's proposed simplification of the content requirements would reduce the burden hours by 50 percent, resulting in 80 burden hours per RFA. Table G provides the estimated ten-year cost to host railroads based on FRA's proposal to simplify the RFA process.

TABLE G—TEN-YEAR COST OF JOINT RFAS AND SIMPLIFIED RFAS

Year	Submissions	Hour burden per submission	Total annual cost savings	7-Percent	3-Percent
1	15	80	$92,967	$92,967	$92,967
2	15	80	92,967	86,885	90,259
3	15	80	92,967	81,201	87,630
4	15	80	92,967	75,889	85,078
5	15	80	92,967	70,924	82,600
6	15	80	92,967	66,284	80,194
7	15	80	92,967	61,948	77,858
8	15	80	92,967	57,895	75,591
9	15	80	92,967	54,108	73,389
10	15	80	92,967	50,568	71,251
Total	150		929,670	698,669	816,818

Overall, FRA expects that simplifying the content requirements for RFAs to PTCSPs, as well as permitting host railroads utilizing the same type of PTC system to submit joint RFAs, will result in a ten-year cost savings of $6.1 million, discounted at 7 percent, or $7.2 million, discounted at 3 percent.

TABLE H—TOTAL TEN-YEAR COST SAVINGS ASSOCIATED WITH PROPOSED § 236.1021

Year	Current host railroad costs (without proposed regulation)	Cost of joint RFAs and simplified RFA process (with proposed rule)	Total annual cost savings	7-Percent	3-Percent
1	$830,505	$92,967	$737,538	$737,538	$737,538
2	855,296	92,967	762,329	712,457	740,126
3	867,692	92,967	774,725	676,675	730,253
4	892,483	92,967	799,516	652,643	731,671
5	904,879	92,967	811,912	619,404	721,373
6	929,670	92,967	836,703	596,558	721,747
7	942,066	92,967	849,099	565,790	711,107
8	966,857	92,967	873,890	544,215	710,552
9	979,252	92,967	886,285	515,826	699,642
10	1,004,044	92,967	911,077	495,565	698,264
Total	9,172,744	929,670	8,243,074	6,116,671	7,202,273

In addition, FRA's proposed changes to the RFA process will result in cost savings for the government, through a reduction in time needed to review an RFA with the existing contents under 49 CFR 236.1021(d)(1)–(7). Under the proposed rule, FRA will review a streamlined RFA with the more focused information that new proposed paragraph (m)(2) would require.

Table I below outlines the assumptions that FRA used to calculate the governmental cost savings. FRA's estimates assume there will be PTC system changes that are complex and will require additional time to review, as well as system changes that are less complex.

TABLE I—GOVERNMENT ADMINISTRATIVE COST ASSUMPTIONS

Staff level	Average employee count needed	Average hourly burden	Average hourly salary	Fully burdened rate	Cost savings per staff level
GS–15	1	10	$77.75	$136.07	$1,315
GS–14	2	105	62.34	109.10	19,171
GS–13	2	119	49.71	86.99	20,646
Total	5	234	189.81	332.17	41,132

[49] For I–ETMS systems, FRA estimates the total number of annual RFAs to PTCSPs would be reduced from 52 (under the existing regulation) to 4 (under the proposed rule)—*i.e.,* 2 RFAs per year from the set of railroads whose I–ETMS is certified as a mixed PTC system and 2 RFAs per year from the set of railroads whose I–ETMS is certified as a non-vital, overlay PTC system.

Without the proposed rule, FRA would be required to review and approve or deny all 67 of the RFAs to PTCSPs that would be submitted annually. FRA estimated that over the next ten years, the total cost to the government would be $30.4 million. Table J provides an overview of the ten-year government burden without the proposed rule.

TABLE J—TEN-YEAR GOVERNMENT BURDEN

[Without proposed rule]

Year	Submissions	Government cost to review each submission	Total annual cost	7-Percent	3-Percent
1	67	$41,132	$2,755,871	$2,755,871	$2,755,871
2	69	41,132	2,838,136	2,652,463	2,755,471
3	70	41,132	2,879,268	2,514,864	2,713,986
4	72	41,132	2,961,533	2,417,493	2,710,222
5	73	41,132	3,002,665	2,290,719	2,667,829
6	75	41,132	3,084,930	2,199,512	2,661,088
7	76	41,132	3,126,062	2,083,027	2,618,028
8	78	41,132	3,208,327	1,997,985	2,608,664
9	79	41,132	3,249,460	1,891,215	2,565,153
10	81	41,132	3,331,724	1,812,237	2,553,489
Total	740	411,324	30,437,976	22,615,387	26,609,802

Based on the proposed changes to § 236.1021, the number of RFAs that FRA would be required to review will decrease from 67 to 15 per year, beginning in the first year. This reduction is the same as seen in the cost savings above. The resulting reduction would mean that the new government cost to review the RFAs would be reduced to $6.2 million over the ten-year period. Table K below outlines the government costs under the proposed rule.

TABLE K—TEN-YEAR NEW GOVERNMENT BURDEN

Year	Submissions	Government cost to review each submission	Total annual cost savings	7-Percent	3-Percent
1	15	$41,132	$616,986	$616,986	$616,986
2	15	41,132	616,986	576,622	599,016
3	15	41,132	616,986	538,899	581,568
4	15	41,132	616,986	503,644	564,630
5	15	41,132	616,986	470,696	548,184
6	15	41,132	616,986	439,902	532,218
7	15	41,132	616,986	411,124	516,716
8	15	41,132	616,986	384,228	501,666
9	15	41,132	616,986	359,091	487,054
10	15	41,132	616,986	335,600	472,868
Total	150	411,324	6,169,860	4,636,793	5,420,906

FRA estimates that its proposed changes will result in a ten-year government cost savings of $18.0 million, discounted at 7 percent, or $21.2 million, discounted at 3 percent.

TABLE L—GOVERNMENT ADMINISTRATIVE COST SAVINGS

Year	Current government cost to review submissions (without proposed rule)	Government cost to review submissions (with proposed rule)	Total annual cost savings	7-Percent	3-Percent
1	$2,755,871	$616,986	$2,138,885	$2,138,885	$2,138,885
2	2,838,136	616,986	2,221,150	2,075,841	2,156,456
3	2,879,268	616,986	2,262,282	1,975,965	2,132,418
4	2,961,533	616,986	2,344,547	1,913,849	2,145,592
5	3,002,665	616,986	2,385,679	1,820,023	2,119,645
6	3,084,930	616,986	2,467,944	1,759,610	2,128,870
7	3,126,062	616,986	2,509,076	1,671,904	2,101,312
8	3,208,327	616,986	2,591,341	1,613,757	2,106,998

TABLE L—GOVERNMENT ADMINISTRATIVE COST SAVINGS—Continued

Year	Current government cost to review submissions (without proposed rule)	Government cost to review submissions (with proposed rule)	Total annual cost savings	7-Percent	3-Percent
9	3,249,460	616,986	2,632,474	1,532,124	2,078,099
10	3,331,724	616,986	2,714,738	1,476,638	2,080,621
Total	30,437,976	6,169,860	24,268,116	17,978,594	21,188,896

Results

This proposed rule would reduce the burden on railroads while not adversely affecting railroad safety. To oversee the performance and reliability of railroads' PTC systems, FRA is proposing to expand the reporting requirement under 49 CFR 236.1029(h), as described above. FRA estimates that the total ten-year industry cost associated with the expanded reporting requirement under § 236.1029(h) will be $324,158, discounted at 7 percent, or $379,231, discounted at 3 percent.

Though FRA is proposing to expand certain reporting requirements, the regulatory and administrative burden on host railroads will be reduced overall. The proposed simplification of RFAs to PTCSPs will reduce the number of burden hours per RFA. Also, FRA is proposing to permit host railroads utilizing the same type of PTC system to submit joint RFAs to their PTCDPs and PTCSPs, thus reducing the number of submissions railroads will need to submit in the future.

FRA expects that its proposed changes will result in a ten-year cost savings for the railroad industry of $6.1 million, discounted at 7 percent, or $7.2 million, discounted at 3 percent. In addition, during the same period, FRA expects that the proposed changes will produce government cost savings amounting to $18.0 million, discounted at 7 percent, or $21.2 million, discounted at 3 percent.

FRA estimates that the total net cost savings for this proposed rule will be $23.8 million, discounted at 7 percent, or $28.0 million, discounted at 3 percent. The annualized cost savings will be $3.4 million, discounted at 7 percent, or $3.3 million, discounted at 3 percent.

TABLE M—TOTAL TEN-YEAR NET COST SAVINGS

Year	Total industry cost savings	Total government cost savings	Total industry costs	Total net cost savings	7-Percent	3-Percent
1	$737,538	$2,138,885	$43,385	$2,833,038	$2,833,038	$2,833,038
2	762,329	2,221,150	45,244	2,938,235	2,746,014	2,852,655
3	774,725	2,262,282	47,103	2,989,904	2,611,498	2,818,271
4	799,516	2,344,547	37,807	3,106,256	2,535,631	2,842,665
5	811,912	2,385,679	39,046	3,158,545	2,409,639	2,806,326
6	836,703	2,467,944	41,525	3,263,122	2,326,561	2,814,797
7	849,099	2,509,076	42,145	3,316,030	2,209,611	2,777,123
8	873,890	2,591,341	44,004	3,421,227	2,130,568	2,781,770
9	886,285	2,632,474	44,934	3,473,825	2,021,798	2,742,269
10	911,077	2,714,738	46,793	3,579,022	1,946,751	2,743,022
Total	8,243,074	24,268,116	431,987	32,079,203	23,771,107	28,011,938
Annualized					3,384,471	3,283,854

FRA requests comments on the assumptions and burden estimates that are used within this analysis.

B. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601, *et seq.*) and Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' (67 FR 53461 (Aug. 16, 2002)) require agency review of proposed and final rules to assess their impacts on small entities. An agency must prepare an Initial Regulatory Flexibility Analysis (IRFA) unless it determines and certifies that a rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. FRA has not determined whether this proposed rule would have a significant economic impact on a substantial number of small entities. Therefore, FRA seeks comment on the potential small business impacts of the proposed requirements in this NPRM. FRA prepared an IRFA, which is included below, to aid the public in commenting on the potential small business impacts of the proposed requirements in this NPRM.

1. Reasons for Considering Agency Action

FRA is initiating the proposed rulemaking to enable railroads to make technological advancements to their PTC systems more efficiently, with FRA's continued oversight, by improving and streamlining the RFA process under 49 CFR 236.1021. Without the proposed rule, each host railroad would be required to submit independently an RFA, with the information required under 49 CFR 236.1021(d)(1)–(7), several times per year and wait for FRA to approve each RFA prior to implementing

enhancements or necessary changes to existing FRA-certified technology.

In addition, FRA is proposing to improve the reporting requirement under 49 CFR 236.1029(h) by, for example, increasing the reporting frequency from annual to biannual, updating the provision to use certain statutory terminology for consistency, and expanding the reporting requirement to encompass positive performance-related information, so FRA can oversee PTC systems' performance and reliability more effectively. To reduce the burden on host railroads, FRA has developed an Excel-based form (Form FRA F 6180.152) in which all the information could be succinctly input and sent to FRA electronically.

2. A Succinct Statement of the Objectives of, and the Legal Basis for, the Proposed Rule

The objective of this proposed rule is to establish an improved process to enable the industry to make technological advancements to FRA-certified PTC systems more efficiently, and with FRA's continued oversight. Instead of the existing approval process under § 236.1021, FRA proposes to require host railroads to comply with a streamlined process, which includes providing certain safety assurances and analysis. This improved process is expected to result in cost savings for both the host railroads and the government. Furthermore, FRA proposes to permit host railroads utilizing the same type of PTC system to submit joint RFAs to their PTCDPs and PTCSPs, which would benefit both the industry and FRA.

FRA is also proposing to expand the reporting requirement under § 236.1029(h) to enable FRA to oversee PTC systems' performance and reliability effectively. The expanded reporting requirement would increase the costs to host railroads, but that minimal cost would be offset by the cost savings associated with FRA's proposed changes to § 236.1021.

The Secretary has broad statutory authority to ''prescribe regulations and issue orders for every area of railroad safety'' under 49 U.S.C. 20103 and regarding PTC technology under 49 U.S.C. 20157(g). This proposed rule will reduce the burden on railroads while not adversely affecting railroad safety. In this proposed rule, FRA proposes to reduce the regulatory and administrative burden on regulated entities by reducing the complexity and number of RFAs host railroads must submit regarding certain enhancements and necessary changes to their FRA-certified PTC systems under § 236.1021 and providing more clarity and precision regarding the reporting requirement under § 236.1029(h), using a form.

3. A Description of and, Where Feasible, an Estimate of the Number of Small Entities to Which the Proposed Rule Would Apply

The Regulatory Flexibility Act of 1980 requires a review of proposed and final rules to assess their impact on small entities, unless the Secretary certifies that the rule would not have a significant economic impact on a substantial number of small entities. ''Small entity'' is defined in 5 U.S.C. 601 as a small business concern that is independently owned and operated and is not dominant in its field of operation. The U.S. Small Business Administration (SBA) has authority to regulate issues related to small businesses, and stipulates in its size standards that a ''small entity'' in the railroad industry is a for-profit ''line-haul railroad'' that has fewer than 1,500 employees, a ''short line railroad'' with fewer than 500 employees, or a ''commuter rail system'' with annual receipts of less than seven million dollars. *See* ''Size Eligibility Provisions and Standards,'' 13 CFR part 121, subpart A.

The proposed rule would directly apply to all host railroads subject to 49 U.S.C. 20157, including, in relevant part, 5 Class II or III, short line, or terminal railroads, and 23 intercity passenger railroads or commuter railroads, some of which may be small entities.

4. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including an Estimate of the Class of Small Entities That Will be Subject to the Requirements and the Type of Professional Skill Necessary for Preparation of the Report or Record

The proposed RFA process would allow railroads to make enhancements and necessary changes to their PTC systems more efficiently. FRA understands that only 5 of the current PTC-mandated host railroads are small entities; however, because this proposed rule would reduce the regulatory costs and hourly burdens on these railroads, the proposed changes would result in a positive impact on those railroads.

FRA is also proposing to amend the reporting requirement under § 236.1029(h) by increasing the frequency from annual to biannual, clarifying the types of statistics and information the reports must include, and expanding the reporting requirement to encompass positive performance-related information.[50] Though this expanded reporting requirement would double the number of submissions and increase the hourly burden, the proposed changes are necessary to enable FRA to oversee the performance and reliability of railroads' PTC systems effectively. FRA estimates that the additional costs associated with the increased reporting requirement will be more than offset by the proposed changes to § 236.1021. Furthermore, FRA assumes that as host railroads become more familiar with the reporting requirements proposed under § 236.1029(h), the hourly burden per submission will be reduced from 12 hours to 10 hours.

FRA expects that the proposed reporting requirement tasks will be completed by one Professional and Administrative employee per host railroad and require a basic understanding of Microsoft Excel.

To calculate the individual costs for small entities, FRA divided the total cost for each year by the number of estimated host railroads. FRA assumes that the hourly burden to submit an RFA is independent of an entity's size because the RFA depends upon the PTC system and not the individual railroad making the submission. The total cost for all host railroads in year one would be $43,385. FRA estimates that the individual cost to each host railroad would be approximately $1,240. The estimated ten-year cost per host railroad that FRA considers a small entity would be approximately $7,997, discounted at 7 percent, or $9,247, discounted at 3 percent. Though the proposed rule would impose costs on those host railroads that are small entities, it would also result in cost savings.

To calculate the individual cost savings for small entities, FRA divided the total cost savings for each year by the number of estimated host railroads. The total annual cost savings in the first year would be $737,538. FRA estimates that the individual cost savings for each host railroad would be $21,073. The estimated ten-year cost savings per host railroad that FRA considers a small entity would be $149,476, discounted at 7 percent, or $173,984, discounted at 3 percent. FRA requests comments on the burden that small entities would face under this proposed rule.

[50] In addition, with respect to tenant railroads, FRA's proposed changes to § 236.1029(h) are generally consistent with the existing regulatory requirement specifying that a tenant railroad must report a PTC system failure or cut out to ''a designated railroad officer of the *host railroad* as soon as safe and practicable.'' *See* § 236.1029(b)(4) (emphasis added).

5. Identification, to the Extent Practicable, of All Relevant Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

FRA is not aware of any relevant Federal rule that duplicates, overlaps with, or conflicts with the proposed rule. As described in this NPRM, the existing and proposed 49 CFR 236.1029(h) (proposed Biannual Report of PTC System Performance, Form FRA F 6180.152) constitutes a permanent reporting requirement, whereas the Statutory Notification of PTC System Failures (Form FRA F 6180.177, OMB Control No. 2130–0553) under 49 U.S.C. 20157(j)(4) is a temporary reporting requirement and expires on approximately December 31, 2021. FRA invites all interested parties to submit comments, data, and information demonstrating the potential economic impact on small entities that will result from the adoption of this proposed rule. FRA particularly encourages small entities potentially impacted by the proposed amendments to participate in the public comment process. FRA will consider all comments received during the public comment period for this NPRM when making a final determination of the rule's economic impact on small entities.

6. A Description of Significant Alternatives to the Rule

FRA is proposing this rulemaking to alleviate burdens on industry and improve the process associated with changes and upgrades to FRA-certified PTC systems and the associated PTCSPs. FRA's proposed changes to § 236.1021 are expected to result in cost savings for both the host railroads and the government. Furthermore, FRA proposes to permit host railroads utilizing the same type of PTC system to submit joint RFAs to their PTCDPs and PTCSPs, which will benefit both the industry and FRA. The main alternative to this rulemaking would be to maintain the status quo.

In the absence of this proposed rule, railroads would continue to submit information under § 236.1029(h) that may not be sufficient for FRA to oversee PTC systems' performance and reliability effectively. FRA notes the NPRM proposes to establish a new form [51] to report the required information under § 236.1029(h), which will help clarify and facilitate this reporting requirement for the industry. The alternative of not issuing the proposed rule would also forgo the more efficient process of allowing host railroads to submit joint RFAs to their PTCDPs and PTCSPs, and to implement certain changes to their PTC systems under the proposed streamlined process under § 236.1021(l) and (m), which would reduce the overall burden of FRA's PTC regulations.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule are being submitted for approval to OMB under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.* Please note that any new or revised requirements, as proposed in this NPRM, are marked by asterisks (*) in the table below. The sections that contain the proposed and current information collection requirements under OMB Control No. 2130–0553 [52] and the estimated time to fulfill each requirement are as follows:

CFR section/subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [53]
235.6(c)—Expedited application for approval of certain changes described in this section.	42 railroads	10 expedited applications.	5 hours	50	$3,850
—Copy of expedited application to labor union	42 railroads	10 copies	30 minutes	5	385
—Railroad letter rescinding its request for expedited application of certain signal system changes.	42 railroads	1 letter	6 hours	6	462
—Revised application for certain signal system changes	42 railroads	1 application	5 hours	5	385
—Copy of railroad revised application to labor union	42 railroads	1 copy	30 minutes	.5	39
236.1—Railroad maintained signal plans at all interlockings, automatic signal locations, and controlled points, and updates to ensure accuracy.	700 railroads	25 plan changes	15 minutes	6.3	485
236.15—Designation of automatic block, traffic control, train stop, train control, cab signal, and PTC territory in timetable instructions.	700 railroads	10 timetable instructions.	30 minutes	5	385
236.18—Software management control plan—New railroads.	2 railroads	2 plans	160 hours	320	24,640
236.23(e)—The names, indications, and aspects of roadway and cab signals shall be defined in the carrier's Operating Rule Book or Special Instructions. Modifications shall be filed with FRA within 30 days after such modifications become effective.	700 railroads	2 modifications	1 hour	2	154
236.587(d)—Certification and departure test results	742 railroads	4,562,500 train departures.	5 seconds	6,337	487,949
236.905(a)—Railroad Safety Program Plan (RSPP)—New railroads.	2 railroads	2 RSPPs	40 hours	80	6,160
236.913(a)—Filing and approval of a joint Product Safety Plan (PSP).	742 railroads	1 joint plan	2,000 hours	2,000	240,000
(c)(1)—Informational filing/petition for special approval	742 railroads	0.5 filings/approval petitions.	50 hours	25	1,925
(c)(2)—Response to FRA's request for further data after informational filing.	742 railroads	0.25 data calls/documents.	5 hours	1	77

[51] Biannual Report of PTC System Performance (Form FRA F 6180.152).

[52] *See also* 84 FR 72121 (Dec. 30, 2019) (60-day ICR notice); 85 FR 15022 (Mar. 16, 2020) (30-day ICR notice). On June 5, 2020, OMB approved the revised ICR, entitled ''PTC and Other Signal Systems'' under OMB Control No. 2130–0553, for a period of three years, expiring on June 30, 2023.

[53] The dollar equivalent cost is derived from the 2019 STB Full Year Wage A&B data series using the appropriate employee group hourly wage rate that includes a 75-percent overhead charge. For Executives, Officials, and Staff Assistants, this cost amounts to $120 per hour. For Professional/Administrative staff, this cost amounts to $77 per hour.

[54] A railroad's final Quarterly PTC Progress Report (Form FRA F 6180.165) will be due on January 31, 2021, assuming the railroad fully implements an FRA-certified and interoperable PTC system by the statutory deadline of December 31, 2020.

[55] A railroad's final Annual PTC Progress Report (Form FRA F 6180.166) will be due on March 31, 2021, assuming it fully implements an FRA-certified and interoperable PTC system by the statutory deadline of December 31, 2020.

[56] The temporary Statutory Notification of PTC System Failures (Form FRA F 6180.177) expires on approximately December 31, 2021 per 49 U.S.C. 20157(j).

CFR section/subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [53]
(d)(1)(ii)—Response to FRA's request for further information within 15 days after receipt of the Notice of Product Development (NOPD).	742 railroads	0.25 data calls/documents.	1 hour	0.25	19
(d)(1)(iii)—Technical consultation by FRA with the railroad on the design and planned development of the product.	742 railroads	0.25 technical consultations.	5 hours	1.3	100
(d)(1)(v)—Railroad petition to FRA for final approval of NOPD.	742 railroads	0.25 petitions	1 hour	0.25	19
(d)(2)(ii)—Response to FRA's request for additional information associated with a petition for approval of PSP or PSP amendment.	742 railroads	1 request	50 hours	50	3,850
(e)—Comments to FRA on railroad informational filing or special approval petition.	742 railroads	0.5 comments/letters	10 hours	5	385
(h)(3)(i)—Railroad amendment to PSP	742 railroads	2 amendments	20 hours	40	3,080
(j)—Railroad field testing/information filing document	742 railroads	1 field test document	100 hours	100	7,700
236.917(a)—Railroad retention of records: results of tests and inspections specified in the PSP.	13 railroads with PSP	13 PSP safety results	160 hours	2,080	160,160
(b)—Railroad report that frequency of safety-relevant hazards exceeds threshold set forth in PSP.	13 railroads	1 report	40 hours	40	3,080
(b)(3)—Railroad final report to FRA on the results of the analysis and countermeasures taken to reduce the frequency of safety-relevant hazards.	13 railroads	1 report	10 hours	10	770
236.919(a)—Railroad Operations and Maintenance Manual (OMM).	13 railroads	1 OMM update	40 hours	40	3,080
(b)—Plans for proper maintenance, repair, inspection, and testing of safety-critical products.	13 railroads	1 plan update	40 hours	40	3,080
(c)—Documented hardware, software, and firmware revisions in OMM.	13 railroads	1 revision	40 hours	40	3,080
236.921 and 923(a)—Railroad Training and Qualification Program.	13 railroads	1 program	40 hours	40	3,080
236.923(b)—Training records retained in a designated location and available to FRA upon request.	13 railroads	350 records	10 minutes	58	4,466
Form FRA F 6180.165—Quarterly PTC Progress Report (49 U.S.C. 20157(c)(2)) [54].	35 railroads	11.7 reports/forms	23.22 hours	271	20,867
Form FRA F 6180.166—Annual PTC Progress Report (49 U.S.C. 20157(c)(1) and 49 CFR 236.1009(a)(5)) [55].	35 railroads	11.7 reports/forms	40.12 hours	468	36,036
Form FRA F 6180.177—Statutory Notification of PTC System Failures (Under 49 U.S.C. 20157(j)(4)) [56].	38 railroads	144 reports/forms	1 hour	144	11,088
236.1001(b)—A railroad's additional or more stringent rules than prescribed under 49 CFR part 236, subpart I.	38 railroads	1 rule or instruction	40 hours	40	4,800
236.1005(b)(4)(i)–(ii)—A railroad's submission of estimated traffic projections for the next 5 years, to support a request, in a PTCIP or an RFA, not to implement a PTC system based on reductions in rail traffic.	The burden is accounted for under 49 CFR 236.1009(a) and 236.1021.				
(b)(4)(iii)—A railroad's request for a *de minimis* exception, in a PTCIP or an RFA, based on a minimal quantity of PIH materials traffic.	7 Class I railroads	1 exception request	40 hours	40	3,080
(b)(5)—A railroad's request to remove a line from its PTCIP based on the sale of the line to another railroad and any related request for FRA review from the acquiring railroad.	The burden is accounted for under 49 CFR 236.1009(a) and 236.1021.				
(g)(1)(i)—A railroad's request to temporarily reroute trains not equipped with a PTC system onto PTC-equipped tracks and vice versa during certain emergencies.	38 railroads	45 rerouting extension requests.	8 hours	360	27,720
(g)(1)(ii)—A railroad's written or telephonic notice of the conditions necessitating emergency rerouting and other required information under 236.1005(i).	38 railroads	45 written or telephonic notices.	2 hours	90	6,930
(g)(2)—A railroad's temporary rerouting request due to planned maintenance not exceeding 30 days.	38 railroads	720 requests	8 hours	5,760	443,520
(h)(1)—A response to any request for additional information from FRA, prior to commencing rerouting due to planned maintenance.	38 railroads	10 requests	2 hours	20	1,540
(h)(2)—A railroad's request to temporarily reroute trains due to planned maintenance exceeding 30 days.	38 railroads	160 requests	8 hours	1,280	98,560
236.1006(b)(4)(iii)(B)—A progress report due by December 31, 2020, and by December 31, 2022, from any Class II or III railroad utilizing a temporary exception under this section.	262 railroads	5 reports	16 hours	80	6,160
(b)(5)(vii)—A railroad's request to utilize different yard movement procedures, as part of a freight yard movements exception.	The burden is accounted for under 49 CFR 236.1015 and 236.1021.				

CFR section/subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [53]
236.1007(b)(1)—For any high-speed service over 90 miles per hour (mph), a railroad's PTC Safety Plan (PTCSP) must additionally establish that the PTC system was designed and will be operated to meet the fail-safe operation criteria in Appendix C.	The burden is accounted for under 49 CFR 236.1015 and 236.1021.				
(c)—An HSR–125 document accompanying a host railroad's PTCSP, for operations over 125 mph.	38 railroads	1 HSR–125 document	3,200 hours	3,200	384,000
(c)(1)—A railroad's request for approval to use foreign service data, prior to submission of a PTCSP.	38 railroads	0.3 requests	8,000 hours	2,667	205,359
(d)—A railroad's request in a PTCSP that FRA excuse compliance with one or more of this section's requirements.	38 railroads	1 request	1,000 hours	1,000	120,000
236.1009(a)(2)—A PTCIP if a railroad becomes a host railroad of a main line requiring the implementation of a PTC system, including the information under 49 U.S.C. 20157(a)(2) and 49 CFR 236.1011.	264 railroads	1 PTCIP	535 hours	535	64,200
(a)(3)—Any new PTCIPs jointly filed by a host railroad and a tenant railroad.	264 railroads	1 joint PTCIP	267 hours	267	32,040
(b)(1)—A host railroad's submission, individually or jointly with a tenant railroad or PTC system supplier, of an unmodified Type Approval.	264 railroads	1 document	8 hours	8	616
(b)(2)—A host railroad's submission of a PTCDP with the information required under 49 CFR 236.1013, requesting a Type Approval for a PTC system that either does not have a Type Approval or has a Type Approval that requires one or more variances.	264 railroads	1 PTCDP	2,000 hours	2,000	154,000
(d)—A host railroad's submission of a PTCSP	The burdens are accounted for under 49 CFR 236.1015.				
(e)(3)—Any request for full or partial confidentiality of a PTCIP, Notice of Product Intent (NPI), PTCDP, or PTCSP.	38 railroads	10 confidentiality requests.	8 hours	80	6,160
(h)—Any responses or documents submitted in connection with FRA's use of its authority to monitor, test, and inspect processes, procedures, facilities, documents, records, design and testing materials, artifacts, training materials and programs, and any other information used in the design, development, manufacture, test, implementation, and operation of the PTC system, including interviews with railroad personnel.	38 railroads	36 interviews and documents.	4 hours	144	11,088
(j)(2)(iii)—Any additional information provided in response to FRA's consultations or inquiries about a PTCDP or PTCSP.	38 railroads	1 set of additional information.	400 hours	400	30,800
236.1011(a)–(b)—PTCIP content requirements	The burdens are accounted for under 49 CFR 236.1009(a) and (e) and 236.1021.				
(e)—Any public comment on PTCIPs, NPIs, PTCDPs, and PTCSPs.	38 railroads	2 public comments	8 hours	16	1,232
236.1013, PTCDP and NPI content requirements	The burdens are accounted for under 49 CFR 236.1009(b), (c), and (e) and 236.1021.				
236.1015—Any new host railroad's PTCSP meeting all content requirements under 49 CFR 236.1015.	264 railroads	1 PTCSP	8,000 hours	8,000	616,000
(g)—A PTCSP for a PTC system replacing an existing certified PTC system.	38 railroads	0.3 PTCSPs	3,200 hours	1,067	82,159
(h)—A quantitative risk assessment, if FRA requires one to be submitted.	38 railroads	0.3 assessments	800 hours	267	20,559
236.1017(a)—An independent third-party assessment, if FRA requires one to be conducted and submitted.	38 railroads	0.3 assessments	1,600 hours	533	63,960
(b)—A railroad's written request to confirm whether a specific entity qualifies as an independent third party.	38 railroads	0.3 written requests	8 hours	3	231
—Further information provided to FRA upon request	38 railroads	0.3 sets of additional information.	20 hours	7	539
(d)—A request not to provide certain documents otherwise required under Appendix F for an independent, third-party assessment.	38 railroads	0.3 requests	20 hours	7	539
(e)—A request for FRA to accept information certified by a foreign regulatory entity for purposes of 49 CFR 236.1017 and/or 236.1009(i).	38 railroads	0.3 requests	32 hours	11	847
236.1019(b)—A request for a passenger terminal main line track exception (MTEA).	38 railroads	1 MTEA	160 hours	160	12,320
(c)(1)—A request for a limited operations exception (based on restricted speed, temporal separation, or a risk mitigation plan).	38 railroads	1 request and/or plan	160 hours	160	12,320
(c)(2)—A request for a limited operations exception for a non-Class I, freight railroad's track.	10 railroads	1 request	160 hours	160	12,320
(c)(3)—A request for a limited operations exception for a Class I railroad's track.	7 railroads	1 request	160 hours	160	12,320

CFR section/subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [53]
(d)—A railroad's collision hazard analysis in support of an MTEA, if FRA requires one to be conducted and submitted.	38 railroads	0.3 collision hazard analysis.	50 hours	17	1,309
(e)—Any temporal separation procedures utilized under the 49 CFR 236.1019(c)(1)(ii) exception.	The burdens are accounted for under 49 CFR 236.1019(c)(1).				
236.1021(a)–(d)—Any RFA to a railroad's PTCIP or PTCDP.	38 railroads	10 RFAs	160 hours	1,600	123,200
(e)—Any public comments, if an RFA includes a request for approval of a discontinuance or material modification of a signal or train control system and a **Federal Register** notice is published.	5 interested parties	10 RFA public comments.	16 hours	160	12,320
(l)—Any jointly filed RFA to a PTCDP or PTCSP (* Note: This is a new proposed paragraph to authorize host railroads to file joint RFAs in certain cases, but such RFAs are already required under FRA's existing regulations *).	The burdens are accounted for under 49 CFR 236.1021(a)–(d) and (m).				
(m)—Any RFA to a railroad's PTCSP (* Note: Revised requirement. This is a new proposed paragraph with a simplified process governing RFAs to PTCSPs *).	38 railroads	15 RFAs	80 hours	1,200	92,400
236.1023(a)—A railroad's PTC Product Vendor List, which must be continually updated.	38 railroads	2 updated lists	8 hours	16	1,232
(b)(1)—All contractual arrangements between a railroad and its hardware and software suppliers or vendors for certain immediate notifications.	The burdens are accounted for under 49 CFR 236.1015 and 236.1021.				
(b)(2)–(3)—A vendor's or supplier's notification, upon receipt of a report of any safety-critical failure of its product, to any railroads using the product.	10 vendors or suppliers.	10 notifications	8 hours	80	6,160
(c)(1)–(2)—A railroad's process and procedures for taking action upon being notified of a safety-critical failure or a safety-critical upgrade, patch, revision, repair, replacement, or modification, and a railroad's configuration/revision control measures, set forth in its PTCSP.	The burdens are accounted for under 49 CFR 236.1015 and 236.1021.				
(d)—A railroad's submission, to the applicable vendor or supplier, of the railroad's procedures for action upon notification of a safety-critical failure, upgrade, patch, or revision to the PTC system and actions to be taken until it is adjusted, repaired, or replaced.	38 railroads	2.5 notifications	16 hours	40	3,080
(e)—A railroad's database of all safety-relevant hazards, which must be maintained after the PTC system is placed in service.	38 railroads	38 database updates	16 hours	608	46,816
(e)(1)—A railroad's notification to the vendor or supplier and FRA if the frequency of a safety-relevant hazard exceeds the threshold set forth in the PTCDP and PTCSP, and about the failure, malfunction, or defective condition that decreased or eliminated the safety functionality.	38 railroads	8 notifications	8 hours	64	4,928
(e)(2)—Continual updates about any and all subsequent failures.	38 railroads	1 update	8 hours	8	616
(f)—Any notifications that must be submitted to FRA under 49 CFR 236.1023.	The burdens are accounted for under 49 CFR 236.1023(e), (g), and (h).				
(g)—A railroad's and vendor's or supplier's report, upon FRA request, about an investigation of an accident or service difficulty due to a manufacturing or design defect and their corrective actions.	38 railroads	0.5 reports	40 hours	20	1,540
(h)—A PTC system vendor's or supplier's reports of any safety-relevant failures, defective conditions, previously unidentified hazards, recommended mitigation actions, and any affected railroads.	10 vendors or suppliers.	20 reports	8 hours	160	12,320
(k)—A report of a failure of a PTC system resulting in a more favorable aspect than intended or other condition hazardous to the movement of a train, including the reports required under part 233.	The burdens are accounted for under 49 CFR 236.1023(e), (g), and (h) and 49 CFR part 233.				
236.1029(b)(4)—A report of an en route failure, other failure, or cut out to a designated railroad officer of the host railroad.	150 host and tenant railroads.	1,000 reports	30 minutes	500	38,500
(h)—Form FRA F 6180.152—Biannual Report of PTC System Performance (*Revised requirement and new form*).	38 railroads	76 reports	12 hours	912	70,224

CFR section/subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [53]
236.1033—Communications and security requirements	The burdens are accounted for under 49 CFR 236.1009 and 236.1015.				
236.1035(a)–(b)—A railroad's request for authorization to field test an uncertified PTC system and any responses to FRA's testing conditions.	38 railroads	10 requests	40 hours	400	30,800
236.1037(a)(1)–(2)—Records retention	The burdens are accounted for under 49 CFR 236.1009 and 236.1015.				
(a)(3)–(4)—Records retention	The burdens are accounted for under 49 CFR 236.1039 and 236.1043(b).				
(b)—Results of inspections and tests specified in a railroad's PTCSP and PTCDP.	38 railroads	800 records	1 hour	800	61,600
(c)—A contractor's records related to the testing, maintenance, or operation of a PTC system maintained at a designated office.	20 contractors	1,600 records	10 minutes	267	20,559
(d)(3)—A railroad's final report of the results of the analysis and countermeasures taken to reduce the frequency of safety-related hazards below the threshold set forth in the PTCSP.	38 railroads	8 final reports	160 hours	1,280	98,560
236.1039(a)–(c), (e)—A railroad's PTC Operations and Maintenance Manual (OMM), which must be maintained and available to FRA upon request.	38 railroads	2 OMM updates	10 hours	20	1,540
(d)—A railroad's identification of a PTC system's safety-critical components, including spare equipment.	38 railroads	1 identified new component.	1 hour	1	77
236.1041(a)–(b) and 236.1043(a)—A railroad's PTC Training and Qualification Program (*i.e.,* a written plan).	38 railroads	2 programs	10 hours	20	1,540
236.1043(b)—Training records retained in a designated location and available to FRA upon request.	150 host and tenant railroads.	150 PTC training record databases.	1 hour	150	11,550
Total	N/A	4,567,923 responses	N/A	49,116	4,107,626

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. Pursuant to 44 U.S.C. 3506(c)(2)(B), FRA solicits comments concerning: Whether these information collection requirements are necessary for the proper performance of the functions of FRA, including whether the information has practical utility; the accuracy of FRA's estimates of the burden of the information collection requirements; the quality, utility, and clarity of the information to be collected; and whether the burden of collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, may be minimized.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to Ms. Hodan Wells, Information Clearance Officer, at 202–493–0440 or via email at *Hodan.Wells@dot.gov.*

D. Federalism Implications

Executive Order 13132, ''Federalism,'' requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' *See* 64 FR 43255 (Aug. 10, 1999). ''Policies that have federalism implications'' are defined in the Executive Order to include regulations having ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' *Id.* Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

FRA has analyzed this proposed rule under the principles and criteria contained in Executive Order 13132. FRA has determined this proposed rule would not have a substantial direct effect on the States or their political subdivisions; on the relationship between the Federal government and the States or their political subdivisions; or on the distribution of power and responsibilities among the various levels of government. In addition, FRA has determined this proposed rule does not impose substantial direct compliance costs on State and local governments. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

This proposed rule could have preemptive effect by the operation of law under a provision of the former Federal Railroad Safety Act of 1970, repealed and recodified at 49 U.S.C. 20106. Section 20106 provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the ''essentially local safety or security hazard'' exception to section 20106.

FRA has analyzed this proposed rule in accordance with the principles and criteria contained in Executive Order 13132. As explained above, FRA has determined that this proposed rule has no federalism implications, other than the possible preemption of State laws under Federal railroad safety statutes, specifically 49 U.S.C. 20106. Accordingly, FRA has determined that preparation of a federalism summary impact statement for this proposed rule is not required.

E. International Trade Impact Assessment

The Trade Agreements Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. This proposed rule is purely domestic in nature and is not expected to affect trade opportunities for U.S. firms doing business overseas or for foreign firms doing business in the United States.

F. Environmental Impact

FRA has evaluated this proposed rule consistent with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321, *et seq.*), the Council of Environmental Quality's NEPA implementing regulations at 40 CFR parts 1500–1508, and FRA's NEPA implementing regulations at 23 CFR part 771, and determined that it is categorically excluded from environmental review and therefore does not require the preparation of an environmental assessment (EA) or environmental impact statement (EIS). Categorical exclusions (CEs) are actions identified in an agency's NEPA implementing regulations that do not normally have a significant impact on the environment and therefore do not require either an EA or EIS. *See* 40 CFR 1508.4. Specifically, FRA has determined that this proposed rule is categorically excluded from detailed environmental review pursuant to 23 CFR 771.116(c)(15), ''Promulgation of rules, the issuance of policy statements, the waiver or modification of existing regulatory requirements, or discretionary approvals that do not result in significantly increased emissions of air or water pollutants or noise.''

This proposed rule does not directly or indirectly impact any environmental resources and would not result in significantly increased emissions of air or water pollutants or noise. Instead, the proposed rule is likely to result in safety benefits. In analyzing the applicability of a CE, FRA must also consider whether unusual circumstances are present that would warrant a more detailed environmental review. *See* 23 CFR 771.116(b). FRA has concluded that no such unusual circumstances exist with respect to this proposed rule and the proposal meets the requirements for categorical exclusion under 23 CFR 771.116(c)(15).

Pursuant to Section 106 of the National Historic Preservation Act and its implementing regulations, FRA has determined this undertaking has no potential to affect historic properties. *See* 16 U.S.C. 470. FRA has also determined that this rulemaking does not approve a project resulting in a use of a resource protected by Section 4(f). *See* Department of Transportation Act of 1966, as amended (Pub. L. 89–670, 80 Stat. 931); 49 U.S.C. 303.

G. Executive Order 12898 (Environmental Justice)

Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' and DOT Order 5610.2B, dated November 18, 2020, require DOT agencies to consider environmental justice principles by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations. The DOT Order instructs DOT agencies to address compliance with Executive Order 12898, Executive Order 13771, and requirements within the DOT Order in rulemaking activities, as appropriate. FRA has evaluated this proposed rule and has determined it would not cause disproportionately high and adverse human health and environmental effects on minority populations or low-income populations.

H. Unfunded Mandates Reform Act of 1995

Under section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires that ''before promulgating any general notice of proposed rulemaking that is likely to result in promulgation of any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement'' detailing the effect on State, local, and tribal governments and the private sector. This proposed rule would not result in the expenditure, in the aggregate, of $100,000,000 or more (as adjusted annually for inflation) in any one year, and thus preparation of such a statement is not required.

I. Energy Impact

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' 66 FR 28355 (May 22, 2001). FRA has evaluated this proposed rule under Executive Order 13211 and determined that this proposed rule is not a ''significant energy action'' within the meaning of Executive Order 13211.

Executive Order 13783, ''Promoting Energy Independence and Economic Growth,'' requires Federal agencies to review regulations to determine whether they potentially burden the development or use of domestically produced energy resources, with particular attention to oil, natural gas, coal, and nuclear energy resources. 82 FR 16093 (Mar. 31, 2017). FRA has evaluated this proposed rule under Executive Order 13783 and determined that this rule would not burden the development or use of domestically produced energy resources.

J. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *https://www.transportation.gov/privacy.* To facilitate comment tracking and response, DOT encourages commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

List of Subjects in 49 CFR Part 236

Penalties, Positive train control, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, FRA proposes to amend 49 CFR part 236, as follows:

PART 236—RULES, STANDARDS, AND INSTRUCTIONS GOVERNING THE INSTALLATION, INSPECTION, MAINTENANCE, AND REPAIR OF SIGNAL AND TRAIN CONTROL SYSTEMS, DEVICES, AND APPLIANCES

■ 1. The authority citation for part 236 continues to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 20133, 20141, 20157, 20301–20303, 20306, 20501–20505, 20701–20703, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 2. Amend § 236.1003 in paragraph (b) by adding the definitions of ''Cut out'', ''Initialization failure'', and ''Malfunction'' in alphabetical order to read as follows:

§ 236.1003 Definitions.

* * * * *

(b) * * *

Cut out means any disabling of a PTC system, subsystem, or component en route, including when the PTC system cuts out on its own or a person cuts out the system, unless the cut out was necessary to exit PTC-governed territory and enter non-PTC territory.

* * * * *

Initialization failure means any instance when a PTC system fails to activate on a locomotive or train, unless the PTC system successfully activates during a subsequent attempt in the same location or before entering PTC-governed territory. For the types of PTC systems that do not initialize by design, a failed departure test is considered an initialization failure for purposes of the reporting requirement under § 236.1029(h), unless the PTC system successfully passes the departure test during a subsequent attempt in the same location or before entering PTC-governed territory.

* * * * *

Malfunction means any instance when a PTC system, subsystem, or component fails to perform the functions mandated under 49 U.S.C. 20157(i)(5), this subpart, or the applicable host railroad's PTCSP.

* * * * *

■ 3. Amend § 236.1021 by:

■ a. Revising paragraphs (a), (c), (d) introductory text, and (d)(4);

■ b. Removing paragraph (d)(7); and

■ c. Adding paragraphs (l) and (m).

The revisions and additions read as follows:

§ 236.1021 Discontinuances, material modifications, and amendments.

(a) No changes, as defined by this section, to a PTCIP or PTCDP may be made unless:

(1) The railroad files a request for amendment (RFA) to the applicable PTCIP or PTCDP with the Associate Administrator; and

(2) The Associate Administrator approves the RFA.

* * * * *

(c) In lieu of a separate filing under part 235 of this chapter, a railroad may request approval of a discontinuance or material modification of a signal or train control system by filing an RFA to its PTCIP or PTCDP with the Associate Administrator.

(d) FRA will not approve an RFA to a PTCIP or PTCDP unless the request includes:

* * * * *

(4) The changes to the PTCIP or PTCDP, as applicable;

* * * * *

(l) Any RFA to a PTCDP or PTCSP pursuant to this section may be submitted jointly with other host railroads utilizing the same type of PTC system. However, only host railroads with the same PTC System Certification classification under § 236.1015(e) may jointly file an RFA to their PTCSPs. Any joint RFA to multiple host railroads' PTCSPs must include the information required under paragraph (m) of this section. The joint RFA must also include the written confirmation and statement specified under paragraphs (m)(2)(iii) and (iv) of this section from each host railroad jointly filing the RFA.

(m) No changes, as specified under paragraph (h)(3) or (4) of this section, may be made to an FRA-certified PTC system or an FRA-approved PTCSP unless the host railroad first complies with the following process:

(1) The host railroad revises its PTCSP to account for each proposed change to its PTC system and summarizes such changes in a chronological table of revisions at the beginning of its PTCSP;

(2) The host railroad electronically submits the following information in an RFA to the Director of FRA's Office of Railroad Systems, Technology, and Automation:

(i) A summary of the proposed changes to any safety-critical elements of a PTC system, including a summary of how the changes to the PTC system would affect its safety-critical functionality, how any new hazards have been addressed and mitigated, whether each change is a planned change that was previously included in all required analysis under § 236.1015 or an unplanned change, and the reason for the proposed changes, including whether the changes are necessary to address or resolve an emergency or urgent issue;

(ii) Any associated software release notes;

(iii) A confirmation that the host railroad has notified any applicable tenant railroads of the proposed changes, any associated effect on the tenant railroads' operations, and any actions the tenant railroads must take in accordance with the configuration control measures set forth in the host railroad's PTCSP;

(iv) A statement from the host railroad's Chief Engineer and Chief Operating Officer, or executive officers of similar qualifications, verifying that the modified PTC system would meet all technical requirements under this subpart, provide an equivalent or greater level of safety than the existing PTC system, and not adversely impact interoperability with any tenant railroads; and

(v) Any other information that FRA requests; and

(3) A host railroad shall not make any changes, as specified under paragraph (h)(3) or (4) of this section, to its PTC system until the Director of FRA's Office of Railroad Systems, Technology, and Automation approves the RFA.

(i) FRA will approve, approve with conditions, or deny the RFA within 45 days of the date on which the RFA was filed under paragraph (m)(2) of this section.

(ii) FRA reserves the right to notify a railroad that changes may proceed prior to the 45-day mark, including in an emergency or under other circumstances necessitating a railroad's immediate implementation of the proposed changes to its PTC system.

(iii) FRA may require a railroad to modify its RFA or its PTC system to the extent necessary to ensure safety or compliance with the requirements of this part.

(iv) Following any FRA denial of an RFA, each applicable railroad is prohibited from making the proposed changes to its PTC system until the railroad both sufficiently addresses FRA's questions, comments, and concerns and obtains FRA's approval. Consistent with paragraph (l) of this section, any host railroads utilizing the same type of PTC system, including the same certification classification under § 236.1015(e), may jointly submit information to address FRA's questions, comments, and concerns following any denial of an RFA under this section.

■ 4. Amend § 236.1029 by revising paragraph (h) to read as follows:

§ 236.1029 PTC system use and failures.

* * * * *

(h) *Biannual Report of PTC System Performance.* (1) Each host railroad

subject to 49 U.S.C. 20157 or this subpart shall electronically submit a Biannual Report of PTC System Performance on Form FRA F 6180.152, containing the following information for the applicable reporting period, separated by the host railroad, each applicable tenant railroad, and each PTC-governed track segment (*e.g.,* territory, subdivision, district, main line, branch, or corridor), consistent with the railroad's PTC Implementation Plan:

(i) The total number of PTC system initialization failures, and subtotals identifying the number of initialization failures where the source or cause was the onboard subsystem, wayside subsystem, communications subsystem, back office subsystem, or a non-PTC component;

(ii) The total number of PTC system cut outs, and subtotals identifying the number of cut outs where the source or cause was the onboard subsystem, wayside subsystem, communications subsystem, back office subsystem, or a non-PTC component;

(iii) The total number of PTC system malfunctions, and subtotals identifying the number of malfunctions where the source or cause was the onboard subsystem, wayside subsystem, communications subsystem, back office subsystem, or a non-PTC component;

(iv) The number of intended enforcements by the PTC system and any other instances in which the PTC system prevented an accident or incident;

(v) The number of scheduled attempts at initialization of the PTC system;

(vi) The number of trains governed by the PTC system; and

(vii) The number of train miles governed by the PTC system.

(2) A host railroad's Biannual Report of PTC System Performance (Form FRA F 6180.152) shall also include a summary of any actions the host railroad and its tenant railroads are continually taking to improve the performance and reliability of the PTC system.

(3) Each host railroad shall electronically submit a Biannual Report of PTC System Performance (Form FRA F 6180.152) to FRA by the following due dates: July 31 (covering the period from January 1 to June 30), and January 31 (covering the period from July 1 to December 31 of the prior calendar year).

(4) Each tenant railroad that operates on a host railroad's PTC-governed main line(s), unless the tenant railroad is currently subject to an exception under § 236.1006(b)(4) or (5), shall submit the information required under paragraphs (h)(1) and (2) of this section to each applicable host railroad by July 15 (for the report covering the period from January 1 to June 30) and by January 15 (for the report covering the period from July 1 to December 31 of the prior calendar year).

Issued in Washington, DC

Quintin C. Kendall,

Deputy Administrator.

[FR Doc. 2020–27097 Filed 12–17–20; 8:45 am]

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Notices

Federal Register

Vol. 85, No. 244

Friday, December 18, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–CN–20–0091]

Cotton Research and Promotion Program: Determination of Whether To Conduct a Referendum Regarding 1990 Amendments to the Cotton Research and Promotion Act

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the Department's determination, based on a review by the Agricultural Marketing Service, that it is not necessary to conduct a referendum among producers and importers on continuation of the 1990 amendments to the Cotton Research and Promotion Act. The 1990 amendments require the Secretary of Agriculture to conduct a review to determine whether to hold a continuance referendum. Although USDA is of the view that a referendum is not needed, it will initiate a sign-up period, as required by the Act, to allow cotton producers and importers the opportunity to request a continuance referendum.

FOR FURTHER INFORMATION CONTACT: Shethir M. Riva, Director, Research and Promotion Division, Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia, 22406, telephone (540) 361–2726, or email at *CottonRP@usda.gov.*

SUPPLEMENTARY INFORMATION: In July 1991, the Agricultural Marketing Service (AMS) implemented the 1990 amendments to the Cotton Research and Promotion Act (7 U.S.C. 2101–2118) (Act). These amendments provided for: (1) Importer representation on the Cotton Board by an appropriate number of persons—to be determined by the Secretary—who import cotton or cotton products into the United States (U.S.) and are selected by the Secretary from nominations submitted by importer organizations certified by the Secretary of Agriculture; (2) assessments levied on imported cotton and cotton products at a rate determined in the same manner as for U.S. cotton; (3) increasing the amount the Secretary can be reimbursed for conducting a referendum from $200,000 to $300,000; (4) reimbursing government agencies who assist in administering the collection of assessments on imported cotton and cotton products; and (5) terminating the right of producers to demand an assessment refund.

Results of the initial July 1991 referendum showed that of the 46,220 valid ballots received, 27,879 or 60 percent of the persons voted in favor of the amendments to the Cotton Research and Promotion Order (7 CFR part 1205) (Order) and 18,341 or 40 percent opposed the amendments. AMS developed implementing regulations for the import assessment effective July 31, 1992 (57 FR 29181); the elimination of the producer refund effective July 31, 1992 (57 FR 29181); and provided for importer representation on the Cotton Board effective December 21, 1991 (56 FR 65979).

USDA conducted previous reviews of the 1990 amendments, and for each review, the Department prepared reports that described the impact of the Cotton Research and Promotion Program on the cotton industry and the views of those receiving its benefits. Following each review, USDA announced its decision not to conduct a referendum regarding the amendments to the Order (61 FR 52772, 67 FR 1714, 72 FR 9918, and 78 FR 32228, respectively) and subsequently held sign-up periods, affording all eligible persons to request a continuance referendum on the 1990 Act amendments. The results of each sign-up period did not meet the criteria as established by the Act for a continuance referendum and, therefore, referenda were not conducted.

In 2017, USDA solicited comments from all interested parties, including persons who pay the assessments, as well as from organizations representing cotton producers and importers regarding whether they favor the continuation of the amendments to the Cotton Research and Promotion Order (82 FR 11892). Three comments, which included comments from two certified producer organizations that nominate producers to the Board, voiced strong support for the continuance of the program and noted that the programs and administration of the Cotton Research and Promotion Act have been beneficial, carries out the intent and purpose, and that there should be no referendum.

USDA has reviewed the Cotton Research and Promotion Program major program activities and accomplishments, including evaluations of advertising and marketing activities and other functional areas; the results of producer and importer awareness and satisfaction surveys; and data from the Foreign Agricultural Service. USDA also reviewed the results of the Cotton Board's 2016 independent program evaluation, which assessed the effectiveness of the Cotton Research and Promotion Program; the strength of cotton's competitive position; the ability to maintain and expand domestic and foreign markets; increases in the number of uses for cotton; and estimates of a return on investment for stakeholders and qualitative benefits and returns associated with the Cotton Research and Promotion Program.

In 2020, the Department prepared a 5-year report that described the impact of the Cotton Research and Promotion Program on the cotton industry. The review report is available upon written request to the Research and Promotion Staff at the address and email provided above. The review report concluded that the 1990 amendments to the Act were successfully implemented and are operating as intended. The report also noted that there is a general consensus within the cotton industry that the Cotton Research and Promotion Program and the 1990 amendments to the Act are operating as intended. Written comments, economic data, and results from independent evaluations support this conclusion.

Although USDA found no compelling reason to conduct a referendum regarding the 1990 Act amendments to the Cotton Research and Promotion Order, some program participants support a referendum. Therefore, USDA will initiate a sign-up period in accordance with the Act. During this sign-up period, eligible producers and importers may sign-up to request such a referendum through USDA, or by

mailing such a request. The Secretary will conduct a referendum if requested by 10 percent or more of the number of cotton producers and importers voting in the most recent referendum (July 1991), with not more than 20 percent of such request from producers in one state or importers of cotton.

Current procedures for the conduct of a sign-up period appear at 7 CFR 1205.10–1205.30. These procedures will be updated as appropriate prior to the beginning of the sign-up period.

Authority: 7 U.S.C. 2101–2118.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–27877 Filed 12–17–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc No. AMS–FGIS–20–0061]

Mycotoxin Test Kit Design Specifications and Performance Criteria

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) evaluates the conformance of mycotoxin test kits to AMS-established design specifications and performance criteria. Only test kits that conform to all of the AMS requirements are approved for the official testing of grains and related commodities. AMS proposes to make several changes to the existing test kit criteria to improve testing services and better facilitate domestic and international trade. AMS is seeking public comment on the proposed changes to the criteria.

DATES: Comments are due by January 19, 2021.

ADDRESSES: The current criteria documents subject to the changes in this notice are available for review at *https://www.ams.usda.gov/services/fgis/standardization/tke.* Additional technical information regarding the proposed changes can be found at *https://www.ams.usda.gov/sites/default/files/media/technical-doc-frn-ams-fgis-20-0061.pdf.*

To submit Comments: Go to *Regulations.gov* (*http://www.regulations.gov*). Instructions for submitting and reading comments are detailed on the site. Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at *http://www.regulations.gov* and should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Thomas A. Weber, Analytical Chemistry Branch Chief, Technology and Science Division, Federal Grain Inspection Service, AMS, USDA, 816–891–0449, *Thomas.A.Weber@usda.gov.*

SUPPLEMENTARY INFORMATION: Mycotoxins are toxic chemicals produced by certain fungal species under favorable environmental conditions. Regulators have set maximum allowable concentration levels for specific mycotoxins in food and feed to ensure the safety of consumers. Mycotoxin levels are a critical factor in the trade of grain and quantitative mycotoxin testing is an integral part of buyer-seller contract specifications.

Under the authority of the United States Grains Standards Act (7 U.S.C. 71–87k), as amended, and the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, AMS provides official mycotoxin testing services throughout the United States for domestic and export grains, oilseeds, and processed-grain commodities. Official testing services are provided for aflatoxins, deoxynivalenol, fumonisins, ochratoxin A, and zearalenone. Testing at field locations requires rapid, inexpensive, and accurate methods to effectively assess US grain quality. An essential part of ensuring the quality of official mycotoxin testing is the AMS test kit evaluation program, through which test kits are evaluated and certified for conformance to specific criteria. Only test kits having AMS certification are approved for official mycotoxin testing.

AMS establishes the test kit performance criteria and periodically updates them to improve testing accuracy and to meet the official mycotoxin testing program's operational needs. AMS last updated the criteria in 2016. AMS proposes to update the test kit performance criteria with the following changes in 2021. AMS is seeking comments on the impact of making these changes.

Minimum Ranges of Conformance

For each mycotoxin, AMS has established a minimum range of concentrations that must be covered in the test kit's scope. The test kit must conform to the AMS accuracy requirements throughout this range. AMS proposes to expand the minimum ranges of conformance for fumonisins, ochratoxin A, and zearalenone test kits to meet the current and anticipated testing needs of the grain industry.

The US Food and Drug Administration has set the highest industry guidance level for fumonisins in corn at 100 parts-per-million (ppm). As a result, AMS proposes to expand the current minimum range of conformance from 0.50–30 ppm to 0.50–100 ppm so that it includes this highest guidance level.

Since the measurement of mycotoxin concentrations is not exact, multiple measurements will have results that vary by some amount. To ensure a mycotoxin concentration is below the maximum level allowed, there is a need to measure sufficiently below that level, considering the expected variation in results. For this reason, AMS proposes to expand the minimum ranges of conformance for ochratoxin A and zearalenone test kits to lower concentrations than currently required.

Codex Alimentarius, an internationally recognized food safety standard setting body, recommends a maximum of 5 parts-per-billion (ppb) ochratoxin A in wheat, barley, and rye. Therefore, AMS proposes to expand the minimum range of conformance for ochratoxin A from 5.0–100 ppb to 1.0–100 ppb. AMS is interested in comments on whether the maximum conformance limit should also be changed from 100 ppb to 20 ppb, resulting in a narrower minimum range of conformance (*i.e.,* 1.0–20 ppb).

International regulators, including the European Union (EU) have established maximum levels for zearalenone at 100 ppb in cereals and other grains. To test sufficiently below this regulatory limit, AMS proposes to expand the minimum range of conformance from 100–1000 ppb to 20–1000 ppb.

Evaluation of Mycotoxin Test Kit Accuracy

To evaluate test kit accuracy, AMS requires analyses of reference materials to be performed at different concentrations across the range of conformance. At least 95% of these individual results must be within the acceptable range for each of the tested concentrations to meet AMS accuracy requirements. AMS proposes to change

the way the acceptable ranges are calculated to align with international standards for evaluating method performance. Tables 1–5 compare the current acceptable ranges with the revised ranges based on the proposed method. The actual ranges may differ slightly from the listed ones, because results from the certification of reference materials would be included in determining the ranges. The proposed change will require greater accuracy from the test kits. Test kit manufacturers and other interested parties are encouraged to review the additional technical information, which serves as the basis for these changes at *https://www.ams.usda.gov/sites/default/files/media/technical-doc-frn-ams-fgis-20-0061.pdf.*

TABLE 1—AFLATOXINS

Aflatoxins (ppb)	Acceptable range (ppb)	
	Current	Proposed
5.0	2.5–7.5	3.5–6.5
20	12–28	14–26
100	68–130	69–130
300	200–400	220–380

TABLE 2—DEOXYNIVALENOL

Deoxynivalenol (ppm)	Acceptable range (ppm)	
	Current	Proposed
0.50	0.30–0.70	0.38–0.62
2.0	1.5–2.5	1.6–2.4
5.0	4.0–6.0	4.1–5.9
30	24–36	26–34

TABLE 3—FUMONISINS

Fumonisins (ppm)	Acceptable range (ppm)	
	Current	Proposed
0.50	0.32–0.68	0.38–0.62
2.0	1.4–2.6	1.6–2.4
5.0	3.7–6.3	4.1–5.9
30	22–38	26–34
100	74–130	89–110

TABLE 4—OCHRATOXIN A

Ochratoxin A (ppb)	Acceptable range (ppb)	
	Current	Proposed
1.0		0.69–1.3
5.0	3.0–7.0	3.5–6.5
20	12–28	14–26
100	60–140	69–130

TABLE 5—ZEARALENONE

Zearalenone (ppb)	Acceptable range (ppb)	
	Current	Proposed
20		14–26
100	50–150	69–130
250	150–350	180–320
1000	600–1400	780–1200

Number of Readers

Mycotoxin concentrations are determined by an electronic instrument, often referred to as a ''reader'' by test kit manufacturers and users. AMS has observed variation in test results during side-by-side comparisons of identical reader models. Therefore, AMS proposes to use three separate readers during the evaluation process.

Test Kit Manufacturer Analysts

AMS proposes to update the criteria documents to allow up to two analysts from the test kit manufacturer to participate in the performance verification study conducted at the AMS facility. Participation by the test kit manufacturer promotes transparency and trust in the program.

Extraction Method

Each mycotoxin has one or two primary grains, which must be included in the scope of the test kit. AMS identifies a primary grain based on the known occurrence of the mycotoxin and the frequency of official testing requests. Table 6 shows the list of primary grains by mycotoxin.

TABLE 6—LIST OF PRIMARY GRAINS BY MYCOTOXIN

Mycotoxin	Primary Grain(s)
Aflatoxins	Corn
Deoxynivalenol	Corn and Wheat
Fumonisins	Corn
Ochratoxin A	Wheat
Zearalenone	Corn

Any other commodities for which a manufacturer seeks test kit approval are referred to as ''additional commodities.'' AMS requires the use of naturally contaminated samples to evaluate test kit accuracy for the primary grain, but allows artificial fortification through the addition of standard solutions for additional commodity samples. A standard solution is a known amount of the mycotoxin dissolved in a solvent. AMS proposes to require that the extraction method used for the primary grain(s) be the same extraction method used for additional commodities. This change would provide evidence that the method can generate accurate results for both naturally contaminated grain and artificially contaminated commodities.

Update Criteria Issuance and Conformance

AMS proposes to issue the updated performance criteria within six months after the end of the comment period. Test kit submissions received more than one year after issuing the new criteria would be required to meet the new performance criteria to earn a certificate of conformance. During the transition year, manufacturers could choose to submit under the old or new criteria. However, certificates of conformance granted under the old performance criteria would expire after one year. In contrast, those granted under the new performance criteria would expire after three years. The expiration dates for existing certificates of conformance would not be affected.

Authority: 7 U.S.C. 71–87k; 7 US C 1621–1627

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–27850 Filed 12–17–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Generic Clearance for the Special Nutrition Programs Quick Response Surveys (SNP QRS)

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a revision of a currently approved collection to conduct short, quick-turnaround surveys of State and local agencies providing food, education, and other services in the Child Nutrition and Supplemental Nutrition and Safety Programs administered at the federal level by the Food and Nutrition Service (FNS). These programs include the Special Supplemental Nutrition Program for Women, Infants, and Children; National School Lunch Program; School Breakfast Program; Special Milk Program; Fresh Fruit and Vegetable Program; Summer Food Service Program; Child and Adult Care Food Program; USDA Foods in Schools;

Food Distribution Program on Indian Reservations; The Emergency Food Assistance Program; and the Commodity Supplemental Food Program.

DATES: Written comments must be received on or before February 16, 2021.

ADDRESSES: Comments may be submitted via email to *amy.rosenthal@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Amy Rosenthal at 703–305–2017 or *amy.rosenthal@usda.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Generic Clearance for the Special Nutrition Programs Quick Response Surveys (SNP QRS).

Form Number: N/A.

OMB Number: 0584–0613.

Expiration Date: 2/28/21.

Type of Request: Revision of a currently approved collection.

Abstract: The Food and Nutrition Service (FNS) intends to request approval from the Office of Management and Budget (OMB) for a generic clearance that will allow FNS to conduct short, quick-turnaround surveys of State, local, and Tribal agencies and businesses that receive food, funds, and nutrition information through the Child Nutrition and Supplemental Nutrition and Safety Programs.

These programs include the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); National School Lunch Program (NSLP); School Breakfast Program (SBP); Special Milk Program; Fresh Fruit and Vegetable Program (FFVP); Summer Food Service Program (SFSP); Child and Adult Care Food Program (CACFP); USDA Foods in Schools; Food Distribution Program on Indian Reservations (FDPIR); The Emergency Food Assistance Program (TEFAP); and the Commodity Supplemental Food Program (CSFP).

The Healthy Hunger-Free Kids Act of 2010 (Pub. L. 111–296, Sec. 305) mandates programs under its authorization to cooperate with USDA program research and evaluation activities. Traditionally, FNS conducts large, program-specific studies to collect information on numerous features of each program. Such studies often take several years to complete. Quick response surveys provide a system for rapidly collecting current information on a specific feature or issue, and, therefore, enable FNS to administer the programs more effectively.

The data collection activities under this clearance will include: (1) An annual sample frame data collection and (2) quick-response surveys. The annual sample frame data collection will request contact information from the States for the local agencies within their purview. The quick-response survey data collections will be used to survey key administrators of the SNP at the State, local, and site level to answer policy and implementation questions.

Following standard OMB requirements, FNS will submit a change request to OMB for each data collection activity undertaken under this generic clearance. The respondents will be identified at the time that each change request is submitted to OMB. FNS will provide OMB with the instruments and supporting materials describing the research project and specific pre-testing activities.

This revision makes minor changes to the information collection as originally approved. The USDA Foods in Schools program is included as a separate program, and minor updates to the sample sizes reflect the most recent estimates of the number of State, Local and Tribal agencies and businesses involved in the programs and the distribution of local-level providers between government agencies and businesses. The type of information to be collected, the methods of collection, and the frequency of collection will remain the same; however, we have removed references to reminder emails from the burden table. The estimated number of total responses has decreased from 83,582 (250,745 over three years) to 36,515 (109,545 over three years), and the total burden hours estimate has decreased from 11,508 (34,523 hours over three years) to 10,288 (30,864 hours over 3 years).

Affected Public: State, Local and Tribal Governments and Businesses. State, Local and Tribal government respondents will include: (1) State Program Directors, including WIC State Agency directors and nutrition education and breastfeeding coordinators, directors of the Child Nutrition programs (NSLP, SBP, FFVP, SFSP, CACFP), directors of State Distributing Agencies (CSFP, TEFAP, USDA Foods in Schools), and FDPIR State Agencies and Indian Tribal Organizations; and (2) local-level program administrators, including Local WIC Agencies and Sites, School Food Authorities (SFAs), Schools, SFSP Sponsors and Sites, USDA Foods in Schools Local Agencies and Providers, TEFAP Eligible Recipient Agencies (ERAs) and Emergency Food Organizations (EFOs), and CSFP Local Agencies. Business respondents will include not-for-profit local WIC Sites, not-for-profit SFSP Sponsors and Sites, for-profit and not-for-profit CACFP Sponsors and Providers, not-for-profit TEFAP ERAs and EFOs, and not-for-profit CSFP Local Agenices.

Estimated Number of Respondents: The total estimated number of annual respondents is 35,999. This includes all State Program Directors (516 total) and a sample of local-level program administrators from local government agencies (17,203 total) and businesses (18,280 total). The total number of respondents includes 7,097 local program administrators from both local agencies (3,441 total) and businesses (3,656 total) whom FNS expects will not respond to the QRS survey request.

Estimated Number of Responses per Respondent: Once per year, each State agency responsible for a program will be asked to provide contact information for their respective local agencies as part of the sample frame data collection. State agencies will also be asked to complete up to one survey per year for each program it oversees. Local agencies and businesses will be asked to complete up to one survey per year for each program they operate. FNS estimates that respondents will average 1.02 responses per year (29,418 responses/28,902 respondents), with non-respondents averaging one response per year. Across all participants (respondents and non-respondents combined) the estimated average number of responses per year is approximately 1.01 (36,515 responses/35,999 total respondents).

Estimated Total Annual Responses: The estimated total annual responses is 36,515, for a total of 109,545 responses over all three years.

Estimated Time per Response: The estimated time of response ranges from 20 minutes (.33 hours) to 1 hour for respondents and 1 minute (.02 hours) for non-respondents, depending on the data collection activity, as shown in the table below. The average estimated time across all responses is approximately 17 minutes (0.28 hours).

Estimated Total Annual Burden on Respondents: The estimated total annual burden is 10,288 hours, for a total of 30,864 over all three years. See the table below for estimated total annual burden for each type of respondent.

				Responsive					Non-Responsive					All		
	Type of respondent	Instrument	Sample Size	Number of respondents	Frequency of Response	Total Annual Responses	Hours per response	Annual burden (hours)	Number of Non-respondents	Frequency of Response	Total Annual Responses	Hours per response	Annual burden (hours)	Total Annual Responses	Hours per response	Total Annual Burden Estimate (hours)
State Agencies	WIC State Agency	Contact Info Request	89	89	1	89	1	89.0	0	0	0	0	0	89	1.00	89.0
		QRS Survey	89	89	1	89	0.33	29.7	0	0	0	0	0	89	0.33	29.7
	NSLP/SBP/FFVP State Agency	Contact Info Request	56	56	1	56	1	56.0	0	0	0	0	0	56	1.00	56.0
		QRS Survey	56	56	1	56	0.33	18.7	0	0	0	0	0	56	0.33	18.7
	SFSP State Agency	Contact Info Request	54	54	1	54	1	54.0	0	0	0	0	0	54	1.00	54.0
		QRS Survey	54	54	1	54	0.33	18.0	0	0	0	0	0	54	0.33	18.0
	CACFP State Agency	Contact Info Request	54	54	1	54	1	54.0	0	0	0	0	0	54	1.00	54.0
		QRS Survey	54	54	1	54	0.33	18.0	0	0	0	0	0	54	0.33	18.0
	Type of respondent	Instrument	Sample Size	Number of respondents	Frequency of Response	Total Annual Responses	Hours per response	Annual burden (hours)	Number of Non-respondents	Frequency of Response	Total Annual Responses	Hours per response	Annual burden (hours)	Total Annual Responses	Hours per response	Total Annual Burden Estimate (hours)
	TEFAP State Agency	Contact Info Request	55	55	1	55	1	55.0	0	0	0	0	0	55	1.00	55.0
		QRS Survey	55	55	1	55	0.33	18.4	0	0	0	0	0	55	0.33	18.4
	FDPIR State Agency/ITO	Contact Info Request	105	105	1	105	1	105.0	0	0	0	0	0	105	1.00	105.0
		QRS Survey	105	105	1	105	0.33	35.1	0	0	0	0	0	105	0.33	35.1
	USDA Foods in Schools State Agency	Contact Info Request	52	52	1	52	1	52.0	0	0	0	0	0	52	1.00	52.0
		QRS Survey	52	52	1	52	0.33	17.4	0	0	0	0	0	52	0.33	17.4
	CSFP State Agency	Contact Info Request	51	51	1	51	1	51.0	0	0	0	0	0	51	1.00	51.0
		QRS Survey	51	51	1	51	0.33	17.0	0	0	0	0	0	51	0.33	17.0
	State Agencies Sub-Total		516	516	2	1,032	0.67	688	0	0	0	0.00	0.00	1,032	0.67	688.3

Local Agencies	Local WIC Agency	QRS Survey	1,196	956	1	956	0.33	319.4	239	1	239	0.02	4.0	1,196	0.27	323.4
	Local WIC Site	QRS Survey	2,750	2,200	1	2,200	0.33	734.8	550	1	550	0.02	9.2	2,750	0.27	744.0
	SFA (NSLP/SBP/FFVP)	QRS Survey	2,500	2,000	1	2,000	0.33	668.0	500	1	500	0.02	8.4	2,500	0.27	676.4
	School (NSLP/SBP/FFVP)	QRS Survey	2,500	2,000	1	2,000	0.33	668.0	500	1	500	0.02	8.4	2,500	0.27	676.4
	SFSP Sponsor	QRS Survey	1,313	1,050	1	1,050	0.33	350.7	263	1	263	0.02	4.4	1,313	0.27	355.1
	SFSP Site	QRS Survey	1,838	1,470	1	1,470	0.33	491.0	368	1	368	0.02	6.1	1,838	0.27	497.1
	TEFAP ERA	QRS Survey	90	72	1	72	0.33	24.0	18	1	18	0.02	0.3	90	0.27	24.3
	TEFAP EFO	QRS Survey	525	420	1	420	0.33	140.3	105	1	105	0.02	1.8	525	0.27	142.0
	USDA Foods in Schools Local Agency	QRS Survey	1,875	1,500	1	1,500	0.33	501.0	375	1	375	0.02	6.3	1,875	0.27	507.3
	USDA Foods in Schools Provider	QRS Survey	2,250	1,800	1	1,800	0.33	601.2	450	1	450	0.02	7.5	2,250	0.27	608.7
	CSFP Local Agency	QRS Survey	368	294	1	294	0.33	98.2	74	1	74	0.02	1.2	368	0.27	99.5
	Local Agencies Sub-Total		17,203	13,762	1	13,762	0.33	4,596.7	3,441	1	3,441	0.02	57.5	17,203	0.27	4,654.1
	Type of respondent	**Instrument**	**Sample Size**	**Number of respondents**	**Frequency of Response**	**Total Annual Responses**	**Hours per response**	**Annual burden (hours)**	**Number of Non-respondents**	**Frequency of Response**	**Total Annual Responses**	**Hours per response**	**Annual burden (hours)**	**Total Annual Responses**	**Hours per response**	**Total Annual Burden Estimate (hours)**
	Local WIC Site	QRS Survey	399	319	1	319	0.33	106.5	80	1	80	0.02	1.3	399	0.27	107.8
	SFSP Sponsor	QRS Survey	563	450	1	450	0.33	150.3	113	1	113	0.02	1.9	563	0.27	152.2
	SFSP Site	QRS Survey	788	630	1	630	0.33	210.4	158	1	158	0.02	2.6	788	0.27	213.1
	CACFP Sponsor	QRS Survey	4,262	3,410	1	3,410	0.33	1,138.8	852	1	852	0.02	14.2	4,262	0.27	1153.0
	CACFP Provider	QRS Survey	8,489	6,791	1	6,791	0.33	2,268.3	1,698	1	1,698	0.02	28.4	8,489	0.27	2296.6
	TEFAP ERA	QRS Survey	210	168	1	168	0.33	56.1	42	1	42	0.02	0.7	210	0.27	56.8
	TEFAP EFO	QRS Survey	2,100	1,680	1	1,680	0.33	561.1	420	1	420	0.02	7.0	2,100	0.27	568.1
	CSFP Local Agency	QRS Survey	1,470	1,176	1	1,176	0.33	392.9	294	1	294	0.02	4.9	1,470	0.27	397.8
	Businesses Sub-Total		18,280	14,624	1	14,624	0.33	4,884	3,656	1	3,656	0.02	61	18,280	0.27	4,945
	TOTAL*		**35,999**	**28,902**	**1.02**	**29,418**	**0.35**	**10,169**	**7,097**	**1.00**	**7,097**	**0.02**	**119**	**36,515**	**0.28**	**10,288**

* Totals may not add up due to rounding.

Pamilyn Miller,

Administrator, Food and Nutrition Service.

[FR Doc. 2020–27834 Filed 12–17–20; 8:45 am]

BILLING CODE 3410–30–C

DEPARTMENT OF AGRICULTURE

Forest Service

Forest Service Manual 2420, ''Timber Appraisal,'' Forest Service Handbook 2409.19, ''Renewable Resources,'' Chapters 10, 20, 30, 60 and 80

AGENCY: Forest Service, USDA.

ACTION: Notice of availability for public comment.

SUMMARY: The United States Department of Agriculture (USDA), United States Forest Service (Forest Service), is revising directives related to timber appraisal and renewable resources.

DATES: Comments must be received in writing by February 16, 2021.

ADDRESSES: Comments may be submitted electronically to *https://cara.ecosystem-management.org/Public/CommentInput?project=ORMS-2747.* Written comments may be mailed to Dave Wilson, Acting Assistant Director, Forest Management, Range and Vegetation Ecology, 201 14th Street SW, Washington, DC 20024. All timely received comments, including names and addresses, will be placed in the record and will be available for public inspection and copying. The public may inspect comments received at *https://cara.ecosystem-management.org/Public/ReadingRoom?project=ORMS-2747.*

FOR FURTHER INFORMATION CONTACT: Dave Wilson, Acting Assistant Director, Forest Management, Range and Vegetation Ecology, at 202–578–9916 or by electronic mail to *david.wilson@usda.gov.* Individuals using telecommunication devices for the deaf may call the Federal Information Relay Service at 800–877–8339 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The proposed directives reorganize and eliminate redundant policies and procedures, delete obsolete references and update agency policies and procedures to reflect new authorities and timber management practices that have been implemented since previous revisions to the directives were made available. An analysis of existing agency policy in Forest Service Handbooks and Manuals was conducted to identify revisions needed to support this initiative.

The proposed directives update Forest Service Manual 2420, ''Timber Appraisal'', Forest Service Handbook 2409.19, ''Renewable Resources'' Chapters 10, 20, 30, 60 and add a new Chapter 80 ''Good Neighbor Authority'' in Forest Service Handbook 2409.19, ''Renewable Resources''. These directives set forth policy, responsibilities, and direction for several aspects of management and implement the agency's goal of providing more current direction.

The Forest Service has determined that the changes to the manual and handbook formulate standards, criteria, or guidelines applicable to a Forest Service program and are therefore publishing the proposed manual and handbook for public comment in accordance with 36 CFR part 216. The Forest Service is seeking public comment on the proposed directives, including the sufficiency of the proposed directives in meeting the stated objectives, ways to enhance the utility and clarity of information within the direction, or ways to streamline processes outlined.

Forest Service National Environmental Policy Act procedures exclude from documentation in an environmental assessment or impact statement ''rules, regulations, or policies to establish service wide administrative procedures, program processes, or instructions.'' 36 CFR 220.6(d)(2). The Agency's conclusion is that these proposed directives fall within this category of actions and that no extraordinary circumstances exist as currently defined that require preparation of an environmental assessment or an environmental impact statement.

After the public comment period closes, the Forest Service will consider timely comments that are within the scope of the proposed directive in the development of the final directive. A notice of the final directive, including a response to timely comments, will be posted on the Forest Service's web page at *https://www.fs.fed.us/about-agency/regulations-policies/comment-on-directives.*

Tina Johna Terrell,

Associate Deputy Chief,National Forest System.

[FR Doc. 2020–27949 Filed 12–17–20; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Forest Service Manual 2200, Chapters Zero, 10, 20, 30, 40, 50 and 70; Forest Service Handbook 2209.13, Chapters 10, 20, 30, 40, 50, 60, 70, 80 and 90; and Forest Service Handbook 2209.16, Chapter 10; Rangeland Management; Public Notice and Comment for Changes to Forest Service Directives

AGENCY: Forest Service, USDA.

ACTION: Issuance of proposed directives; notice of availability for public comment.

SUMMARY: The United States Department of Agriculture (USDA), United States Forest Service (Forest Service), is publishing for public comment proposed revisions to directives governing rangeland management, grazing permit administration, and grazing allotment administration.

DATES: Comments must be received in writing by February 16, 2021.

ADDRESSES: Comments may be submitted electronically to *https://cara.ecosystem-management.org/Public/CommentInput?project=ORMS-2514.* Written comments may be mailed to U.S. Forest Service, Director, Forest Management, Range Management and Vegetation Ecology, 201 14th Street SW, Washington, DC 20250–1124. All timely received comments, including names and addresses, will be placed in the record and will be available for public inspection and copying. The public may inspect comments received at *https://cara.ecosystemmanagement.org/Public/ReadingRoom?project=ORMS-2514.*

FOR FURTHER INFORMATION CONTACT: Myra Black, Program Manager, Forest Management, Range Management and Vegetation Ecology, at 202–650–7365, or by electronic mail to *myra.black@usda.gov.* Individuals using telecommunication devices for the deaf may call the Federal Information Relay Service at 800–877–8339 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The directives proposed for revision are the primary source of administrative direction to Forest Service employees regarding the rangeland management program and have been in place for approximately 30 years. The proposed revisions would make the directives easier to use, current, and consistent with recent legislation. The updates would provide greater management flexibility and would enhance the clarity of policies and procedures

applicable to the rangeland management program.

The proposed directives would update Forest Service Manual 2200, Rangeland Management, Chapters Zero, 10, 20, 30, 40, 50 and 70; Forest Service Handbook (FSH) 2209.13, Grazing Permit Administration, Chapters 10, 20, 30, 40, 50, 60, 70, 80 and 90; and FSH 2209.16, Allotment Administration, Chapter 10. Some of the proposed revisions to the directives formulate standards, criteria, or guidelines applicable to the rangeland management program and are therefore subject to public notice and comment per 36 CFR part 216. Other proposed revisions do not require public notice and comment under 36 CFR part 216 because they do not formulate standards, criteria, and guidelines applicable to the rangeland management program. Examples include revisions to conform to recent legislation and clarifying changes such as modifying terminology. These proposed revisions are interspersed throughout the chapters and are not specifically identified in the directives posted on the Agency's website. The Forest Service is publishing all of the proposed revisions for public comment. Forest Service National Environmental Policy Act (NEPA) procedures exclude from documentation in an environmental assessment or impact statement ''rules, regulations, or policies to establish servicewide administrative procedures, program processes, or instructions.'' 36 CFR 220.6(d)(2). The Agency's conclusion is that these proposed directives fall within this category of actions and that no extraordinary circumstances exist as currently defined that require preparation of an environmental assessment or an environmental impact statement.

The proposed directives and additional information on the proposed directives can be found at *https://www.fs.fed.us/rangeland-management/directives.shtml.* The additional information describes the purpose of the directives and why they are being updated and includes documents that will assist with review of the proposed directives and a schedule of informational webinars on the proposed directives.

After the public comment period closes, the Forest Service will consider timely and relevant comments in the development of the final directives. A notice of the final directives, including a response to timely and relevant comments, will be posted on the Forest Service's web page at *https://www.fs.fed.us/about-agency/regulations-policies/comment-on-directives.*

Tina Johna Terrell,

Associate Deputy Chief, National Forest System.

[FR Doc. 2020–27945 Filed 12–17–20; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the South Carolina Advisory Committee; Cancellation

AGENCY: Commission on Civil Rights.

ACTION: Notice; cancellation of meeting.

SUMMARY: The Commission on Civil Rights published a notice in the **Federal Register** concerning a meeting of the South Carolina Advisory Committee. The meeting scheduled for Wednesday, December 16, 2020 at 12:00 p.m. (EST) is cancelled. The notice is in the **Federal Register** of Tuesday, December 1, 2020, in FR Doc. 2020–26428, on page 77145.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez, (202) 618–4158, *bdelaviez@usccr.gov*.

Dated: December 14, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–27864 Filed 12–17–20; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Rhode Island Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the Rhode Island State Advisory Committee to the Commission will convene a meeting on January 13, 2021 at 12:00 p.m. (ET). The purpose of the meeting is to discuss the Committee's draft memo on licensing for formerly incarcerated individuals in Rhode Island.

DATES: Wednesday, January 13, 2021 at 12:00 p.m. (ET).

ADDRESSES: Public Web Conference Registration Link (video and audio): *https://tinyurl.com/RISACJan13.*

FOR FURTHER INFORMATION CONTACT: Mallory Trachtenberg at *mtrachtenberg@usccr.gov* or by phone at (202) 809–9618.

SUPPLEMENTARY INFORMATION: The meeting is available to the public through the web link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing. may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with conference details found through registering at the web link above.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Mallory Trachtenberg at *mtrachtenberg@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Wednesday, January 13, 2021 from 12 p.m. (ET)

I. Welcome and Roll Call
II. Announcements and Updates
III. Approval of Minutes
IV. Draft Memo Discussion: Licensing for Formerly Incarcerated Individuals in Rhode Island
V. Public Comment
VI. Next Steps
VII. Adjournment

Dated: December 15, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–27953 Filed 12–17–20; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Minnesota Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules

and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Minnesota Advisory Committee (Committee) will hold a meeting via the online platform WebEx on Tuesday, January 5, 2021 at 12:00 p.m. Central Time. The purpose of the meeting is to discuss civil rights concerns in the state.

DATES: The meeting will be held on:

- Monday, January 05, 2021, at 12:00 p.m. Central Time—*https://civilrights.webex.com/civilrights/j.php?MTID=m9d809654a21ba6fdba4a642c2ebbc6df.*

Join by phone, 800–360–9505 USA Toll Free, Access code: 199 855 7308.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 499–4066.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individual who is deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Minnesota Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Chair's Comments
III. Committee Discussion
IV. Public Comment
VI. Adjournment

Dated: December 15, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–27956 Filed 12–17–20; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting via Webex of the Arizona Advisory Committee (Committee) to the Commission will be held at 1:00 p.m. (Mountain Time) Tuesday, February 9, 2021 for the purpose of discussing the testimony received on the effects of COVID–19 on the Native American community.

DATES: The meeting will be held on Tuesday, February 9, 2021 at 1:00 p.m. Mountain Time.

Access Information: Register at: https://tinyurl.com/y2phyj2m.

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer, (DFO) at *bpeery@usccr.gov* or by phone at (202) 701–1376. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl2AAA.* Please click on the ''Committee Meetings'' tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Approval of Minutes
III. Discussion on Testimony
IV. Public Comment
V. Adjournment

Dated: December 14, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–27870 Filed 12–17–20; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that the Arizona Advisory Committee (Committee) to the Commission will hold a series of meetings via Webex on Tuesday, January 12, Tuesday, January 19, and Tuesday, January 26, Tuesday, February 2, 2021 at 1:00 p.m. Mountain Time for the purpose of gathering testimony regarding the effects of COVID–19 on Native American Communities.

DATES: The meetings will be held on:

- Tuesday, January 12, 2021 from 1:00 p.m.–3:00 p.m. Mountain Time
- Tuesday, January 19, 2021 from 1:00 p.m.–3:00 p.m. Mountain Time
- Tuesday, January 26, 2021 from 1:00 p.m.–3:00 p.m. Mountain Time
- Tuesday, February 2, 2021 from 1:00 p.m.–3:00 p.m. Mountain Time

Access Information

Panel 1—Researchers and Academics

Tuesday, January 12th at 1:00 p.m. MT—Register at: https://tinyurl.com/y6cvbfpk

Panel 2—Advocates and Frontline Workers

Tuesday, January 19th at 1:00 p.m. MT—Register at: https://tinyurl.com/yxhstzk8

Panel 3—Healthcare Providers and Public Health Experts

Tuesday, January 26th at 1:00 p.m. MT—Register at: https://tinyurl.com/y22b8lhr

Panel 4—Government Officials

Tuesday, February 2nd at 1:00 p.m. MT—Register at: https://tinyurl.com/y4fartu5

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer, (DFO) at *bpeery@usccr.gov* or by phone at (202) 701–1376.

SUPPLEMENTARY INFORMATION: Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl2AAA.*

Please click on the ''Committee Meetings'' tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Opening Remarks
II. Panelist Testimony
III. Committee Q&A
IV. Public Comment
V. Adjournment

Dated: December 14, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–27868 Filed 12–17–20; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Virginia Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Virginia Advisory Committee (Committee) will hold a meetings via Webex on Monday, January 11, 2021 at 11:00 a.m. Eastern Time. The purpose of the meeting is the Committee will discuss civil rights concerns in the state.

DATES: The meetings will be held on:

- Monday, January 11, 2021, at 11:00 a.m. Eastern Time *https://civilrights.webex.com/civilrights/j.php?MTID=mcede57ade5d639be38fe98c2fbe81ea2.*

Join by phone: 8003609505 USA Toll Free, Access code: 199 783 5045.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call in number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individual who is deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Melissa Wojnaroski at *mwojnaroski@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Oklahoma Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. SAC Discussion
III. Committee Q & A
IV. Public Comment
VI. Adjournment

Dated: December 14, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–27845 Filed 12–17–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Economic Development Administration

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Information Collection: Form ED–209, Revolving Loan Fund Financial Report

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 21, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Economic Development Administration (EDA), Department of Commerce.

Title: Revolving Loan Fund (RLF) Financial Report.

OMB Control Number: 0610–0095.

Form Number(s): ED–209.

Type of Request: Extension of a currently approved information collection.

Number of Respondents: 1,700.

Average Hours per Response: 3 hours.

Burden Hours: 5,100 hours.

Needs and Uses: The EDA Revolving Loan Fund (RLF) Program, authorized under section 209 of the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3149), has served as an important pillar of EDA investment programs since the establishment of the RLF Program in 1975. The purpose of the RLF Program is to provide regions with a flexible and continuing source of capital, to be used with other economic development tools, for creating and retaining jobs and inducing private investment that will contribute to long-term economic stability and growth. EDA provides RLF grants to eligible recipients, which include State and local governments, Indian Tribes, and non-profit organizations, to operate a lending program that offers loans with flexible repayment terms, primarily to small businesses in distressed communities that are unable to obtain traditional bank financing. These loans enable small businesses to expand and lead to new employment opportunities that pay competitive wages and benefits.

RLF recipients must submit to EDA Form ED–209, RLF Financial Report, which collects limited performance information that EDA uses to oversee and monitor RLF grants (13 CFR 307.14(a)). EDA currently requires Form ED–209 to be submitted on an annual basis for high-performing RLFs and on a semi-annual basis for other RLFs.

EDA recently awarded numerous new RLF grants. This has increased the estimated number of respondents that will be required to submit Form ED–209 and the estimated number of burden hours associated with Form ED–209. On March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), appropriating $1,500,000,000 in supplemental funds to EDA to ''prevent, prepare for, and respond to coronavirus . . . including for necessary expenses for responding to economic injury as a result of coronavirus.'' EDA used a significant portion of those funds to fund RLF grants. As a result, the number of respondents required to submit Form ED–209 will increase substantially. Although Form ED–209 is being extended without change, and the estimated amount of time required to complete Form ED–209 remains unchanged at three hours, the estimated annual burden hours for Form ED–209 is increasing because of the increased number of RLF grants and respondents required to complete Form ED–209.

Affected Public: EDA RLF grant recipients: State and local governments, Indian Tribes, and non-profit organizations.

Frequency: Semi-annual and Annual.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0610–0095.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–27826 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–34–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 201214–0339]

RIN 0694–XC069

Notice of Termination National Security Investigation of Imports of Mobile Cranes

AGENCY: Office of Technology Evaluation, Bureau of Industry and Security, U.S. Department of Commerce.

ACTION: Notice of termination of investigation.

SUMMARY: In this notice, the Department is announcing that on November 23, 2020, the Secretary of Commerce terminated an investigation under section 232 of the Trade Expansion Act of 1962, as amended, which was initiated on May 19, 2020, to determine whether imports of mobile cranes threatened to impair the national security. Notice of the investigation and a request for public comments was published in the **Federal Register** on May 26, 2020. The investigation was originally requested in an application submitted by the Manitowoc Company, Inc. (''Manitowoc'') on December 19, 2019.

DATES: The investigation was terminated on November 23, 2020.

ADDRESSES: Documents related to this investigation are available through the Federal eRulemaking Portal: *https://www.regulations.gov* under docket number BIS–2020–0009.

FOR FURTHER INFORMATION CONTACT:

For questions regarding this notice, contact Erika Maynard, Industrial Studies Division, Office of Technology Evaluation, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482–0194, *Mobilecranes232@bis.doc.gov.* For more information about the section 232 program, including the regulations and the text of previous investigations, please see *www.bis.doc.gov/232.*

SUPPLEMENTARY INFORMATION:

Background

On November 23, 2020, the Secretary of Commerce terminated an investigation under section 232 of the Trade Expansion Act of 1962, as amended, which was initiated on May 19, 2020, to determine whether imports of mobile cranes threatened to impair the national security. Notice of the investigation and a request for public comments was published in the **Federal Register** on May 26, 2020 (85 FR 31439). The investigation was originally requested in an application submitted by the Manitowoc Company, Inc. (''Manitowoc'') on December 19, 2019.

On September 8, 2020, the Bureau of Industry and Security (BIS) received a formal request from Manitowoc to withdraw its application and terminate the investigation. Manitowoc stated that the current economic environment is very different from when Manitowoc submitted the application in December 2019, given the effects of the COVID–19 pandemic. The Secretary of Commerce has evaluated the request to withdraw and has determined that it is appropriate to terminate the investigation.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–27863 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–017]

Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission in Part, and Intent to Rescind in Part; 2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain producers/exporters of passenger vehicle and light truck tires (passenger tires) from the People's Republic of China (China) received countervailable subsidies during the period of review (POR) January 1, 2018 through December 31, 2018. Interested parties are invited to comment on these preliminary results.

DATES: Applicable December 18, 2020.

FOR FURTHER INFORMATION CONTACT: Jason Willoughby, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5509.

SUPPLEMENTARY INFORMATION:

Background

On October 7, 2019, Commerce published a notice of initiation of an administrative review of the countervailing duty order on passenger tires from China.[1] On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[2] On June 18, 2020, Commerce extended the deadline for the preliminary results of this review by 117 days.[3] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[4] Accordingly, the deadline for the preliminary results of this review was postponed to December 15, 2020.

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5] A list of topics discussed in the Preliminary Decision Memorandum is included as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order[6]

The products covered by the *Order* are certain passenger vehicle and light truck tires from China. For a complete description of the scope, see the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. We received timely withdrawals of the requests for review, for which no other parties requested a review, for the following companies: Cooper (Kunshan) Tire Co., Ltd.; Haohua Orient International Trade Ltd.; Qingdao Keter International Co., Limited; Qingdao Lakesea Tyre Co., Ltd.; Qingdao Odyking Tyre Co., Ltd.; Qingdao Sentury Tire Co. Ltd.; Riversun Industry Limited; Safe & Well (HK) International Trading Limited; Shandong Guofeng Rubber Plastics Co., Ltd.; Shandong Hengyu Science & Technology Co., Ltd.; Shandong Linglong Tyre Co., Ltd.; Shandong New Continent Tire Co., Ltd.; Shandong Wanda Boto Tyre Co., Ltd.; Shandong Yongsheng Rubber Group Co., Ltd.; Shouguang Firemax Tyre Co., Ltd.; Windforce Tyre Co., Limited; and Zhaoqing Junhong Co., Ltd.[7] Therefore, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* with respect to these companies.

Intent to Rescind Administrative Review, in Part

It is Commerce's practice to rescind an administrative review of a countervailing duty order, pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.[8] Normally, upon completion of an administrative review, the suspended entries are liquidated at the countervailing duty assessment rate calculated for the review period.[9] Therefore, for an administrative review of a company to be conducted, there must be a reviewable, suspended entry that Commerce can instruct CBP to liquidate at the calculated countervailing duty

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 53411 (October 7, 2019). (*Initiation Notice*).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results,'' June 18, 2020.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China; and Rescission, in Part, 2018,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 47902 (August 10, 2015) (*Order*).

[7] *See* Haohua Orient International Trade Ltd., Qingdao Lakesea Tyre Co., Ltd., Riversun Industry Limited, Safe & Well (HK) International Trading Limited, and Windforce Tyre Co., Limited's Letter, ''Passenger Vehicle and Light Truck Tires from the People's Republic of China Withdrawal of Request for Review,'' dated October 9, 2019; Shandong Guofeng Rubber Plastics Co., Ltd.'s Letter, ''Passenger Vehicle and Light Truck Tires from People's Republic of China: Withdrawal of Request for Administrative Review,'' dated November 1, 2019; ITG Voma Corporation's Letter, ''Passenger Vehicle and Light Truck Tires from People's Republic of China: Withdrawal of Request for Administrative Review,'' dated November 1, 2019; Shandong New Continent Tire Co., Ltd., Qingdao Sentury Tire Co. Ltd., and Shandong Linglong Tyre Co., Ltd.'s Letter, ''New Continent, Sentury, & Linglong Withdrawal of Review Request in POR 4 of the Countervailing Duty Order on Passenger Vehicle and Light Truck Tires (''PVLT'') From the People's Republic of China (C–570–017),'' dated November 8, 2019; Zhaoqing Junhong Co., Ltd.'s Letter, ''Passenger Vehicle and Light Truck Tires from the People's Republic of China—Withdrawal of Request for Review,'' dated December 6, 2019; Cooper Tire & Rubber Company and its wholly-owned subsidiary, Cooper (Kunshan) Tire Co., Ltd.'s Letter, ''Passenger Vehicle And Light Truck Tires from the People's Republic of China: Withdrawal Of Request For 2018 Administrative Review Of CKT,'' dated December 23, 2019; Qindao Keter International Co., Limited, Qingdao Odyking Tyre Co., Ltd., Shandong Hengyu Science & Technology Co., Ltd., Shandong Yong Sheng Rubber Group Co., Ltd., and Shouguang Firemax Tyre Co., Ltd.'s Letter, ''Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China—Withdrawal of Request for Administrative Review,'' dated January 2, 2020; and Shandong Wanda Boto Tyre Co., Ltd.'s Letter ''Passenger Vehicle and Light Truck Tires from People's Republic of China: Withdrawal of Request for Administrative Review,'' dated January 6, 2020.

[8] *See, e.g., Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review;* 2015, 82 FR 14349 (March 20, 2017); *see also Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017,* 84 FR 14650 (April 11, 2019).

[9] *See* 19 CFR 351.212(b)(2).

assessment rate calculated for the review period.[10]

According to the CBP import data, three of the six companies subject to this review, which were not chosen as mandatory respondents and which did not withdraw their review requests, did not have reviewable entries of subject merchandise during the POR for which liquidation is suspended. Accordingly, in the absence of reviewable, suspended entries of subject merchandise during the POR by these three companies, we intend to rescind this administrative review, with respect to these three companies, in accordance with 19 CFR 351.213(d)(3).[11]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). In reaching these preliminary results, Commerce relied on facts otherwise available, with the application of adverse inferences.[12] For further information, *see* ''Use of Facts Otherwise Available and Application of Adverse Inferences'' in the accompanying Preliminary Decision Memorandum.

Preliminary Rate for Companies Not Selected for Individual Review

To determine the rate for companies not selected for individual examination in administrative reviews, Commerce's practice is to weight average the net subsidy rates for the selected mandatory companies, excluding rates that are zero, *de minimis,* or based entirely on facts available. In this review, we preliminarily calculated rates based entirely on facts available for each of the mandatory respondents during the POR. In countervailing duty administrative reviews, where the number of respondents being individually examined has been limited, Commerce has determined that a ''reasonable method'' to determine the rate applicable to companies that were not individually examined when all the rates of selected mandatory respondents are zero, *de minimis,* or based entirely on adverse facts available is to assign to the non-selected respondents the average of the most recently determined rates that are not zero, *de minimis,* or based entirely on facts available.[13] However, if a non-selected respondent has its own calculated rate that is contemporaneous with or more recent than such previous rates, Commerce has found it appropriate to apply that calculated rate to the non-selected respondent, even when that rate is zero or *de minimis.*[14]

With regard to the three remaining non-selected companies, which have no prior individual rates from prior segments, we are assigning the rate of 20.05 percent *ad valorem,* which is the average of the above-*de minimis* rates calculated in the last review.

Preliminary Results of Review

We preliminarily determine the following net countervailable subsidy rates for the period January 1, 2018 through December 31, 2018:

Producers/exporters	Subsidy rate (percent *ad valorem*)
Shandong Duratti Rubber Corporation Co. Ltd	116.50
Shandong Longyue Rubber Co. Ltd	116.50
Shandong Anchi Tyres Co., Ltd	116.50
Triangle Tyre Co. Ltd	116.50
Review-Specific Average Rate Applicable to the Following Companies:	
Jiangsu Hankook Tire Co., Ltd	20.05
Qingdao Fullrun Tyre Corp., Ltd	20.05
Shandong Province Sanli Tire Manufactured Co., Ltd	20.05

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of this review. For the companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2018 through December 31, 2018, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice.

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Public Comment

Interested parties may submit written comments (case briefs) on the preliminary results no later than 30 days from the date of publication of this **Federal Register** notice, and rebuttal comments (rebuttal briefs) within seven days after the time limit for filing case briefs. Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[15] All briefs must be filed electronically using ACCESS.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice. Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues addressed at the hearing will be limited to those raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.

[10] *See* 19 CFR 351.213(d)(3).

[11] These three companies are: Hankook Tire China Co., Ltd.; Qingdao Fullrun Tyre Tech Corp., Ltd.; and Qingdao Powerich Tyre Co., Ltd. Note that Qingdao Fullrun Tyre Tech Corp., Ltd. was incorrectly identified as Qingdao Fullrun Tech Tyre Corp., Ltd. in the *Initiation Notice.*

[12] *See* section 776 of the Act.

[13] *See, e.g., Circular Welded Carbon Steel Pipes and Tubes from Turkey: Final Results of Countervailing Duty Administrative Review; Calendar Year 2012 and Rescission of Countervailing Duty Administrative Review, in Part,* 79 FR 51140 (August 27, 2014); *see also Cut-to-Length Carbon-Quality Steel Plate from the Republic of Korea: Final Results of Countervailing Duty Administrative Review; 2012,* 79 FR 46770 (August 11, 2014), and accompanying Issues and Decision Memorandum at ''Non-Selected Rate.''

[14] *Id.*

[15] *See* 19 CFR 351.309(c)(2) and 351.309(d)(2).

An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[16]

Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1), unless this deadline is extended.

Notification to Interested Parties

These preliminary results and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: December 14, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Partial Rescission of Review
IV. Intent to Rescind Administrative Review, In Part
V. Rate for Non-Selected Companies Under Review
VI. Scope of the Order
VII. Use of Facts Otherwise Available and Application of Adverse Inferences
VIII. Conclusion

[FR Doc. 2020–27950 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–DS–P

[16] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements); *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19*, 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period*, 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

United States-Mexico-Canada Agreement (USMCA), Article 10.12; Binational Panel Review: Notice of Request for Panel Review

AGENCY: United States Section, USMCA Secretariat, International Trade Administration, Department of Commerce.

ACTION: Notice of USMCA Request for Panel Review in the matter of Certain Softwood Lumber Products from Canada: Final Affirmative Countervailing Duty Administrative Review, 2017–2018 (Secretariat File Number: USA–CDA–2020–10.12–01).

SUMMARY: A Request for Panel Review was filed on behalf of the Government of Canada, the Government of Alberta, the Government of British Columbia, the Government of New Brunswick, the Government of Ontario, the Government of Québec, Alberta Softwood Lumber Trade Council (''ASLTC''), British Columbia Lumber Trade Council (''BCLTC''), Conseil de l'Industrie forestiere du Québec (''CIFQ''), Ontario Forest Industries Association (''OFIA''), J.D. Irving, Limited (''JDI''), Resolute FP Canada Inc. (''Resolute''), and West Fraser Mills Ltd. with the United States Section of the USMCA Secretariat on December 10, 2020, pursuant to USMCA Article 10.12. Panel Review was requested of the U.S. International Trade Administration's Final Results of the Countervailing Duty Administrative Review (2017–2018) in Certain Softwood Lumber from Canada, which was published in the **Federal Register** on December 1, 2020 (85 FR 77, 163). The USMCA Secretariat has assigned case number USA–CDA–2020–10.12–01 to this request.

FOR FURTHER INFORMATION CONTACT: Vidya Desai, Acting United States Secretary, USMCA Secretariat, Room 2061, 1401 Constitution Avenue NW, Washington, DC 20230, 202–482–5438.

SUPPLEMENTARY INFORMATION: Article 10.12 of Chapter 10 of USMCA provides a dispute settlement mechanism involving trade remedy determinations issued by the Government of the United States, the Government of Canada, and the Government of Mexico. Following a Request for Panel Review, a Binational Panel is composed to review the trade remedy determination being challenged and issue a binding Panel Decision. There are established USMCA *Rules of Procedure for Article 10.12 (Binational Panel Reviews),* which were adopted by the three governments for panels requested pursuant to Article 10.12(2) of USMCA which requires Requests for Panel Review to be published in accordance with Rule 40. For the complete Rules, please see *https://can-mex-usa-sec.org/secretariat/agreement-accord-acuerdo/usmca-aceum-tmec/rules-regles-reglas/article-article-articulo_10_12.aspx?lang=eng.*

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 44 no later than 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is January 11, 2021);

(b) A Party, an investigating authority or other interested person who does not file a Complaint but who intends to participate in the panel review shall file a Notice of Appearance in accordance with Rule 45 no later than 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is January 25, 2021);

(c) The panel review will be limited to the allegations of error of fact or law, including challenges to the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and to the procedural and substantive defenses raised in the panel review.

December 14, 2020.

Vidya Desai,

Acting U.S. Secretary, USMCA Secretariat.

[FR Doc. 2020–27830 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–867]

Large Power Transformers From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review, 2018–2019; Preliminary Determination of No Shipments; and Preliminary Successor-in-Interest Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Hyosung Heavy Industries Corporation (Hyosung) made sales of subject merchandise at less than normal value during the period of review (POR), August 1, 2018 through July 31, 2019. Interested parties are invited to comment on these preliminary results.

DATES: Applicable December 18, 2020.

FOR FURTHER INFORMATION CONTACT: John Drury, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0195.

SUPPLEMENTARY INFORMATION:

Background

Commerce initiated this review on October 7, 2019.[1] We selected one mandatory respondent in this review, Hyosung. On April 24, 2020, Commerce

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 53411 (October 7, 2019).

exercised its discretion to toll all deadlines for administrative reviews conducted pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), by 50 days.[2] Additionally, on July 21, 2020, Commerce exercised its discretion to toll the deadlines for all preliminary and final results in administrative reviews conducted pursuant to section 751(a)(1) of the Act, by a total of 60 days.[3] For a more detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum, dated concurrently with these results and hereby adopted by this notice.[4]

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* A list of topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The scope of this order covers large liquid dielectric power transformers having a top power handling capacity greater than or equal to 60,000 kilovolt amperes (60 megavolt amperes), whether assembled or unassembled, complete or incomplete. The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States at subheadings 8504.23.0040, 8504.23.0080 and 8504.90.9540. This tariff classification is provided for convenience and Customs purposes; however, the written description of the scope of the order is dispositive.[5]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Determination of No Shipments

On October 23, 2019, LSIS Co., Ltd (LSIS) timely notified Commerce that it had no exports, sales, or entries of subject merchandise during the POR.[6] Commerce issued a no shipment inquiry to U.S. Customs and Border Protection (CBP), and CBP found no evidence of shipments from LSIS during the POR.[7] Thus, based on record evidence, we preliminary determine that LSIS had no shipments during the POR. Consistent with Commerce's practice, we find that it is not appropriate to rescind the review with respect to LSIS but, rather, to complete the review and issue appropriate instructions to CBP based on the final results of this review.[8]

Preliminary Results of Successor-in-Interest Analysis

On May 8, 2020, LS Electric Co., Ltd. (LS Electric) requested that Commerce initiate a successor-in-interest changed circumstances review, and also requested that Commerce combine the notice of initiation of a changed circumstances review with the preliminary results of review.[9] LS Electric stated that changed circumstances are sufficient to warrant such a review because LSIS had changed its name to LS Electric Co., Ltd., as of March 25, 2020.[10]

We are not initiating a separate changed circumstances review, but instead, evaluating LS Electric's request as part of this administrative review. Based on our analysis of the information on the record, we preliminarily determine that LS Electric is the successor-in-interest to LSIS. *See* the Preliminary Decision Memorandum for further information.

Preliminary Results of Review

We preliminarily determine that, for the period August 1, 2018 through July 31, 2019, the following weighted-average dumping margins exist:

Producer/exporter	Weighted-average dumping margin (percent)
Hyosung Heavy Industries Corporation	52.75
Hyundai Electric & Energy Systems Co., Ltd	52.75
Iljin Electric Co., Ltd	52.75
Iljin	52.75

Disclosure and Public Comment

Commerce will disclose to parties to the proceeding any calculations performed in connection with these preliminary results of review within five days after the date of publication of this notice.[11] Interested parties are invited to comment on these preliminary results. Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[12] Rebuttal briefs, the content of which is limited to the issues raised in the case briefs, must be filed within seven days from the deadline date for the submission of case briefs.[13]

Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[14] Case and rebuttal briefs should be filed using ACCESS.[15] Case and rebuttal briefs must be served on interested parties.[16] Executive summaries should be limited to five pages total, including footnotes.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a request to the Assistant Secretary for Enforcement and

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[4] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Large Power Transformers from the Republic of Korea; 2018–2019'' (Preliminary Decision Memorandum), dated concurrently with this notice.

[5] The full text of the scope of the order is contained in Preliminary Decision Memorandum.

[6] *See* Letter, ''Large Power Transformers from the Republic of Korea: LSIS Co., Ltd.'s No Shipment Letter,'' dated October 23, 2019.

[7] *See* Memorandum, ''Large Power Transformers from the Republic of Korea; 2018–2019 Administrative Review: No Shipment Inquiry with Respect to LSIS,'' dated November 21, 2019.

[8] *See, e.g., Certain Frozen Warmwater Shrimp From Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp From Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR 51306 (August 28, 2014); *Magnesium Metal From the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922, 26923 (May 13, 2010), unchanged in *Magnesium Metal From the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (September 17, 2010).

[9] *See* Letter ''*Large Power Transformers from the Republic of Korea:* Request for Changed Circumstances Review Concurrent with Administrative Review (POR 08/01/2018—07/31/2019),'' dated May 8, 2020 (LSIS Request).

[10] *Id.* at 1–2.

[11] *See* 19 CFR 351.224(b).

[12] *See* 19 CFR 351.309(c)(1)(ii).

[13] *See* 19 CFR 351.309(d)(1); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[14] *See* 19 CFR 351.309(c)(2).

[15] *See, generally,* 19 CFR 351.303.

[16] *See* 19 CFR 351.303(f).

Compliance within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date and time of the hearing two days before the scheduled date.

Commerce intends to publish the final results of this administrative review, including the results of its analysis of issues raised in any case or rebuttal brief, no later than 120 days after publication of these preliminary results, unless extended.[17]

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If a respondent's weighted-average dumping margin is not zero or *de minimis* in the final results of this review and the respondent reported reliable entered values, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the POR to each importer to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). If the respondent has not reported reliable entered values, we will calculate a per-unit assessment rate for each importer by dividing the total amount of dumping for the examined sales made during the POR to that importer by the total sales quantity associated with those transactions. Where an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries, without regard to antidumping duties, in accordance with 19 CFR 351.106(c)(2). If the respondent's weighted-average dumping margin is zero or *de minimis* in the final results of review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews, i.e.,* ''{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'' [18]

Regarding entries of subject merchandise during the POR that were produced by Hyosung and for which they did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate un-reviewed entries at the all-others rate of 22.00 percent, as established in the less-than-fair-value investigation of the order, if there is no rate for the intermediate company(ies) involved in the transaction.[19] For a full discussion of this matter, *see Assessment Policy Notice.*[20]

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Hyosung and other companies listed above will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or in the investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 22.00 percent, the rate established in the investigation of this proceeding.[21] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: December 14, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Deadline for Submission of Updated Sales and Cost Information
IV. Scope of the Order
V. Preliminary Determination of No Shipments
VI. Preliminary Results of Successor-in-Interest Analysis
VII. Discussion of the Methodology
VIII. Rate for Non-Selected Companies
IX. Recommendation

[FR Doc. 2020–27913 Filed 12–17–20; 8:45 am]

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[17] *See* section 751(a)(3)(A) of the Act; *see also* 19 CFR 351.213(h).

[18] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

[19] *See Large Power Transformers from the Republic of Korea: Antidumping Duty Order,* 77 FR 53177 (August 31, 2012).

[20] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

[21] *See Large Power Transformers from the Republic of Korea: Antidumping Duty Order,* 77 FR 53177 (August 31, 2012).

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Small Business Innovation Research (SBIR) Program Application Cover Sheet

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize

the public's reporting burden. Public comments were previously requested via the **Federal Register** on September 25, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Institute of Standards and Technology (NIST).

Title: Small Business Innovation Research (SBIR) Program Application Cover Sheet.

OMB Control Number 0693–0072.

Form Number(s): None.

Type of Request: Revision and extension of a current information collection.

Number of Respondents: 100.

Average Hours per Response: 30 minutes.

Burden Hours: 50 hours.

Needs and Uses: The information collected in the Cover Sheet provides identifying information and demographic data for use in NIST's annual report to the SBA on the program. The technical abstract is used in prevention of fraud, waste, and abuse by providing a method to compare similar applications to other agency SBIR programs. The abstract and potential commercial applications of successful applicants are posted on the agency website.

Affected Public: Applicants to the NIST SBIR Program.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority:

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0693–0072.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–27883 Filed 12–17–20; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA580]

Fisheries of the Exclusive Economic Zone Off Alaska; North Pacific Halibut and Sablefish Individual Fishing Quota Cost Recovery Programs

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of standard prices and fee percentage.

SUMMARY: NMFS publishes the individual fishing quota (IFQ) standard prices and fee percentage for cost recovery for the IFQ Program for the halibut and sablefish fisheries of the North Pacific (IFQ Program). The fee percentage for 2020 is 3.0 percent. This action is intended to provide holders of halibut and sablefish IFQ permits with the 2020 standard prices and fee percentage to calculate the required payment for IFQ cost recovery fees due by January 31, 2021.

DATES: The standard prices and fee percentages are valid on December 18, 2020.

FOR FURTHER INFORMATION CONTACT: Charmaine Weeks, Fee Coordinator, 907–586–7231.

SUPPLEMENTARY INFORMATION:

Background

NMFS Alaska Region administers the IFQ Program in the North Pacific. The IFQ Program is a limited access system authorized by the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Northern Pacific Halibut Act of 1982. Fishing under the IFQ Program began in March 1995. Regulations implementing the IFQ Program are set forth at 50 CFR part 679.

In 1996, the Magnuson-Stevens Act was amended to, among other purposes, require the Secretary of Commerce to ''collect a fee to recover the actual costs directly related to the management and enforcement of any . . . individual quota program.'' This requirement was further amended in 2006 to include collection of the actual costs of data collection, and to replace the reference to ''individual quota program'' with a more general reference to ''limited access privilege program'' at § 304(d)(2)(A). Section 304(d)(2) of the Magnuson-Stevens Act also specifies an upper limit on these fees, when the fees must be collected, and where the fees must be deposited.

On March 20, 2000, NMFS published regulations at § 679.45 implementing cost recovery for the IFQ Program (65 FR 14919). Under the regulations, an IFQ permit holder must pay a cost recovery fee for every pound of IFQ halibut and IFQ sablefish that is landed on their IFQ permit(s). The IFQ permit holder is responsible for self-collecting the fee for all IFQ halibut and IFQ sablefish landings on their permit(s). The IFQ permit holder is also responsible for submitting IFQ fee payment(s) to NMFS on or before the due date of January 31 of the year following the year in which the IFQ landings were made. The total dollar amount of the fee due is determined by multiplying the NMFS published fee percentage by the ex-vessel value of all IFQ landings made on the permit(s) during the IFQ fishing year. As required by § 679.45(d)(1) and (d)(3)(i), NMFS publishes this notice of the fee percentage for the halibut and sablefish IFQ fisheries in the **Federal Register** during or before the last quarter of each year.

Standard Prices

The fee is based on the sum of all payments made to fishermen for the sale of the fish during the year. This includes any retro-payments (*e.g.,* bonuses, delayed partial payments, post-season payments) made to the IFQ permit holder for previously landed IFQ halibut or sablefish.

For purposes of calculating IFQ cost recovery fees, NMFS distinguishes between two types of ex-vessel value: Actual and standard. Actual ex-vessel value is the amount of all compensation, monetary or non-monetary, that an IFQ permit holder received as payment for his or her IFQ fish sold. Standard ex-vessel value is the default value used to calculate the fee. IFQ permit holders have the option of using actual ex-vessel value if they can satisfactorily document it; otherwise, the standard ex-vessel value is used.

Section 679.45(b)(3)(iii) requires the Regional Administrator to publish IFQ standard prices during the last quarter of each calendar year. These standard prices are used, along with estimates of IFQ halibut and IFQ sablefish landings, to calculate standard ex-vessel values. The standard prices are described in U.S. dollars per IFQ equivalent pound for IFQ halibut and IFQ sablefish landings made during the year. According to § 679.2, IFQ equivalent pound(s) means the weight amount, recorded in pounds, and calculated as round weight for sablefish and headed and gutted weight for halibut, for an IFQ landing. The weight of halibut in

pounds landed as guided angler fish is converted to IFQ equivalent pound(s) as specified in § 300.65(c)(5)(ii)(E) of this title. NMFS calculates the standard prices to closely reflect the variations in the actual ex-vessel values of IFQ halibut and IFQ sablefish landings by month and port or port-group. The standard prices for IFQ halibut and IFQ sablefish are listed in the tables that follow the next section. Data from ports are combined as necessary to protect confidentiality.

Fee Percentage

NMFS calculates the fee percentage each year according to the factors and methods described at § 679.45(d)(2). NMFS determines the fee percentage that applies to landings made in the previous year by dividing the total costs directly related to the management, data collection, and enforcement of the IFQ Program (management costs) during the previous year by the total standard ex-vessel value of IFQ halibut and IFQ sablefish landings made during the previous year (fishery value). NMFS captures the actual management costs associated with certain management, data collection, and enforcement functions through an established accounting system that allows staff to track labor, travel, contracts, rent, and procurement. NMFS calculates the fishery value as described under the section, Standard Prices.

Using the fee percentage formula described above, the estimated percentage of management costs to fishery value for the 2020 calendar year is 4.3 percent of the standard ex-vessel value; however, the fee percentage must not exceed 3.0 percent pursuant to § 304(d)(2)(B) of the Magnuson-Stevens Act. Therefore, the 2020 fee percentage is set at 3.0 percent. An IFQ permit holder is to use the fee percentage of 3.0 percent to calculate his or her fee for IFQ equivalent pound(s) landed during the 2020 halibut and sablefish IFQ fishing season. An IFQ permit holder is responsible for submitting the 2020 IFQ fee payment to NMFS on or before January 31, 2021. Payment must be made in accordance with the payment methods set forth in § 679.45(a)(4). NMFS no longer accepts credit card information by phone or in-person for fee payments. NMFS has determined that the practice of accepting credit card information by phone or in-person no longer meets agency standards for protection of personal financial information (81 FR 23645, April 22, 2016).

The 2020 fee percentage of 3.0 percent is the same as the 2019 fee percentage of 3.0 percent (84 FR 70153, December 20, 2019). Between 2019 and 2020 there was a net 1.6 percent decrease in management costs; however, the decrease in costs was offset by a 31.3 percent drop in the value of the halibut and sablefish harvests over the same time period. The drop in value was primarily due to low ex-vessel prices in both the sablefish and halibut fisheries in 2020. The drop in value, despite the decrease in management costs, impacted the fee percentage to raise it to its actual value of 4.3 percent. As noted above, however, the fee percentage is capped at 3.0 percent for the IFQ program.

TABLE 1—REGISTERED BUYER STANDARD EX-VESSEL PRICES BY LANDING LOCATION FOR THE 2020 IFQ SEASON [1]

Landing location	Period ending	Halibut standard ex vessel price	Sablefish standard ex vessel price
CORDOVA			
	March 31		
	April 30		
	May 31		
	June 30	4.16	
	July 31	3.89	
	August 31	2.78	
	September 30	4.12	1.89
	October 31	4.12	1.89
	November 30	4.12	1.89
HOMER			
	March 31		
	April 30		
	May 31	4.2	1.44
	June 30	4.46	1.69
	July 31	4.57	
	August 31	4.38	1.94
	September 30	4.21	
	October 31	4.21	
	30-Nov	4.21	
KETCHIKAN			
	March 31		
	April 30		
	May 31	3.81	
	June 30	4.07	
	July 31	4.18	
	August 31	4.69	
	September 30	4.8	
	October 31	4.8	
	November 30	4.8	
KODIAK			
	March 31		
	April 30	3.93	1.39
	May 31	3.75	1.31
	June 30	3.83	1.57
	July 31	4.14	1.35
	August 31	4.19	1.73
	September 30	4.1	1.57
	October 31	4.1	1.57
	November 30	4.1	1.57
PETERSBURG			
	March 31		
	April 30		
	May 31		

TABLE 1—REGISTERED BUYER STANDARD EX-VESSEL PRICES BY LANDING LOCATION FOR THE 2020 IFQ SEASON [1]—Continued

Landing location	Period ending	Halibut standard ex vessel price	Sablefish standard ex vessel price
	June 30	3.97	
	July 31	4.47	
	August 31	4.39	
	September 30	4.15	
	October 31	4.15	
	November 30	4.15	
SEWARD			
	March 31		
	April 30		
	May 31		
	June 30		
	July 31	4.75	1.63
	August 31	4.37	1.63
	September 30		
	October 31		
	November 30		
SITKA			
	March 31	3.97	
	April 30	3.76	2.06
	May 31	4.03	1.85
	June 30	4.24	2.11
	July 31	4.28	2.24
	August 31		
	September 30	4.17	1.92
	October 31	4.17	1.92
	November 30	4.17	1.92
YAKUTAT			
	March 31		
	April 30		
	May 31		
	June 30	4.3	
	July 31	4.68	
	August 31	4.34	
	September 30	4.28	
	October 31	4.28	
	November 30	4.28	
PORT GROUP BERING SEA [2]			
	March 31		
	April 30		
	May 31	3.41	1.65
	June 30	3.53	1.56
	July 31	3.61	
	August 31	3.87	1.93
	September 30	3.88	1.3
	October 31	3.88	1.3
	November 30	3.88	1.3
PORT GROUP CENTRAL GOA [3]			
	March 31	4.16	1.92
	April 30	3.94	2
	May 31	4	2
	June 30	4.23	2.14
	July 31	4.36	1.64
	August 31	4.18	1.76
	September 30	4.13	1.61
	October 31	4.13	1.61
	November 30	4.13	1.61
PORT GROUP SE ALASKA [4]			
	March 31	4.41	2.28
	April 30	3.96	2.02
	May 31	4.03	1.94
	June 30	4.17	2.03
	July 31	4.25	1.97
	August 31	4.44	2.14
	September 30	4.36	2.07
	October 31	4.36	2.07
	November 30	4.36	2.07
ALL-ALASKA [5]			
	March 31	4.34	2.16
	April 30	3.92	1.97
	May 31	3.98	1.92
	June 30	4.1	1.98
	July 31	4.19	1.77
	August 31	4.15	1.85
	September 30	4.13	1.8
	October 31	4.13	1.8
	November 30	4.13	1.8
ALL [5]			
	March 31	4.34	2.16

TABLE 1—REGISTERED BUYER STANDARD EX-VESSEL PRICES BY LANDING LOCATION FOR THE 2020 IFQ SEASON [1]—Continued

Landing location	Period ending	Halibut standard ex vessel price	Sablefish standard ex vessel price
	April 30	3.92	1.97
	May 31	3.98	1.92
	June 30	4.1	1.98
	July 31	4.19	1.77
	August 31	4.15	1.85
	September 30	4.13	1.8
	October 31	4.13	1.8
	November 30	4.13	1.8

[1] *Note:* In many instances, prices are not shown in order to comply with confidentiality guidelines when there are fewer than three processors operating in a location during a month.

[2] *Landing Locations Within Port Group—Bering Sea:* Adak, Akutan, Akutan Bay, Atka, Bristol Bay, Chefornak, Dillingham, Captains Bay, Dutch Harbor, Egegik, Ikatan Bay, Hooper Bay, King Cove, King Salmon, Kipnuk, Mekoryuk, Naknek, Nome, Quinhagak, Savoonga, St. George, St. Lawrence, St. Paul, Togiak, Toksook Bay, Tununak, Beaver Inlet, Ugadaga Bay, Unalaska.

[3] *Landing Locations Within Port Group—Central Gulf of Alaska:* Anchor Point, Anchorage, Alitak, Chignik, Cordova, Eagle River, False Pass, West Anchor Cove, Girdwood, Chinitna Bay, Halibut Cove, Homer, Kasilof, Kenai, Kenai River, Alitak, Kodiak, Port Bailey, Nikiski, Ninilchik, Old Harbor, Palmer, Sand Point, Seldovia, Resurrection Bay, Seward, Valdez, Whittier.

[4] *Landing Locations Within Port Group—Southeast Alaska:* Angoon, Baranof Warm Springs, Craig, Edna Bay, Elfin Cove, Excursion Inlet, Gustavus, Haines, Hollis, Hoonah, Hyder, Auke Bay, Douglas, Tee Harbor, Juneau, Kake, Ketchikan, Klawock, Metlakatla, Pelican, Petersburg, Portage Bay, Port Alexander, Port Graham, Port Protection, Point Baker, Sitka, Skagway, Tenakee Springs, Thorne Bay, Wrangell, Yakutat.

[5] *Landing Locations Within Port Group—All:* For Alaska: All landing locations included in 2, 3, and 4. For California: Eureka, Fort Bragg, other California. For Oregon: Astoria, Aurora, Lincoln City, Newport, Warrenton, other Oregon. For Washington: Anacortes, Bellevue, Bellingham, Nagai Island, Edmonds, Everett, Granite Falls, Ilwaco, La Conner, Port Angeles, Port Orchard, Port Townsend, Rainier, Fox Island, Mercer Island, Seattle, Standwood, other Washington. For Canada: Port Hardy, Port Edward, Prince Rupert, Vancouver, Haines Junction, other Canada.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 14, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–27881 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA704]

Pacific Fishery Management Council; Public Meeting.

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) will host an online meeting of the Area 2A Pacific halibut governmental management entities, that is open to the public.

DATES: The meeting will be held Monday, January 4, 2021, from 10:30 a.m. until 2 p.m., Pacific Standard Time, or until business for the day has been completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Ehlke, Pacific Council; telephone: (503) 820–2426.

SUPPLEMENTARY INFORMATION: The primary purpose of the online meeting is to prepare and develop recommendations for the 2021 International Pacific Halibut Commission's (IPHC) annual meeting held online from January 25 through January 29, 2021. Recommendations generated from the 2A managers meeting will be communicated to the IPHC by the Pacific Council's representatives. Attendees may also address other topics relating to Pacific halibut management.

Although nonemergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2412 at least 10 business days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 15, 2020.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–27972 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA705]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Ad Hoc Ecosystem Workgroup (EWG) will hold an online meeting, which is open to the public.

DATES: The online meeting will be held on Tuesday, January 5, 2021, from 10 a.m. to 12 p.m., Pacific Standard Time or until business is completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris

Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2280, extension 412 for technical assistance.

Council Address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kit Dahl, Staff Officer, Pacific Council; telephone: (503) 820–2422.

SUPPLEMENTARY INFORMATION: The EWG has been tasked with updating the Pacific Council's Fishery Ecosystem Plan. The Pacific Council directed the EWG to complete a draft of Chapter 3, prepare a preliminary draft of Chapter 4, and an outline of Chapter 5 for review at its March 2021 meeting. The primary focus of this work session will be reviewing work completed to date and planning the tasks necessary to complete this assignment. The EWG may also discuss other matters on the Pacific Council's March 2021 meeting agenda, particularly other ecosystem or administrative items.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C.1801 *et seq.*

Dated: December 15, 2020.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–27973 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0649–XA703]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a 3-day meeting via webinar of its Standing, Reef Fish, Mackerel, Socioeconomic and Ecosystem Scientific and Statistical Committees (SSC)

DATES: The meeting will be held on Tuesday, January 5, 2021 to Thursday, January 7, 2021. See **SUPPLEMENTARY INFORMATION** for specific times.

ADDRESSES: The meeting will take place via webinar; you may register by visiting *www.gulfcouncil.org* and clicking on the SSC meeting on the calendar.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Ryan Rindone, Lead Fishery Biologist, Gulf of Mexico Fishery Management Council; *ryan.rindone@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Tuesday, January 5, 2021; 9 a.m.–5 p.m., EST

The meeting will begin with Introductions and Adoption of Agenda, Approval of Verbatim Minutes and Meeting Summary from September 14–15, 2020 webinar meeting and October 30, 2020 joint webinar meeting with the South Atlantic SSC, review Scope of Work, selection of SSC Representative for the January 25–28, 2021 Gulf Council Meeting.

The Committees will review SEDAR 70: Gulf of Mexico Greater Amberjack Stock Assessment; SEDAR 70 Stock Assessment Report, Presentation and Projections, Something's Fishy and Stock Assessment Executive Summary. The Committees will then discuss the Sea Grant/NMFS Greater Amberjack Research Program, and adjourn for the day.

Wednesday, January 6, 2021; 9 a.m.–5 p.m., EST

The Committees will review and hold discussions on Red Grouper Recreational Landings Data, followed by a Review of Council Proposed Interim Analysis Schedule. The Committees will then review Red Snapper Supply Chains and Markets, followed by the Great Red Snapper Count (GRSC), including a presentation, the project report, and a discussion on SEFSC integration of GRSC data into the interim analysis process. The Committees will then review *Testing assumptions about sex change and spatial management in the protogynous gag grouper, Mycteroperca microlepis,* and then adjourn for the day.

Thursday, January 7, 2021; 9 a.m.–3 p.m., EST

The Committees will review a presentation and background materials on Gulf of Mexico Habitat Research, and will then discuss. The Committees will then review a Request for Participants: SEDAR 79: Southeastern U.S. Mutton Snapper.

The Committees will consider carryover of uncaught commercial quota for Individual Fishing Quota (IFQ) managed species; and, will review a presentation on 2020 Commercial landings for IFQ species, consider updated ABC recommendations for IFQ species in 2021 and receive a summary presentation on Carryover Provisions and Framework Modifications.

Lastly, the Committee will discuss Other Business items and receive public comment.

—Meeting Adjourns

The meeting will be broadcast via webinar. You may register for the webinar by visiting *www.gulfcouncil.org* and clicking on the SSC meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committees for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committee will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 15, 2020.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–27971 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA593]

Fisheries of the Exclusive Economic Zone off Alaska; North Pacific Observer Program Standard Ex-Vessel Prices

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of standard ex-vessel prices.

SUMMARY: NMFS publishes standard ex-vessel prices for groundfish and halibut for the calculation of the observer fee under the North Pacific Observer Program (Observer Program). This notice is intended to provide information to vessel owners, processors, registered buyers, and other Observer Program participants about the standard ex-vessel prices that will be used to calculate the observer fee for landings of groundfish and halibut made in 2021. NMFS will send invoices to processors and registered buyers subject to the fee by January 15, 2022. Fees are due to NMFS on or before February 15, 2022.

DATES: The standard prices are valid on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: For general questions about the observer fee and standard ex-vessel prices, contact Abby Jahn at (907)586–7445. For questions about the fee billing process, contact Charmaine Weeks at (907)586–7231. Additional information about the Observer Program is available on NMFS Alaska Region's website at *https://www.fisheries.noaa.gov/alaska/fisheries-observers/north-pacific-observer-program.*

SUPPLEMENTARY INFORMATION:

Background

Regulations at 50 CFR part 679, subpart E, governing the Observer Program, require the deployment of NMFS-certified observers (observers) and electronic monitoring (EM) systems to collect information necessary for the conservation and management of the Bering Sea and Aleutian Islands (BSAI) and Gulf of Alaska (GOA) groundfish and halibut fisheries. Fishery managers use information collected by observers to monitor quotas, manage groundfish and prohibited species catch, and document and reduce fishery interactions with protected resources. Scientists use observer-collected information for stock assessments and marine ecosystem research.

The Observer Program includes two observer coverage categories: the partial coverage category and the full coverage category. All groundfish and halibut vessels and processors subject to observer coverage are included in one of these two categories. Defined at 50 CFR 679.51, the partial coverage category includes vessels and processors that are not required to have an observer or EM at all times, and the full coverage category includes vessels and processors required to have all of their fishing and processing activity observed. Vessels and processors in the full coverage category arrange and pay for observer services from a permitted observer provider. Observer coverage and EM for the partial coverage category is funded through a system of fees based on the ex-vessel value of groundfish and halibut. Throughout this notice, the term ''processor'' refers to shoreside processors, stationary floating processors, and catcher/processors in the partial coverage category.

Landings Subject to Observer Coverage Fee

Pursuant to section 313 of the Magnuson-Stevens Act, NMFS is authorized to assess a fee on all landings accruing against a Federal total allowable catch (TAC) for groundfish or a commercial halibut quota made by vessels that are subject to Federal regulations and not included in the full coverage category. A fee is only assessed on landings of groundfish from vessels designated on a Federal Fisheries Permit or from vessels landing individual fishing quota (IFQ) or community development quota (CDQ) halibut or IFQ sablefish. Within the subset of vessels subject to the observer fee, only landings accruing against an IFQ allocation or a Federal TAC for groundfish are included in the fee assessment. A table with additional information about which landings are subject to the observer fee is at § 679.55(c) and on page 2 of an informational bulletin titled ''Observer Fee Collection'' that can be downloaded from the NMFS Alaska Region website at *https://www.fisheries.noaa.gov/resource/document/observer-fee-collection-north-pacific-groundfish-and-halibut-fisheries-observer.*

Fee Determination

A fee equal to 1.65 percent of the ex-vessel value will be assessed on the landings of groundfish and halibut subject to the fee beginning on January 1, 2021. The fee is increased from 1.25 percent to 1.65 percent to support observer and electronic monitoring deployment at rates more likely to meet the Council's and NMFS' monitoring objectives (85 FR 41424, July 10, 2020). Ex-vessel value is determined by multiplying the standard price for groundfish by the round weight equivalent for each species, gear, and port combination, and the standard price for halibut by the headed and gutted weight equivalent. Standard prices are determined by aggregating prices by species, gear, and area grouping to arrive at an average price per pound for each grouping. NMFS reviews each vessel landing report and determines whether the reported landing is subject to the observer fee and, if so, which groundfish species in the landing are subject to the observer fee. All IFQ or CDQ halibut in a landing subject to the observer fee will be included in the observer fee calculation. For any landed groundfish or halibut subject to the observer fee, NMFS will apply the appropriate standard ex-vessel prices for the species, gear type, and port, and calculate the observer fee associated with the landing.

Processors and registered buyers can access the landing-specific, observer fee information through NMFS Web Application (*https://alaskafisheries.noaa.gov/webapps/efish/login*) or eLandings (*https://elandings.alaska.gov/*). Observer fee information is either available immediately or within 24 hours after a landing report is submitted electronically. A time lag occurs for some landings because NMFS must process each landing report through the catch accounting system to determine which groundfish in a landing accrues against a Federal TAC and are subject to the observer fee.

Under the fee system, catcher vessel owners split the fee with the registered buyers or owners of shoreside or stationary floating processors. While the owners of catcher vessels and processors in the partial coverage category are each responsible for paying their portion of the fee, the owners of shoreside or stationary floating processors and registered buyers are responsible for collecting the fees from catcher vessels, and remitting the full fee to NMFS. Owners of catcher/

processors in the partial coverage category are responsible for remitting the full fee to NMFS.

NMFS sends invoices to processors and registered buyers by January 15 of each calendar year. The total fee amount is determined by the sum of the fees reported for each landing at that processor or registered buyer in the prior calendar year. Processors and registered buyers must pay the fees to NMFS using NMFS Web Application by February 15 each year. Processors and registered buyers have access to this system through a User ID and password issued by NMFS. Instructions for electronic payment will be provided on the NMFS Alaska Region website at *https://www.fisheries.noaa.gov/alaska/commercial-fishing/observer-fee-collection-and-payment-north-pacific-groundfish-and-halibut* and on the observer fee invoice to be mailed to each processor and registered buyer.

Standard Prices

This notice provides the standard ex-vessel prices for groundfish and halibut species subject to the observer fee in 2021. Data sources for ex-vessel prices are:

- For groundfish other than sablefish IFQ and sablefish accruing against the fixed gear sablefish CDQ reserve, the State of Alaska's Commercial Fishery Entry Commission's (CFEC) gross revenue data, which are based on the Commercial Operator Annual Report (COAR) and Alaska Department of Fish and Game (ADF&G) fish tickets; and
- For halibut IFQ, halibut CDQ, sablefish IFQ, and sablefish accruing against the fixed gear sablefish CDQ reserve, the IFQ Buyer Report that is submitted to NMFS annually by each registered buyer that operates as a shoreside processor and receives and purchases IFQ landings of sablefish and halibut or CDQ landings of halibut under § 679.5(l)(7)(i).

The standard prices in this notice were calculated using the following procedures for protecting confidentiality of data submitted to or collected by NMFS. NMFS does not publish any price information that would permit the identification of an individual or business. For NMFS to publish a standard price for a particular species-gear-port combination, the price data used to calculate the standard price must represent landings from at least four different vessels to at least three different processors in a port or port group. Price data that are confidential because fewer than four vessels or three processors contributed data to a particular species-gear-port combination have been aggregated.

Groundfish Standard Ex-Vessel Prices

Table 1 shows the groundfish species standard ex-vessel prices that will be used to calculate the fee for 2021. These prices are based on the CFEC gross revenue data, which are based on landings data from ADF&G fish tickets and information from the COAR. The COAR contains statewide buying and production information, and is considered the most complete routinely collected information to determine the ex-vessel value of groundfish harvested from waters off Alaska.

The standard ex-vessel prices for groundfish were calculated by adding ex-vessel value from the CFEC gross revenue files for 2017, 2018, and 2019 by species, port, and gear category, and adding the volume (round weight equivalent) from the CFEC gross revenue files for 2017, 2018, and 2019 by species, port, and gear category, and then dividing total ex-vessel value over the three-year period in each category by total volume over the three-year period in each category. This calculation results in an average ex-vessel price per pound by species, port, and gear category for the three-year period. Three gear categories were used for the standard ex-vessel prices: (1) Non-trawl gear, including hook-and-line, pot, jig, troll, and others (Non-Trawl); (2) non-pelagic trawl gear (NPT); and (3) pelagic trawl gear (PTR).

CFEC ex-vessel value and volume data are available in the fall of the year following the year the fishing occurred. Thus, it is not possible to base ex-vessel fee liabilities on standard prices that are less than two years old. For the 2021 groundfish standard ex-vessel prices, the most recent ex-vessel value and volume data available are from 2020.

If a particular groundfish species is not listed in Table 1, the standard ex-vessel price for a species group (if it exists in the management area) will be used. If price data for a particular species remained confidential once aggregated to the outside of Alaska (ALL) level, data are aggregated by species group (Flathead Sole; GOA Deep-water Flatfish; GOA Shallow-water Flatfish; GOA Skate, Other; and Other Rockfish). Standard prices for the groundfish species groups are shown in Table 2.

If a port-level price does not meet the confidentiality requirements, the data are aggregated by port group. Port-group data for Southeast Alaska (SEAK) and the Eastern GOA excluding Southeast Alaska (EGOAxSE) also are presented separately when price data are available. Port-group data are aggregated by regulatory area in the GOA (Eastern GOA, Central GOA, and Western GOA) and by subarea in the BSAI (BS subarea and AI subarea). If confidentiality requirements are still not met by aggregating prices across ports at these levels, the prices are aggregated at the level of BSAI or GOA, then statewide (AK) and ports outside of Alaska (OTAK), and finally all ports, including those outside of Alaska (ALL).

Standard prices are presented separately for non-pelagic trawl and pelagic trawl when non-confidential data are available. NMFS also calculated prices for a ''Pelagic Trawl/Non-pelagic Trawl Combined'' (PTR/NPT) category that can be used when combining trawl price data for landings of a species in a particular port or port group will not violate confidentiality requirements. Creating this standard price category allows NMFS to assess a fee on 2021 landings of some of the species with pelagic trawl gear based on a combined trawl gear price for the port or port group.

If no standard ex-vessel price is listed for a species or species group and gear category combination in Table 1, Table 2, or Table 3, no fee will be assessed on that landing. Volume and value data for that species will be added to the standard ex-vessel prices in future years, if the data become available and display of a standard ex-vessel price meets confidentiality requirements.

TABLE 1—STANDARD EX-VESSEL PRICES FOR GROUNDFISH SPECIES FOR 2021 OBSERVER COVERAGE FEE

[Based on volume and value from 2017, 2018, and 2019]

Species (species code) [1 2]	Port/area [3 4]	Non-trawl	NPT	PTR	PTR/NPT
Alaska Plaice Flounder (133)	Kodiak	—	$0.11	—	$0.11
	CGOA	—	0.11	—	0.11
	GOA	—	0.11	—	0.11
	AK	—	0.11	—	0.11
	ALL	—	0.11	—	0.11

TABLE 1—STANDARD EX-VESSEL PRICES FOR GROUNDFISH SPECIES FOR 2021 OBSERVER COVERAGE FEE—Continued

[Based on volume and value from 2017, 2018, and 2019]

Species (species code) [1 2]	Port/area [3 4]	Non-trawl	NPT	PTR	PTR/NPT
Arrowtooth Flounder (121)	Kodiak	—	0.08	$0.08	—
	CGOA	—	0.08	0.08	—
	GOA	—	0.08	0.08	—
	AK	—	0.08	0.08	—
	ALL	—	0.08	0.08	—
Atka Mackerel (193)	Kodiak	—	0.17	0.16	—
	CGOA	—	0.17	0.16	—
	GOA	—	0.17	0.16	—
	AK	—	0.17	0.13	—
	ALL	—	0.17	0.13	—
Black Rockfish (142)	AK	$0.52	0.15	—	0.15
Bocaccio Rockfish (137)	SEAK	0.46	—	—	—
	EGOA	0.42	—	—	—
	GOA	0.42	—	—	—
	AK	0.42	—	—	—
	ALL	0.42	—	—	—
Butter Sole (126)	Kodiak	—	0.15	—	0.15
	CGOA	—	0.15	—	0.15
	GOA	—	0.15	—	0.15
	AK	—	0.15	—	0.15
	ALL	—	0.15	—	0.15
Canary Rockfish (146)	Craig	0.26	—	—	—
	Juneau	0.38	—	—	—
	Ketchikan	0.45	—	—	—
	Sitka	0.55	—	—	—
	SEAK	0.52	—	—	—
	EGOAxSE	0.40	—	—	—
	Homer	0.44	—	—	—
	Seward	0.55	—	—	—
	CGOA	0.54	—	—	—
	GOA	0.51	—	—	—
	AK	0.51	—	—	—
	ALL	0.51	—	—	—
China Rockfish (149)	Sitka	0.55	—	—	—
	SEAK	0.52	—	—	—
	Cordova	0.31	—	—	—
	EGOAxSE	0.30	—	—	—
	Homer	0.55	—	—	—
	Seward	0.41	—	—	—
	CGOA	0.54	—	—	—
	GOA	0.46	—	—	—
	AK	0.46	—	—	—
	ALL	0.46	—	—	—
Copper Rockfish (138)	Sitka	0.49	—	—	—
	SEAK	0.46	—	—	—
	Cordova	0.43	—	—	—
	EGOAxSE	0.43	—	—	—
	Homer	0.47	—	—	—
	Seward	0.43	—	—	—
	CGOA	0.45	—	—	—
	GOA	0.44	—	—	—
	AK	0.44	—	—	—
	ALL	0.44	—	—	—
Dover Sole (124)	Kodiak	—	0.09	—	0.09
	CGOA	—	0.09	—	0.09
	GOA	—	0.09	—	0.09
	AK	—	0.09	—	0.09
	ALL	—	0.09	—	0.09
Dusky Rockfish (172)	Juneau	0.62	—	—	—
	Sitka	0.54	—	—	—
	SEAK	0.55	—	—	—
	EGOAxSE	0.30	—	—	—
	Homer	0.50	—	—	—
	Kodiak	0.42	0.17	0.18	—
	Seward	0.57	—	—	—
	CGOA	0.44	0.17	0.18	—
	GOA	0.45	0.17	0.18	—
	AK	0.45	0.17	0.18	—
	ALL	0.45	0.17	0.18	—
English Sole (128)	Kodiak	—	0.14	—	0.14
	CGOA	—	0.14	—	0.14

TABLE 1—STANDARD EX-VESSEL PRICES FOR GROUNDFISH SPECIES FOR 2021 OBSERVER COVERAGE FEE—Continued

[Based on volume and value from 2017, 2018, and 2019]

Species (species code) [1 2]	Port/area [3 4]	Non-trawl	NPT	PTR	PTR/NPT
	GOA	—	0.14	0.14	—
	AK	—	0.14	0.14	—
	ALL	—	0.14	0.14	—
Flathead Sole (122)	Kodiak	—	0.15	0.15	—
	CGOA	—	0.15	0.15	—
	GOA	—	0.15	0.15	—
	AK	—	0.15	0.15	—
	ALL	—	0.15	0.15	—
Northern Rockfish (136)	Kodiak	0.22	0.16	0.16	—
	CGOA	0.23	0.16	0.16	—
	GOA	0.23	0.16	0.16	—
	AK	0.82	0.16	0.16	—
	ALL	0.82	0.16	0.16	—
Octopus (870)	Homer	0.86	—	—	—
	Kodiak	0.50	0.58	—	0.58
	CGOA	0.54	0.58	—	0.58
	GOA	0.55	0.58	—	0.58
	Dutch Harbor	0.38	—	—	—
	BS	0.65	—	—	—
	BSAI	0.55	—	—	—
	AK	0.55	0.57	—	0.57
	ALL	0.55	0.57	—	0.57
Pacific Cod (110)	Craig	0.19	—	—	—
	Juneau	0.60	—	—	—
	Ketchikan	0.26	—	—	—
	Petersburg	0.31	—	—	—
	Sitka	0.48	—	—	—
	SEAK	0.56	—	—	—
	Cordova	0.58	—	—	—
	EGOAxSE	0.52	—	—	—
	Homer	0.49	—	—	—
	Kodiak	0.44	0.40	0.41	—
	Seward	0.48	—	—	—
	CGOA	0.45	0.40	0.41	—
	WGOA	0.37	—	—	—
	GOA	—	0.36	0.36	—
	Dillingham	0.48	—	—	—
	Dutch Harbor	0.37	0.35	—	0.35
	BS	0.38	0.35	0.12	—
	BSAI	0.38	0.36	0.13	—
	Stationary Floating Processor	0.39	0.35	—	0.35
	AK	0.39	0.36	0.35	—
	ALL	0.39	0.36	0.35	—
Pacific Ocean Perch (141)	Kodiak	—	0.19	0.20	—
	Seward	0.18	—	—	—
	CGOA	0.18	0.19	0.20	—
	GOA	0.64	0.19	0.20	—
	BS	—	—	0.05	0.05
	BSAI	—	—	0.05	0.05
	AK	0.64	0.19	0.18	—
	ALL	0.63	0.19	0.18	—
Pollock (270)	Kodiak	0.05	0.11	0.11	—
	Seward	0.06	—	—	—
	CGOA	0.05	0.11	0.11	—
	WGOA	—	—	0.12	0.12
	GOA	0.05	0.11	0.11	—
	Dutch Harbor	—	0.14	—	0.14
	BS	—	0.14	0.13	—
	BSAI	—	0.14	0.13	—
	Stationary Floating Processor	—	0.08	—	0.11
	AK	0.05	0.11	0.11	—
	ALL	0.05	0.11	0.11	—
Quillback Rockfish (147)	Craig	0.70	—	—	—
	Juneau	0.42	—	—	—
	Ketchikan	0.77	—	—	—
	Petersburg	0.24	—	—	—
	Sitka	0.79	—	—	—
	SEAK	0.66	—	—	—
	Cordova	0.38	—	—	—
	EGOAxSE	0.39	—	—	—
	Homer	0.47	—	—	—

TABLE 1—STANDARD EX-VESSEL PRICES FOR GROUNDFISH SPECIES FOR 2021 OBSERVER COVERAGE FEE—Continued

[Based on volume and value from 2017, 2018, and 2019]

Species (species code) [1 2]	Port/area [3 4]	Non-trawl	NPT	PTR	PTR/NPT
	Seward	0.46	—	—	—
	CGOA	0.46	—	—	—
	GOA	0.56	—	—	—
	AK	0.56	—	—	—
	ALL	0.56	—	—	—
Redbanded Rockfish (153)	Juneau	0.32	—	—	—
	Ketchikan	0.29	—	—	—
	Petersburg	0.23	—	—	—
	Sitka	0.48	—	—	—
	SEAK	0.37	—	—	—
	EGOAxSE	0.29	—	—	—
	Homer	0.36	—	—	—
	Kodiak	0.23	—	—	—
	Seward	0.36	—	—	—
	CGOA	0.31	—	—	—
	GOA	0.35	0.16	—	0.16
	AK	0.35	0.16	—	0.16
	ALL	0.36	0.16	—	0.16
Redstripe Rockfish (158)	SEAK	0.49	—	—	—
	EGOA	0.47	—	—	—
	Seward	0.53	—	—	—
	CGOA	0.42	—	—	—
	GOA	0.45	—	—	—
	AK	0.45	—	—	—
	ALL	0.45	—	—	—
Rex Sole (125)	Kodiak	—	0.35	0.35	—
	CGOA	—	0.35	0.35	—
	GOA	—	0.36	0.50	—
	AK	—	0.36	0.47	—
	ALL	—	0.36	0.47	—
Rock Sole (123)	Kodiak	—	0.18	0.18	—
	CGOA	—	0.18	0.18	—
	GOA	—	0.18	0.18	—
	AK	—	0.18	0.18	—
	ALL	—	0.18	0.18	—
Rosethorn Rockfish (150)	Sitka	0.44	—	—	—
	SEAK	0.45	—	—	—
	EGOA	0.45	—	—	—
	Seward	0.41	—	—	—
	CGOA	0.41	—	—	—
	GOA	0.44	—	—	—
	AK	0.44	—	—	—
	ALL	0.44	—	—	—
Rougheye Rockfish (151)	Craig	0.30	—	—	—
	Juneau	0.32	—	—	—
	Ketchikan	0.32	—	—	—
	Petersburg	0.35	—	—	—
	Sitka	0.49	—	—	—
	SEAK	0.43	—	—	—
	Cordova	0.31	—	—	—
	Whittier	0.47	—	—	—
	EGOAxSE	0.28	—	—	—
	Homer	0.40	—	—	—
	Kodiak	0.30	0.22	0.22	—
	Seward	0.43	—	—	—
	CGOA	0.35	0.22	0.22	—
	GOA	0.38	0.23	0.22	—
	AK	0.38	0.23	0.22	—
	ALL	0.38	0.23	0.22	—
Sablefish (blackcod) (710)	Kodiak	[5] n/a	2.12	—	2.12
	CGOA	[5] n/a	2.12	—	2.12
	GOA	[5] n/a	2.05	—	2.03
	AK	[5] n/a	2.05	0.51	—
	ALL	[5] n/a	2.05	0.51	—
Shortraker Rockfish (152)	Juneau	0.34	—	—	—
	Ketchikan	0.31	—	—	—
	Petersburg	0.30	—	—	—
	Sitka	0.46	—	—	—
	SEAK	0.39	—	—	—
	Cordova	0.47	—	—	—
	Whittier	0.48	—	—	—

TABLE 1—STANDARD EX-VESSEL PRICES FOR GROUNDFISH SPECIES FOR 2021 OBSERVER COVERAGE FEE—Continued

[Based on volume and value from 2017, 2018, and 2019]

Species (species code) [1 2]	Port/area [3 4]	Non-trawl	NPT	PTR	PTR/NPT
	EGOAxSE	0.50	—	—	—
	Homer	0.36	—	—	—
	Kodiak	0.28	0.19	0.18	—
	Seward	0.41	—	—	—
	CGOA	0.38	0.19	0.18	—
	GOA	0.39	0.38	0.18	—
	AK	0.39	0.38	0.18	—
	ALL	0.39	0.38	0.18	—
Silvergray Rockfish (157)	Craig	0.24	—	—	—
	Juneau	0.40	—	—	—
	Ketchikan	0.53	—	—	—
	Sitka	0.51	—	—	—
	SEAK	0.44	—	—	—
	Cordova	0.45	—	—	—
	EGOAxSE	0.34	—	—	—
	Homer	0.39	—	—	—
	Seward	0.41	—	—	—
	CGOA	0.41	—	—	—
	GOA	0.43	—	—	—
	AK	0.43	—	—	—
	ALL	0.43	—	—	—
Skate, Alaska (703)	GOA	0.39	—	—	—
	AK	0.39	—	—	—
	ALL	0.39	—	—	—
Skate, Big (702)	EGOA	0.40	—	—	—
	Homer	0.40	—	—	—
	Kodiak	0.45	0.46	0.45	—
	Seward	0.38	—	—	—
	CGOA	0.43	0.46	0.45	—
	GOA	0.43	0.46	0.44	—
	AK	0.43	0.46	0.44	—
	ALL	0.43	0.46	0.44	—
Skate, Longnose (701)	SEAK	0.40	—	—	—
	EGOAxSE	0.27	—	—	—
	Homer	0.37	—	—	—
	Kodiak	0.45	0.46	0.46	—
	Seward	0.38	—	—	—
	CGOA	0.42	0.46	0.46	—
	GOA	0.40	0.46	0.42	—
	AK	0.40	0.46	0.42	—
	ALL	0.40	0.46	0.42	—
Skate, Other (700)	SEAK	0.33	—	—	—
	EGOA	0.33	—	—	—
	GOA	0.35	—	—	0.30
	AK	0.35	0.05	—	0.05
	ALL	0.35	0.05	—	0.05
Starry Flounder (129)	Kodiak	—	0.08	—	0.08
	CGOA	—	0.08	—	0.08
	GOA	—	0.08	—	0.08
	AK	—	0.08	—	0.08
	ALL	—	0.08	—	0.08
Thornyhead Rockfish (Idiots) (143)	Juneau	0.98	—	—	—
	Ketchikan	1.10	—	—	—
	Petersburg	0.99	—	—	—
	Sitka	0.99	—	—	—
	SEAK	1.00	—	—	—
	Cordova	0.57	—	—	—
	EGOAxSE	0.71	—	—	—
	Homer	0.65	—	—	—
	Kodiak	0.55	0.63	—	0.63
	Seward	0.72	—	—	—
	CGOA	0.65	0.63	—	0.63
	WGOA	0.80	—	—	—
	GOA	—	0.65	—	0.65
	Adak	0.50	—	—	—
	AI	0.52	—	—	—
	BS	0.68	—	—	—
	AK	0.78	0.65	—	0.65
	Bellingham	0.87	—	—	—
	OTAK	0.87	—	—	—
	ALL	0.78	0.65	—	0.65

TABLE 1—STANDARD EX-VESSEL PRICES FOR GROUNDFISH SPECIES FOR 2021 OBSERVER COVERAGE FEE—Continued

[Based on volume and value from 2017, 2018, and 2019]

Species (species code) [1 2]	Port/area [3 4]	Non-trawl	NPT	PTR	PTR/NPT
Tiger Rockfish (148)	Juneau	0.41	—	—	—
	Sitka	0.53	—	—	—
	SEAK	0.48	—	—	—
	Cordova	0.34	—	—	—
	EGOAxSE	0.38	—	—	—
	Homer	0.41	—	—	—
	Seward	0.43	—	—	—
	CGOA	0.42	—	—	—
	GOA	0.44	—	—	—
	AK	0.44	—	—	—
	ALL	0.44	—	—	—
Vermilion Rockfish (184)	Sitka	0.54	—	—	—
	SEAK	0.59	—	—	—
	EGOA	0.59	—	—	—
	GOA	0.59	—	—	—
	AK	0.59	—	—	—
	ALL	0.59	—	—	—
Widow Rockfish (156)	GOA	0.76	—	—	—
	AK	0.76	—	—	—
	ALL	0.76	—	—	—
Yelloweye Rockfish (145)	Craig	1.73	—	—	—
	Juneau	1.31	—	—	—
	Ketchikan	1.89	—	—	—
	Petersburg	1.12	—	—	—
	Sitka	2.12	—	—	—
	SEAK	1.86	—	—	—
	Cordova	0.99	—	—	—
	Whittier	0.97	—	—	—
	EGOAxSE	0.99	—	—	—
	Homer	0.88	—	—	—
	Kodiak	0.33	0.25	—	0.25
	Seward	0.70	—	—	—
	CGOA	0.69	0.25	—	0.25
	WGOA	0.47	—	—	—
	GOA	—	0.25	—	0.25
	BSAI	0.14	—	—	—
	AK	1.61	0.25	—	0.25
	Bellingham	1.21	—	—	—
	OTAK	1.21	—	—	—
	ALL	1.60	0.25	—	0.25
Yellowtail Rockfish (155)	Sitka	0.66	—	—	—
	SEAK	0.63	—	—	—
	EGOA	0.63	—	—	—
	Homer	0.48	—	—	—
	Seward	0.81	—	—	—
	CGOA	0.65	—	—	—
	GOA	0.64	—	—	—
	AK	0.64	—	—	—
	ALL	0.64	—	—	—

— = no landings in last 3 years or the data is confidential.

[1] If species is not listed, use price for the species group in Table 2 if it exists in the management area. If no price is available for the species or species group in Table 1, Table 2, or Table 3, no fee will be assessed on that landing. That species will come into standard ex-vessel prices in future years.

[2] For species codes, see Table 2a to 50 CFR part 679.

[3] Regulatory areas are defined at § 679.2. (AK = Alaska; ALL = all ports including those outside Alaska; BS = Bering Sea subarea; BSAI = Bering Sea/Aleutian Islands; CGOA = Central Gulf of Alaska; EGOA = Eastern Gulf of Alaska; EGOAxSE = Eastern Gulf of Alaska except Southeast Alaska; GOA = Gulf of Alaska; SEAK = Southeast Alaska; WGOA = Western Gulf of Alaska).

[4] If a price is listed for the species, port, and gear type combination, that price will be applied to the round weight equivalent for groundfish landings. If no price is listed for the port and gear type combination, use port group and gear type, or see Table 2 or Table 3.

[5] n/a = ex-vessel prices for sablefish landed with hook-and-line, pot, or jig gear are listed in Table 3 with the prices for IFQ and CDQ landings.

TABLE 2—STANDARD EX-VESSEL PRICES FOR GROUNDFISH SPECIES GROUPS FOR 2021 OBSERVER COVERAGE FEE

[Based on volume and value from 2017, 2018, and 2019]

Species group [1]	Port/area [2 3]	Non-trawl	NPT	PTR	PTR/NPT
Flathead Sole (FSOL)	Kodiak	—	$0.15	$0.15	—
	CGOA	—	0.15	0.15	—
	GOA	—	0.15	0.15	—
	AK	—	0.15	0.15	—

TABLE 2—STANDARD EX-VESSEL PRICES FOR GROUNDFISH SPECIES GROUPS FOR 2021 OBSERVER COVERAGE FEE—Continued

[Based on volume and value from 2017, 2018, and 2019]

Species group [1]	Port/area [2 3]	Non-trawl	NPT	PTR	PTR/NPT
GOA Deep Water Flatfish [4] (DFL4)	Kodiak	—	0.09	—	$0.09
	CGOA	—	0.09	—	0.09
	GOA	—	0.09	—	0.09
GOA Shallow Water Flatfish [5] (SFL1)	Kodiak	—	0.18	0.16	—
	CGOA	—	0.18	0.16	—
	GOA	—	0.18	0.16	—
GOA Skate, Other (USKT)	SEAK	$0.33	—	—	—
	EGOA	0.33	—	—	—
	CGOA	0.42	—	—	—
	GOA	0.35	—	—	0.30
Other Rockfish [6 7] (ROCK)	Craig	0.28	—	—	—
	Juneau	0.56	—	—	—
	Ketchikan	0.31	—	—	—
	Petersburg	0.39	—	—	—
	Sitka	0.51	—	—	—
	SEAK	0.48	—	—	—
	Cordova	0.83	—	—	—
	Whittier	0.75	—	—	—
	EGOAxSE	0.77	—	—	—
	Homer	0.79	—	—	—
	Kodiak	0.32	0.19	—	0.19
	Seward	0.62	—	—	—
	CGOA	0.62	0.19	—	0.19
	WGOA	0.62	—	—	—
	GOA	—	0.20	—	0.20
	Adak	0.51	—	—	—
	AI	0.53	—	—	—
	BS	0.65	—	—	—
	AK	—	0.23	—	0.23

— = no landings in last 3 years or the data is confidential.

[1] If groundfish species is not listed in Table 1, use price for the species group if it exists in the management area. If no price is available for the species or species group in Table 1, Table 2, or Table 3, no fee will be assessed on that landing. That species will come into standard ex-vessel prices in future years.

[2] Regulatory areas are defined at § 679.2. (AK = Alaska; BS = Bering Sea subarea; BSAI = Bering Sea/Aleutian Islands; CGOA = Central Gulf of Alaska; EGOA = Eastern Gulf of Alaska; EGOAxSE = Eastern Gulf of Alaska except Southeast Alaska; GOA = Gulf of Alaska; SEAK = Southeast Alaska; WGOA = Western Gulf of Alaska).

[3] If a price is listed for the species, port, and gear type combination, that price will be applied to the round weight equivalent for groundfish landings. If no price is listed for the port and gear type combination, use port group and gear type combination.

[4] "Deep-water flatfish" in the GOA means Dover sole, Greenland turbot, Kamchatka flounder, and deepsea sole.

[5] "Shallow-water flatfish" in the GOA means all flatfish not including "deep-water flatfish", flathead sole, rex sole, or arrowtooth flounder.

[6] In the GOA:

"Other rockfish" means *Sebastes aurora* (aurora), *S. melanostomus* (blackgill), *S. paucispinis* (bocaccio), *S. goodei* (chilipepper), *S. crameri* (darkblotch), *S. elongatus* (greenstriped), *S. variegatus* (harlequin), *S. wilsoni* (pygmy), *S. babcocki* (redbanded), *S. proriger* (redstripe), *S. zacentrus* (sharpchin), *S. jordani* (shortbelly), *S. brevispinis* (silvergray), *S. diploproa* (splitnose), *S. saxicola* (stripetail), *S. miniatus* (vermilion), *S. reedi* (yellowmouth), *S. entomelas* (widow), and *S. flavidus* (yellowtail). In the Eastern GOA only, other rockfish also includes northern rockfish, *S. polyspinis.*

"Other rockfish" in the Western and Central Regulatory Areas and in the West Yakutat District means other rockfish and demersal shelf rockfish. The "other rockfish" species group in the SEO District only includes other rockfish.

"Demersal shelf rockfish" means *Sebastes pinniger* (canary), *S. nebulosus* (china), *S. caurinus* (copper), *S. maliger* (quillback), *S. helvomaculatus* (rosethorn), *S. nigrocinctus* (tiger), and *S. ruberrimus* (yelloweye).

[7] "Other rockfish" in the BSAI includes all *Sebastes* and *Sebastolobus* species except for dark rockfish, Pacific ocean perch, northern rockfish, blackspotted/rougheye rockfish, and shortraker rockfish.

Halibut and Sablefish IFQ and CDQ Standard Ex-vessel Prices

Table 3 shows the observer fee standard ex-vessel prices for halibut and sablefish. These standard prices are calculated as a single annual average price, by species and port or port group. Volume and ex-vessel value data collected on the 2020 IFQ Buyer Report for landings made from October 1, 2019, through September 30, 2020, were used to calculate the standard ex-vessel prices for the 2021 observer fee for halibut IFQ, halibut CDQ, sablefish IFQ, and sablefish landings that accrue against the fixed gear sablefish CDQ reserve.

TABLE 3—STANDARD EX-VESSEL PRICES FOR HALIBUT IFQ, HALIBUT CDQ, SABLEFISH IFQ, AND SABLEFISH ACCRUING AGAINST THE FIXED GEAR SABLEFISH CDQ RESERVE FOR THE 2021 OBSERVER FEE

[Based on 2020 IFQ buyer reports]

Species	Port/area [1]	Price [2]
Halibut (200)	Craig	$4.26
	Ketchikan	4.54

TABLE 3—STANDARD EX-VESSEL PRICES FOR HALIBUT IFQ, HALIBUT CDQ, SABLEFISH IFQ, AND SABLEFISH ACCRUING AGAINST THE FIXED GEAR SABLEFISH CDQ RESERVE FOR THE 2021 OBSERVER FEE—Continued

[Based on 2020 IFQ buyer reports]

Species	Port/area [1]	Price [2]
	Petersburg	4.27
	Sitka	4.36
	SEAK	4.33
	Cordova	3.69
	EGOAxSE	4.10
	Homer	4.62
	Kodiak	4.21
	Seward	4.54
	CGOA	4.44
	GOA	4.33
	BS	3.82
	BSAI	3.82
	AK	4.21
	ALL	4.21
Sablefish (710)	Sitka	2.34
	SEAK	2.32
	Cordova	1.81
	EGOAxSE	1.96
	Homer	2.07
	Kodiak	1.78
	Seward	2.36
	CGOA	2.14
	GOA	2.18
	AK	2.12
	ALL	2.12

[1] Regulatory areas are defined at § 679.2. (AK = Alaska; ALL = all ports including those outside Alaska; AI = Aleutian Islands subarea; BS = Bering Sea subarea; CGOA = Central Gulf of Alaska; EGOAxSE = Eastern Gulf of Alaska except Southeast Alaska; SEAK = Southeast Alaska; WGOA = Western Gulf of Alaska).

[2] If a price is listed for the species and port combination, that price will be applied to the round weight equivalent for sablefish landings and the headed and gutted weight equivalent for halibut landings. If no price is listed for the port, use port group.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 14, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries,National Marine Fisheries Service.

[FR Doc. 2020–27824 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA708]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Southern Oregon/Northern California Coast (SONCC) Coho Workgroup (Workgroup) will host an online meeting that is open to the public.

DATES: The meeting will be held Tuesday, January 5, 2021, from 9 a.m. until 5 p.m., Pacific Standard Time, or until business for the day has been completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Ehlke, Pacific Council; telephone: (503) 820–2426.

SUPPLEMENTARY INFORMATION: The purpose of the meeting will be to discuss Pacific Council guidance from their November 2020 meeting and continue to develop associated modeling and analysis needed to prepare for a progress report on a risk analysis and potential harvest control rule alternatives for Pacific Council consideration at their April 2021 meeting. The Workgroup may also discuss and prepare for future Workgroup meetings and future meetings with the Pacific Council and its advisory bodies.

Although nonemergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2412 at least 10 business days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 15, 2020.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–27974 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Applications for Trademark Registration

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), in accordance with the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0009 (Applications for Trademark Registration). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before February 16, 2021.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0009 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Catherine Cain, Attorney Advisor, Office of the Commissioner for Trademarks, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8946; or by email to *Catherine.Cain@uspto.gov* with ''0651–0009 comment'' in the subject line. Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) administers the Trademark Act, 15 U.S.C. 1051 *et seq.,* which provides for the Federal registration of trademarks, service marks, collective trademarks and service marks, collective membership marks, and certification marks. Individuals and businesses who use their marks, or intend to use their marks, in commerce regulated by Congress may file an application with the USPTO to register their marks. Registered marks remain on the register indefinitely, so long as the owner of the registration files the necessary maintenance documents.

This information collection addresses submissions required by the regulations at 37 CFR part 2 for initial applications regarding the registration of trademarks, service marks, collective trademarks and service marks, collective membership marks, and certification marks. These regulations also mandate that each registered mark appear in the principle register or supplemental register, and that each entry include the mark, the goods and/or services in connection with which the mark is used, ownership information, dates of use, and certain other information. The USPTO also provides similar information concerning pending applications. The register and pending application information may be accessed by an individual or by businesses to determine the availability of a mark. By accessing the USPTO's information, parties may reduce the possibility of initiating use of a mark previously adopted by another. The Federal trademark registration process may thereby reduce the number of filings between both litigating parties and the courts.

II. Method of Collection

Items in this information collection must be submitted via online electronic submissions. In limited circumstances, applicants may also be permitted to submit the information in paper form by mail, fax, or hand delivery.

III. Data

OMB Control Number: 0651–0009.

Form Numbers:

- PTO 1478 (Trademark/Service Mark Application, Principal Register)
- PTO 1479 (Trademark/Service Mark Form, Supplemental Register)
- PTO 1480 (Certification Mark Form, Principal Register)
- PTO 1481 (Collective Membership Mark Form, Principal Register)
- PTO 1482 (Collective Trademark/Service Mark Form, Principal Register)

Type of Review: Revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Estimated Number of Respondents: 506,837 respondents per year.

Estimated Number of Responses: 506,837 responses per year.

Estimated Time per Response: The USPTO estimates that it takes the public approximately 40 minutes (0.67 hours) to 50 minutes (0.83 hours), depending on the complexity of the situation, to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 377,830 hours.

Estimated Total Annual Respondent Cost Burden: $151,132,000.

TABLE 1—TOTAL HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = (c)	Rate [1] ($/hour) (d)	Estimated annual respondent cost burden (c) × (d) = (e)
1	Use-Based Trademark/Service Mark Applications (TEAS Standard).	94,956	94,956	0.75 (45 minutes)	71,217	$400	$28,486,800
1	Use-Based Trademark/Service Mark Applications (TEAS Plus).	90,111	90,111	0.83 (50 minutes)	74,792	400	29,916,800
2	Intent to Use Trademark/Service Mark Application (TEAS Standard).	99,770	99,770	0.67 (40 minutes)	66,846	400	26,738,400
2	Intent to Use Trademark/Service Mark Application (TEAS Plus).	94,678	94,678	0.75 (45 minutes)	71,009	400	28,403,600
3	Applications for Registration of Trademark/Service Mark under 37 CFR § 44 (TEAS Standard).	13,318	13,318	0.67 (40 minutes)	8,923	400	3,569,200

TABLE 1—TOTAL HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS—Continued

Item No.	Item	Estimated annual respondents	Estimated annual responses (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = (c)	Rate [1] ($/hour) (d)	Estimated annual respondent cost burden (c) × (d) = (e)
3	Applications for Registration of Trademark/Service Mark under 37 CFR 44 (TEAS Plus).	12,638	12,638	0.75 (45 minutes)	9,479	400	3,791,600
	Totals	405,471	405,471		302,266		120,906,400

TABLE 2—TOTAL HOURLY BURDEN FOR INDIVIDUALS OR HOUSEHOLDS RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = (c)	Rate [2] ($/hour) (d)	Estimated annual respondent cost burden (c) × (d) = (e)
1	Use-Based Trademark/Service Mark Applications (TEAS Standard).	23,739	23,739	0.75 (45 minutes)	17,804	$400	$7,121,600
1	Use-Based Trademark/Service Mark Applications (TEAS Plus).	22,528	22,528	0.83 (50 minutes)	18,698	400	7,479,200
2	Intent to Use Trademark/Service Mark Application (TEAS Standard).	24,942	24,942	0.67 (40 minutes)	16,711	400	6,684,400
2	Intent to Use Trademark/Service Mark Application (TEAS Plus).	23,669	23,669	0.75 (45 minutes)	17,752	400	7,100,800
3	Applications for Registration of Trademark/Service Mark under 37 CFR § 44 (TEAS Standard).	3,329	3,329	0.67 (40 minutes)	2,230	400	892,000
3	Applications for Registration of Trademark/Service Mark under 37 CFR 44 (TEAS Plus).	3,159	3,159	0.75 (45 minutes)	2,369	400	947,600
	Totals	101,366	101,366		75,564		30,225,600

Estimated Total Annual (Non-hour) Respondent Cost Burden: $152,980,250. There are no capital start-up, maintenance, or recordkeeping fees associated with this information collection. However, this information collection does have annual (non-hour) cost burden in the form of filing fees, processing fees, and postage costs. The USPTO amended its regulations to set, increase, or decrease certain trademark fees, to become effective January 2, 2021, including the fees in this information collection.

A complete application must include a filing fee for each class of goods and services. Therefore, the total filing fees associated with this information collection can vary depending on the number of classes in each application. The total filing fees of $152,714,650, shown in the table below, reflect the filing fee for one class associated with this information collection.

TABLE 3—TOTAL NON-HOUR RESPONDENT COST BURDEN

Item No.	Item	Estimated annual responses (a)	Amount [3] (b)	Totals (a) × (b) = (c)
1	Use-Based Trademark/Service Mark Applications (TEAS Standard)	118,695	$350	$41,543,250
1	Use-Based Trademark/Service Mark Applications (TEAS Plus)	112,639	250	28,159,750
2	Intent to Use Trademark/Service Mark Application (TEAS Standard)	124,712	350	43,649,200
2	Intent to Use Trademark/Service Mark Application (TEAS Plus)	118,347	250	29,586,750
3	Applications for Registration of Trademark/Service Mark under 37 CFR § 44 (TEAS Standard).	16,647	350	5,826,450
3	Applications for Registration of Trademark/Service Mark under 37 CFR 44 (TEAS Plus).	15,797	250	3,949,250
	Totals	506,837		152,714,650

[1] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

[2] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

[3] This fee rate is effective on January 2, 2021.

In addition, the USPTO charges a processing fee of $100 per class for TEAS Plus applications that do not meet the TEAS Plus filing requirements. In such cases, the applicant will be required to submit the additional processing fee of $100 per class. The total processing fees associated with this information collection can vary depending on the number of classes in each application. The total processing fees of $265,600 is shown in the table below.

In addition, the USPTO charges a processing fee of $100 per class for TEAS Plus applications that do not meet the TEAS Plus filing requirements. In such cases, the applicant will be required to submit the additional processing fee of $100 per class. The total processing fees associated with this information collection can vary depending on the number of classes in each application. The total processing fees of $265,000 is shown in the table below.

TABLE 4—PROCESSING FEES

Item No.	Item	Responses (a)	Amount [4] (b)	Totals (a) × (b) = (c)
1	Processing fee for applications that fail to meet the additional filing and processing requirements for reduced filing fee (TEAS Plus).	2,656	$100	$265,600
	Totals	2,656	.....	265,600

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this information collection in the form of filing fees ($152,714,650) and processing fees ($265,600) is $152,980,250.

Respondent's Obligation: Required to obtain or retain benefits.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. The USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personal identifying information in a comment, be aware that the entire comment—including personal identifying information—may be made publicly available at any time. While you may ask in your comment to withhold personal identifying information from public view, the USPTO cannot guarantee that it will be able to do so.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–27904 Filed 12–17–20; 8:45 am]

BILLING CODE 3510–16–P

[4] This fee rate is scheduled to become effective on January 2, 2021.

COMMODITY FUTURES TRADING COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of a New System of Records.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is establishing a new system of records, CFTC–55, ''Dental Benefits Records'' to cover records pertaining to the administration of CFTC's dental benefits program. This includes the collection and management of records relating to dental procedures covered under the program, enrollment and claims forms, and communications with CFTC employees regarding their coverage, eligibility data, and billing.

DATES: In accordance with 5 U.S.C. 552(e)(4) and (e)(11) this notice will go in to effect without further notice on December 18, 2020 unless otherwise revised pursuant to comments received. All routine uses will go in to effect on January 19, 2021. Comments must be received on or before January 19, 2021.

ADDRESSES: You may submit comments identified as pertaining to ''Dental Benefits Records'' by any of the following methods:

- *CFTC website: https://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail, above.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://www.cftc.gov.* You should submit only information that you wish to make available publicly.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse, or remove any or all of a submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the notice will be retained in the comment file and will be considered as required under all applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Charlie Cutshall, Chief Privacy Officer, *privacy@cftc.gov,* 202–418–5833, Office of the Executive Director, Commodity Futures Trading Commission, Three

Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Dental Benefits Program

As part of the Farm Security and Rural Investment Act of 2002 (FSRIA), CFTC received authority to implement pay and benefit parity with other Federal Financial Regulatory Agencies in order to better attract and retain employees. Following a study of pay and benefits, CFTC implemented a new dental insurance program for employees and their dependents effective July 11, 2004.

II. The Privacy Act

Under the Privacy Act of 1974, 5 U.S.C. 552a, a ''system of records'' is defined as any group of records under the control of a Federal government agency from which information about individuals is retrieved by name or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act establishes the means by which government agencies must collect, maintain, and use information about an individual in a government system of records.

Each government agency is required to publish a notice in the **Federal Register** in which the agency identifies and describes each system of records it maintains, the reasons why the agency uses the information therein, the routine uses for which the agency will disclose such information outside the agency, and how individuals may exercise their rights under the Privacy Act.

In accordance with 5 U.S.C. 552a(r), CFTC has provided a report of this new system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

Dental Benefits Records; CFTC–55.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

This system is located at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. Records maintained as part of this system of records are also located at site of the benefits provider.

SYSTEM MANAGER(S):

Chief Human Capital Officer, *benefits@cftc.gov,* Office of the Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The collection of this information is authorized under 7 U.S.C. 2(a)(7) and the rules promulgated thereunder.

PURPOSE(S) OF THE SYSTEM:

These records are collected and maintained to administer the CFTC's dental benefits programs for its employees and their enrolled dependents, and to assist in personnel management.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

CFTC employees (but not retirees) and their enrolled dependents.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in the system may contain any or all of the following types of information on participating employees and their enrolled dependents: First name; last name; Social Security number; date of birth; phone number; email address; home address; member ID number; enrollee's employing agency; dental care procedure information regarding procedures performed on the individual; dental care diagnoses and treatments, including any prescribed drugs; and, provider charges, including amounts paid by the plan and amounts paid by the enrollee.

RECORD SOURCE CATEGORIES:

Information is provided by the individual to whom the record pertains, the benefit provider, and staff of the Human Resources Branch in the Office of the Executive Director.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

These records and information in these records may be disclosed:

(a) To contractors performing or working on a contract for the Federal government when necessary to accomplish an agency function.

(b) To the appropriate Federal, State, local, territorial, Tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting violations or potential violations of law whether criminal, civil, or regulatory in nature, or charged with enforcing or implementing such law.

(c) To the Merit Systems Protection Board or the Office of Special Counsel for the purpose of litigation, including administrative proceedings, appeals, special studies of the civil service and other merit systems.

(d) To a Federal agency in response to its request in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract or the issuance of a license, or a grant or other benefit by the requesting agency, to the extent that the information may be relevant to the requesting agency's decision on the matter.

(e) To the Department of Justice or in a proceeding before a court, adjudicative body, or other administrative body which the agency is authorized to appear, when

(1) the Commission, or any component thereof;

(2) any employee of the Commission in his or her official capacity;

(3) any Commission of the agency in his or her official capacity where the Department of Justice or the agency has agreed to represent the employee; or

(4) the United States, when the Commission determines that litigation is likely to affect the agency or any of its components;

Is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or the Commission is deemed by the agency to be relevant and necessary to the litigation provided, however, that in each case it has been determined that the disclosure is compatible with the purpose for which the records were collected.

(f) To appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records; (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(g) To another Federal agency or Federal entity, when the Commission determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system of records are stored electronically or on paper in secure facilities. Electronic records are stored on secure networks maintained by the Commission and benefits provider, and on other electronic media as needed, such as encrypted hard drives and back-up media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information covered by this system of records notice may be retrieved by a member's ID number or by an individual's name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The Records maintained by a health care facility or dispensary relating to an individual patient's personal medical history, physical condition, or any treatment or examination thereof for non-work-related purposes which come to be in the CFTC's possession are maintained in accordance with GRS 2.7–070, DAA–GRS–2017–0010–0012 and are destroyed 10 years after the most recent encounter.

Records of an individual's enrollment in an agency-sponsored dental plan are maintained in accordance with GRS 2.2–041, DAA–GRS–2017–0007–0005. These records are destroyed when superseded or obsolete, or upon separation or transfer of employee, whichever is earlier.

Records associated with the procurement of contracted services of an agency-sponsored dental benefit program are coved by GRS 1.1, 010, DAA–GRS–2013–0003–0001 and must be maintained for 6 years after final payment of the contract or cancellation of the contract then must be destroyed. The benefits provider has implemented policies and processes to securely destroy records in accordance with the applicable retention schedule or upon instruction from the Commission.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical, and physical security measures employed by the CFTC and benefits provider. Administrative safeguards include maintenance of written policies, standards, and procedures reinforced by training and periodic auditing. Technical security safeguards include restrictions on computer access to authorized individuals who have a legitimate need to know the information; required use of strong passwords that are frequently changed; multi-factor authentication for remote access and access to many network components; use of encryption for certain data types and transfers; firewalls and intrusion detection applications; and regular review of security procedures and best practices to enhance security. Physical safeguards include restrictions on building access to authorized individuals, use of security guard services, and video surveillance.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.3 for full details on what to include in a Privacy Act access request.

CONTESTING RECORD PROCEDURES:

Individuals contesting the content of records about themselves contained in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.8 for full details on what to include in a Privacy Act amendment request.

NOTIFICATION PROCEDURES:

Individuals seeking notification of any records about themselves contained in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.3 for full details on what to include in a Privacy Act notification request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Issued in Washington, DC, on December 14, 2020, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–27865 Filed 12–17–20; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Availability of the Draft Integrated Disposition Report and Environmental Assessment for the Upper St. Anthony Falls Lock and Dam, Hennepin County, Minnesota

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of availability; request for comments.

SUMMARY: The St. Paul District, Army Corps of Engineers (Corps) is publishing this notice to announce that the draft Integrated Disposition Report and Environmental Assessment (DR/EA) for the Upper St. Anthony Falls Lock and Dam (USAF) is available for public review and comment in accordance with the National Environmental Policy Act (NEPA). The Corps provides all interested persons an opportunity to view and/or print the EA via the internet through the St. Paul District's Home Page (*https://www.mvp.usace.army.mil/*).

DATES: To ensure consideration, written comments must be received or postmarked within 60 days from the date of this notice. Any comments received after the closing date may not be considered in final decisions for the Corps' action.

ADDRESSES: Comments on the DR/EA may be submitted by one of the following methods:

Email should be sent to: *MplsLocksDisposition@usace.army.mil.*

Mail/Courier—Written comments should be sent to: District Engineer,U.S. Army Corps of Engineers St. Paul District, ATTN: Regional Planning and Environment Division North, 180 Fifth Street East, Suite 700, St. Paul, Minnesota 55101–1678.

If submitting comments by email, the following should be included in the subject line or first line of the message ''USAF Disposition Study DR/EA Comments''. Comments should be specific and pertain only to the issues relating to the action and the EA. The Corps will include all comments in the project record.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be publicly available. While you can ask us in your comment to withhold your personal identifying information from public review, the Corps cannot

guarantee that we will be able to do so. Such information is not required for you to submit comments on the study.

All submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses will be available for public review to the extent consistent with applicable law.

FOR FURTHER INFORMATION CONTACT: General questions about the study may be directed to Nan Bischoff, Project Manager, U.S. Army Corps of Engineers, St. Paul District, 180 Fifth Street East, Suite 700, St. Paul, MN 55101–1678; telephone (651) 290–5426; email: *Nanette.m.bischoff@usace.army.mil.*

SUPPLEMENTARY INFORMATION: The Corps operates USAF Lock and Dam, located on the Mississippi River in Minneapolis, Minnesota. Section 2010 of Water Resources Reform and Redevelopment Act of 2014, Public Law 113–121, directed the Corps to close the lock to navigation operations but to continue to carry out emergency lock operations necessary to mitigate flood damages. Navigation at the lock ceased on June 9th, 2015. Prior to the closure of USAF, the lock operated as part of a system to support navigation on the upper reaches of the Mississippi River 9-foot navigation channel.

Section 216 of the Flood Control Act of 1970 authorizes the Secretary of the Army to review operations of completed projects, when found advisable due to changed physical, economic, or environmental conditions. Disposition studies are a specific type of Section 216 study with the intent to determine whether a water resources development project operated and maintained by the Corps of Engineers should be de-authorized and the associated real property and Government-owned improvements disposed of.

The USAF Disposition Study analyzes three primary alternatives at the USAF site: (1) No action; (2) complete de-authorization by Congress of the Federal missions at the site and disposal of the properties according to Federal law; and (3) partial de-authorization and disposal. The partial disposition alternative will maintain the emergency flood mitigation capability of the structure. If the Corps of Engineers determines that Federal interest no longer exists, it must consider, and may recommend, disposal of the project or separable elements of the project under existing authorities.

The Disposition Study ends when the final report is approved by the Corps of Engineers' Headquarters Office. Deauthorization would require Congressional Approval.

Results of the study are summarized in the draft DR/EA, which includes an analysis of potential environmental effects and concludes the action would not constitute a major federal action significantly affecting the quality of the human environment. In accordance with the National Environmental Policy Act of 1969 (NEPA), the Corps is making the draft DR/EA available for public comments and will be holding one or more virtual public meetings summarizing the report prior to the comment deadline via Facebook Live or similar web-based platform. Additional details on these meeting(s) will be posted at least two weeks beforehand on the Saint Paul District's website: *https://www.mvp.usace.army.mil/.*

Authority: The District publishes this notice congruent with the National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321 *et seq.*), and its implementing regulations (40 CFR parts 1500–1508).

Edward E. Belk, Jr.,

Director of Programs.

[FR Doc. 2020–27964 Filed 12–17–20; 8:45 am]

BILLING CODE 3720–58–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Meetings

TIME AND DATE: 1:00 p.m., December 18, 2020.

PLACE: This meeting will be held via teleconference.

STATUS: Closed. The Board invoked the exemption described in 5 U.S.C. 552b(c)(2) and 10 CFR 1704.4(b). The Board determined that it is necessary to close this meeting to the public since an open meeting would likely disclose information related solely to the internal personnel rules and practices of the agency.

MATTERS TO BE CONSIDERED: At this meeting, members of the Board will receive a staff briefing and deliberate on appropriate agency reorganization to accommodate the Executive Director of Operations position.

CONTACT PERSON FOR MORE INFORMATION: Tara Tadlock, Director of Board Operations, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW, Suite 700, Washington, DC 20004–2901, (800) 788–4016. This is a toll-free number.

Dated: December 16, 2020.

Thomas Summers,

Acting Chairman.

[FR Doc. 2020–28135 Filed 12–16–20; 4:15 pm]

BILLING CODE 3670–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0087]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Comprehensive Literacy Program Evaluation: Comprehensive Literacy State Development (CLSD) Program Evaluation

AGENCY: Institute of Educational Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before January 19, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Tracy Rimdzius, 202–245–7283.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the

following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Comprehensive Literacy Program Evaluation: Comprehensive Literacy State Development (CLSD) Program Evaluation

OMB Control Number: 1850–0945

Type of Review: A revision of a currently approved collection

Respondents/Affected Public: Individuals and Households; State, Local, and Tribal Governments

Total Estimated Number of Annual Responses: 612

Total Estimated Number of Annual Burden Hours: 331

Abstract: The data collection described in this submission includes activities for the legislatively mandated evaluation of the Comprehensive Literacy State Development (CLSD) Program. The evaluation will provide information on the implementation of the program and its impact on student reading achievement. The CLSD evaluation is the second component of an evaluation of the U.S. Department of Education's comprehensive literacy programs. An earlier clearance package (OMB control number 1850–0945) covered the first component of the evaluation—an implementation study of the Striving Readers Comprehensive Literacy Program (the precursor program to CLSD). The CLSD evaluation will include an examination of implementation, a randomized trial to estimate the impact of CLSD funding on teacher and student outcomes, and a longitudinal comparison of trends in achievement in CLSD and similar, non-CLSD schools. This package requests clearance for data collection associated with the implementation analyses, the randomized trial, and initial data collection for the comparisons of longitudinal trends. A separate package will be submitted at a later date for all remaining data collection activities for the comparisons of longitudinal trends, which will take place following the 2023–24 school year.

Dated: December 15, 2020.

Stephanie Valentine,

PRA Coordinator,Strategic Collections and Clearance,Governance and Strategy Division,Office of Chief Data Officer,Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–27878 Filed 12–17–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0129]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Implementation of Key Federal Policies in the Wake of the Coronavirus Pandemic

AGENCY: Institute of Educational Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 19, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Erica Lee, 202–245–7437.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Implementation of Key Federal Policies in the Wake of the Coronavirus Pandemic.

OMB Control Number: 1850–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 228.

Total Estimated Number of Annual Burden Hours: 177.

Abstract: The coronavirus pandemic significantly disrupted K–12 educational operations and learning in spring 2020 and is likely to do so again during the 2020–21 school year. Federal education policies and funding are intended to support state and local agencies as they respond to the crisis. But the crisis may also shape the way federal programs are carried out. The U.S. Department of Education (the Department), through its Institute for Education Sciences (IES), is requesting clearance for a new data collection to examine how the pandemic may be influencing: (1) Implementation of, and waivers, from key provisions of the Elementary and Secondary Education Act, reauthorized as the Every Student Succeeds Act of 2015 (ESSA), and (2) state and district use of federal funds, including those provided specifically to help in the pandemic recovery, and (3) supports for English learners (ELs) in districts with high EL enrollments. The surveys of all state education agencies and a nationally representative sample of school districts is being conducted as part of an ongoing evaluation of Titles I and IIA of ESSA. Interviews of district and school personnel in high-EL districts are being conducted as part of an ongoing evaluation of Title III of ESSA.

Dated: December 15, 2020.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–27879 Filed 12–17–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Application for New Awards; Native American and Alaska Native Children in School Program

AGENCY: Office of English Language Acquisition, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2021 for the Native American and Alaska Native Children in School (NAM) Program, Assistance Listing Number 84.365C. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: December 18, 2020.

Deadline for Notice of Intent to Apply: January 4, 2021.

Deadline for Transmittal of Applications: March 3, 2021.

Deadline for Intergovernmental Review: May 3, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR–2019–02–13/pdf/2019–02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Celeste McLaughlin, U.S. Department of Education, 400 Maryland Avenue SW, room 4W206, Washington, DC 20202. Telephone: (202) 453–6054. Email: *NAM2021@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the NAM program is to award grants to eligible entities to develop and enhance capacity to provide effective instruction and support to Native American and Alaska Native students, including Native Hawaiian and Native American Pacific Islander students, who are identified as English learners (ELs). The goal of this program is to support the teaching, learning, and studying of Native American languages while also increasing the English language proficiency and academic achievement of students served.

Background: Through previous competitions, the NAM program has funded a range of grantees that are currently implementing 17 projects across the country. As we are focused on closing longstanding achievement and attainment gaps that have continued to grow, there is also a need to increase the knowledge of what practices work to effectively improve learning outcomes for Native American and Alaska Native ELs.

Congress, in the Native American Languages Act of 1990, recognized the fundamental importance of preserving Native American languages. This legislation provides that it is the policy of the United States to:

Preserve, protect, and promote the rights and freedom of Native Americans to use, practice, and develop Native American languages.

25 U.S.C. 2903(1)

In addition, the legislation states that it is the policy of the United States to encourage and support the use of Native American languages as a medium of instruction in order to encourage and support—

(A) Native American language survival,

(B) Educational opportunity,

(C) Increased student success and performance,

(D) Increased student awareness and knowledge of their culture and history, and

(E) Increased student and community pride.

25 U.S.C. 2903(3)

This Federal policy is supported by growing recognition of the importance of Native language preservation in facilitating educational success for Native students. In a 2007 study by Teachers of English to Students of Other Languages (TESOL), the majority of Native youth surveyed stated that they value their Native language, view it as integral to their sense of self, want to learn it, and view it as a means of facilitating their success in school and life.[1] Collaborative efforts between educators, families, and communities, the study suggests, may be especially promising ways to ensure that all Native students have the critical opportunity to learn their Native languages.

Not only is Native language instruction critical for student engagement and fostering a rich sense of self, but research has shown that students who are bilingual have certain cognitive and social benefits that their monolingual peers may lack.[2] Additionally, for students who are classified as ELs, well-implemented language instruction educational programs (as defined in this notice), including dual language approaches, may result in ELs performing equal to or better than their peers in English-only language instruction programs. These approaches have shown promise in increasing language acquisition in English and Native languages, and may also promote greater achievement in the academic content areas, including English language arts and mathematics.[3]

Therefore, to facilitate high-quality language instruction and academic success for Native American and Alaska Native students who are classified as ELs, this competition includes an absolute priority for projects that will support the preservation and revitalization of Native American languages while also increasing the English language proficiency of the children served under the project.

For this competition, the Department also seeks projects designed to promote seamless integration of in-person and remote learning needs through digital learning. Accordingly, this notice includes an invitational priority related to instructional adaptation for remote learning and educator professional development related to remote instruction.

In addition, the Department is interested in projects designed to promote literacy. Families play a critical role in preparing their children to enter kindergarten ready to succeed in school and in life. Research suggests that when families and schools work together and support each other in their respective roles, children have a more positive attitude toward school and experience more school success. Specifically, research has found that having parents reinforce specific literacy skills is effective in improving children's

[1] Romero-Little, M.E., McCarty, T.L., Warhol, L., and Zepeda, O. (2007). Language policies in practice: Preliminary findings from a large-scale study of Native American language shift. *TESOL Quarterly* 41:3, 607–618.

[2] Valentino, R.A., and Reardon, S.F. (2015). Effectiveness of four instructional programs designed to serve English language learners: Variation by ethnicity and initial English proficiency. *Educational Evaluation and Policy Analysis,* doi: 10.3102/0162373715573310.

[3] Lindholm-Leary, K.J. (2001). Dual-language education (Vol. 28). Multilingual Matters.

literacy.[4] Accordingly, this notice includes two invitational priorities related to remote learning and promoting literacy. The promoting literacy invitational priority is from the Department's Notice of Final Supplemental Priorities and Definitions for Discretionary Grant Programs, published in the **Federal Register** on March 2, 2018 (83 FR 9096). An applicant may address these priorities by proposing to improve remote learning and build greater and more effective family engagement in the education of the children it proposes to serve.

In order to grow the evidence available on effective ways to support Native American and Alaska Native ELs, we include a selection criterion to evaluate the extent to which an applicant's proposed project design is supported by a logic model that connects key project components to outcomes relevant to the program's purpose. Under the Government Performance and Results Act (GPRA), the Department has established measures that constitute the Department's indicators of success for this program. Consequently, we advise an applicant for a grant under this program to carefully consider these measures in conceptualizing the approach to, and evaluation for, its proposed project. Each grantee will be required to provide, in its annual performance and final reports, data about its progress in meeting these measures. Such evaluations help ensure that projects contribute to expanding the knowledge base on effective language instruction educational programs, including dual language practices, that prepare Native American and Alaska Native ELs to achieve college, career, and life success.

Priorities: This notice includes an absolute priority and two invitational priorities. The absolute priority is from section 3127 of the Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (ESEA) (20 U.S.C. 6848).

Absolute Priority: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Projects that support the teaching, learning, and studying of Native American languages while also increasing the English language proficiency of the children served.

Invitational Priorities: For FY 2021 and any subsequent years in which we make awards from the list of unfunded applications from this competition, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1) we do not give an application that meets an invitational priority a competitive or absolute preference over other applications.

These priorities are:

Remote Learning

Under this invitational priority, an applicant must propose a project that is designed to address one or both of the following priority areas:

(a) Adopting and supporting models that leverage technology (*e.g.,* universal design for learning, competency-based education, or hybrid/blended learning) and provide high-quality digital learning content, applications, and tools.

(b) Providing personalized and job-embedded professional learning to build the capacity of educators to effectively use technology to create remote learning experiences that advance student engagement and learning (*e.g.,* synchronous and asynchronous professional learning, professional learning networks or communities, and coaching).

For the purpose of this invitational priority—

Remote learning means programming where at least part of the learning occurs away from the physical school building in a manner that addresses a learner's educational needs. Remote learning may include online, hybrid/blended learning, or non-technology-based learning (*e.g.,* lab kits, project supplies, paper packets); and

Competency-based education (CBE) (also called proficiency-based or mastery-based learning) means learning based on knowledge and skills that are transparent and measurable. Progression is based on demonstrated mastery of what students are expected to know (knowledge) and be able to do (skills), rather than seat time or age.

Promoting Literacy

Projects that provide families with evidence-based (as defined in this notice) strategies for promoting literacy. Such strategies may include providing families with access to books or other physical or digital materials or content about how to support their child's reading development, or providing family literacy activities as defined in section 203(9) of the Workforce Innovation and Opportunity Act (WIOA).

Definitions: The following definitions are from 34 CFR 77.1, sections 3201 and 8101 of the ESEA (20 U.S.C. 7011 and 7801), and section 203(9) of the WIOA and apply to the priorities, selection criteria, and performance measures in this notice. The source of each definition is noted in parentheses following the text of the definition.

Ambitious means promoting continued, meaningful improvement for program participants or for other individuals or entities affected by the grant, or representing a significant advancement in the field of education research, practices, or methodologies. When used to describe a performance target, whether a performance target is ambitious depends upon the context of the relevant performance measure and the baseline for that measure. (34 CFR 77.1)

Baseline means the starting point from which performance is measured and targets are set. (34 CFR 77.1)

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes. (34 CFR 77.1)

English learner, when used with respect to an individual, means an individual—

(A) Who is aged 3 through 21;

(B) Who is enrolled or preparing to enroll in an elementary school or secondary school;

(C)(i) Who was not born in the United States or whose Native language is a language other than English;

(ii)(I) Who is a Native American or Alaska Native, or a Native resident of the outlying areas; and

(II) Who comes from an environment where a language other than English has had a significant impact on the individual's level of English language proficiency; or

(iii) Who is migratory, whose Native language is a language other than English, and who comes from an environment where a language other than English is dominant; and

(D) Whose difficulties in speaking, reading, writing, or understanding the English language may be sufficient to deny the individual—

(i) The ability to meet the State's challenging State academic standards;

(ii) The ability to successfully achieve in classrooms where the language of instruction is English; or

(iii) The opportunity to participate fully in society. (Section 8101 of the ESEA)

[4] Henderson, A.T. & Mapp, K.L. (2002). A new wave of evidence: The impact of school, family, and community connections on student achievement. Austin: SEDL.

Evidence-based means the proposed project component is supported by one or more of strong evidence, moderate evidence, promising evidence, or evidence that demonstrates a rationale. (34 CFR 77.1)

Family literacy activities means activities that are of sufficient intensity and quality, to make sustainable improvements in the economic prospects for a family and that better enable parents or family members to support their children's learning needs, and that integrate all of the following activities:

(A) Parent or family adult education and literacy activities that lead to readiness for postsecondary education or training, career advancement, and economic self-sufficiency.

(B) Interactive literacy activities between parents or family members and their children.

(C) Training for parents or family members regarding how to be the primary teacher for their children and full partners in the education of their children.

(D) An age-appropriate education to prepare children for success in school and life experiences. (Section 203(9) of the WIOA)

Language instruction educational program means an instruction course—

(A) In which an English learner is placed for the purpose of developing and attaining English proficiency, while meeting challenging State academic standards; and

(B) That may make instructional use of both English and a child's Native language to enable the child to develop and attain English proficiency, and may include the participation of English proficient children if such course is designed to enable all participating children to become proficient in English and a second language. (Section 3201 of the ESEA)

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes. (34 CFR 77.1)

Note: Applicants may use resources such as the Pacific Education Laboratory's Education Logic Model Application (*https://ies.ed.gov/ncee/edlabs/regions/pacific/elm.asp* or *https://eric.ed.gov/?id=ED544752*) to help design their logic models.

Native Hawaiian or Native American Pacific Islander Native language educational organization means a nonprofit organization with—

(A) A majority of its governing board and employees consisting of fluent speakers of the traditional Native American languages used in the organization's educational programs; and

(B) Not less than five years successful experience in providing educational services in traditional Native American languages. (Section 3201 of the ESEA)

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project. (34 CFR 77.1)

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for those teachers). (34 CFR 77.1)

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program. (34 CFR 77.1)

Program Authority: 20 U.S.C. 6822.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Government-wide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended in 2 CFR part 3474.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration's budget request for FY 2021 does not include funds for this program. However, we are inviting applications to allow enough time to complete the grant process before the end of the current fiscal year, if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2022 and any subsequent year from the list of unfunded applications from this competition.

Estimated Range of Awards: $275,000–325,000 per year.

Estimated Average Size of Awards: $300,000.

Estimated Number of Awards: 8.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* The following entities, when they operate elementary, secondary, or postsecondary schools primarily for Native American children (including Alaska Native children), are eligible applicants under this program:

(a) Indian Tribes.

(b) Tribally sanctioned educational authorities.

(c) Native Hawaiian or Native American Pacific Islander Native language educational organizations.

(d) Elementary schools or secondary schools that are operated or funded by the Department of the Interior's Bureau of Indian Education, or a consortium of these schools.

(e) Elementary schools or secondary schools operated under a contract with or grant from the Bureau of Indian Education in consortium with another such school or a Tribal or community organization.

(f) Elementary schools or secondary schools operated by the Bureau of Indian Education and an IHE, in consortium with an elementary school or secondary school operated under a contract with or a grant from the Bureau of Indian Education or a Tribal or community organization.

Note: Eligible applicants applying as a consortium should read and follow the regulations in 34 CFR 75.127 through 75.129.

Under section 3112(c) of the ESEA, EL students served under NAM grants must not be included in the child count submitted by a school district under section 3114(a) for purposes of receiving funding under the English Language Acquisition State Grants program.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses a restricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Equitable Participation by Public and Private School Students and*

Educational Personnel in an ESEA Title III Program: An entity that receives a grant under the NAM program must provide for the equitable participation of private school children and their teachers or other educational personnel. To ensure that grant program activities address the needs of private school children, the applicant must engage in timely and meaningful consultation with appropriate private school officials during the design and development of the program. This consultation must take place before the applicant makes any decision that affects the opportunities for participation by eligible private school children, teachers, and other educational personnel. Administrative direction and control over grant funds must remain with the grantee. (See section 8501 of the ESEA, Participation by Private School Children and Teachers.)

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the NAM competition, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Consistent with the process followed in the FY 2016 and FY 2018 competitions, we plan to post on our website the abstracts of all applications. Therefore, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 35 pages and (2) use the following standards:

- A ''page'' is 8.5'' x 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210. The maximum score for all of these criteria is 100 points. The maximum score for each criterion is indicated in parentheses.

(a) *Quality of the project design.* (up to 40 points)

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(2) The extent to which the design for implementing and evaluating the proposed project will result in information to guide possible replications of project activities or strategies including information about the effectiveness of the approach or strategies employed by the project.

(3) The extent to which the proposed project demonstrates a rationale (as defined in this notice).

(b) *Quality of project personnel.* (up to 10 points)

The Secretary considers the quality of the personnel who will carry out the proposed project. In determining the quality of project personnel, the Secretary considers the following factors:

(1) The extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(2) The qualifications, including relevant training and experience, of key project personnel.

(c) *Quality of the management plan.* (up to 30 points)

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(2) The extent to which the time commitments of the project director and the principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(d) *Quality of the project evaluation.* (up to 20 points)

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(2) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

The Department will screen applications that are submitted for NAM grants in accordance with the requirements in this notice and determine which applications meet the eligibility and other requirements. Peer reviewers will review all eligible applications for NAM grants that are submitted by the established deadline on the four selection criteria.

Applicants should note, however, that we may screen for eligibility at multiple points during the competition process, including before and after peer review; applicants that are determined to be ineligible will not receive a grant award regardless of peer reviewer scores or comments. If we determine that a NAM grant application does not meet a NAM eligibility requirement, the application will not be considered for funding.

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www2.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection, analysis, and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* Under GPRA, Federal departments and agencies must clearly describe the goals and objectives of programs, identify resources and actions needed to accomplish goals and objectives, develop a means of measuring progress made, and regularly report on achievement. One important source of program information on successes and lessons learned is the project evaluation conducted under individual grants.

(a) *Measures.* The Department has developed the following GPRA performance measures for evaluating the overall effectiveness of the NAM program and for Department reporting under 34 CFR 75.110:

- *Measure 1:* The number and percentage of ELs served by the project who score proficient or above on the State reading assessment.
- *Measure 2:* The number and percentage of ELs served by the project who have attained proficiency in English as measured by the State-approved English language proficiency assessment.
- *Measure 3:* The number and percentage of students participating in the Native language program who are making progress in learning a Native language, as determined by each grantee, including through measures such as performance tasks, portfolios, and pre- and post-tests.

(b) *Baseline data.* Applicants must provide baseline data for each of the GPRA performance measures listed in paragraph (a) and include why each proposed baseline is valid; or, if the applicant has determined that there are no established baseline data for a particular performance measure, explain why there is no established baseline and

explain how and when, during the project period, the applicant will establish a valid baseline for the performance measure. 34 CFR 75.110

(c) *Performance measure targets.* In addition, the applicant must propose in its application annual targets for the measures listed in paragraph (a). Applications must also include the following information as directed under 34 CFR 75.110(b) and (c):

(1) Why each proposed performance target (as defined in this notice) is ambitious (as defined in this notice) yet achievable compared to the baseline for the performance measure.

(2) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data.

(3) The applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

Note: If the applicant does not have experience with collection and reporting of performance data through other projects or research, the applicant should provide other evidence of capacity to successfully carry out data collection and reporting for its proposed project.

(d) *Performance reports.* All grantees must submit an annual performance report and final performance report with information that is responsive to these performance measures. The Department will consider these data in making annual continuation awards.

(1) The performance reports for all NAM 2021 grantees must include the following project performance data (34 CFR 75.253, 75.590, 75.591, and 75.720):

- The number of students who are eligible to participate in the program.
- The number of participants in the program.
- The number of participants who met the performance target.

(2) The performance reports for the NAM 2021 grantees that addressed the promoting literacy priority must also include the number of family literacy activities including the number of or access to books or other physical or digital materials or content that they provided.

(e) *Department evaluations.* Consistent with 34 CFR 75.591, grantees funded under this program must comply with the requirements of any evaluation of the program conducted by the Department or an evaluator selected by the Department.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Lorena McElwain,

Assistant Deputy Secretary and Director, Office of English Language Acquisition.

[FR Doc. 2020–27882 Filed 12–17–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ21–5–000]

City of Banning, California; Notice of Petition for Declaratory Order

Take notice that on December 9, 2020, pursuant to Rules 205 and 207 of the Commission's Rules of Practice and Procedure, 18 CFR 385.205, 385.207, and consistent with the provisions of the Transmission Owner (TO) Tariff, the City of Banning, California (Banning), submitted a petition for a declaratory order by the Commission (1) accepting Banning's annual revisions to its Transmission Revenue Balancing Account Adjustment (TRBAA); (2) approving Banning's annual update to the costs of its Existing Transmission Contract (ETC) with Southern California Edison Company (SCE) for purposes of recovery of such costs through the ETC Pass-Through Clause contained in Banning's TO Tariff; (3) accepting revisions to Appendix I to Banning's TO Tariff to reflect Banning's revised TRBAA, ETC costs, and updated Base and High Voltage Transmission Revenue Requirements (TRRs); (4) to the extent necessary, waiving the sixty-day notice requirement provided for in the Commission's regulations at 18 CFR 35.3(a); (5) waiving the filing fee associated with this Petition that is provided for by Rule 207 of the Commission's Rules of Practice and Procedure, 18 CFR 385.207; and (6) granting any other relief or waivers necessary or appropriate for approval and implementation of the revisions to Banning's Base TRR (including the updated ETC cost components), TRBAA, High Voltage TRR, and modifications to Banning's TO Tariff effective as of January 1, 2021, as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission strongly encourages electronic filings of comments, protests

and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on December 30, 2020.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27934 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–628–000]

Harry Allen Solar Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Harry Allen Solar Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 4, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27936 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21–53–000.

Applicants: Centerfield Cooper Solar, LLC.

Description: Self-Certification of Exempt Wholesale Generator of Centerfield Cooper Solar, LLC.

Filed Date: 12/14/20.

Accession Number: 20201214–5119.

Comments Due: 5 p.m. ET 1/4/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2042–035; ER10–1944–008; ER10–2051–010; ER10–1942–027; ER17–696–015; ER14–2931–008; ER10–2043–010; ER10–2029–012; ER10–2041–010; ER18–1321–003; ER10–2040–010; ER20–1939–001; ER10–1938–030; ER10–2036–011; ER10–1934–029; ER10–1893–029; ER10–3051–034; ER10–2985–033; ER10–3049–034; ER10–1889–008; ER10–3260–010; ER10–1895–008; ER10–1870–008; ER11–4369–014; ER16–2218–014; ER10–1862–029; ER10–1858–008; ER13–1401–008; ER10–2044–010.

Applicants: Calpine Energy Services, L.P., Bethpage Energy Center 3, LLC, Calpine Bethlehem, LLC, Calpine Construction finance Co., L.P., Calpine Energy Solutions, LLC, Calpine Fore River Energy Center, LLC, Calpine Mid-Atlantic Generation, LLC, Calpine Mid-Atlantic Marketing, LLC, Calpine Mid Merit, LLC, Calpine Mid-Merit II, LLC, Calpine New Jersey Generation, LLC, Calpine Northeast Development, LLC, Calpine PowerAmerica—CA, LLC, Calpine Vineland Solar, LLC, CES Marketing IX, LLC, CES Marketing X, LLC, Champion Energy, LLC, Champion Energy Marketing LLC, Champion Energy Services, LLC, CPN Bethpage 3rd Turbine, Inc., Granite Ridge Energy, LLC, KIAC Partners,Nissequogue Cogen Partners, North American Power and Gas, LLC, North American Power Business, LLC, TBG Cogen Partners, Power Contract Financing, L.L.C., Westbrook Energy Center, LLC, Zion Energy LLC

Description: Response to November 13, 2020 Deficiency Letter of Calpine Corporation indirect subsidiaries et al.

Filed Date: 12/14/20.

Accession Number: 20201214–5134.

Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: ER12–162–030; ER10–2984–050; ER11–2044–036 ER13–1266–033; ER15–2211–030.

Applicants: Bishop Hill Energy II LLC, CalEnergy, LLC, Merrill Lynch Commodities, Inc., MidAmerican Energy Company, MidAmerican Energy Services, LLC.

Description: Central Region Triennial Market Power Analysis of Bishop Hill Energy II LLC, et al.

Filed Date: 12/11/20.

Accession Number: 20201211–5205.

Comments Due: 5 p.m. ET 2/9/21.

Docket Numbers: ER21–635–000.

Applicants: Portland General Electric Company.

Description: § 205(d) Rate Filing: PGE–BPA E&P Agreement to be effective 12/14/2020.

Filed Date: 12/11/20.

Accession Number: 20201211–5169.

Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: ER21–636–000.

Applicants: American Electric Power Service Corporation, Ohio Power Company, AEP Ohio Transmission Company, Inc., PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: AEP submits Arlington FA re: ILDSA SA No. 1336 to be effective 2/10/2021.

Filed Date: 12/11/20.

Accession Number: 20201211–5178.

Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: ER21–637–000.

Applicants: Foxglove Wind LLC, Moonlite Wind 2 LLC.

Description: Request for Limited Waiver of Tariff Provisions, et al. of Foxglove Wind LLC, et al.

Filed Date: 12/11/20.

Accession Number: 20201211–5203.

Comments Due: 5 p.m. ET 12/21/21.

Docket Numbers: ER21–638–000.

Applicants: RWE Renewables Americas, LLC.

Description: Request for COVID–19 Related Waiver of Tariff Provisions, et al. of RWE Renewables Americas, LLC.

Filed Date: 12/11/20.

Accession Number: 20201211–5204.

Comments Due: 5 p.m. ET 12/21/21.

Docket Numbers: ER21–639–000.

Applicants: Wapello Solar LLC.

Description: Baseline eTariff Filing: Application for Market Based Rate Authority to be effective 12/17/2020.

Filed Date: 12/14/20.

Accession Number: 20201214–5056.

Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: ER21–640–000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: ISO–NE & NEPOOL; Changes to Qualification of Energy Eff. Resources in the FCM to be effective 2/12/2021.

Filed Date: 12/14/20.

Accession Number: 20201214–5107.

Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: ER21–641–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of ISA, SA No. 4519, Queue No. AA2–159 re: Withdrawal to be effective 1/15/2021.

Filed Date: 12/14/20.

Accession Number: 20201214–5114.

Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: ER21–643–000.

Applicants: Louisville Gas and Electric Company.

Description: § 205(d) Rate Filing: KYMEA Amended Wholesale Distribution Service Agreement No. 22 to be effective 12/15/2020.

Filed Date: 12/14/20.

Accession Number: 20201214–5133.

Comments Due: 5 p.m. ET 1/4/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27935 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3309–021]

Marlow Hydro, LLC; Notice of Application Tendered for Filing With the Commission, Soliciting Additional Study Requests, Establishing Procedural Schedule for Relicensing, and Setting Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 3309–021.

c. *Date filed:* December 1, 2020.

d. *Applicant:* Marlow Hydro, LLC (Marlow Hydro).

e. *Name of Project:* Nash Mill Dam Project.

f. *Location:* On the Ashuelot River, in the town of Marlow, Cheshire County, New Hampshire. The project does not occupy federal land.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Anthony Rosario and Carole Rosario, 139 Henniker St., Hillsborough, New Hampshire 03244, (603) 494–1854, (603) 494–3897, or email at *t-iem@tds.net* or *cprabr@tds.net.*

i. *FERC Contact:* Adam Peer at (202) 502–8449, or email *adam.peer@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: January 30, 2021.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–3309–021.

m. The application is not ready for environmental analysis at this time.

n. Marlow Hydro electronically filed the final license application cover letter and exhibit G drawings with the Commission on November 30, 2020 at 6:39 p.m. and the license application on December 1, 2020 at 10:03 a.m. Pursuant to 18 CFR 385.2001(a)(2), any document received after 5:00 p.m. eastern time is considered filed on the next regular business day. By this notice, the requirement under 18 CFR 16.20(c) to file the subsequent license application at least 24 months before the expiration of the current license (*i.e.,* no later than November 30, 2020 at 5:00 p.m.) is waived.

o. Project *Description:* The existing Nash Mill Dam Project utilizes water from the 2-acre impoundment and consists of: (1) A 249-foot-long dam consisting of: (i) A 57-foot-long, 9 foot-high concrete gravity spillway topped with 3-foot-high wooden flashboards, (ii) a 12-foot-long concrete intake section, and (iii) two, 12-foot-high earthen dam sections totaling 180 feet in length; (2) an intake structure with a 10-foot-high, 10-foot-wide trash rack; (3) a 1,500 foot-long, 48-inch diameter steel penstock; (4) a 31-foot-long, 18-foot-wide powerhouse located on the north side of the Ashuelot River that contains two vertical-shaft, fixed propeller turbine-generator units and one horizontal-shaft turbine-generator unit for a total installed capacity of 225 kilowatts; (5) a 600-foot-long tailrace; (6) a 1,800-foot-long bypassed reach; (7) a 1,400 foot-long transmission line and a 12.5-kilovolt transformer; and (8) appurtenant facilities. The average annual generation was 558,923 kilowatt-hours for the period from 2009 to 2018.

Marlow Hydro currently operates the project in run-of-river mode and releases a minimum flow of 5 cubic feet per second (cfs) into the bypassed reach.

Marlow Hydro proposes to continue to operate in run-of-river mode and to increase the minimum flow released into the bypassed reach to 12 cfs.

p. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (*e.g.,* license application) via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document (P–3309). At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19) issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or (202) 502–8659 (TTY).

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

q. *Procedural schedule and final amendments:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary) February 2021

Request Additional Information February 2021

Issue Notice of Acceptance May 2021

Issue Scoping Document 1 for comments June 2021

Request Additional Information (if necessary) September 2021

Issue Scoping Document 2 September 2021

Issue Notice of Ready for Environmental Analysis September 2021

r. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27930 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–639–000]

Wapello Solar LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced Wapello Solar LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 4, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all

interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27937 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–627–000]

Dry Lake Solar Holdings LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Dry Lake Solar Holdings LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 4, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27938 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ21–6–000]

City of Riverside, California; Notice of Petition for Declaratory Order

Take notice that on December 10, 2020, pursuant to Rules 205 and 207 of the Commission's Rules of Practice and Procedure, 18 CFR 385.205, 385.207, and consistent with the provisions of the Transmission Owner (TO) Tariff, the City of Riverside, California (Riverside), submitted a petition for a declaratory order by the Commission (1) accepting Riverside's annual revision to its Transmission Revenue Balancing Account Adjustment (TRBAA); (2) approving Riverside's annual update to the costs of its Existing Transmission Contracts (ETCs) with Southern California Edison Company (SCE) for purposes of recovery of such costs through the ETC Passthrough Clause contained in Riverside's TO Tariff; (3) accepting revisions to Appendix I to Riverside's TO Tariff to reflect Riverside's revised TRBAA, ETC costs, and updated Base and High Voltage Transmission Revenue Requirements (TRRs); (4) to the extent necessary, waiving the sixty-day notice requirement provided for in the Commission's regulations at 18 CFR35.3(a); (5) waiving the filing fee associated with this Petition that is provided for by Rule 207 of the Commission's Rules of Practice and Procedure, 18 CFR 385.207; and (6) granting any other relief or waivers necessary or appropriate for approval and implementation of the revisions to Riverside's Base TRR (including the updated ETC cost components), TRBAA, High Voltage TRR, and modifications to Riverside's TO Tariff effective as of January 1, 2021, as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://*

ferc.gov) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on December 31, 2020.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27927 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Effectiveness of Exempt Wholesale Generator and Foreign Utility Company Status

Wilmot Energy Center, LLC	EG20–240–000
Mohave County Wind Farm LLC.	EG20–241–000
	Weaver Wind Maine Master Tenant, LLC
	EG20–242–000
Weaver Wind, LLC	EG20–243–000
Harts Mill Solar, LLC	EG20–244–000
Townsite Solar, LLC	EG20–245–000
Altamont Winds LLC	EG20–246–000
Bluebell Solar II, LLC	EG20–247–000
Concho Bluff LLC	EG20–248–000
Hill Top Energy Center LLC	EG20–249–000
Topaz Generating, LLC	EG20–250–000
Muscle Shoals Solar, LLC	EG21–1–000
Fort Hills Energy LP	FC20–15–000]

Take notice that during the month of November 2020, the status of the above-captioned entities as Exempt Wholesale Generators or Foreign Utility Companies became effective by operation of the Commission's regulations. 18 CFR 366.7(a) (2020).

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27926 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–630–000]

325MK 8ME LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of 325MK 8ME LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 4, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27933 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–632–000]

Toms River Merchant Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Toms River Merchant Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in ordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 4, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the

eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: December 14, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–27932 Filed 12–17–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9054–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed December 7, 2020 10 a.m. EST Through December 14, 2020 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20200260, Final Supplement, BR, CA, B.F. Sisk Dam Raise and Reservoir Expansion Project, Review Period Ends: 01/19/2021, Contact: Casandra Arthur 530–892–6202.

EIS No. 20200261, Draft Supplement, USACE, FL, Port Everglades Harbor, Broward County, Florida, Comment Period Ends: 02/01/2021, Contact: Angela Dunn 904–232–2336.

Amended Notice

EIS No. 20200210, Draft, STB, UT, Uinta Basin Railway, Comment Period Ends: 01/28/2021, Contact: Joshua Wayland 202–245–0330.

Revision to FR Notice Published 10/30/2020; Extending the Comment Period from 12/14/2020 to 01/28/2021.

EIS No. 20200242, Draft, USACE, VA, Surry To Skiffes Creek to Whealton Transmission Project, Comment Period Ends: 02/10/2021, Contact: Randy Steffey 757–201–7579.

Revision to FR Notice Published 11/27/2020; Extending the Comment Period from 01/11/2021 to 02/10/2021.

Dated: December 14, 2020.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2020–27888 Filed 12–17–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2019–0502; FRL–10017–44]

Perchloroethylene (PCE); Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final Toxic Substances Control Act (TSCA) risk evaluation of perchloroethylene (PCE). The purpose of conducting risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation, without consideration of costs or other nonrisk factors. EPA has determined that specific conditions of use of PCE present an unreasonable risk of injury to health or the environment. For those conditions of use for which EPA has found an unreasonable risk, EPA must move to address that unreasonable risk through risk management measures enumerated in TSCA. EPA has also determined that specific conditions of use do not present unreasonable risk of injury to health or the environment. For those conditions of use for which EPA has found no unreasonable risk to health or the environment, the Agency's determination is a final Agency action and is issued via order in the risk evaluation.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0502, is available online at *http://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Yvette Selby-Mohamadu, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–5245; email address: *selby-mohamadu.yvette@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are or may be interested in risk evaluations of chemical substances under TSCA, 15 U.S.C. 2601 *et seq.* Since other entities may also be interested in this final risk evaluation, the EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is the Agency's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to ''determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.'' 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k). TSCA section 6(i) directs that a determination of ''no unreasonable risk'' shall be issued by order and considered to be a final Agency action, while a determination of ''unreasonable risk'' is not considered to be a final Agency action. 15 U.S.C. 2605(i).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

The statute requires that the risk evaluation process be completed within a specified timeframe and provide an opportunity for public comment on a draft risk evaluation prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4).

Subsection 5.4.1 of the final risk evaluation for PCE constitutes the order required under TSCA section 6(i)(1), and the ''no unreasonable risk'' determinations in that subsection are considered to be a final Agency action effective on the date of issuance of the order. In conducting risk evaluations, ''EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation. . ..'' 40 CFR 702.47. Under EPA's implementing regulations, ''[a] determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.'' 40 CFR 702.49(d). For purposes of TSCA section 19(a)(1)(A), the date of issuance of the TSCA section 6(i)(1) order for PCE shall be at 1:00 p.m. Eastern time (standard or daylight, as appropriate) on the date that is two weeks after the date when this notice is published in the **Federal Register**, which is in accordance with 40 CFR 23.5.

C. What action is EPA taking?

EPA is announcing the availability of the risk evaluation of the chemical substance identified in Unit II. In this risk evaluation EPA has made unreasonable risk determinations on some of the conditions of use within the scope of the risk evaluation for this chemical. For those conditions of use for which EPA has found an unreasonable risk of injury to health or the environment, EPA must initiate regulatory action to address those risks through risk management measures enumerated in 15 U.S.C. 2605(a).

EPA also is announcing the availability of the information required to be provided publicly with each risk evaluation, which is available online at *http://www.regulations.gov* in the dockets identified. 40 CFR 702.51. Specifically, EPA has provided:

- The scope document and problem formulation (in Docket ID No. EPA–HQ–OPPT–2016–0732);
- Draft risk evaluation and final risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0502);
- All notices, determinations, findings, consent agreements, and orders (in Docket ID No. EPA–HQ–OPPT–2019–0502);
- Any information required to be provided to the Agency under 15 U.S.C. 2603 (in Docket ID No. EPA–HQ–OPPT–2016–0732 and Docket ID No. EPA–HQ–OPPT–2019–0502);
- A nontechnical summary of the risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0502);
- A list of the studies, with the results of the studies, considered in carrying out each risk evaluation (Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-)) in Docket ID No. EPA–HQ–OPPT–2019–0502);
- The final peer review report, including the response to peer review and public comments received during peer review (in Docket ID No. EPA–HQ–OPPT–2019–0502); and
- Response to public comments received on the draft scope and the draft risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0502).

II. TSCA Risk Evaluation

A. What is EPA's risk evaluation process for existing chemicals under TSCA?

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. As this chemical is one of the first ten chemical substances undergoing risk evaluation, the chemical substance was not required to go through prioritization (81 FR 91927, December 19, 2016) (FRL–9956–47). The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other nonrisk factors, use reasonably available information and approaches in a manner that is consistent with the requirements in TSCA for the use of the best available science, and ensure decisions are based on the weight of the scientific evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on EPA's website at *http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-*

existing-chemicals-under-tsca. As explained in the preamble to EPA's final rule on procedures for risk evaluation (82 FR 33726, July 20, 2017) (FRL–9964–38), the specific regulatory process set out in 40 CFR part 702, subpart B will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

Prior to the publication of this final risk evaluation, a draft risk evaluation was subject to peer review and public comment. EPA reviewed the peer review report from the Science Advisory Committee on Chemicals (SACC) and public comments and has supplemented the risk evaluation in response to these comments as appropriate. The public comments and peer review report are in Docket EPA–HQ–OPPT–2019–0502 at *www.regulations.gov.* Prior to the publication of the draft risk evaluation, EPA made available the scope and problem formulation, and solicited public input on uses and exposure. EPA's documents and the public comments are in Docket EPA–HQ–OPPT–2019–0502. Additionally, information about the scope, problem formulation, and draft risk evaluation phases of the TSCA risk evaluation for this chemical is available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-perchloroethylene.*

B. What is Perchloroethylene?

Perchloroethylene is currently manufactured, processed, distributed, used, and disposed of as part of a wide range of industrial, commercial, and consumer conditions of use, including production of fluorinated compounds, and as a solvent in dry cleaning and vapor degreasing. Consumer and commercial products that contain perchloroethylene include adhesives (arts and crafts, as well as light repairs), aerosol degreasing, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish and other cleaners used for wiping surfaces. The yearly aggregate production volume for perchloroethylene ranged from 388 to 324 million pounds between 2012 and 2015 according to CDR data.

Authority: 15 U.S.C. 2601 *et seq.*

Andrew Wheeler,

Administrator.

[FR Doc. 2020–27880 Filed 12–17–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 17305]

Federal Advisory Committee Act; Technological Advisory Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC) Technological Advisory Council will hold a meeting on Thursday January 14, 2021 via conference call and available to the public via the internet at *http://www.fcc.gov/live,* from 10:00 a.m. to 12:30 p.m.

DATES: Thursday January 14, 2021.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Michael Ha, Deputy Chief, Policy and Rules Division 202–418–2099; *michael.ha@fcc.gov.*

SUPPLEMENTARY INFORMATION: At the January 14th meeting, the TAC will consider and vote on a white paper prepared by the Artificial Intelligence working group and recommendations from its four working groups: 5G/IOT/V–RAN, Future of Unlicensed Operations, Artificial Intelligence, and 5G Radio Access Network Technology. This agenda may be modified at the discretion of the TAC Chair and the Designated Federal Officer (DFO). Meetings are broadcast live with open captioning over the internet from the FCC Live web page at *http://www.fcc.gov/live/.* The public may submit written comments before the meeting to Michael Ha, the FCC's Designated Federal Officer for Technological Advisory Council by email: *michael.ha@fcc.gov* or U.S. Postal Service Mail (Michael Ha, Federal Communications Commission, 45 L Street NE, Washington, DC 20554). Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Office of Engineering and Technology at 202–418–2470 (voice), (202) 418–1944 (fax). Such requests should include a detailed description of the accommodation needed. In addition, please include your contact information. Please allow at least five days advance notice; last minute requests will be accepted but may not be possible to fill.

Federal Communications Commission.

Ronald T. Repasi,

Acting Chief, Office of Engineering and Technology.

[FR Doc. 2020–27832 Filed 12–17–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS20–14]

Agency Information Collection Activities; Renewal of an Approved Information Collection: Reporting information for the AMC Registry

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council (ASC)

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the ASC invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection request entitled ''Reporting information for the AMC Registry.''

DATES: Written comments must be received on or before February 16, 2021 to be assured of consideration.

ADDRESSES: Commenters are encouraged to submit comments by the Federal eRulemaking Portal or email, if possible. You may submit comments, identified by Docket Number AS20–14, by any of the following methods:

- *Federal eRulemaking Portal: https://www.Regulations.gov.* Follow the instructions for submitting comments. Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov*, including instructions for submitting public comments.
- *E-Mail: webmaster@asc.gov.* Include the docket number in the subject line of the message.
- *Fax:* (202) 289–4101. Include the docket number of fax cover sheet.
- *Mail:* Address to Appraisal Subcommittee, Attn: Lori Schuster, Management and Program Analyst, 1325 G Street NW, Suite 500, Washington, DC 20005.
- *Hand Delivery/Courier:* 1325 G Street NW, Suite 500, Washington, DC 20005.

In general, the ASC will enter all comments received into the docket and publish those comments on the *Regulations.gov* website without change, including any business or

personal information that you provide, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. The ASC will summarize and/or include your comments in the request for OMB's clearance of this information collection.

You may review comments and other related materials that pertain to this action by any of the following methods:

• *Viewing Comments Electronically:* Go to *https://www.Regulations.gov.* Enter ''Docket ID AS20–14'' in the Search box and click ''Search.'' Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov*, including instructions for viewing public comments, viewing other supporting and related materials, and viewing the docket after the close of the comment period.

• *Viewing Comments Personally:* You may personally inspect comments at the ASC office, 1325 G Street NW, Suite 500, Washington, DC 20005. To make an appointment, please call Lori Schuster at (202) 595–7578.

FOR FURTHER INFORMATION CONTACT: Alice M. Ritter, General Counsel, at (202) 595–7577, or Lori Schuster, Management and Program Analyst, at (202) 595–7578, Appraisal Subcommittee, 1325 G Street NW, Suite 500, Washington, DC 20005.

SUPPLEMENTARY INFORMATION: *Title:* Reporting information for the AMC Registry.

OMB Number: 3139–0009.

Abstract: The Dodd-Frank Act requires the ASC to maintain the National Registry of Appraisal Management Companies (AMC Registry) of those AMCs that are either: (1) registered with and subject to supervision by a State that has elected to register and supervise AMCs; or (2) are Federally regulated AMCs. In order for a State that elects to register and supervise AMCs to enter an AMC on the AMC Registry, the following items are required entries by the State via extranet application on the AMC Registry:

State Abbreviation
State Registration Number for AMC
Employer Identification Number (EIN)
AMC Name
Street Address
City
State
Zip
License or Registration Status
Effective Date
Expiration Date
AMC Type (State or multi-State)
Disciplinary Action
Effective Date
Expiration Date
Number of Appraisers (for invoicing registry fee)

States listing AMCs on the AMC Registry enter the above information for each AMC for the initial entry only. After the initial entry, the information is retained on the AMC Registry, and will only need to be amended if necessary by the State. The estimate for burden assumes that 51 States will elect to register and supervise AMCs, and that the average number of AMCs in a State will be 90. This estimate is based on information currently available on the AMC Registry, and will be high for some States, and low for other States. As of December 11, 2020, 36 States are submitting data to the AMC Registry. The initial entry by a State on a single AMC is estimated to take 15 minutes. Subsequent entries to amend information on an AMC, annually or periodically, are estimated to be negligible.

Current Action: Annual Burden has been decreased from 1,875 hours to 1,173 as the number of 150 that was used in the original estimate has been decreased to 90.

Type of Review: Extension of a currently approved collection.

Affected Public: States.

Estimated Number of Respondents: 51 States.

Estimated burden per Response: 15 minutes.

Frequency of Response: Annually and on occasion.

Estimated total Annual Burden: 1,173 hours.

By the Appraisal Subcommittee,

James R. Park,

Executive Director.

[FR Doc. 2020–27970 Filed 12–17–20; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than January 19, 2021.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *Hyperion Bancshares, Inc., Philadelphia, Pennsylvania;* to become a bank holding company by acquiring Hyperion Bank through the merger of Hyperion Interim Bank with and into Hyperion Bank, a wholly owned subsidiary of Hyperion Bancshares, Inc., all of Philadelphia, Pennsylvania.

Board of Governors of the Federal Reserve System, December 15, 2020.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2020–27961 Filed 12–17–20; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') requests that the Office of Management and Budget (''OMB'') extend for an additional three years the current Paperwork Reduction Act (''PRA'') clearance for the information collection requirements in the Business

Opportunity Rule (''Rule''). That clearance expires on January 31, 2021.

DATES: Comments must be submitted by January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Christine M. Todaro, Attorney, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, CC–8528, Washington, DC 20580, (202) 326–3711.

SUPPLEMENTARY INFORMATION: *Title of Collection:* Disclosure Requirements Concerning Business Opportunities, 16 CFR part 437.

OMB Control Number: 3084–0142.

Type of Review: Extension without change of currently approved collection.

Affected Public: Private Sector: Businesses and other for-profit entities.

Abstract: The Business Opportunity Rule requires business opportunity sellers to furnish prospective purchasers a disclosure document that provides information regarding the seller, the seller's business, and the nature of the proposed business opportunity, as well as additional information to substantiate any claims about actual or potential sales, income, or profits for a prospective business opportunity purchaser. The seller must also preserve information that forms a reasonable basis for such claims. The Rule is designed to ensure that prospective purchasers receive information to help them evaluate business opportunities. Sellers must disclose five key items of information in a simple, one-page document: (1) The seller's identifying information; (2) whether the seller makes a claim about the purchaser's likely earnings (and, if yes, the seller must provide information supporting any such claims); (3) whether the seller, its affiliates, or key personnel have been involved in certain legal actions (and, if yes, the seller must provide a separate list of those actions); (4) whether the seller has a cancellation or refund policy (and, if yes, the seller must provide a separate document stating the material terms of such policies); and (5) a list of persons who have purchased the business opportunity within the previous three years. Misrepresentations and omissions are prohibited under the Rule, and for sales conducted in languages other than English, all disclosures must be provided in the language in which the sale is conducted.

Estimated Annual Burden Hours: 10,065.

Estimated Annual Labor Costs: $703,141.

Estimated Annual Non-Labor Costs: $3,057,203.[1]

Request for Comment

On July 28, 2020, the Commission sought comment on the information collection requirements associated with the Privacy Rule. 85 FR 45427 (July 28, 2020). No relevant comments were received. Pursuant to the OMB regulations, 5 CFR part 1320, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew clearance for the Rule's information collection requirements.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential'' as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2020–27831 Filed 12–17–20; 8:45 am]

BILLING CODE 6750–01–P

[1] This number differs slightly from the annual non-labor cost estimate ($3,056,503) published in the Commission's July 28, 2020 **Federal Register** notice due to a transcription error relating to the number of entities marketing business opportunities in a language other than English.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21–21AN; Docket No. CDC–2020–0115]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''Examining Safety and Health Among Aviation Industry Workers in Alaska: A Survey.'' The goals of this survey are to collect information on injuries and illness; identify the perceived safety and health needs and concerns; develop safety guidance; and assist in generating hypotheses for future research on health and safety topics among Alaska aviation industry workers.

DATES: CDC must receive written comments on or before February 16, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0115 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger,

Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Examining Safety and Health Among Aviation Industry Workers in Alaska: A Survey—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. The Occupational Safety and Health Act, 91 (section 20[a][1]), authorizes NIOSH to conduct research to advance the health and safety of workers.

The Alaska Department of Labor and Workforce Development received over 320,000 reports of occupational injury or illness which cost more than $3 billion in workers' compensation benefits from 2000–2013. Maintenance technicians and ramp/baggage/cargo/dock agents made up the largest number of claims from the aviation industry. Among these workers, the most frequently observed injury event was overexertion/bodily reaction, which most often led to sprains, strains, and tears.

NIOSH is proposing to update findings from a NIOSH-funded survey conducted in Alaska during 2001–2002 on attitudes and practices of pilots and aviation operators. This project is part of a larger National Occupational Research Agenda project ''Improving Safety in the Commercial Aviation Industry in Alaska'' which includes a survey of aviation workers in Alaska using workers' compensation claims data to guide the selection of employee groups to target for survey participation.

The goals of this study are (1) To better understand work practices and the work environment where injuries occur in the aviation industry, (2) To identify and quantify the characteristics, attitudes, practices, and observations of workers to determine potential risk factors, and (3) To provide a snapshot of workers' perceived safety and health needs and concerns. The results of the study will be used to develop denominators for each occupation; identify statistically significant correlations between attitudes, behaviors, company policies, and accident rates; guide the development of prioritized evidence-based interventions and safety solutions for these workers and potentially other workers with similar tasks and in similar environments; and generate hypotheses for future research on health and safety topics in the aviation industry.

NIOSH has contracted with the University of Alaska Anchorage's Institute of Social and Economic Research (ISER) to develop and conduct the surveys. ISER conducted the previous survey of Alaska operators and pilots in 2001 and 2002 and has extensive experience in survey research in Alaska. The statewide survey questionnaire will be administered to air taxi and commuter airline operators (including the subset of single-pilot operators), commercial pilots, ramp/baggage/cargo/dock agents, customer service agents, and maintenance technicians.

The questionnaire for operators requests the number of employed pilots, ramp/baggage/cargo/dock agents, customer service agents, and maintenance technicians. This second element in the sample design will allow for the determination of the number of employees in each occupational group needed to complete the survey. The operator questionnaire requests the number of employees in the four occupational groups—pilots, mechanics, customer service agents, and ramp/baggage/cargo/dock agents, and their names and contact information.

The burden table lists the estimated population size of 306 operators; 820 commercial pilots; 1,400 maintenance technicians; 1,100 ramp/baggage/cargo/dock agents; and 1,600 customer service agents based on data from the Alaska Department of Labor and Workforce Development (2016). The total burden for all surveys, is estimated to be 1,547 hours. CDC is requesting a one-year approval. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Operators	Operator_Survey	306	1	25/60	128
Pilots	Pilot_Survey	820	1	25/60	342
Maintenance technicians	Maintenance Technician_Survey	1400	1	15/60	350
Ramp/baggage/cargo/dock agents	RBCD_Survey	1100	1	15/60	275
Customer Service Agents	CSA_Survey	1600	1	15/60	400
All non-respondents	Non-respondent Questionnaire	1045	1	3/50	52

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Total					1,547

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–27818 Filed 12–17–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–21–21BG; Docket No. CDC–2020–0118]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled the Prevention Research Centers (PRC) National Program Evaluation Reporting System (PERS). The purposes of the information collection system are to monitor progress on PRC program inputs, activities, outputs, and outcomes; support program management, evaluation, and improvement; facilitate internal and external reporting; and demonstrate accountability for Congressional funding. CDC has received and incorporated feedback from PRCs on the current version of PERS.

DATES: CDC must receive written comments on or before February 16, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0118 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Prevention Research Centers National Program Evaluation Reporting System (PERS)—NEW—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 1984, Congress passed Public Law 98–551 directing the Department of Health and Human Services (DHHS) to establish Centers for Research and Development of Health Promotion and Disease Prevention. Beginning in 1986, the CDC received funding to lead the Prevention Research Centers (PRC) Program. Each PRC receives funding from the CDC to establish its core infrastructure and functions and conduct a core research project. Core research projects reflect each PRC's area of expertise and community needs. PRC core research projects align with the health disparities and goals outlined in Healthy People 2020 and Healthy People 2030. PRCs also have the opportunity to apply for additional competitive CDC funding to complete special interest projects (SIPs) to focus on a topic of interest or a gap in scientific evidence.

In 2018, the CDC published program announcement DP19–001 for the current PRC Program funding cycle (September 30, 2019—September 29, 2024). Twenty-six PRCs were selected through a competitive, external, peer-review process. The program is now in its second year of the current five-year funding cycle. Each PRC is housed within an accredited school of public health or an accredited school of

medicine or osteopathy with a preventive medicine residency program. The PRCs conduct outcomes-oriented, applied prevention research, on priority public health topics using a multi-disciplinary and community-engaged approach. Partners include, but are not limited to, state, local, and tribal health departments, departments of education, schools and school districts, community-based organizations, healthcare providers, and health organizations. Partners collaborate with the PRCs to assess community needs; identify research priorities; set research agendas; conduct research projects and related activities such as training and technical assistance; translate research findings; and disseminate research results to public health practitioners, other researchers, and the general public.

In 2020, CDC convened a work group consisting of representatives from 11 PRCs to review proposed data fields in PERS and provide feedback to CDC. Their feedback was used to refine the data fields and ensure feasibility of the data collection and reporting by PRCs. These data will be used for program monitoring and evaluation purposes.

CDC's proposed information collection plan is as follows: CDC will use the information reported by PRCs through PERS to identify training and technical assistance needs, respond to requests for information from Congress and other sources, monitor grantees' compliance with cooperative agreement requirements, evaluate progress made in achieving goals and objectives, and inform program improvement efforts. In addition, these monitoring data will support CDC's ability to describe the impact and effectiveness of the PRC Program.

The CDC currently funds 26 PRCs and each center will annually report the required information to the CDC through PERS during years 3–5 of the cooperative agreement. The average, estimated annualized burden per respondent is 25 hours. The total, estimated, annualized burden for all respondents is 650 hours. The proposed web-based data collection system will allow data entry during the entire year, which will enable respondents to distribute burden throughout each funding year. Response burden is estimated to decrease significantly in years four and five, because cumulative reporting means some sections will require little to no editing through the funding cycle. The average estimated annualized burden for year three is expected to be 32 hours whereas the average estimated annualized burden for years four and five is expected to be 21 hours.

OMB approval is requested for three years, which will cover the last three years in the current funding cycle. As stated in the program announcement, PRC Program recipients are required to report data in PERS. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
PRCs	PERS	26	1	25	650

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–27819 Filed 12–17–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2020–0123]

Announcement and Request for comment on Non-Substantive Changes to Three Data Collections

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a public docket to obtain comment on non-substantive changes to three data collections conducted by CDC's National Center for Health Statistics (NCHS). Although CDC has already obtained approval from the Office of Management and Budget (OMB) under the Paperwork Reduction Act on these non-substantive changes, CDC is requesting public comment on these non-substantive changes.

DATES: Electronic or written comments must be received by February 16, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0123, by either of the following methods.

Note: CDC does not accept comments by email.

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name, Docket Number, and the OMB number associated with the survey about which comments are being provided. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above. Do not submit comments by email.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: With this notice, CDC is providing public notice regarding the addition of a small number of COVID–19 related questions to each of the following surveys National Ambulatory Medical Care Survey (NAMCS) OMB Control No. 0920–0278, National Electronic Health Records Survey (NEHRS) OMB Control No. 0920–1015, and National Hospital Care Survey (NHCS) OMB Control No. 0920–0212. These new questions are designed to provide information that is essential to CDC's emergency response to the outbreak of a novel coronavirus. Because these three OMB numbers are associated with ongoing, long-term collections, OMB requires that public comments be solicited to inform any adjustments to the wording of the questions or modification of the specific content of the COVID–19 related

questions in future rounds of data collections.

National Ambulatory Medical Care Survey (NAMCS) (OMB Control No. 0920–0278, Exp. 05/31/2022)

NAMCS obtains nationally representative estimates on the provision of health care in physician offices and community health centers (CHCs).

NAMCS added a short block of questions related to COVID–19 in both (1) the traditional office-based Physician Induction Interview, and (2) the Community Health Center (CHC) Director Induction Interview to provide essential information on how the pandemic affected care provided in office based physician offices and CHCs. The five questions (some with sub-questions) added are presented below. No one respondent would answer all sub-questions. Since the interviewer has gained efficiency in the response options for the other non-COVID–19 questions, the additional five questions will be absorbed by the current estimated burden calculations. Therefore, no change in burden is expected.

NAMCS–1 Traditional Physician Induction Interview

Now I would like to ask you a few questions about the coronavirus disease (COVID–19) and the impact it had on operations in your office and on your staff.

During the past THREE months, how often did your office experience shortages of any of the following personal protective equipment due to the onset of the coronavirus disease (COVID–19) pandemic?

Respirators or other approved facemasks
Eye protection, isolation gowns, or gloves

During the past THREE months, did your office have the ability to test patients for coronavirus disease (COVID–19) infection?

During the past THREE months, how often did your office have a location where patients could be referred to for coronavirus disease (COVID–19) testing?

During the past THREE months, did your office need to turn away or refer elsewhere any patients with confirmed or presumptive positive coronavirus disease (COVID–19) infection?

During the past THREE months, did any of the following clinical care providers in your office test positive for coronavirus disease (COVID–19) infection?
Physicians
Physician assistants
Nurse practitioners
Certified nurse-midwives
Registered nurses/licensed practical nurses
Other clinical care providers

During January and February 2020, was your office using telemedicine or telehealth technologies (for example, audio with video, web videoconference) to assess, diagnose, monitor, or treat patients?

After February 2020, did your office's use of telemedicine or telehealth technologies to conduct patient visits increase?

After February 2020, how much has your office's use of telemedicine or telehealth technologies to conduct patient visits increased?

After February 2020, has your office started using telemedicine or telehealth technologies?

Since your office started using these technologies, how many of your patient visits have been conducted using telemedicine or telehealth technologies?

NAMCS–1 Community Health Center (CHC) Respondent Induction Interview

Now I would like to ask you a few questions about the coronavirus disease (COVID–19) and the impact it had on operations in your CHC and on your staff.

During the past THREE months, how often did your center experience shortages of any of the following personal protective equipment due to the onset of the coronavirus disease (COVID–19) pandemic?

Respirators or other approved facemasks
Eye protection, isolation gowns, or gloves

During the past THREE months, did your center have the ability to test patients for coronavirus disease (COVID–19) infection?

During the past THREE months, how often did your center experience shortages of coronavirus disease (COVID–19) tests for any patients who needed testing?

During the past THREE months how often did your center have a location where patients could be referred to for coronavirus disease (COVID–19) testing?

During the past THREE months, did your center need to turn away or refer elsewhere any patients with confirmed or presumptive positive coronavirus disease (COVID–19) infection?

During the past THREE months, did any of the following clinical care providers in your center test positive for coronavirus disease (COVID–19) infection?

Physicians
Physician assistants
Nurse practitioners
Certified nurse-midwives
Registered nurses/licensed practical nurses
Other clinical care providers

During January and February 2020, was your center using telemedicine or telehealth technologies (for example, audio with video, web videoconference) to assess, diagnose, monitor, or treat patients?

After February 2020, did your center's use of telemedicine or telehealth technologies to conduct patient visits increase?

After February 2020, how much has your center's use of telemedicine or telehealth technologies to conduct patient visits increased?

After February 2020, has your center started using telemedicine or telehealth technologies?

Since your center started using these technologies, how many of your patient visits have been conducted using telemedicine or telehealth technologies?

National Electronic Health Records Survey (NEHRS) (OMB Control No. 0920–1015, Exp. 12/31/2022)

NEHRS collects information on office-based physicians' adoption and use of electronic health record (EHR) systems, practice information, patient engagement, controlled substances prescribing practices, use of health information exchange (HIE), and the documentation and burden associated with medical record systems(which include both paper-based and EHR systems).

Six telemedicine technology questions to assess the use of telemedicine to provide clinical services to patients in response to the COVID–19 pandemic were added to NEHRS. The additional six questions will be absorbed by the current estimated burden calculations. Therefore, no change in burden is expected.

NEHRS Questions

Does your practice use telemedicine technology (*e.g.,* audio, audio with video, web videoconference) for patient visits?

1. Since January 2020, what percentage of your patient visits were through telemedicine technology?
2. What type(s) of telemedicine tools did you use for patient visits?
3. What, if any, issues affected your use of telemedicine?
4. To what extent are you able to provide similar quality of care during telemedicine visits as you do during in-person visits?
5. Please rate your overall satisfaction with using telemedicine technology for patient visits.
6. Do you plan to continue using telemedicine visits (in addition to in-person visits) when appropriate once the COVID–19 pandemic is over?

National Hospital Care Survey (NHCS) (OMB Control No. 0920–0212, Exp. 03/31/2022)

NHCS collects information on inpatient hospital stays. The six questions related to COVID–19 were added to the NHCS Annual Hospital Interview were designed to provide insight into the impact of COVID–19 on the operations of hospital emergency departments (EDs) in the United States. These questions will ask about: (1) Shortages of COVID–19 tests, (2) creation of outside COVID–19 screening areas, (3) referrals for patients with confirmed or presumptive positive COVID–19 infection, (4) clinical care providers at the responding hospital testing positive for COVID–19, (5) the number of inpatient/emergency department ED visits for the year that were related to confirmed COVID–19, and (6) the number of inpatient/ED visits for the year that were related to presumptive positive COVID–19. The additional data collected from these questions only posed a minimal burden

on respondents; and was absorbed in the OMB burden previously approved.

NHCS Questions:

1. In the past year, did your hospital experience shortages of coronavirus disease (COVID–19) tests for any patients with presumptive positive COVID–19 infection?

2. In the past year, did your hospital create areas outside the hospital entrance to screen patients for coronavirus disease (COVID–19) infection?

3. In the past year, did your hospital need to turn away or refer elsewhere any patients with confirmed or presumptive positive coronavirus disease (COVID–19) infection?

4. In the past year, did any of the following clinical care providers in your hospital test positive for coronavirus disease (COVID–19) infection?

a. Physicians
b. Physician assistants
c. Nurse practitioners
d. Certified nurse-midwives
e. Registered nurses/licensed practical nurses
f. Other clinical care providers

5. For calendar year 2020, how many inpatient/ED visits at your hospital were related to CONFIRMED coronavirus disease (COVID–19) infections, by quarter or by year? Fill in the grid below.

6. For calendar year 2020, how many inpatient/ED visits at your hospital were Confirmed COVID–19 visits and how many were Presumptive Positive COVID–19 visits by quarter or by year?

Dated: December 14, 2020.

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–27820 Filed 12–17–20; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2020–0124]

Advisory Committee on Immunization Practices (ACIP); Correction

Notice is hereby given of a change in the meeting of the *Advisory Committee on Immunization Practices (ACIP);* December 18, 2020, 12:00 p.m.—6:00 p.m., EST; and December 20, 2020, 12:00 p.m.—6:00 p.m., EST (times subject to change, see the ACIP website for any updates: *http://www.cdc.gov/vaccines/acip/index.html*), which was published in the **Federal Register** on December 11, 2020, Volume 85, Number 239, page 80108.

The meeting dates and times should read as follows:

DATES: The meeting will be held on December 19—20, 2020 from 11 a.m. to 4:30 p.m., EST (times subject to change, see the ACIP website for any updates: *http://www.cdc.gov/vaccines/acip/index.html*).

Written comments must be received on or before December 21, 2020.

The meeting is open to the public.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road, NE, MS–H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–28090 Filed 12–16–20; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10346]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* . Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Appeals of Quality Bonus Payment Determinations;

Use: Section 1853(o) of the Social Security Act (the Act) requires CMS to make QBPs to MA organizations that achieve performance rating scores of at least 4 stars under a five-star rating system. While CMS has applied a Star Rating system to MA organizations for a number of years, prior to the QBP program these Star Ratings were used only to provide additional information for beneficiaries to consider in making their Part C and D plan elections. Additionally, section 1854(b)(1)(C)(v) of the Act, as added by the Affordable Care Act, also requires CMS to change the share of savings that MA organizations must provide to enrollees as the beneficiary rebate specified at § 422.266(a) based on the level of a sponsor's Star Rating for quality performance.

The information collected on the Request for Reconsideration form from MA organizations is considered by the reconsideration official and potentially the hearing officer to review CMS's determination of the organization's eligibility for a QBP. The form asks MA organizations to select the Star Ratings measure(s) they believe was miscalculated or used incorrect data and describe what they believe is the issue. Under § 422.260(c)(3)(ii) these are the only bases for appeals. In conducting the reconsideration, the reconsideration official will review the QBP determination, the evidence and findings upon which it was based, and any other written evidence submitted by the organization with their Request for Reconsideration or by CMS before the reconsideration determination is made.

The administrative review process is a two-step process that includes a request for reconsideration and a request for an informal hearing on the record after CMS has sent the MA organization the reconsideration decision. Both steps are conducted at the contract level. The first step allows the MA organization to request a reconsideration of how its Star Rating for the given measure in question was calculated and/or what data were included in the measure. If the MA organization is dissatisfied with CMS's reconsideration decision, the contract may request an informal hearing to be conducted by a hearing officer designated by CMS. MA organizations will have 10 business days from the time we issue the notice of QBP status to submit a request for reconsideration. MA organizations will have 10 business days after the issuance of the reconsideration determination to request an informal hearing on the record. *Form Number:* CMS–10346 (OMB control number: 0938–1129); *Frequency:* Yearly; *Affected Public:* Private Sector; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 160. (For policy questions regarding this collection contact Joy Binion at 410–786–6567.)

Dated: December 15, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–27885 Filed 12–17–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Placement and Transfer of Unaccompanied Alien Children Into ORR Care Provider (0970–0554)

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR) Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to continue to collect information that will allow Unaccompanied Alien Children (UAC) Program to place UAC referred to ORR by Federal agencies into care provider facilities and to transfer UAC within the ORR care provider network. These information collections were originally approved under emergency approval for 6 months. This request is to continue data collection. Information collections related to other aspects of the UAC Programs, such as sponsorship and health care, are covered under OMB Numbers 0970–0278, 0970–0385, 0970–0466, 0970–0490, 0970–0498, 0970–0509, and 0970–0543.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The components of this information request include:

1. *Placement Authorization (Form P–1):* This instrument is used by ORR to authorize a care provider to provide care and services to UAC placed in their facility. Care providers sign the instrument to acknowledge certain responsibilities related to the care of the UAC. This form is currently approved under OMB Number 0970–0498.

2. *Authorization for Medical, Dental, and Mental Health Care (Form P–2):* This instrument is used by ORR to authorize a care provider to provide medical, dental, and mental health care services to UAC placed in their facility. Care providers sign the instrument to acknowledge certain responsibilities related to the care of the UAC.

3. *Notice of Placement in a Restrictive Setting (Form P–4/4s):* This instrument is used by care providers to document and inform UAC of the reason they have been placed in a restrictive setting. This form is currently approved under OMB Number 0970–0498 under the title Notice of Placement in Secure or Staff Secure.

4. *Long Term Foster Care Placement Memo (Form P–5):* This instrument is used by care providers to ensure continuity of services and tracking of records for a UAC following transfer. This form is currently approved under OMB Number 0970–0498.

5. *Intakes Placement Checklist (Form P–7):* This instrument is used by ORR Intakes staff to determine whether initial placement in a restrictive setting is appropriate for a UAC. This form is currently approved under OMB Number 0970–0498 under the title Further Assessment Swift Track (FAST) Placement Tool.

6. *Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8):* This instrument is used by care providers to ensure that all criteria for transfer of a UAC to an influx care facility have been met.

7. *Medical Checklist for Transfers (Form P–9A):* This instrument is used by care providers to ensure that UAC are medically cleared for transfer within the ORR care provider network, excluding transfer to an influx care facility.

8. *Medical Checklist for Influx Transfers (Form P–9B):* This instrument is used by care providers to ensure that UAC are medically cleared for transfer to an influx care facility.

9. *Transfer Request (Form P–10):* This instrument is used by care provider

facilities, ORR contractor staff, and ORR Federal staff to process recommendations and decisions for transfer of a UAC within the ORR care provider network. This form is currently approved under OMB Number 0970–0498 under the title Transfer Request and Tracking Form.

10. *Transfer Request and Tracking Form (Form P–11):* This instrument is used by care providers to track the physical transfer of the UAC and their belongings.

11. *UAC Portal Capacity Report (Form P–12):* This instrument is used by care providers and ORR to track availability of beds in care provider facilities. This form is currently approved under OMB Number 0970–0498.

12. *Add New UAC (Form P–13):* This instrument is used by Federal agencies to refer UAC to ORR custody and by ORR Intakes staff to place UAC in an ORR care provider facility.

13. *Notice of Transfer to ICE Chief Counsel—Change of Address/Change of Venue (Form P–14):* This instrument is used by care providers to notify DHS of the transfer of a UAC within the ORR care provider network so that DHS may file a Motion for Change of Venue and/or Change of Address with the Executive Office for Immigration Review to ensure the UAC's immigration case is transferred to the local immigration court, if applicable. This form is currently approved under OMB Number 0970–0498.

Respondents: ORR grantee and contractor staff; other Federal agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Annual total number of respondents	Annual total number of responses per respondent	Average burden minutes per response	Annual total burden hours
Placement Authorization (Form P–1)	206	377	1	1,294
Authorization for Medical, Dental, and Mental Health Care (Form P–2)	206	377	1	1,294
Notice of Placement in a Restrictive Setting (Form P–4/4s)	15	68	20	340
Long Term Foster Care Placement Memo (Form P–5)	30	4	15	30
Intakes Placement Checklist (Form P–7)	16	4,343	15	17,372
Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8)	206	11	15	567
Medical Checklist for Transfers (Form P–9A)	206	29	5	498
Medical Checklist for Influx Transfers (Form P–9B)	206	11	10	378
Transfer Request (Form P–10)	206	39	45	6,026
Transfer Request and Tracking Form (Form P–11)	206	39	10	1,339
UAC Portal Capacity Report (Form P–12)	206	365	5	6,266
Add New UAC (Form P–13)	50	1,390	15	17,375
Notice of Transfer to ICE Chief Counsel—Change of Address/Change of Venue (Form P–14)	206	39	10	1,339
Estimated Annual Burden Total:				54,117

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; Flores v. Reno Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–27901 Filed 12–17–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Release of Unaccompanied Alien Children From ORR Custody (0970–0552)

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS), is proposing to continue to collect information that will allow Unaccompanied Alien Children (UAC) Program to process release of UAC from ORR custody and provide services after release. These information collections were originally approved under emergency approval for 6 months. This request is to continue data collection. Information collections related to other aspects of the UAC Programs, such as sponsorship and health care, are covered under OMB Numbers 0970–0278, 0970–0385, 0970–0466, 0970–0490, 0970–0498, 0970–0509, and 0970–0543.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The components of this information request include:

1. Discharge Notification (Form R–2): This instrument is used by care provider facilities to notify stakeholders of the transfer of a UAC to another care provider facility or the release of a UAC from ORR custody.

2. Notice to Immigration and Customs Enforcement (ICE) Chief Counsel—Release of Unaccompanied Alien Child to Sponsor and Request to Change Address (Form R–3): This instrument is used by care provider facilities to notify ICE Chief Counsel of the release of a UAC and request a change of address.

3. Release Request (Form R–4): This instrument is used by care provider facilities, ORR contractor staff, and ORR Federal staff to process recommendations and decisions for release of a UAC from ORR custody.

4. Safety and Well-Being Follow-Up Call Report (Form R–6): This instrument is used by care provider facilities to document the outcome of calls made to UAC and their sponsors after release to

ensure the child is safe and refer the sponsor to additional resources as needed.

Respondents: ORR grantee and contractor staff; and released children and sponsors.

ANNUAL BURDEN ESTIMATES

Instrument	Annual total number of respondents	Annual total number of responses per respondent	Average burden minutes per response	Annual total burden minutes
Discharge Notification (Form R–2)	206	416	7	599,872
Notice to ICE Chief Counsel—Release of Unaccompanied Alien Child to Sponsor and Request to Change Address (Form R–3)	206	377	3	232,986
Release Request (Form R–4)	206	356	45	3,300,120
Safety and Well-Being Follow Up Call Report (R–6)	206	354	30	2,187,720
Estimated Annual Burden Total:				6,320,698

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; Flores v. Reno Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–27896 Filed 12–17–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Services Provided to Unaccompanied Alien Children (0970–0553)

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR) Administration for Children and Families (ACF), Department of Health and Human Services (HHS), is proposing to continue to collect information that will allow Unaccompanied Alien Children (UAC) Program to provide services to UAC as required by statute and ORR policy. These information collections were originally approved under emergency approval for 6 months. This request is to continue data collection. Information collections related to other aspects of the UAC Programs, such as sponsorship and health care, are covered under OMB Numbers 0970–0278, 0970–0385, 0970–0466, 0970–0490, 0970–0498, 0970–0509, and 0970–0543.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The components of this information request include:

1. Sponsor Assessment (Form S–5): This instrument is used by case managers to document their assessment of the suitability of a potential sponsor to provide for the safety and well-being of a UAC.

2. Home Study Report (Form S–6): This instrument is used by home study providers to document their assessment of a potential sponsor after performing a home site visit.

3. New Sponsor (Form S–7): This instrument is used by care providers to assign a potential sponsor to a UAC in the ORR database and track certain information related to the potential sponsor for safety and suitability assessment purposes. This form is currently approved under OMB Number 0970–0498.

4. Initial Intakes Assessment (Form S–8): This instrument is used by care providers to screen UAC for trafficking or other safety concerns, special needs, danger to self and others, medical conditions, and mental health concerns. This form is currently approved under OMB Number 0970–0498.

5. Assessment for Risk (Form S–9): This instrument is an assessment administered by care providers to reduce the risk that a child or youth is sexually abused or abuses someone else while in ORR custody.

6. UAC Assessment (Form S–11): This instrument is an assessment used by care providers to document information about the UAC that is used to inform provision of services (*e.g.,* case management, legal, education, medical, mental health, home studies), screen for trafficking or other safety concerns, and identify special needs. This form is currently approved under OMB Number 0970–0498.

7. UAC Case Review (Form S–12): This instrument is used by care providers to document new information obtained after completion of the UAC Assessment. This form is currently approved under OMB Number 0970–0498.

8. Individual Service Plan (Form S–13): This instrument is used by care providers to document all services provided to the UAC. This form is currently approved under OMB Number 0970–0498.

9. UAC Long Term Foster Care Travel Request (Form S–14): This instrument is used by long term foster care providers to request ORR approval for a UAC to travel with their foster family outside of the local community. This form is currently approved under OMB Number 0970–0498.

10. Child Advocate Recommendation and Appointment (Form S–15): This instrument is used by care providers and other stakeholders to recommend appointment of a child advocate for a UAC. The child advocate contractor then enters whether a child advocate is available and ORR approves the appointment. This form is currently approved under OMB Number 0970–0498.

11. Summary Notes: Thirty Day Restrictive Placement Case Review (Form S–16): This instrument is used by care providers to document their thirty day review for UAC in placed in a restrictive setting.

12. UAC Case Status: This instrument is used by care providers to monitor the status of high-level milestones in a UAC's case.

Respondents: ORR grantee and contractor staff; UAC; sponsors; and child advocates.

ANNUAL BURDEN ESTIMATES

Instrument	Annual total number of respondents	Annual total number of responses per respondent	Average burden minutes per response	Annual total burden hours
Sponsor Assessment (Form S–5)	206	327	60	67,362
Home Study Report (Form S–6)	11	364	45	3,003
New Sponsor (Form S–7)	206	327	20	22,454
Initial Intakes Assessment (Form S–8)	206	363	15	18,695
Assessment for Risk (Form S–9)	206	794	30	81,782
UAC Assessment (Form S–11)	206	369	45	57,011
UAC Case Review (Form S–12)	206	764	30	78,692
Individual Service Plan (Form S–13)	206	985	15	50,728
UAC Long Term Foster Care Travel Request (Form S–14)	30	9	15	68
Child Advocate Referral and Appointment (Form S–15)	206	5	15	258
Summary Notes Thirty Day Restrictive Placement Case Review (Form S–16)	15	68	30	510
UAC Case Status	206	354	3	3,646
Estimated Annual Burden Total:				384,207

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; Flores v. Reno Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–27898 Filed 12–17–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Advance Planning Document (APD) Process (OMB #0970–0417)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families' (ACF) Office of Child Support Enforcement (OCSE) is requesting an update to the Advance Planning Document (APD) process (OMB #0970–0417). OCSE proposes revisions to the annual burden estimates to reflect an increase in the number of states seeking approval to implement modernization solutions in efforts to replace antiquated legacy child support enforcement systems and to address an excess demand for emergency funding requests due to the impacts of the COVID–19 pandemic.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The APD process, established at 45 CFR part 95, subpart F, is the procedure by which states request and obtain approval for Federal Financial Participation (FFP) in their cost of acquiring Automated Data Processing (ADP) equipment and services.

State child support agencies are required to establish and operate a federally approved statewide ADP and information retrieval system to assist in child support enforcement. States are required to submit an initial APD containing information to assist the Secretary of the U.S. Department of Health and Human Services (HHS) in determining if the state computerized support enforcement project planning and implementation meets federal certification requirements needed for the approval of FFP. States are then required to submit annual APD updates to HHS to report project status and request ongoing FFP for systems development, enhancements, operations, and maintenance. As-needed APDs are also submitted to acquire FFP when major milestone are missed or significant changes to project schedules occur. Based on an assessment of the information provided in the APD, states that do not meet the federal requirements necessary for approval are required to conduct periodic independent verification and validation services for high-risk project oversight.

In addition to the APDs providing HHS with the information necessary to determine the allowable level of federal funding for state systems projects, states also submit associated procurement and data security documents, such as the request for proposals (RFPs), contracts, contract amendments, and the biennial security review reports.

Respondents: State child support agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
RFP and Contract	50	4.5	4	900	300
Emergency Funding Request	21	1	2	42	14
Biennial Reports	54	1.5	1.5	121.5	40.5
Advance Planning Document	44	3.6	120	19,008	6,336
Operational Advance Planning Document	10	3	30	900	300
Independent Verification and Validation (ongoing)	3	12	10	360	120
Independent Verification and Validation (semiannually)	4	6	16	384	128
Independent Verification and Validation (quarterly)	10	12	30	3,600	1,200
System Certification	3	3	240	2,160	720

Estimated Total Annual Burden Hours: 9,158.50.

Authority: 45 CFR part 95, subpart F.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–27916 Filed 12–17–20; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1072]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 19, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0780. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for Participation in FDA Fellowship and Traineeship Programs

OMB Control Number 0910–0780—Revision

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. The proposed information collection involves brief online applications completed by applicants applying to FDA's Fellowship and Traineeship programs. These voluntary online applications will allow the Agency to easily and efficiently elicit and review information from students and healthcare professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA.

In the **Federal Register** of October 19, 2018 (83 FR 53065), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medical Device Fellowship Program	250	1	250	1	250
FDA Traineeship Program	1,000	1	1,000	1	1,000
Reagan-Udall Fellowship at FDA	50	1	50	1	50
Total					1,300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Because FDA is developing two new training programs, Trainee Program and Reagan-Udall Fellowship, our estimated burden for the information collection reflects an overall increase of 2 hours. FDA has removed the Commissioner's Fellowship Program and Regulatory Science Internship Program from this information collection as these programs have been discontinued.

FDA published a 30-day notice for this information collection on February 3, 2020 (85 FR 5966). FDA is reopening the 30-day comment period in order to satisfy PRA requirements. No changes have been made to the information collection.

Dated: December 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27963 Filed 12–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1359]

Sugars That Are Metabolized Differently Than Traditional Sugars; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice entitled ''Sugars that Are Metabolized Differently than Traditional Sugars'' that appeared in the **Federal Register** of October 19, 2020. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested persons to develop and submit data, information, and/or comments for this request for information and comments.

DATES: FDA is extending the comment period on the notice published October 19, 2020 (85 FR 66335). Submit either electronic or written comments on the notice by February 16, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 16, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 16, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1359 for ''Sugars that Are Metabolized Differently than Traditional Sugars.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of October 19, 2020 (85 FR 66335), we published a notice requesting information and comments entitled ''Sugars that Are Metabolized Differently Than Traditional Sugars.'' This action opened a docket with a 60-day comment period to receive information and comments related to the nutrition labeling of sugars that are metabolized differently than traditional sugars.

FDA has received a request for a 60-day extension for this comment period in order to allow additional time for

interested persons to develop and submit data, information, and/or comments for this notice. We have concluded that it is reasonable to extend the comment period for 60 days. FDA believes that this extension allows adequate time for any interested persons to submit data, information, and/or comments.

Dated: December 11, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27749 Filed 12–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB No. 0906–0017, Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 16, 2021.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB No. 0906–0017, Revision.

Abstract: This clearance request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Performance Measurement Information System.

The MIECHV Program, administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services to pregnant women and to parents with young children up to kindergarten entry. States, certain non-profit organizations, and Tribal entities are eligible to receive funding from the MIECHV program and have the flexibility to tailor the program to serve the specific needs of their communities. HRSA is revising the data collection forms for the MIECHV program by making the following changes:

- *Form 1, Table 1:* Update table to include reporting for gender non-conforming participants and unknown/did not report participant gender.
- *Form 1, Tables 3, 4, 6, 7, 8, 9, 10, 11, and 18:* Update tables to include reporting for gender non-conforming participants and unknown/did not report adult participant gender.
- *Form 1, Tables 3, 5, 6, 7, 18, 19, and 20:* Update tables to remove index child gender reporting.
- *Form 1, Table 15:* Change table title to ''Home Visits''.
- *Form 1, Table 15:* Update table to collect the number of home visits completed virtually.
- *Form 1, Tables 4, 9, 10, and 18:* Update tables to include reporting for new and continuing adult participants.
- *Form 1, Tables 5, 19, and 20:* Update tables to include reporting for new and continuing index children.
- *Form 1, Table 16:* Add new table to include reporting on father and additional caregiver engagement.
- *Form 1, Tables 16, 17, 18, 19, 20, and 21:* Update table numbers to reflect the addition of Table 16.
- *Form 2, Measure 13:* Change measure name to ''Behavioral Concern Inquiries''
- *Form 2, Measure 16:* Update measure to reflect caregiver health insurance coverage status.
- *Form 2:* Add two measures to collect information on substance use screening and referrals.

Need and Proposed Use of the Information: HRSA uses performance information to demonstrate program accountability and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to revise demographic, service utilization, and select clinical indicators for participants enrolled in home visiting services. In addition, HRSA will collect a set of standardized performance and outcome indicators that correspond with the statutorily identified benchmark areas.

This information will be used to demonstrate awardees' compliance with legislative and programmatic requirements. It will also be used to monitor and provide continued oversight for awardee performance and to target technical assistance resources to awardees. In the future, HRSA anticipates that MIECHV funding decisions may be allocated, in part, based on awardee performance, including on benchmark performance areas. This notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, information can be collected in a timely manner.

Likely Respondents: MIECHV Program awardees that are states, territories, and, where applicable, nonprofit organizations providing home visiting services within states.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Form 1: Demographic, Service Utilization, and Select Clinical Indicators	56	1	56	560	31,360
Form 2: Performance Indicators and Systems Outcome Measures	56	1	56	221	12,376
Total	56		56		43,736

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–27919 Filed 12–17–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Diabetes and Aging.

Date: February 18, 2021.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Anita H. Undale, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 827–7428, *anita.undale@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2020.

Miguelina Perez,

Program Analyst,Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27943 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group Function, Integration, and Rehabilitation Sciences Subcommittee.

Date: February 19, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NICHD/NIH, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Helen Huang, Ph.D., Scientific Review Officer, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2137D, Bethesda, MD 20892, 301–435–8207, *helen.huang@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: December 14, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27859 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Council of Councils.

The meeting will be held as a virtual meeting and will be open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*https://videocast.nih.gov/watch=41242*).

Name of Committee: Council of Councils.

Open: December 30, 2020.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: Presentation and Discussion of the Proposed Addition of a New Office to Division of Program Coordination, Planning, and Strategic Initiatives.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Robin Kawazoe, Acting Executive Secretary, Council of Councils, Deputy Director, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892, *kawazoer@mail.nih.gov.* 301–402–9852.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/* where an agenda will be posted before the meeting date.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: December 14, 2020.

Tyeshia Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27815 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2) and Coronavirus Disease 2019 (COVID–19) (R21, R01 Clinical Trials Not Allowed).

Date: January 14–15, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E72A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E72A, Rockville, MD 20892, 240–669–5023, *fdesilva@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 15, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27977 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Brain Initiative RFA (EB–20–002) Review SEP.

Date: February 10, 2021.

Time: 9:00 a.m. to 07:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–4794, *dennis.hlasta@nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Brain Initiative RFAs (EB–20–001; EB–19–002) Review SEP.

Date: February 24, 2021.

Time: 9:30 a.m. to 05:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–3398, *hayesj@mail.nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 NCBIB Review C–SEP.

Date: March 1–3, 2021.

Time: 10:00 a.m. to 02:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Manana Sukhareva, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–3397, *sukharem@mail.nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 NCBIB Review D–SEP.

Date: March 8–10, 2021.

Time: 9:00 a.m. to 01:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–3398, *hayesj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, HHS)

Dated: December 14, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27860 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

The meeting will be open to the public. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). Individuals who plan to attend and need special assistance, or reasonable accommodations should notify the Contact Person listed below in advance of the meeting.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: January 25, 2021.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: Reports from the Division Director and other staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room LD30, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pamela Gilden, Branch Chief, Science Planning and Operations Branch, Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 8D49, Rockville, MD 20852–9831, 301–594–9954, *pamela.gilden@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 14, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27861 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy And Infectious Diseases; Notice of Closed Meeting.

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Data and Safety Management Center (CDSMC).

Date: January 15, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kelly L. Hudspeth, Ph.D., Scientific Review Officer, Scientific Review Program Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240–669–5067, *kelly.hudspeth@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 15, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27979 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting.

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Comprehensive and Rapid Response to NIAID Research Programs, Task Area B.

Date: January 15, 2021.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Ron Otten, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G30, Rockville, MD 20852, 301–496–7650, *ron.otten@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 15, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27980 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Allergy and Infectious Diseases Council.

The meeting will be open to the public as indicated below. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). Individuals who plan to attend and need special assistance, or reasonable accommodations should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Allergy and Infectious Diseases Council.

Date: January 25, 2021.

Open: 10:30 a.m. to 11:40 a.m.

Agenda: Report from the Institute Director.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room LD30, Rockville, MD 20892 (Virtual Meeting).

Closed: 11:40 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room LD30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Matthew J. Fenton, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 4F50, Bethesda, MD 20892, 301–496–7291, *fentonm@niaid.nih.gov*.

Name of Committee: National Advisory Allergy and Infectious Diseases Council Allergy, Immunology and Transplantation Subcommittee.

Date: January 25, 2021.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room LD30, Rockville, MD 20892 (Virtual Meeting).

Open: 12:30 p.m. to adjournment.

Agenda: Reports from the Division Director and other staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room LD30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Matthew J. Fenton, Ph.D., Director Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 4F50, Bethesda, MD 20892 301–496–7291, *fentonm@niaid.nih.gov.*

Name of Committee: National Advisory Allergy and Infectious Diseases Council Microbiology and Infectious Diseases Subcommittee.

Date: January 25, 2021.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room LD30, Rockville, MD 20892 (Virtual Meeting).

Open: 12:30 p.m. to adjournment.

Agenda: Reports from the Division Director and other staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room LD30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Matthew J. Fenton, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 4F50, Bethesda, MD 20892, 301–496–7291, *fentonm@niaid.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.niaid.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 15, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27976 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34 Clinical Trials Not Allowed).

Date: January 14, 2021.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kelly L. Hudspeth, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240–669–5067, *kelly.hudspeth@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 15, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27978 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel COPE AKI Applications.

Date: March 9–10, 2021.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard Bethesda, MD 20892 (Teleconference Call).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–4721, *ryan.morris@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 15, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27947 Filed 12–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2020–0670]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0127

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0127, Marine Transportation System Recovery; without change.

Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before February 16, 2021.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2020–0670] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. Consistent with the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda, the Coast Guard is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2020–0670], and must be received by February 16, 2021.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Marine Transportation System Recovery.

OMB Control Number: 1625–0127.

Summary: This information collection captures data on facilities, vessels and shared transportation infrastructure prior to a port disruption to be able to characterize the port in its normal fully functioning condition.

Need: 46 U.S.C. 70011, 70051 and 70103 require the U.S. Coast Guard to take action to prevent damage to, or the destruction of, bridges, other structures, on or in navigable waters or shore area adjacent; to minimize damage from and respond to a transportation security incident; and to safeguard against destruction of vessels, harbors, ports and waterfront facilities in the United States and all territorial waters during a national emergency. This information is needed to establish a Marine Transportation System (MTS) Essential Elements of Information baseline. Following a port disruption, Facility Status information is needed to determine the best course of action for port recovery. Respondents are vessel and facility operators.

Forms:

- CG–11410, Marine Transportation System Recovery Essential Elements of Information
- CG–11410A, Marine Transportation System Recovery Facility Status.

Respondents: Owners or operators of U.S. waterfront facilities.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 225 hours to 338 hours a year, due to an increase in the annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: December 15, 2020.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2020–27946 Filed 12–17–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2020–0014; OMB No. 1660–0132]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Consolidated FEMA-National Training and Education Division (NTED) Level 3 Training Evaluation Forms; Correction

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: 30-day notice and request for comments, correction.

SUMMARY: The Federal Emergency Management Agency (FEMA) published a document in the **Federal Register** on November 25, 2020, inviting the general public to comment on a reinstatement, with change, of a previously approved information collection for which approval has expired. The document contained incorrect cost estimates.

DATES: This correction is effective December 18, 2020.

ADDRESSES: For information on submitting comments, see the November 25, 2020, document at 85 FR 75349.

FOR FURTHER INFORMATION CONTACT: For any questions, please contact Dalia Abdelmeguid at *FEMA-NTES@fema.dhs.gov* or via phone 202–431–7739. You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2020–26052, beginning on page 75349 in the **Federal Register** of Wednesday, November 25, 2020, the following corrections are made:

1. On page 75350, in the middle column, ''*Estimated Total Annual Respondent Cost:* $1,489,450.'' is corrected to read ''*Estimated Total Annual Respondent Cost:* $1,466,298.''

2. On page 75350, in the middle column, ''*Estimated Total Annual Cost to the Federal Government:* $168,913.'' is corrected to read ''*Estimated Total Annual Cost to the Federal Government:* $180,082.''

Maile Arthur,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2020–27915 Filed 12–17–20; 8:45 am]

BILLING CODE 9111–53–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2020–0007]

Agency Information Collection Activities: 1670–0027: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), The Department of Homeland Security (DHS).

ACTION: 30- Day Notice and request for comments; Extension of Information Collection Request, 1670–0027.

SUMMARY: The Cybersecurity and Infrastructure Security Agency (CISA) will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. CISA previously published a notice about this ICR, in the **Federal Register** on July 20, 2020, for a 60-day public comment period. No comments were received. In this notice, CISA solicits additional public comments concerning this ICR for 30-days.

DATES: Comments are encouraged and will be accepted until January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* . Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: If additional information is required contact: The Department of Homeland Security (DHS), Cybersecurity and Infrastructure Agency (CISA), Mia Bruce, 703–235–3519, *nppd-prac@hq.dhs.gov*

SUPPLEMENTARY INFORMATION: The information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. CISA will submit the information collection abstracted below to the OMB for approval. By qualitative feedback we mean information that provides useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of study..

This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between CISA and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public.

If this information is not collected, vital feedback from customers and stakeholders on CISA's services will be unavailable. CISA will only submit a collection for approval under this generic clearance if it meets the following conditions:

1. The collections are voluntary;
2. The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
3. The collections are noncontroversial and do not raise issues of concern to other Federal agencies;
4. Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
5. Personally identifiable information is collected only to the extent necessary and is not retained;
6. Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the CISA (if released, CISA must indicate the qualitative nature of the information);
7. Information gathered will not be used for the purpose of substantially

informing influential policy decisions; and

8. Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing personal information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

This is an EXTENSION of an existing information collection. The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 1670–0027.

Frequency: Annually.

Affected Public: State, Local, Tribal, and Territorial Governments and Private Sector.

Number of Respondents: 10,500,630.

Estimated Time Per Respondent: 0.05 HOURS.

Total Burden Hours: 525,430 HOURS.

Total Respondent Opportunity Cost: $19,261,418.

Total Respondent Out-of-Pocket Cost: $0.

Total Government Cost: $200,000.

Samuel Vazquez,

(Acting) Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2020–27903 Filed 12–17–20; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2020–0008]

Cybersecurity and Infrastructure Security Agency (CISA) Speaker Request Form

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments; New collection (Request for a new OMB Control Number, 1670–NEW.

SUMMARY: DHS CISA External Affairs will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are due by February 16, 2021.

ADDRESSES: You may submit comments, identified by docket number CISA–2020–0008, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Email: CISA.Speakers@cisa.dhs.gov.* Please include docket number CISA–2020–0008 in the subject line of the message.
- *Mail:* Written comments and questions about this Information Collection Request should be forwarded to DHS/CISA/External Affairs, ATTN: 245 Murray Lane SW, Mail Stop 0380, Washington, DC 20598–0609.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket and comments received, please go to *www.regulations.gov* and enter docket number CISA–2020–0008.

Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Marilyn Stackhouse, 703–235–2162, *CISA.Speakers@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Cybersecurity and Infrastructure Security Agency Act of 2018 (P.L. 115–278) created the Cybersecurity and Infrastructure Security Agency (CISA). CISA is responsible for protecting the Nation's critical infrastructure from physical and cyber threats. This mission requires effective coordination and collaboration from government and private sector organizations. As part of the collaboration efforts, CISA receives requests for CISA employees to give presentations and speeches at various events.

This digital collection of information is necessary to ensure an efficient and timely process to schedule outreach and engagement with CISA stakeholders. This information may be disclosed as generally permitted under 5 U.S.C 522.

The Speaker Request Form will be the first point of contact between CISA and

the public to initiate CISA speaking engagements. The form will be available on *www.cisa.gov* and any member of the public can submit a request for a CISA employee to speak at an event. The form will be used by CISA to track and manage external speaking engagements. The information will also be used to schedule and determine the most appropriate CISA speaker based on date, time, location, presentation format, and topic. The form collects information regarding the requested speaking engagement, *e.g.,* the host organization, the speaking topic, agenda, and additional event details. The requested information helps CISA determine whether the speaker should attend the engagement and/or how CISA should best prepare for the event.

The information is used to determine if accepting the request will further CISA's mission.

The CISA Speakers Bureau team will use the information to identify a speaker and route the Speakers Request Form to that person for consideration. Confirmed CISA speaking engagements are then sent to DHS Public Affairs for awareness.

The form will be available on *www.cisa.gov* as a fillable pdf and/or webform, and will be submitted to the CISA External Affairs Speakers Bureau. The data collected will be stored in an internal SharePoint site.

This is a NEW collection of information.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Title of Collection: CISA Speaker Request Form.

OMB Control Number: 1670–NEW.

Frequency: Annually.

Affected Public: State, Local, Tribal, and Territorial Governments.

Number of Annualized Respondents: 1,300.

Estimated Time per Respondent: 0.25 hours.

Total Annualized Burden Hours: 325.

Total Annualized Respondent Opportunity Cost: $11,914.

Total Annualized Respondent Out-of-Pocket Cost: $0.

Total Annualized Government Cost: $0.

Samuel Vazquez,

Acting Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2020–27902 Filed 12–17–20; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7029–N–11]

60-Day Notice of Proposed Information Collection: The Rent Reform Demonstration

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The U.S. Department of Housing and Urban Development (HUD) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* February 16, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–5534 (this is not a toll-free number) or email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: The Rent Reform Demonstration: 6-Year Long-Term Follow-Up.

OMB Approval Number: 2528–0306.

Type of Request (*i.e., new, revision or extension of currently approved collection):* Revision or extension of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The Department is conducting this study under contract with MDRC and its subcontractors (The Bronner Group, Quadel Consulting Corporation, and the Urban Institute). The project is a random assignment trial of an alternative rent system. Families are randomly assigned to participate either in the new/alternative rent system or to continue in the current system. For voucher holders, outcomes of the alternative system are hypothesized to be increases in earnings, employment, and job retention among others. Random assignment will limit the extent to which selection bias drives observed results. The evaluation will document the progress of a group of housing voucher holders, who will be drawn from current residents, and the impact of the alternative rent system on the families as well as the administrative burden on Public Housing Agencies (PHAs). Three PHAs continue to participate in the long-term evaluation:

(1) Lexington Housing Authority (LHA), Lexington, Kentucky;

(2) Louisville Metro Housing Authority (LMHA), Louisville, Kentucky;

(3) San Antonio Housing Authority (SAHA), San Antonio, Texas; and

Data collection efforts include the families that are part of the treatment and control groups, as well as PHA staff. Data will be gathered through a variety of methods including informational interviews and discussions, direct observation, and analysis of administrative records. The work

covered under this information request is for data collection proposed for the 6-year follow-up phase of the Rent Reform Demonstration.

Respondents: Public housing agency administrators/staff managing or implementing the new rent policy and participants enrolled in the HUD Rent Reform Demonstration.

Estimated Number of Respondents:

• *Public Housing Authority Staff:* A maximum of 33.

• *Families with housing vouchers participating in the Rent Reform Demonstration:* A maximum of 60.

Estimated Time per Response: 90 to 120 minutes, depending on the interview.

Frequency of Response: 1 interview.

Estimated Total Annual Burden Hours: 144 hours.

Estimated Total Annual Cost: $2,125.62

Respondent's Obligation: Voluntary.

Legal Authority: The data collection is conducted under Title 12, United States Code, Section.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
Study Participant Interviews and/or Focus Groups	60	1	60	1.5	90	[1] $7.25	$652.50
PHA Staff Interviews	24	1	24	1.5	36	[2] 26.67	960.12
Cost Study Data Collection Activities with PHA staff	9	1	9	2	18	[3] 28.50	513.00
Total	93				144		2,125.62

[1] Households participating in the Rent Reform Demonstration will range widely in employment position and earnings. We have estimated the hourly wage at the expected prevailing minimum wage, which is $7.25 per hour in Kentucky and Texas. Moreover, we expect about 50 percent of the participants to be employed at the time of the field research (based on analysis of employment data for the study sample). Based on this, we assumed 50% of tenants would be working at the federal minimum wage.

[2] For program staff participating in interviews, the estimate uses the median hourly wages of selected occupations (classified by Standard Occupational Classification (SOC) codes) was sourced from the Occupational Employment Statistics from the U.S. Department of Labor's Bureau of Labor Statistics. Potentially relevant occupations and their median hourly wages are:

Occupation	SOC code	Median hourly wage rate
Community and Social Service Specialist	21–1099	$21.05
Social/community Service Manager	11–9151	32.28

Source: Occupational Employment Statistics, accessed online November 20, 2020 at *http://www.bls.gov/oes/current/oes_stru.htm*.
To estimate cost burden to program staff respondents, we use an average of the occupations listed, or $26.67/hr.

[3] The Cost Study Data collection assumes 2 managers and 1 specialist will be interviewed by site.

1701z and Section 3507 of the Paperwork Reduction Act of 1995, 44, U.S.C., 35, as amended.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance

of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of

information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected, and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

The General Deputy Assistant Secretary for Policy Development and Research, Todd M. Richardson, having reviewed and approved this document, is delegating the authority to electronically sign this document to submitter, Nacheshia Foxx, who is the **Federal Register** Liaison for HUD, for purposes of publication in the **Federal Register**.

Nacheshia Foxx,

Federal Register Liaison for the Department of Housing and Urban Development.

[FR Doc. 2020–27891 Filed 12–17–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7024–N–56]

30-Day Notice of Proposed Information Collection:

2021 Rental Housing Finance Survey; OMB Control No. 2528–0276

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* January 19, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax:202–395–5806, Email: *OIRA Submission@omb.eop.gov*

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email her at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number

through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on June 4, 2020 at 85 FR 34458.

A. Overview of Information Collection

Title of Information Collection: 2021 Rental Housing Finance Survey.

OMB Approval Number: 2528–0276.

Type of Request: Revision of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The Rental Housing Finance Survey (RHFS) provides a measure of financial, mortgage, and property characteristics of rental housing properties in the United States. RHFS focuses on mortgage financing of rental housing properties, with emphasis on new originations for purchase-money mortgages and refinancing, and the characteristics of these new originations.

The RHFS will collect data on property values of residential structures, characteristics of residential structures, rental status and rental value of units within the residential structures, commercial use of space within residential structures, property management status, ownership status, a detailed assessment of mortgage financing, and benefits received from Federal, state, local, and non-governmental programs.

Many of the questions are the same or similar to those found on the 1995 Property Owners and Managers Survey, the rental housing portion of the 2001 Residential Finance Survey, and previous collections of the Rental Housing Finance Survey. This survey does not duplicate work done in other existent HUD surveys or studies that deal with rental units financing.

Policy analysts, program managers, budget analysts, and Congressional staff can use the survey's results to advise executive and legislative branches about the mortgage finance characteristics of the rental housing stock in the United States and the suitability of public policy initiatives. Academic researchers and private organizations will also utilize the data to facilitate their research and projects.

The Department of Housing and Urban Development (HUD) needs the RHFS data for the following two reasons:

1. This is the only source of information on the rental housing finance characteristics of rental properties.

2. HUD needs this information to gain a better understanding of the mortgage finance characteristics of the rental housing stock in the United States to evaluate, monitor, and design HUD programs.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Responding rental properties	10,000.00	1.00	10,000.00	1.00	10,000.00	$0.00	$0.00
Total	10,000.00	1.00	10,000.00	1.00	10,000.00	$0.00	$0.00

Legal authority: This survey is conducted under Title 13, U.S.C., Section 8b and Title 12, U.S.C., Section 1701z–1 *et seq.*

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) Ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2020–27884 Filed 12–17–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7024–N–57]

30-Day Notice of Proposed Information Collection: Strategies for Removing the Regulatory Impediments to the Financing and Siting of Factory-Built Housing in American Communities OMB Control No. 2528–NEW

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* January 19, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding

this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax:202–395–5806, Email: *OIRA Submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410; email her at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on February 14, 2020 at 85 FR 8604.

A. Overview of Information Collection

Title of Information Collection: Strategies for Removing the Regulatory Impediments to the Financing and Siting of Factory-Built Housing in American Communities.

OMB Approval Number: 2528-New.

Type of Request: New.

Form Number: N/A.

Description of the need for the information and proposed use: To assess the cost-effectiveness of factory-built housing as a potential affordable housing option in urban and suburban communities, HUD seeks to better understand the regulatory barriers preventing or limiting the use of factory-built housing. This study is framed by the general research question: What are the main drivers or barriers to the financing, siting and development of factory-built housing systems in various communities? A significant portion of the work of this study will involve identifying the types of barriers, their potential impact (or stringency), and their use in various communities. This process will involve research on several different communities in order to develop a typology of different barriers, catalog the community contexts where different barriers are more prevalent, and develop opportunity cost estimates of different barriers in different contexts. Information will be collected online and by telephone from local land use planning officials and manufacturers and dealers of factory-built housing to help determine the extent to which regulatory barriers limit the development of factory-built housing systems as an affordable housing option.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
Outreach Efforts	90.00	1.00	90.00	0.21	18.90	$36.65	$692.69
In-Depth Interviews	30.00	1.00	30.00	0.75	22.50	$36.65	$824.63
In-Depth Interviews (Manufacturers/Dealers)	5.00	1.00	5.00	0.75	3.75	$59.56	$223.35
Total	125.00	1.00	125.00	0.36	45.15	$38.55	$1,740.67

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) Ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2020–27924 Filed 12–17–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–MB–2020–N151; FF09M21200–201–FXMB1231099BPP0; OMB Control Number 1018–0171]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Establishment of Annual Migratory Bird Hunting Seasons

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference OMB Control Number 1018–0171 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the information collection request (ICR) at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

On April 2, 2020, we published in the **Federal Register** (85 FR 18532) a proposed rule to begin the process of establishing migratory bird hunting regulations for certain Tribes on Federal Indian reservations, off-reservation trust lands, and ceded lands for the 2020–21 migratory bird hunting season. That **Federal Register** document also contained notice of our intent to request that OMB approve this related information collection. In that notice, we solicited comments for 60 days, ending on June 1, 2020. We did not receive any comments in response to that proposed rule.

Additionally, on May 1, 2020, the Migratory Bird Program shared the proposed rule document with the Flyway Council representatives to solicit their feedback on the information collection requirements. We extended the comment period for the Flyway Councils to provide comments until October 30, 2020, so that they could share the information during their annual August/September Flyway Council meetings. We did not receive any comments in response to that additional comment opportunity.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed information collection request (ICR) that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Migratory game birds are those bird species so designated in conventions between the United States and several foreign nations for the protection and management of these birds. Under the Migratory Bird Treaty Act (16 U.S.C. 703–712), the Secretary of the Interior is authorized to determine when ''hunting, taking, capture, killing, possession, sale, purchase, shipment, transportation, carriage, or export of any * * * bird, or any part, nest, or egg'' of migratory game birds can take place, and to adopt regulations for this purpose. These regulations are written after giving due regard to ''the zones of temperature and to the distribution, abundance, economic value, breeding habits, and times and lines of migratory flight of such birds'' and are updated annually (16 U.S.C. 704(a)). This responsibility has been delegated to the Service as the lead Federal agency for managing and conserving migratory birds in the United States. However, migratory game bird management is a cooperative effort of State, Tribal, and Federal governments. Migratory game bird hunting seasons provide opportunities for recreation and sustenance; aid Federal, State, and Tribal governments in the management of migratory game birds; and permit harvests at levels compatible with migratory game bird population status and habitat conditions.

The Service develops migratory game bird hunting regulations by establishing the frameworks, or outside limits, for season lengths, bag limits, and areas for migratory game bird hunting. Acknowledging regional differences in hunting conditions, the Service has administratively divided the Nation into four Flyways for the primary purpose of managing migratory game birds. Each Flyway (Atlantic, Mississippi, Central, and Pacific) has a Flyway Council, a formal organization generally composed of one member from each State and Province in that Flyway. The Flyway Councils, established through the Association of Fish and Wildlife Agencies, also assist in researching and providing migratory game bird management information for Federal, State, and Provincial governments, as well as private conservation entities and the general public.

We request the following information to establish annual migratory bird hunting seasons:

Information Requested To Establish Annual Migratory Bird Hunting Seasons

As a result of the incremental annual rulemaking process explained above, the information requested from States is solicited during a different point in the overall rulemaking process than the information requested from Tribal governments. However, the final rules published at the end of the rulemaking process each year incorporate all information received from the State and Tribal governments. Therefore, this ICR incorporates both the annual requests for Tribal proposals in the proposed rules and the information requested annually from the States during subsequent proposed rules (all under the same Regulatory Identifier Number; we post all rules electronically on the Service's website (*https://www.fws.gov/policy/frsystem/default.cfm*). State and Tribal governments are aware of this process that affords them the opportunity to provide comments on the information collection requirements identified in the PRA section of each rule.

The information identified below, necessary to establish annual migratory bird hunting seasons, is solicited annually from State (including U.S. territory) and Tribal governments. The required information, received at various times in the year prior to the actual hunting season as part of the rulemaking process described above, is used by the Service as part of the final rulemaking process necessary to open

annual hunting seasons otherwise closed by law.

Details Needed From States and U.S. Territories

State and U.S. territory governments that wish to establish annual migratory game bird hunting seasons are required to provide the requested dates and other details for hunting seasons in their respective States or Territories. The information is provided to the Service in a non-form format, usually via letter or spreadsheet, in response to solicitations for the information sent to the State governments each year via an emailed letter and as part of the first final rule (for the frameworks).

Details Needed From Tribal Governments

Tribes that wish to use the guidelines (published June 4, 1985, 50 FR 23459—copy uploaded to ROCIS) to establish special hunting regulations for the annual migratory game bird hunting season are required to submit a proposal that includes:

(1) The requested migratory game bird hunting season dates and other details regarding the proposed regulations;

(2) Harvest anticipated under the proposed regulations; and

(3) Tribal capabilities to enforce migratory game bird hunting regulations.

For those situations where it could be shown that failure to limit Tribal harvest could seriously impact the migratory game bird resource, we also request information on the methods employed to monitor harvest and any potential steps taken to limit level of harvest.

A Tribe that desires the earliest possible opening of the migratory game bird season for nontribal members should specify this request in its proposal, rather than request a date that might not be within the final Federal frameworks. Similarly, unless a Tribe wishes to set more restrictive regulations than Federal regulations will permit for nontribal members, the proposal should request the same daily bag and possession limits and season length for migratory game birds that Federal regulations are likely to permit the States in the Flyway in which the reservation is located.

Reports (50 CFR part 20): The following reports are requested from the States and are submitted either annually or every 3 years as explained in the following text.

Reports From Experimental Hunting Seasons and Season Structure Changes (Required)

Atlantic Flyway Council

- Delaware—Experimental tundra swan season (Yearly updates and Final report).
- Florida (Completed)—Experimental teal-only season (Yearly updates and Final report).

Mississippi Flyway Council

- Alabama—Experimental sandhill crane season (Yearly updates and Final report).

Central Flyway Council

- Nebraska (Completed)—Experimental teal season (Yearly updates and Final report).
- New Mexico—Sandhill crane season in Estancia Valley: Yearly updates and Final report. This report was changed from experimental to operational. Annual data are still required, but there is not a final report, since this monitoring will occur in perpetuity (or as long as the State has that hunt area).
- Wyoming—Split (three-way) season for Canada geese (Final report only).

Pacific Flyway Council

- California—Zones and split season for white-fronted geese (Final report only).

Additional State-Specific Annual Reports

State-Specific

- Arizona—Sandhill crane racial composition of the harvest conducted at 3-year intervals.
- North Carolina and Virginia—Tundra swan harvest and hunter participation data (Yearly).
- Montana (Central Flyway portion), North Dakota, and South Dakota—Tundra swan harvest and hunter participation data (Yearly).
- Montana (Pacific Flyway portion)—Swan harvest-monitoring program to measure species composition (Yearly).
- Montana (Pacific Flyway portion), Utah, and Nevada—Swan harvest-monitoring program to measure the species composition and report detailing swan harvest, hunter participation, reporting compliance, and monitoring of swam populations in designated hunt areas (Yearly).

Reports and monitoring are used for a variety of reasons. Some are used to monitor species composition of the harvest for those areas where species intermingling can confound harvest management, and potential overharvest of one species can be of management concern. Others are used to determine overall harvest for those species and/or areas that are not sampled well by our overall harvest surveys due to either the limited nature/area of the hunt or season, or where the harvest needs to closely monitored. Experimental season reports are used to determine whether the experimental season is achieving its intended goals and objectives, without causing unintended harm to other species and ultimately whether the experimental season should proceed to operational status. Most experimental seasons are 3-year trials with yearly reports and a final report. Most of the other reports and monitoring are conducted either annually or at 3-year intervals.

Title of Collection: Establishment of Annual Migratory Bird Hunting Seasons, 50 CFR part 20.

OMB Control Number: 1018–0171.

Form Numbers: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal governments.

Total Estimated Number of Annual Respondents: 82 (from 52 State governments and Territories and 30 Tribal governments).

Total Estimated Number of Annual Responses: 99 (includes State and Tribal governments and additional reports from States).

Estimated Completion Time per Response: Varies from 4 hours to 650 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 9,878.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2020–27887 Filed 12–17–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–MB–2020–N152; FXMB123109WEBB0–201–FF09M26000; OMB Control Number 1018–0019]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; North American Woodcock Singing Ground Survey

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference OMB Control Number 1018–0019 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the information collection request (ICR) at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

On August 3, 2020, we published in the **Federal Register** (85 FR 46692) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on October 2, 2020. We received the following comments in response to that notice:

Comment 1: The Atlantic Flyway Council expressed its support for continuation of the survey. Continuation of the survey is critical for the responsible management of American woodcock, an important migratory game bird in the Atlantic Flyway and North America. The SURVEY provides the only long-term, range-wide monitoring program for American woodcock. The results of the SURVEY form the basis of the American woodcock harvest strategy used to set the annual hunting regulations for American woodcock in the Atlantic, Mississippi, and Central Flyways. The data collection and reporting estimates provided by the U. S. Fish and Wildlife Service are reasonable and accurate.

Agency Response to Comment 1: No action was taken, since the support was positive and there were no recommendations for improvement.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed information collection request (ICR) that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Migratory Bird Treaty Act (16 U.S.C. 703–712) designates the Department of the Interior as the primary agency responsible for managing migratory bird populations frequenting the United States and setting hunting regulations that allow for the well-being of migratory bird populations. These responsibilities dictate that we gather accurate data on various characteristics of migratory bird populations.

The North American Woodcock Singing Ground Survey is an essential part of the migratory bird management program. Federal, State, Provincial, Tribal, and local conservation agencies conduct the survey annually to provide the data necessary to determine the population status of the American woodcock. In addition, the information is vital in assessing the relative changes in the geographic distribution of the species. We use the information primarily to develop recommendations for hunting regulations. Without information on the population's status, we might promulgate hunting regulations that:

- Are not sufficiently restrictive, which could cause harm to the woodcock population, or
- Are too restrictive, which would unduly restrict recreational opportunities afforded by woodcock hunting.

The Service, State, and Provincial conservation agencies, university associates, and other interested parties use the data for various research and management projects.

Title of Collection: North American Woodcock Singing Ground Survey.

OMB Control Number: 1018–0019.

Form Number: FWS Form 3–156.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State, Provincial, local, and Tribal employees.

Total Estimated Number of Annual Respondents: 808.

Total Estimated Number of Annual Responses: 808.

Estimated Completion Time per Response: Varies from 1.75 hours to 1.88 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 1,515.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2020–27889 Filed 12–17–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#-31254; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before December 5, 2020, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by January 4, 2021.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before December 5, 2020. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

ARKANSAS

Benton County

Bella Vista Village Country Club, (Arkansas Designs of E. Fay Jones MPS), 98 Clubhouse Dr., Bella Vista, MP100006021

Conway County

Highway A–1 Bridge, (Historic Bridges of Arkansas MPS), Old US 64 west of Hivilies Dr., Plumerville, MP100006022

Fulton County

Castleberry Building, 102 South Main St., Salem, SG100006023

Garland County

City Cemetery, 740 Adams St., Hot Springs, SG100006024

Ouachita County

Spring-Harrison Historic District, Spring St. roughly between Greening and Thompson Sts.' Clifton St. roughly between Spring and Harrison Sts., and Harrison St. roughly between Van Buren and Clifton Sts., Camden, SG100006026

Perry County

Perry Rock Island Railroad Depot, (Historic Railroad Depots of Arkansas MPS), 8 German Rd., Perry, MP100006027

Pulaski County

Daniel, Irvin and Elizabeth House, 1622 Waterside Dr., North Little Rock, SG100006028

Locust Street Overpass

Locust St. between S.A. Jones Dr. (East 9th St.) and East 13th St., North Little Rock, SG100006030

Newbill-Porter House

3900 North Lookout St., Little Rock, SG100006031

Oak Forest United Methodist Church

2415 Fair Park Blvd., Little Rock, SG100006032

Millett, Robert and Marion, House No. 1

1708 Waterside Dr., North Little Rock, SG100006033

Vestal, Walter, House

331 Goshen Ave., North Little Rock, SG100006034

Sebastian County

United Hebrew Congregation Tilles Memorial Temple, 126 North 47th St., Fort Smith, SG100006035

ILLINOIS

Cook County

Pyle-National Company Plant, 1334 North Kostner Ave., Chicago, SG100006017

LOUISIANA

Orleans Parish

Nelson, Médard, Home and School, 1218–1220 Burgundy St., New Orleans, SG100005998

MICHIGAN

Ingham County

North Lansing Historic Commercial District (Boundary Increase), Generally, 611 East-127 West Cesar E. Chavez Ave., 1207–1250 Turner Rd., 901–1135 North Washington St., and adjacent streets, Lansing, BC100006010

MINNESOTA

Carver County

District No. 22 School, 17380 Homestead Rd., San Francisco Township, SG100006006

Dakota County

Hudson Manufacturing Company Factory, 200 West 2nd St., Hastings, SG100006002

Dodge County

West Concord High School, 600 1st St. West, West Concord, SG100006007

Hennepin County

Northrup. King & Company Complex, 1500 Jackson St. NE, Minneapolis, SG100006005

Ramsey County

Roselawn Chapel and Administration Building, 803 West Larpenteur Ave., Roseville, SG100006008

NEW YORK

Dutchess County

Rhinebeck Village Historic District (Boundary Increase), (Rhinebeck Town MRA), Portions of Platt Ave., Mill, Oak, Mulberry, and North Parsonage Sts., Rhinebeck, BC100006011

Tompkins County

Cayuga Preventorium, 1420 Taughannock Blvd., Ithaca vicinity, SG100006012

PENNSYLVANIA

Philadelphia County

St. Gabriel's Roman Catholic Church Complex, 1432–48 South 29th St., 2922–28 and 2930–36 Dickinson St., Philadelphia, SG100006036

SOUTH CAROLINA

Florence County

Ebony Guest House, 712–714 Wilson St., Florence, SG100006018

Richland County

Citadel Shirt Corporation, 1215 Shop Rd., Columbia vicinity, SG100006019

Leevy's Funeral Home

(Segregation in Columbia, South Carolina MPS), 1831 Taylor St., Columbia, MP100006020

UTAH

Box Elder County

Tremonton Historic District, Roughly bounded by 600 South, 400 West, 800 North, and 300 East, Tremonton, SG100006013

Millard County

Fillmore Armory, (Public Works Buildings TR), 35 West Center St., Fillmore, MP100006003

Salt Lake County

Magna Commercial Downtown Historic District, (Historic Resources of Magna, Utah, 1850–1972 MPS), Along West Main St., Magna, MP100006004

Nelson, Harlan and Marie, House, 2785 East Lancaster Dr., Salt Lake City, SG100006014

A request for removal has been made for the following resource:

ARKANSAS

Lincoln County

Tracy, Charles Hampton, House, 2794 Blair Rd, Star City vicinity, OT10001156

Additional documentation has been received for the following resources:

MICHIGAN

Ingham County

North Lansing Historic Commercial District (Additional Documentation), East Grand River Ave. and Turner St., Lansing, AD76001029

Wayne County

Rosedale Park Historic District (Additional Documentation), Roughly bounded by Fenkell St., Outer Dr. West, Grand River Ave., Southfield Frwy., Glastonbury Ave., Lyndon St., Westwood Dr., Detroit, AD06000587

NEW YORK

Dutchess County

Rhinebeck Village Historic District, (Rhinebeck Town MRA), US 19 and NY 308, Rhinebeck, AD79001578

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nominations and responded to the Federal Preservation Officer within 45 days of receipt of the nominations and supports listing the properties in the National Register of Historic Places.

MICHIGAN

Keweenaw County

New Feldtmann Fire Tower, (Isle Royale National Park Fire Towers MPS), Feldtmann Ridge Trail, Isle Royale NP, Houghton vicinity, MP100006000

Ishpeming Fire Tower, (Isle Royale National Park Fire Towers MPS), Greenstone Ridge Trail, Isle Royale NP, Houghton vicinity, MP100006001

Authority: Section 60.13 of 36 CFR part 60.

Dated: December 9, 2020.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2020–27890 Filed 12–17–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031241; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Wistariahurst Museum, Holyoke, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Wistariahurst Museum has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Wistariahurst Museum. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Wistariahurst Museum at the address in this notice by January 19, 2021.

ADDRESSES: Penni Martorell, Wistariahurst Museum, 238 Cabot Street, Holyoke, MA 01040, telephone (413) 322–5660, email *MartorellP@Holyoke.org.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Wistariahurst Museum, Holyoke, MA. The human remains and associated funerary objects were removed from Holyoke Highlands, Hampden County, MA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Wistariahurst Museum professional staff in consultation with representatives of the Stockbridge Munsee Community, Wisconsin. The Delaware Tribe of Indians; Mohegan Tribe of Indians of Connecticut (previously listed as Mohegan Indian Tribe of Connecticut); and the Narragansett Indian Tribe were invited to consult but did not participate (hereafter, all the above Indian Tribes are referred to as ''The Consulted and Invited Tribes'').

History and Description of the Remains

In March of 1904, human remains representing, at minimum, one individual were removed from Holyoke Highlands in Hampden County, MA. The Holyoke Water Power Company uncovered the human remains while excavating a building site. A newspaper article in the Holyoke Telegram-Transcript of March 9, 1904 describes the circumstances of this discovery:

> One of the most important archaeological discoveries in this Vicinity was made yesterday by workmen of the Holyoke Water Power Company who in making some excavations in this city, unearthed what is supposed to have been the remains of an Indian warrior, long since dead. Undoubtedly the body of the deceased Indian had lain in the ground for several hundred years as it was entirely decomposed; so that not even the bones remained intact with the exception of two small fragments, one of which is supposed to be part of a jaw-bone and the other is so small that its exact kind cannot be determined.
>
> In the same place were found a necklace of copper and shell beads about a foot in length. The copper beads were one-fourth to a half inch in diameter and the copper used in the composition of the beads showed that they were made of sheet metal which had been rolled into shape. As the Indians did no smelting the copper must have come from the west where it is found in large quantities than in this part of the country. The shells used in the beads were oblong-shaped, about 1½ inches long and half an inch in width and were a sort of bone composition. The copper and shell beads alternated every fifth

bead being of shell followed by four copper ones. In the excavation were also a few small conch shells and two tubes of purplish-red sand-stone, one about 10 inches long and one inch in diameter and the other six inches long and the same diameter. . .

The articles discovered, however, will be photographed and the black substance in the tubes will be analyzed. Through the generosity of the Holyoke Water Power Company, all of these important relics have been presented to the Holyoke library association and are now in their possession.

Under the April 1980 Agreement for Judgment in *City of Holyoke* v. *Holyoke Public Library Corporation* (Civil Action No. 75–2093), the Indian and Natural History Collections were deeded to the City of Holyoke, of which the Wistariahurst Museum is a department. No known individual was identified. The 53 associated funerary objects are two steatite tube pipes (one pipe is broken), 43 copper beads, one bone bead, five shell beads, one small bone fragment, and one animal jawbone fragment. With the exception of the beads, all the associated funerary objects are mounted on an orange plaque.

In her article *Native Land Use and Settlements in Northeastern Woodlands* and *Schaghticoke and Points North: Wobanaki Resistance and Persistence,* Native American scholar Marge Bruchac suggests that many Connecticut River Valley Tribes were forced out of the area, and as a consequence, they merged with other Indian Tribes. So, for example, the Nipmuc could have moved in with the Schaghticoke and Stockbridge Munsee. Holyoke, located on the western side of the Connecticut River, would thus have lain at the convergence of these many tribal groups.

Determinations Made by the Wistariahurst Museum

Officials of the Wistariahurst Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 53 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Stockbridge Munsee Community, Wisconsin.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Penni Martorell, Wistariahurst Museum, 238 Cabot Street, Holyoke, MA 01040, telephone (413) 322–5660, email *MartorellP@Holyoke.org,* by January 19, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Stockbridge Munsee Community, Wisconsin may proceed.

The Wistariahurst Museum is responsible for notifying The Consulted and Invited Tribes that this notice has been published.

Dated: December 9, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–27873 Filed 12–17–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031240; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Pueblo Grande Museum, Phoenix, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Pueblo Grande Museum has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Pueblo Grande Museum. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Pueblo Grande Museum at the address in this notice by January 19, 2021.

ADDRESSES: Lindsey Vogel-Teeter, Pueblo Grande Museum, 4619 E Washington Street, Phoenix, AZ 85034, telephone (602) 534–1572, email *lindsey.vogel-teeter@phoenix.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Pueblo Grande Museum, Phoenix, AZ. The human remains and associated funerary objects were removed from Maricopa County, AZ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Pueblo Grande Museum professional staff in consultation with representatives of the Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and the Zuni Tribe of the Zuni Reservation, New Mexico.

History and Description of the Remains

The Pueblo Grande Museum (PGM) has determined that all of the human remains and associated funerary objects listed in this notice are associated with the Hohokam archeological culture (A.D. 1–1450).

Between 1978 and 1979, human remains representing, at minimum, 19 individuals were removed during excavations conducted at site AZ U:9:1(ASM)/Pueblo Grande in Maricopa County, AZ. Although the human remains have been kept in the collections of PGM since they were excavated, the majority of them were not identified as human until 2018, during a review of the faunal collection.

PGM believes the excavations likely encountered a concentration of infant inhumations and cremations that were unnoticed at the time and, therefore, were not documented as burials. The human remains include six infant or fetal inhumations, three inhumations of adolescents or adults, eight cremations, and two isolated individuals of undetermined age. No known individuals were identified. PGM identified associated funerary objects through locational information contained in the excavation field notes. The 227 associated funerary objects are 67 lots of red-on-buff, buffware, and plainware ceramic sherds; 24 pollen samples; 15 flotation sample; 67 lots of faunal and shell remains; 27 lots of lithics; five shell or stone ornaments; one mineral sample; two manos; four ceramic bowls; two ceramic scoops; two projectile points; one insect nest; three lots charcoal; one palette; one stone ring; and five spindle whorls.

Sometime prior to 2004, human remains representing, at minimum, 15 individuals were excavated from either La Ciudad or site AZ U:9:1(ASM)/Pueblo Grande, both of which are in Maricopa County, AZ. The human remains were discovered at PGM in 2004, but were not identified as human until 2020, during a review of the faunal collection. The human remains belong to individuals of varying ages and sexes and include 14 inhumations and one cremation. No known individuals were identified. No associated funerary objects are present.

The Ak-Chin Indian Community (previously listed as Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona); Gila River Indian Community of the Gila River Indian Reservation, Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and the Tohono O'Odham Nation of Arizona comprise one cultural group known as the O'Odham. Cultural continuity between the prehistoric Hohokam archeological culture and present-day O'Odham peoples is supported by continuities in settlement pattern, architectural technologies, basketry, textiles, ceramic technology, and ritual practices. Oral traditions that are documented for the Ak Chin Indian Community (previously lised as Ak-Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and the Tohono O'Odham Nation of Arizona support their cultural affiliation with Hohokam archeological sites in central and southern Arizona.

The Hopi Tribe of Arizona considers all of Arizona to be within traditional Hopi lands or within areas where Hopi clans migrated in the past. Oral traditions and material culture that are documented for the Hopi Tribe support their cultural affiliation with Hohokam sites in central and southern Arizona. Several Hopi clans and religious societies are derived from ancestors who migrated from the south, and likely identified with the Hohokam archeological culture.

Migration from portions of the Southwest to present-day Zuni are documented in the oral traditions of kivas, priesthoods, and medicine societies of the Zuni Tribe of the Zuni Reservation, New Mexico. These traditions support their affiliation with the central and southern Arizona Hohokam archeological culture. Historical linguistic analysis also suggests interaction between ancestral Zuni and Uto-Aztecan speakers during the late Hohokam period.

Determinations Made by the Pueblo Grande Museum

Officials of the Pueblo Grande Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 34 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 227 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Ak-Chin Indian Community (previously listed as the Ak Chin Indian Community (previously listed as Ak-Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona); Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'Odham Nation of Arizona; and the Zuni Tribe of the Zuni Reservation, New Mexico (hereafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Lindsey Vogel-Teeter, Pueblo Grande Museum, 4619 E Washington Street, Phoenix, AZ 85034, telephone (602) 534–1572, email *lindsey.vogel-teeter@phoenix.gov,* by January 19, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The Pueblo Grande Museum is responsible for notifying The Tribes that this notice has been published.

Dated: December 9, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–27876 Filed 12–17–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031248; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: History Colorado, Formerly Colorado Historical Society, Denver, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: History Colorado, formerly Colorado Historical Society, has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to History Colorado. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to History Colorado at the address in this notice by January 19, 2021.

ADDRESSES: Alisa DiGiacomo, NAGPRA Liaison, History Colorado, 1200

Broadway, Denver, CO 80203, telephone (303) 866–4531, email *alisa.digiacomo@state.co.us.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of History Colorado, Denver, CO. One set of human remains was recovered from La Plata County, CO.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by History Colorado professional staff in consultation with representatives of the Arapaho Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapaho Tribes of Oklahoma (previously listed as Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Navajo Nation, Arizona, New Mexico & Utah; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Ohkay Owingeh, New Mexico (previously listed as Pueblo of San Juan); Pueblo of Acoma, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Shoshone-Bannock Tribes of the Fort Hall Reservation; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; Ute Mountain Ute Tribe (previously listed as Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah); Ysleta del Sur Pueblo (previously listed as Ysleta Del Sur Pueblo of Texas); and the Zuni Tribe of the Zuni Reservation, New Mexico.

The Apache Tribe of Oklahoma; Eastern Shoshone Tribe of the Wind River Reservation, Wyoming; Fort Sill Apache Tribe of Oklahoma; Kiowa Indian Tribe of Oklahoma; Pueblo of Isleta, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Tesuque, New Mexico; and the Pueblo of Zia, New Mexico were invited to consult, but did not participate.

Hereafter, all the Indian Tribes listed above are referred to as ''The Consulted and Invited Tribes.''

History and Description of the Remains

In October 2019, human remains representing, at minimum, one individual were discovered on the side of road CR 210, about one mile west of its junction with US 160, within Bodo State Wildlife Area. The La Plata County Coroner ruled out a forensic interest and released jurisdiction over the human remains—a skull—to the Office of the State Archaeologist. Osteological analysis of the human remains (OAHP 343) conducted by the Department of Anthropology at Fort Lewis College determined that the human remains belong to a Native American adult male. No known individual was identified. No associated funerary objects are present.

History Colorado, in partnership with the Colorado Commission of Indian Affairs, Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado, and the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah, conducted tribal consultations among the Tribes with ancestral ties to the State of Colorado to develop the process for disposition of culturally unidentifiable Native American human remains and associated funerary objects originating from inadvertent discoveries on Colorado State and private lands. As a result of the consultation, a process was developed, *Process for Consultation, Transfer, and Reburial of Culturally Unidentifiable Native American Human Remains and Associated Funerary Objects Originating From Inadvertent Discoveries on Colorado State and Private Lands,* (2008, unpublished, on file with the Colorado Office of Archaeology and Historic Preservation). The Tribes consulted are those who have expressed their wishes to be notified of discoveries in the Basin and Plateau Consultation Region (where this individual originated), as established by the *Process.*

The Native American Graves Protection and Repatriation Review Committee (Review Committee) is responsible for recommending specific actions for disposition of culturally unidentifiable human remains. On November 3–4, 2006, the *Process* was presented to the Review Committee for consideration. A January 8, 2007, letter on behalf of the Review Committee from the Designated Federal Officer transmitted the provisional authorization to proceed with the *Process* upon receipt of formal responses from the Jicarilla Apache Nation, New Mexico, and the Kiowa Indian Tribe of Oklahoma, subject to forthcoming conditions imposed by the Secretary of the Interior. On May 15–16, 2008, the responses from the Jicarilla Apache Nation, New Mexico, and the Kiowa Indian Tribe of Oklahoma were submitted to the Review Committee. On September 23, 2008, the Assistant Secretary for Fish and Wildlife and Parks, as the designee for the Secretary of the Interior, transmitted the authorization for the disposition of culturally unidentifiable human remains according to the *Process* and NAGPRA, pending publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

43 CFR 10.11 was promulgated on March 15, 2010, to provide a process for the disposition of culturally unidentifiable Native American human remains recovered from tribal or aboriginal lands as established by the final judgment of the Indian Claims Commission or U.S. Court of Claims, a treaty, Act of Congress, or Executive Order, or other authoritative governmental sources. As there is no evidence indicating that the human remains reported in this notice originated from tribal or aboriginal lands, they are eligible for disposition under the *Process.*

Determinations Made by History Colorado

Officials of History Colorado have determined that:

- Based on osteological analysis, the human remains are Native American.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Pursuant to 43 CFR 10.11(c)(1), a ''tribal land'' or ''aboriginal land'' provenience for the human remains cannot be determined.
- Pursuant to 43 CFR 10.10(g)(2) and 10.16, and the *Process,* the disposition of the human remains may be to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado, and the Ute Mountain Ute Tribe (previously listed as Ute Mountain Tribe of the Ute Mountain Reservation,

Colorado, New Mexico & Utah) (hereafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Alisa DiGiacomo, NAGPRA Liaison, History Colorado, 1200 Broadway, Denver, CO 80203, telephone (303) 866–4531, email *alias.digiacomo@state.co.us,* by January 19, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

History Colorado is responsible for notifying The Consulted and Invited Tribes that this notice has been published.

Dated: December 9, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–27874 Filed 12–17–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR83550000, 212R5065C6, RX.59389832.1009676; OMB Control Number 1006–0023]

Agency Information Collection Activities; Submission To the Office of Management and Budget for Review and Approval; Forms To Determine Compliance by Certain Landholders

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Reclamation (Reclamation), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently Under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Stephanie McPhee, Bureau of Reclamation, 84–55000, P.O. Box 25007, Denver, CO 80225–0007; or via email to *smcphee@usbr.gov.* Please reference OMB Control Number 1006–0023 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this information collection request (ICR), contact Stephanie McPhee by email at *smcphee@usbr.gov,* or by telephone at (303) 445–2897. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **FederalRegister** notice with a 60-day public comment period soliciting comments on this collection of information was published on September 15, 2020 (85 FR 57246). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Identification of limited recipients—Some entities that receive Reclamation irrigation water may believe that they are under the Reclamation Reform Act of 1982 (RRA) forms submittal threshold and, consequently, may not submit the appropriate RRA form(s). However, some of these entities may in fact have a different RRA forms submittal threshold than what they believe it to be due to the number of natural persons benefiting from each entity and the location of the land held by each entity. In addition, some entities that are exempt from the requirement to submit RRA forms due to the size of their landholdings (directly and indirectly owned and leased land) may in fact be receiving Reclamation irrigation water for which the full-cost rate must be paid because the start of Reclamation irrigation water deliveries occurred after October 1, 1981 [43 CFR 426.6(b)(2)]. The information obtained through completion of the Limited Recipient Identification Sheet (Form 7–2536) allows us to establish entities' compliance with Federal reclamation law. The Limited Recipient Identification Sheet is disbursed at our discretion.

Trust review—In order to administer section 214 of the RRA and 43 CFR 426.7, we are required to review and approve all trusts. Land held in trust generally will be attributed to the beneficiaries of the trust rather than the trustee if the criteria specified in the RRA and 43 CFR 426.7 are met. We may extend the option to complete and submit for our review the Trust Information Sheet (Form 7–2537) instead of actual trust documents when we become aware of trusts with a relatively small landholding (40 acres or less in districts subject to the prior law provisions of Federal reclamation law, 240 acres or less in districts subject to the discretionary provisions of Federal reclamation law). If we find nothing on the completed Trust Information Sheet that would warrant the further investigation of a particular trust, that

trustee will not be burdened with submitting trust documents to us for in-depth review. The Trust Information Sheet is disbursed at our discretion.

Acreage limitation provisions applicable to public entities—Land farmed by a public entity can be considered exempt from the application of the acreage limitation provisions provided the public entity meets certain criteria pertaining to the revenue generated through the entity's farming activities (43 CFR 426.10 and the Act of July 7, 1970, Public Law 91–310). We are required to ascertain whether or not public entities that receive Reclamation irrigation water meet such revenue criteria regardless of how much land the public entities hold (directly or indirectly own or lease) [43 CFR 426.10(a)]. In order to minimize the burden on public entities, standard RRA forms are submitted by a public entity only when the public entity holds more than 40 acres subject to the acreage limitation provisions westwide, which makes it difficult to apply the revenue criteria as required to those public entities that hold less than 40 acres. When we become aware of such public entities, we request those public entities complete and submit for our review the Public Entity Information Sheet (Form 7–2565), which allows us to establish compliance with Federal reclamation law for those public entities that hold 40 acres or less and, thus, do not submit a standard RRA form because they are below the RRA forms submittal threshold. In addition, for those public entities that do not meet the exemption criteria, we must determine the proper rate to charge for Reclamation irrigation water deliveries. The Public Entity Information Sheet is disbursed at our discretion.

Acreage limitation provisions applicable to religious or charitable organizations—Some religious or charitable organizations that receive Reclamation irrigation water may believe that they are under the RRA forms submittal threshold and, consequently, may not submit the appropriate RRA form(s). However, some of these organizations may in fact have a different RRA forms submittal threshold than what they believe it to be depending on whether these organizations meet all of the required criteria for full special application of the acreage limitations provisions to religious or charitable organizations [43 CFR 426.9(b)]. In addition, some organizations that (1) do not meet the criteria to be treated as a religious or charitable organization under the acreage limitation provisions, and (2) are exempt from the requirement to submit RRA forms due to the size of their landholdings (directly and indirectly owned and leased land), may in fact be receiving Reclamation irrigation water for which the full-cost rate must be paid because the start of Reclamation irrigation water deliveries occurred after October 1, 1981 [43 CFR 426.6(b)(2)]. The Religious or Charitable Organization Identification Sheet (Form 7–2578) allows us to establish certain religious or charitable organizations' compliance with Federal reclamation law. The Religious or Charitable Organization Identification Sheet is disbursed at our discretion.

Title of Collection: Forms to Determine Compliance by Certain Landholders, 43 CFR part 426.

OMB Control Number: 1006–0023.

Form Numbers: Form 7–2536, Form 7–2537, Form 7–2565, and Form 7–2578.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Entity landholders, trusts, public entities, and religious or charitable organizations identified by Reclamation that are subject to the acreage limitation provisions of Federal reclamation law.

Total Estimated Number of Annual Respondents: 500.

Total Estimated Number of Annual Responses: 500.

Estimated Completion Time Per Response: See table below.

Total Estimated Number of Annual Burden Hours: 72 hours.

Respondent's Obligation: Mandatory.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

Form	Burden estimate per form (in minutes)	Number of respondents	Annual number of responses	Annual burden on respondents (in hours)
Limited Recipient Identification Sheet	5	175	175	15
Trust Information Sheet	5	150	150	13
Public Entity Information Sheet	15	100	100	25
Religious or Charitable Identification Sheet	15	75	75	19
Totals		500	500	72

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Christopher J. Beardsley,

Director, Policy and Programs.

[FR Doc. 2020–27900 Filed 12–17–20; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR83550000, 212R5065C6, RX.59389832.1009676; OMB Control Number 1006–0005]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Individual Landholder's and Farm Operator's Certification and Reporting Forms for Acreage Limitation

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Reclamation (Reclamation), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting

''Currently Under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Stephanie McPhee, Bureau of Reclamation, 84–55000, P.O. Box 25007, Denver, CO 80225–0007; or via email to *smcphee@usbr.gov.* Please reference OMB Control Number 1006–0005 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this information collection request, contact Stephanie McPhee, Bureau of Reclamation, by email at *smcphee@usbr.gov,* or by telephone at (303) 445–2897. You may also view the information collection request at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on September 15, 2020 (85 FR 58245). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed information collection request that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: This information collection is required under the Reclamation Reform Act of 1982 (RRA), Acreage Limitation Rules and Regulations, 43 CFR part 426, and Information Requirements for Certain Farm Operations In Excess of 960 Acres and the Eligibility of Certain Formerly Excess Land, 43 CFR part 428. This information collection requires certain landholders (direct or indirect landowners or lessees) and farm operators to complete forms demonstrating their compliance with the acreage limitation provisions of Federal reclamation law. The forms in this information collection are submitted to districts that use the information to establish each landholder's status with respect to landownership limitations, full-cost pricing thresholds, lease requirements, and other provisions of Federal reclamation law. In addition, forms are submitted by certain farm operators to provide information concerning the services they provide and the nature of their farm operating arrangements. All landholders whose entire westwide landholdings total 40 acres or less are exempt from the requirement to submit RRA forms. Landholders who are ''qualified recipients'' have RRA forms submittal thresholds of 80 acres or 240 acres depending on the district's RRA forms submittal threshold category where the land is held. Only farm operators who provide multiple services to more than 960 acres held in trusts or by legal entities are required to submit forms.

Title of Collection: Individual Landholder's and Farm Operator's Certification and Reporting Forms for Acreage Limitation, 43 CFR part 426 and 43 CFR part 428.

OMB Control Number: 1006–0005.

Form Numbers: Form 7–2180, Form 7–2180EZ, Form 7–2181, Form 7–2184, Form 7–2190, Form 7–2190EZ, Form 7–2191, Form 7–2194, Form 7–21TRUST, Form 7–21PE, Form 7–21PE–IND, Form 7–21FARMOP, Form 7–21VERIFY, Form 7–21FC, Form 7–21XS, Form 7–21XSINAQ, Form 7–21CONT–I, Form 7–21CONT–L, Form 7–21CONT–O, and Form 7–21INFO.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Landholders and farm operators of certain lands in our projects, whose landholdings exceed specified RRA forms submittal thresholds.

Total Estimated Number of Annual Respondents: 13,960.

Total Estimated Number of Annual Responses: 14,239.

Estimated Completion Time per Response: See table below.

Total Estimated Number of Annual Burden Hours: 10,437 hours.

Respondent's Obligation: Mandatory.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

Form No.	Burden estimate per form (in minutes)	Number of respondents	Annual number of responses	Annual burden on respondents (in hours)
Form 7–2180	60	3,595	3,667	3,667
Form 7–2180EZ	45	373	380	285
Form 7–2181	78	1,050	1,071	1,392
Form 7–2184	45	32	33	25
Form 7–2190	60	1,601	1,633	1,633
Form 7–2190EZ	45	96	98	74
Form 7–2191	78	777	793	1,031
Form 7–2194	45	4	4	3
Form 7–21PE	75	135	138	173
Form 7–21PE–IND	12	4	4	1

Form No.	Burden estimate per form (in minutes)	Number of respondents	Annual number of responses	Annual burden on respondents (in hours)
Form 7–21TRUST	60	694	708	708
Form 7–21VERIFY	12	5,069	5,170	1,034
Form 7–21FC	30	214	218	109
Form 7–21XS	30	144	147	74
Form 7–21FARMOP	78	172	175	228
Totals		13,960	14,23939	10,437

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Christopher J. Beardsley,

Director, Policy and Programs.

[FR Doc. 2020–27899 Filed 12–17–20; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR83550000, 212R5065C6, RX.59389832.1009676; OMB Control Number 1006–0006]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Certification Summary Form and Reporting Summary Form for Acreage Limitation

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Reclamation (Reclamation), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently Under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Stephanie McPhee, Bureau of Reclamation, 84–55000, P.O. Box 25007, Denver, CO 80225–0007; or via email to *smcphee@usbr.gov.* Please reference OMB Control Number 1006–0006 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this information collection request (ICR), contact Stephanie McPhee by email at *smcphee@usbr.gov,* or by telephone at (303) 445–2897. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on September 15, 2020 (85 FR 57244). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: This information collection is required under the Reclamation Reform Act of 1982 (RRA), Acreage Limitation Rules and Regulations, 43 CFR part 426, and Information Requirements for Certain Farm Operations In Excess of 960 Acres and the Eligibility of Certain Formerly Excess Land, 43 CFR part 428. The forms in this information collection are to be used by district offices to summarize individual landholder (direct or indirect landowner or lessee) and farm operator certification and reporting forms. This information allows us to establish water user compliance with Federal reclamation law.

Title of Collection: Certification Summary Form and Reporting Summary Form for Acreage Limitation, 43 CFR part 426 and 43 CFR part 428.

OMB Control Number: 1006–0006.

Form Numbers: Form 7–21SUMM–C and Form 7–21SUMM–R.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Contracting entities that are subject to

the acreage limitation provisions of Federal reclamation law.

Total Estimated Number of Annual Respondents: 177.

Total Estimated Number of Annual Responses: 221.

Estimated Completion Time per Response: See table below.

Total Estimated Annual Burden Hours: 8,840 hours.

Respondent's Obligation: Mandatory.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

Form no.	Burden estimate per form (in hours)	Number of respondents	Annual number of responses	Annual burden on respondents (in hours)
7–21SUMM–C and associated tabulation sheets	40	169	211	8,440
7–21SUMM–R and associated tabulation sheets	40	8	10	400
Totals		177	22121	8,840

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Christopher J. Beardsley,

Director, Policy and Programs.

[FR Doc. 2020–27895 Filed 12–17–20; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1550–1553 (Preliminary)]

Polyester Textured Yarn From Indonesia, Malaysia, Thailand, and Vietnam; Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of polyester textured yarn from Indonesia, Malaysia, Thailand, and Vietnam, provided for in subheadings 5402.33.30 and 5402.33.60 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'').[2]

Commencement of Final Phase Investigation

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under § 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under § 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On October 28, 2020, Nan Ya Plastics Corp. America, Lake City, South Carolina and Unifi Manufacturing, Inc., Greensboro, North Carolina filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV imports of polyester textured yarn from Indonesia, Malaysia, Thailand, and Vietnam. Accordingly, effective October 28, 2020, the Commission instituted antidumping duty investigation Nos. 731–TA–1550–1553 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of November 3, 2020 (85 FR 69643). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its conference through written testimony and video conference. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to § 733(a) of the Act (19 U.S.C. 1673b(a)). It completed and filed its determinations in these investigations on December 14, 2020. The views of the Commission are contained in USITC Publication 5148 (December 2020), entitled *Polyester Textured Yarn from Indonesia, Malaysia, Thailand, and Vietnam: Investigation Nos. 731–TA–1550–1553 (Preliminary).*

By order of the Commission.

Issued: December 14, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–27855 Filed 12–17–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1230]

Certain Electric Shavers and Components and Accessories Thereof; Notice of a Commission Determination Not To Review an Initial Determination Granting a Motion for Benepuri LLC To Intervene and To Terminate Respondent Rayenbarny Inc. for Good Cause

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 85 FR 74680 (November 23, 2020).

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 4) of the presiding administrative law judge (''ALJ''), granting a motion by Benepuri LLC of Menands, New York (''Benepuri'') to intervene in the above-referenced investigation and to terminate the investigation as to respondent Rayenbarny Inc. of New York, New York (''Rayenbarny'').

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3179. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: On November 18, 2020, the Commission instituted this investigation based on a complaint filed by Skull Shaver, LLC of Moorestown, New Jersey (''Skull Shaver''). 85 FR 73510–11 (Nov. 18, 2020). The complaint alleged violations of section 337 based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain electric shavers and components and accessories thereof by reason of infringement of certain claims of U.S. Patent Nos. 8,726,528 and D672,504. *Id.* The Commission's notice of investigation named the following eleven entities as respondents: Rayenbarny; Bald Shaver Inc. of Toronto, Canada; Suzhou Kaidiya Garments Trading Co., Ltd. d.b.a. ''Digimator'' of Suzhou, China; Shenzhen Aiweilai Trading Co., Ltd. d.b.a. ''Teamyo'' of Shenzhen, China; Wenzhou Wending Electric Appliance Co., Ltd. of Yueqing City, China; Shenzhen Nukun Technology Co., Ltd. d.b.a. ''OriHea'' of Shenzhen, China; Yiwu Xingye Network Technology Co. Ltd. d.b.a. ''Roziapro'' of Yiwu, China; Magicfly LLC of Hong Kong; Yiwu City Qiaoyu Trading Co., Ltd. of Yiwu, China; Shenzhen Wantong Information Technology Co., Ltd. d.b.a. ''WTONG'' of Shenzhen, China; and Shenzhen Junmao International Technology Co., Ltd. d.b.a. ''Homeas'' of Shenzhen, China. The notice of investigation also named the Office of Unfair Import Investigations (''OUII'') as a party. *Id.*

On November 18, 2020, Benepuri filed a motion to intervene in this investigation, asserting that it has an interest in the investigation because one of its products has been accused and that no other named respondent has an interest in defending Benepuri's product. Benepuri also moved for termination of Rayenbarny as a respondent, stating that the accused product attributed to Rayenbarny, the AsaVea electric shaver, is actually Benepuri's product. Attached to Benepuri's motion is a declaration from the President of Rayenbarny, stating that ''Rayenbarny Inc. has not imported into the United States, sold for importation into the United States, or sold in the United States after importation an electric shaver'' and that ''[t]o the best of my knowledge, the AsaVea electric shaver that is identified in the Complaint in the above referenced Investigation is a product from Benepuri LLC.'' Benepuri Motion, Exhibit B. On November 23, 2020, Skull Shaver and OUII filed responses in support of Benepuri's intervention and Rayenbarny's termination.

On November 30, 2020, the ALJ issued the subject ID granting the motion. Regarding Benepuri's intervention, the ID finds that the motion complies with the requirements of Commission Rule 210.19. 19 CFR 210.19. Specifically, the ID finds that (1) ''Benepuri's motion to intervene was timely filed because it was made on the same day as the November 18, 2020 institution of this Investigation''; (2) ''Benepuri has demonstrated a substantial interest in the Investigation,'' particularly in connection with the accused AsaVea electric shaver; and (3) ''Benepuri's interests are not represented by existing parties.'' ID at 5. Thus, the ID finds that ''Benepuri's intervention in this Investigation is appropriate, and Benepuri should be accorded status as a respondent.'' *Id.* at 5–6 (citing *Network Interface Cards,* Inv. No. 337–TA–455, Comm'n Op. at 10 (July 17, 2001) (a party seeking to intervene should be accorded respondent status when it could itself be a respondent in the investigation, but has been omitted by the complainant for some reason)).

The ID also finds that good cause exists to terminate the investigation as to Rayenbarny under Commission Rule 210.21(a), which provides that ''[a]ny party may move at any time prior to the issuance of an initial determination on violation of section 337 of the Tariff Act of 1930 to terminate an investigation in whole or in part as to any or all respondents, on the basis of . . . good cause . . . .'' 19 CFR 210.21(a). The ID notes that Rayenbarny's declaration states that it ''has not imported into the United States, sold for importation into the United States, or sold in the United States after importation an electric shaver.'' In addition, consistent with Commission Rule 210.21(a)(1), Rayenbarny states that ''there are no agreements, written or oral, express or implied, between any party or Benepuri concerning the subject matter of the Investigation.'' The ID further notes that ''Rayenbarny's termination from this Investigation is in the public interest and will conserve public and private resources.'' ID at 6.

No one petitioned for review of the subject ID. The Commission has determined not to review the subject ID. Benepuri is hereby named a respondent in this investigation and Rayenbarny is hereby terminated from this investigation.

The Commission vote for this determination took place on December 15, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.
Issued: December 15, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–28038 Filed 12–17–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1166]

Certain Foodservice Equipment and Components Thereof; Commission Determination To Review an Initial Determination Granting Summary Determination of No Substantial Injury to a Domestic Industry, and on Review To Reverse the Initial Determination and Remand the Investigation to the Administrative Law Judge

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 52) granting summary determination of no substantial injury to a domestic industry in the above-captioned investigation. On review, the Commission has determined to reverse the ID's grant of summary determination and remand the investigation to the ALJ for further proceedings. The Commission has also determined to deny Complainants' motion for leave to file a reply brief.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 3, 2019, based on a complaint filed on behalf of Illinois Tool Works, Inc. of Glenview, Illinois; Vesta Global Limited of Hong Kong; Vesta (Guangzhou) Catering Equipment Co., Ltd. of China; and Admiral Craft Equipment Corp. of Westbury, New York (collectively, ''Complainants''). 84 FR 31911 (Jul. 3, 2019). The complaint, as supplemented, alleges violations of section 337(a)(1)(A) of the Tariff Act of 1930, as amended, 19 U.S.C. 1337(a)(1)(A), based upon the importation of articles into the United States, or in the sale of such articles by the owner, importer, or consignee of certain foodservice equipment and components thereof by reason of misappropriation of trade secrets and unfair competition through tortious interference with contractual relationships, the threat or effect of which is to destroy or substantially injure a domestic industry. *Id.* at 31911–12. The plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''commercial kitchen equipment and components thereof for use in restaurants, bars, cafes, cafeterias, or the like.'' *Id.* at 31912. The notice of investigation named Guangzhou Rebenet Catering Equipment Manufacturing Co., Ltd.; Zhou Hao; Aceplus International Limited (aka Ace Plus International Ltd.); Guangzhou Liangsheng Trading Co., Ltd.; and Zeng Zhaoliang (collectively, ''Respondents''), all of China as respondents. *Id.* at 31912. The Office of Unfair Import Investigations (''OUII'') is also named as a party. *Id.*

On May 21, 2020, OUII filed a motion for summary determination of no substantial injury to a domestic industry under section 337(a)(1)(A), 19 U.S.C. 1337(a)(1)(A). Complainants opposed the motion, and Respondents supported the motion. OUII also filed a reply brief in support of its motion.

On July 9, 2020, the ALJ issued the subject ID (Order No. 52) granting OUII's motion for summary determination of no substantial injury to a domestic industry under section 337(a)(1)(A). Presuming the existence of a domestic industry as alleged by Complainants, the ID found that ''Complainants have not demonstrated injury'' to ''the specific activities and investments that give rise to [the alleged] domestic industry.'' *Id.* at 16, 18. The ID found that Complainants identified ''generalized competitive harm 'to the industry as a whole,' such as lost sales and profits, rather than pointing specifically to injury or threatened injury to the alleged domestic activities.'' *Id.* at 16. The ID reasoned that ''generalized lost profits and lost sales, *etc.,* cannot suffice to show substantial harm because even a mere importer will suffer such harm if a competitor imports and sells the same products cheaper.'' *Id.* at 17.

On July 20, 2020, Complainants petitioned for review of the ID. Thereafter, Respondents and OUII opposed the petition. On August 4, 2020, Complainants filed a motion for leave to file a reply to Respondents' and OUII's responses to its petition. Respondents and OUII opposed Complainants' motion.

The Commission has determined to review the ID in its entirety and to deny Complainants' motion for leave to file a reply brief. On review, the Commission has determined to reverse the ID's grant of summary determination finding that Complainants' evidentiary showing is insufficient to establish substantial injury to Complainants' alleged domestic industry, and remand the investigation to the ALJ for further proceedings consistent with the Commission's order and concurrent opinion.

The Commission vote for this determination took place on December 14, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.
Issued: December 14, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–27858 Filed 12–17–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[Docket No. 2020R–10]

Objective Factors for Classifying Weapons with ''Stabilizing Braces''

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.

ACTION: Notice; request for comment.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms, and Explosives (''ATF'') is publishing the objective factors it considers when evaluating firearms with an attached stabilizing brace to determine whether they are considered firearms under the National Firearms Act (''NFA'') and/or the Gun Control Act (''GCA''). ATF publishes this notice to inform and invite comment from the industry and public on the proposed guidance, Objective Factors for Classifying Weapons with ''Stabilizing Braces,'' prior to issuing a final document. Upon issuance of final guidance, ATF will provide additional information to aid persons and companies in complying with Federal laws and regulations. This notice also outlines ATF's enforcement priorities regarding persons who, prior to publication of this notice, made or acquired, in good faith, firearms equipped with a stabilized brace. Finally, this notice previews ATF's and the Department of Justice's plan to subsequently implement a separate process for current possessors of stabilizer-equipped firearms to choose to register such firearms in compliance with the NFA, including an expedited application process and the retroactive exemption of such firearms from the collection of NFA taxes.

DATES: Written comments must be postmarked and electronic comments

must be submitted on or before January 4, 2021. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern time on the last day of the comment period.

ADDRESSES: You may submit comments, identified by docket number ATF 2020R–10, by any of the following methods—

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Office of Regulatory Affairs, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, 99 New York Ave. NE, Mail Stop 6N–518, Washington, DC 20226; *ATTN: ATF 2020R–10.*
- *Fax:* (202) 648–9741.

Instructions: All submissions received must include the agency name and docket number (ATF 2020R–10). All properly completed comments received will be posted without change to the Federal eRulemaking portal, *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Andrew Lange, Office of Regulatory Affairs, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Ave. NE, Mail Stop 6N–518, Washington DC 20226; telephone: (202) 648–7070 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Attorney General [1] is responsible for enforcing the NFA, GCA, and the Arms Export Control Act (''AECA'').[2] The Attorney General has delegated the responsibility for administering and enforcing these statutes to the Director of ATF, subject to the direction of the Attorney General and the Deputy Attorney General. *See* 28 CFR 0.130(a)(1)–(2). The ATF Director delegated the authority to classify firearms pursuant to the GCA and NFA to ATF's Firearms Technology Criminal Branch (''FTCB'') and the Firearms Technology Industry Services Branch (''FTISB''), within the Firearms and Ammunition Technology Division (''FATD''), Office of Enforcement Programs & Services (''EPS'').[3]

FATD supports the firearms industry and the general public by, among other things, responding to technical inquiries, and by testing and evaluating firearms submitted to ATF for classification as to their regulation under the GCA and/or NFA. There is no requirement that the firearms industry or the public submit firearms to ATF for assessment of the firearm's proper classification. The statutory definition of ''firearm'' under the GCA and the NFA is different.[4] As a result, whether an item meets the definition of ''firearm'' under the GCA or the NFA affects how it will be regulated under Federal law. For instance, the GCA restricts the transportation, sale, and delivery of short-barreled shotguns and short-barreled rifles. 18 U.S.C. 922(a)(4) and (b)(4). Shotguns having a barrel or barrels of less than 18 inches in length,[5] and rifles having a barrel or barrels less than 16 inches in length,[6] and certain weapons made from shotguns and rifles, are ''firearms'' as defined by the NFA, and are subject to registration and taxes. 26 U.S.C. 5845(a). Therefore, FATD's classifications of a particular firearm allows industry members to plan, develop, and distribute products in compliance with the law, thereby reducing their risk of incurring criminal or civil penalties, or the potential for costly corrective actions, including a possible recall by the manufacturer.

Generally, when FATD evaluates a firearm sample, it examines its overall configuration, physical characteristics, objective design features that are relevant under the statutory definitions of the GCA and NFA, and any other information that directly affects the classification of a particular firearm sample. Even though firearms may appear to have similar features, an ATF classification pertains only to the particular sample submitted, because variations in submissions, applicable statutes, judicial interpretations of these statutes, the manufacturer's or maker's intent,[7] and the objective design features supporting that intent, make the general applicability of any particular classification exceedingly rare.

In recent years, some manufacturers have produced and sold devices designed to be attached to large and/or heavy pistols which are marketed to help a shooter ''stabilize'' his or her arm to support single-handed fire (''braces''). ATF was advised by the first manufacturer to submit an arm brace for classification that the intent of the arm brace was to facilitate one-handed firing of the AR15 pistol for those with limited strength or mobility due to a handicap, and to reduce bruising to the forearm when firing with one hand. According to this manufacturer, the brace concept was inspired by the needs of disabled combat veterans who still enjoy recreational shooting but could not reliably control heavy pistols without assistance. Consequently, ATF agrees that there are legitimate uses for certain ''stabilizing braces.''

The GCA and NFA generally regulate ''firearms'' and not individual components and, as such, ATF does not classify unregulated components or accessories alone. However, components or accessories can affect the overall classification of a firearm because: (1) How a component or accessory is actually used may be relevant in assessing the manufacturer's or maker's intent with respect to the design of a firearm; or (2) the design of a component or accessory may result in a firearm falling within a particular statutory definition. Stabilizing braces are one such component or accessory that ATF has encountered.

ATF's longstanding and publicly known position is that a firearm does not evade classification under the NFA merely because the firearm is configured with a device marketed as a ''stabilizing

[1] National Firearms Act provisions still refer to the ''Secretary of the Treasury.'' 26 U.S.C. ch. 53. However, the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, transferred the functions of ATF from the Department of the Treasury to the Department of Justice, under the general authority of the Attorney General. 26 U.S.C. 7801(a)(2); 28 U.S.C. 599A(c)(1). Thus, for ease of reference, this notice refers to the Attorney General.

[2] National Firearms Act, 26 U.S.C. ch. 53; Gun Control Act, 18 U.S.C. ch. 44; Arms Export Control Act, 22 U.S.C. 2778.

[3] Delegation of Authorities within the Bureau of Alcohol, Tobacco, Firearms and Explosives, Delegation Order 1100.168C (November 5, 2018).

[4] 18 U.S.C. 921(a)(3) (GCA definition of firearm); 26 U.S.C. 5845(a) (NFA definition of firearm).

[5] Under 26 U.S.C. 5845(d), the term ''shotgun'' is further defined to mean ''a weapon designed or redesigned, made or remade, and intended to be fired from the shoulder and designed or redesigned and made or remade to use the energy of the explosive in a fixed shotgun shell to fire through a smooth bore either a number of projectiles (ball shot) or a single projectile for each pull of the trigger, and shall include any such weapon which may be readily restored to fire a fixed shotgun shell.''

[6] Under 26 U.S.C. 5845(c), the term ''rifle'' is further defined to mean ''a weapon designed or redesigned, made or remade, and intended to be fired from the shoulder and designed or redesigned and made or remade to use the energy of the explosive in a fixed cartridge to fire only a single projectile through a rifled bore for each single pull of the trigger, and shall include any such weapon which may be readily restored to fire a fixed cartridge.''

[7] ''When classifying a part as a firearm silencer, the statute imposes an intent requirement. Therefore, the manufacturer's stated intent for the part is clearly relevant,'' however, ''the objective design features of the part must support the stated intent.'' *Sig Sauer, Inc.* v. *Jones,* 133 F. Supp. 3d 364, 370 (D.N.H 2015) *aff'd Sig Sauer, Inc.* v. *Brandon,* 826 F.3d 598 (1st Cir. 2016).

brace'' or ''arm brace.''[8] When an accessory and a weapon's objective design features, taken together, are not consistent with use of the accessory as an arm brace, that is, not to stabilize a handgun when being operated with one hand, such weapon, configured with the accessory may fall within the scope of the NFA, particularly where the accessory functions as a shoulder stock for the weapon. Accordingly, ATF must evaluate whether a particular firearm configured with a stabilizing brace bears the objective features of a firearm designed and intended to be fired from the shoulder, and thus subject to the NFA, on a case-by-case basis.

As the purpose of the NFA is ''to regulate certain weapons likely to be used for criminal purposes,'' *United States* v. *Thompson/Center Arms Co.,* 504 U.S. 505, 517 (1992), ATF cannot ignore the design features of a firearm that place it within the scope of the NFA's regulation simply because the manufacturer characterizes or markets a firearm accessory in a manner that does not correspond to its objective design. The characterization of an accessory by the manufacturer, including assertions in advertising, is not dispositive. If ATF's classification of a submitted sample demonstrates that the objective design features of the firearm, as configured, do not support the manufacturer's purported intent and characterization of the accessory on that particular firearm as a ''stabilizing brace'' or ''arm brace,'' ATF will classify the firearm based on the objective design features, as Federal law requires. *See Sig Sauer* v. *Brandon,* 826 F.3d 598, 601–02 (1st Cir. 2016).

ATF has observed that the development and production of firearms with arm braces has become more prevalent in the firearms industry and, relatedly, that requests for classifications for this kind of firearm design have also increased. Therefore, ATF is publishing this notice to aid the firearms industry and public in understanding the objective design features that FATD considers when evaluating firearm samples submitted with a stabilizing brace or similar attachment.

The objective design features ATF considers in determining whether a weapon with an attached ''stabilizing brace'' has been ''designed or redesigned, made or remade, and intended to be fired from the shoulder'' include, but are not limited to:

- *Type and Caliber.* The type and caliber of firearm to which the stabilizing brace or similar item is installed. A large caliber firearm that is impractical to fire with one hand because of recoil or other factors, even with an arm brace, is likely to be considered a rifle or shotgun.
- *Weight and Length.* The weight and length of the firearm used with the stabilizing brace. A firearm that is so heavy that it is impractical to fire or aim with one hand, or so long that it is difficult to balance the firearm to fire with one hand, is likely to be considered a rifle or shotgun.
- *Length of Pull.* The ''length of pull'' refers to the distance from the trigger to the point at which a stock meets the shoulder. This is a measurement for rifles and shotguns used to accommodate shooters of different sizes. Because an arm brace need only reach the forearm, the distance between the trigger and the back of the brace is generally expected to be shorter than the distance between the trigger and the back of a stock on a weapon designed and intended to be fired from the shoulder. This measurement is not necessarily determinative of the intent of the manufacturer but is used in making an evaluation of the firearm. If a brace is of a length that makes it impractical to attach to the shooter's wrist or forearm, then that may demonstrate that it is not designed as brace but rather for shoulder fire.
- *Attachment Method.* The method of attachment of the stabilizing brace, to include modified stock attachments, extended receiver extensions, and the use of spacers. These items extend the distance between the trigger and the part of the weapon that contacts the shooter, whether it is a stock or stabilizing brace. Use of these items indicates that the weapon is designed and intended to be fired from the shoulder because they extend a stabilizing brace beyond a point that is useful for something other than shoulder support.
- *Stabilizing Brace Design Features.* The objective design features of the attached stabilizing brace itself are relevant to the classification of the assembled weapon, and include:
  - The comparative function of the attachment when utilized as a stabilizing brace compared to its alternate use as a shouldering device;
  - The design of the stabilizing brace compared to known shoulder stock designs;
  - The amount of rear contact surface area of the stabilizing brace that can be used in shouldering the weapon as compared to the surface area necessary for use as a stabilizing brace;
  - The material used to make the attachment that indicates whether the brace is designed and intended to be pressed against the shoulder for support, or actually used on the arm;
  - Any shared or interchangeable parts with known shoulder stocks; and
  - Any other feature of the brace that improves the weapon's effectiveness from the shoulder-firing position without providing a corresponding benefit to the effectiveness of the stability and support provided by the brace's use on the arm.
- *Aim Point.* Appropriate aim point when utilizing the attachment as a stabilizing brace. If the aim point when using the arm brace attachment results in an upward or downward trajectory that could not accurately hit a target, this may indicate the attachment was not designed as a stabilizing brace.
- *Secondary Grip.* The presence of a secondary grip may indicate that the weapon is not a ''pistol'' because it is not designed to be held and fired by one hand.
- *Sights and Scopes.* Incorporation of sights or scopes that possess eye relief incompatible with one-handed firing may indicate that the weapon is not a ''pistol'' because they are designed to be used from a shoulder-fire position and are incompatible for the single-handed shooting that arm braces are designed and intended.
- *Peripheral Accessories.* Installation of peripheral accessories commonly found on rifles or shotguns that may indicate that the firearm is not designed and intended to be held and fired with one hand. This includes, but is not limited to, the installation of bipods/monopods that improve the accuracy of heavy weapons designed and intended to be fired from the shoulder; or the inclusion of a magazine or drum that accepts so many cartridges that it increases the overall weight of the firearm to a degree that it is impractical to fire the weapon with one hand even with the assistance of a stabilizing brace.

These factors are based on known stabilizing braces and similar attachments. No single factor or combination of factors is necessarily dispositive, and FATD examines each weapon holistically on a case-by-case basis. Because of changes in design or configuration of a weapon or

[8] *See* ATF, Open Letter on the Redesign of ''Stabilizing Braces,'' (Jan. 16, 2015); and an open letter to industry counsel clarifying the 2015 Open Letter, *see* Marvin G. Richardson, Assistant Director, ATF Enforcement Programs & Services, 90000:GM, 5000 (Mar. 21, 2017) (made widely available to the public on various websites, for example, see *https://johnpierceesq.com/wp-content/uploads/2017/03/ATF-Letter-March-21-2017.pdf* and *https://www.sigsauer.com/wp-content/uploads/2017/04/atf-letter-march-21-2017.pdf*).

attachment, as well as future changes in technology, this list is not exhaustive and other factors may become relevant to a weapon's classification. Moreover, in addition to the objective design features of a submitted sample, FATD also considers the marketing of both the item and the firearm to which it is attached, compared to the manufacturer's stated intent when submitting an item. FATD has found that manufacturers sometimes assert that a device is a ''*stabilizing brace*'' when submitting a firearm for classification. The same manufacturers will then advertise their products as devices that permit customers to fire their ''*pistols*'' from the shoulder—that is, making a ''short-barreled rifle''—without complying with the requirements of the NFA. This is far from the ''incidental'' use of an arm brace as a shouldering device as described in ATF's 2017 guidance (see footnote 8), but is instead marketing material that directly contradicts the purpose or intent that the manufacturer conveyed to ATF. Although not a determinative factor, the actual use by members of the firearms industry, firearm writers, and the general public may provide further indication of the design and intent. These sources provide insight into the ways that manufacturers market their products. Finally, although the above are the most common objective factors that demonstrate the design and intent of a manufacturer or maker, other factors may be relevant. For example, if FATD classified a firearm with an arm brace as a ''pistol,'' that classification would be subject to FATD's review if the manufacturer sold the product with the instruction that the weapon is actually designed and intended to be fired from the shoulder.

This compilation of relevant objective factors is consistent with what has been applied in evaluations of firearms with an attached stabilizing brace previously conducted by FATD at the request of the firearms industry. By setting out these factors in this notice, ATF is ensuring members of the public are equally aware of the criteria when considering the making or purchase of a firearm. As explained above, FATD's classifications allow industry members to plan, develop, and distribute products that comply with the law, and thereby reduce their risk of incurring criminal or civil penalties, or potentially costly corrective actions, including a possible recall by the manufacturer.

In order to ensure consistency in classifying firearms, FATD uses the following procedure. A firearm voluntarily submitted to FTISB for classification is assigned to a Firearms Enforcement Officer (''FEO'') who evaluates the firearm. This may include disassembly, test-firing, or other processes necessary to determine whether a submission falls under the purview of the NFA, GCA, or AECA. That FEO produces a draft report and that report is peer reviewed by another qualified FEO, and includes a review of the steps taken in the evaluation, the analysis and the conclusions. Therefore, it is not the case that a single FEO is solely responsible for a particular classification. Because of this, prior to any necessary legal review and before the classification letter is signed and finalized, at least two FEOs have reviewed the submission. No classification will depend upon the physical attributes of a particular FEO including, for example, whether a firearm is too heavy to be held and fired in a single hand by the individual examiner, as all FEOs apply the evaluation factors objectively, not subjectively, based on the objective features of the submission that demonstrate, in the present case, the design of the weapon and the intent of the maker or manufacturer. After the review by two FEOs, the classification is then reviewed by the Chief, FTISB, to further ensure consistency.

On August 19, 2020, the Department of Justice (DOJ) published regulations defining ''guidance documents'' and the required procedures that the Department and its components must follow to issue guidance documents consistent with Executive Order 13891. *See* 28 CFR 50.26. The regulation defines the term ''guidance document'' as ''an agency statement of general applicability, intended to have future effect on the behavior of regulated parties that sets forth (i) a policy on a statutory, regulatory, or technical issue, or (ii) an interpretation of a statute or regulation.'' 28 CFR 50.26(a)(1). As ATF started to receive samples of firearms configured with an arm brace for classification, FATD applied objective factors to interpret the NFA and GCA definitions of ''firearm'' to determine when attachment of an accessory purporting to be a stabilizing brace to a specific firearm results in a configuration subject to the provisions of the NFA. Due to the rise of firearms configured in this manner and a correlating increase in the number of classification requests from industry, ATF is publishing this list of objective factors it considers when classifying such firearms, including an explanation as to why those factors are important, to aid industry and the public in understanding ATF's interpretation and application of the NFA and GCA definition of ''firearm'' when evaluating these types of firearms configurations. Although there is no requirement that a guidance document be published for notice and comment,[9] ATF has decided to publish the proposed objective factors in the **Federal Register** for a brief comment period, given the public interest surrounding these issues. ATF will consider the comments it receives before finalizing this guidance.

ATF recognizes that before issuance of this notice, there was a misunderstanding by some that a pistol assembled with any item purported to be a stabilizing brace still would be considered a ''pistol'' regardless of other characteristics. The objective factors discussed here make clear that while some stabilizing braces may lawfully be used on pistols without bringing the firearm within the purview of the NFA, that is not necessarily the case for every ''pistol'' because some firearms are configured or have characteristics such that they meet the statutory definition of ''rifle or shotgun'' (hereafter, ''affected stabilizer-equipped firearms''). ATF understands that most individuals who acquired affected stabilizer-equipped firearms did so in good-faith reliance on representations, made by those selling the stabilizing braces or the firearms, that those firearms were *not* subject to the NFA.

Consequently, following issuance of this notice, ATF and DOJ plan to implement a separate process by which current possessors of affected stabilizer-equipped firearms may choose to register such firearms to be compliant with the NFA. As part of that process, ATF plans to expedite processing of these applications, and ATF has been informed that the Attorney General plans retroactively to exempt such firearms from the collection of NFA taxes if they were made or acquired, prior to the publication of this notice, in good faith. This separate process may include the following options: registering the firearm in compliance with the NFA (described above), permanently removing the stabilizing brace from the firearm and disposing of it, replacing the barrel of the firearm (16'' or greater for a rifle, or 18'' or greater for a shotgun), surrendering the firearm to ATF, or destroying the firearm.

[9] Only ''significant guidance documents,'' as defined 28 CFR 50.27(a)(2), are required to be made available for public notice and comment for at least 30 days, except when the Department or component finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest. 28 CFR 50.27(c)(2)(iii).

Until that process is separately implemented, and absent a substantial public safety concern, ATF will exercise its enforcement discretion not to enforce the registration provisions of the NFA against any person who, before publication of this notice, in good faith acquired, transferred, made, manufactured, or possessed an affected stabilizer-equipped firearms.

This document is not an administrative determination that any particular weapon equipped with a stabilizing arm brace is a ''firearm'' under the NFA. To the extent that the ATF Director subsequently issues such a determination, the ATF Director, at the direction of the Attorney General, plans retroactively to exempt such firearms from the collection of NFA taxes, provided those firearms were made or acquired in good faith prior to the publication of this notice. *See* 26 U.S.C. 7805.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department policies. This guidance does not alter in any way the Department's authority to enforce federal law and is not intended to, does not, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal.

Public Participation

A. Comments Sought

ATF is accepting comments from all interested persons on the use of the objective factors listed in this document. All comments must reference this document's docket number, ATF 2020R–10, be legible, and include the commenter's complete first and last name and full mailing address. ATF will not consider, or respond to, comments that do not meet these requirements or comments containing excessive profanity. Comments that do not meet these criteria will not be considered. ATF will retain anonymous comments and those containing excessive profanity as part of this administrative record, but will not publish such documents on *www.regulations.gov.* ATF will treat all comments as originals and will not acknowledge receipt of comments. In addition, if ATF cannot read your comment due to technical difficulties and cannot contact you for clarification, ATF may not be able to consider your comment.

ATF will carefully consider all comments, as appropriate, received on or before the closing date, and will give comments after that date the same consideration if practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

B. Confidentiality

ATF will make all comments meeting the requirements of this section, whether submitted electronically or on paper, available for public viewing at ATF and on the internet through the Federal eRulemaking Portal, and subject to the Freedom of Information Act (5 U.S.C. 552). Commenters who do not want their name or other personal identifying information posted on the internet should submit comments by mail or facsimile, along with a separate cover sheet containing their personal identifying information. Both the cover sheet and comment must reference this docket number (2020R–10). For comments submitted by mail or facsimile, information contained on the cover sheet will not appear when posted on the internet but any personal identifying information that appears within a comment will not be redacted by ATF and it will appear on the internet.

A commenter may submit to ATF information identified as proprietary or confidential business information. The commenter shall place any portion of a comment that is proprietary or confidential business information under law on pages separate from the balance of the comment with each page prominently marked ''PROPRIETARY OR CONFIDENTIAL BUSINESS INFORMATION'' at the top of the page.

ATF will not make proprietary or confidential business information submitted in compliance with these instructions available when disclosing the comments that it received, but will disclose that the commenter provided proprietary or confidential business information that ATF is holding in a separate file to which the public does not have access. If ATF receives a request to examine or copy this information, it will treat it as any other request under the Freedom of Information Act (5 U.S.C. 552). In addition, ATF will disclose such proprietary or confidential business information to the extent required by other legal process.

C. Submitting Comments

Submit comments in any of three ways (but do not submit the same comment multiple times or by more than one method). Hand-delivered comments will not be accepted.

- *Federal eRulemaking Portal:* ATF recommends that you submit your comments to ATF via the Federal eRulemaking portal at *www.regulations.gov* and follow the instructions. Comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that is provided after you have successfully uploaded your comment.
- *Mail:* Send written comments to the address listed in **ADDRESSES** section of this document. Written comments must appear in minimum 12-point font size (.17 inches), include the commenter's first and last name and full mailing address, be signed, and may be of any length.
- *Facsimile:* Submit comments by facsimile transmission to (202) 648–9741. Faxed comments must:

1. Be legible and appear in minimum 12-point font size (.17 inches);
2. Be 8 ½″ x 11″ paper;
3. Be signed and contain the commenter's complete first and last name and full mailing address; and
4. Be no more than five pages long.

Regina Lombardo,

Acting Director.

[FR Doc. 2020–27857 Filed 12–17–20; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Notice of Extension of Public Comment Period for Proposed Consent Decree Pursuant To the Comprehensive Environmental Response, Compensation, And Liability Act

On December 2, 2020, the Department of Justice lodged a proposed Consent Decree (''Consent Decree'') in the United States District Court for the Northern District of Alabama (Eastern Division), in the lawsuit entitled the *United States of America* v. *Pharmacia, LLC and Solutia, Inc.,* Civil Action No. 1:02–CV–0749 (KOB).

This Consent Decree represents a settlement of certain claims of the United States (''Plaintiff'') against Pharmacia, LLC and Solutia, Inc. (''Defendants'') under Sections 106, 107, and 113 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9606, 9607, and 9613, relating to the Anniston PCB Hazardous Waste Site (''Site'') located in and around Anniston, Alabama. Under the proposed Consent Decree, the

Defendants will be required to implement a Record of Decision (''ROD'') issued by the Environmental Protection Agency (''EPA'') with respect to Operable Units 1 and 2 (''OU1'' and ''OU2'') of the Anniston PCB Site in Anniston, Alabama. The proposed Consent Decree requires the Defendants to finance and conduct the remedial design and remedial action (''RD/RA''), which includes remedial action for both soils and groundwater within OU1 and OU2. These two operable units are outside the plant site (OU3) and consist of both residential and non-residential properties. A previous RD/RA Consent Decree addressing certain properties within OU1 and OU2 identified by EPA as unauthorized waste disposal areas was entered into last year between the United States and MRC Holding Company. This proposed Consent Decree addresses the remainder of OU1 and OU2.

Notice of the Lodging of the proposed Consent Decree was originally published in the **Federal Register** on December 8, 2020. *See* 85 FR 70938–39, Dec. 8, 2020. Publication of the original notice opened a period of public comment for a period of thirty (30) days through January 7, 2021. The publication of the present notice extends the period for public comment on the proposed Consent Decree through February 6, 2021.

Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America* v. *Pharmacia, LLC and Solutia, Inc.,* and the D.J. Ref. No. 90–11–2–07135/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General U.S. DOJ—ENRD P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $11.50 (25 cents per page reproduction cost) payable to the United States Treasury for the Consent Decree and $20.00 for the Consent Decree and Appendices thereto.

Lori Jonas,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–27954 Filed 12–17–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

[OMB Control No. 1218–0NEW;Docket No. 2020–0007]

Information Collection; DOL—Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

AGENCY: Department of Labor.

ACTION: Notice; request for comment.

SUMMARY: The Department of Labor (DOL) has under OMB review the following proposed Information Collection Request ''Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)'' for approval under the Paperwork Reduction Act (PRA).

DATES: Submit comments on or before: January 19, 2021.

ADDRESSES: Submit comments identified by Information Collection 1218–0NEW, DOL Improving Customer Experience (OMB Circular A–11, Section 280 Implementation), by any of the following methods:

- *Federal eRulemaking portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments to *https://www.regulations.gov,* will be posted to the docket unchanged.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street, NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 1218–ONEW, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation).

Instructions: Please submit comments only and cite Information Collection 1218–0NEW, DOL Improving Customer Experience (OMB Circular A–11, Section 280 Implementation) in all correspondence related to this collection. To confirm receipt of your comment(s), please check *regulations.gov,* approximately two-to-three business days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Amira Boland, Office of Management and Budget, 725 17th St NW, Washington, DC 20006, or via email to *amira.c.boland@omb.eop.gov.*

SUPPLEMENTARY INFORMATION:

Title: DOL—Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

Abstract: A modern, streamlined and responsive customer experience means: raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership.

This proposed information collection activity provides a means to garner customer and stakeholder feedback in an efficient, timely manner in accordance with the Administration's commitment to improving customer service delivery as discussed in Section 280 of OMB Circular A–11 at *https://www.performance.gov/cx/a11-280.pdf.*

As discussed in OMB guidance, agencies should identify their highest-impact customer journeys (using customer volume, annual program cost, and/or knowledge of customer priority as weighting factors) and select touchpoints/transactions within those journeys to collect feedback.

These results will be used to improve the delivery of Federal services and programs. It will also provide government-wide data on customer experience that can be displayed on *www.performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

As a general matter, these information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

DOL will only submit collections if they meet the following criteria.

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours or burden-hours per respondent) and are low-cost for both

the respondents and the Federal Government;

• The collections are non-controversial and do not raise issues of concern to other Federal agencies;

• Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;

• Personally identifiable information (PII) is collected only to the extent necessary and is not retained;

• Information gathered is intended to be used for general service improvement and program management purposes

• Upon agreement between OMB and the agency all or a subset of information may be released as part of A–11, Section 280 requirements only on performance.gov. Summaries of customer research and user testing activities may be included in public-facing customer journey maps or summaries.

• Additional release of data must be done coordinated with OMB.

These collections will allow for ongoing, collaborative and actionable communications between the Agency, its customers and stakeholders, and OMB as it monitors agency compliance on Section 280. These responses will inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on services will be unavailable.

Current Action: New Collection of Information.

Type of Review: New.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Estimated Number of Respondents: Below is a preliminary estimate of the aggregate burden hours for this new collection. DOL will provide refined estimates of burden in subsequent notices.

Average Expected Annual Number of Activities: Approximately five types of customer experience activities such as feedback surveys, focus groups, user testing, and interviews.

Average Number of Respondents per Activity: 1 response per respondent per activity.

Annual Responses: 2,001,550.

Average Minutes per Response: 2 minutes—60 minutes, dependent upon activity.

Burden Hours: DOL requests approximately 101,125 burden hours.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection at *Regulations.gov.*

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Crystal Rennie,

Acting Department Clearance Officer.

[FR Doc. 2020–27853 Filed 12–17–20; 8:45 am]

BILLING CODE 4510–04–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0154]

Proposed Extension of Information Collection; Performance Reports for MSHA Grants

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Performance Reports for MSHA Grants.

DATES: All comments must be received on or before February 16, 2021.

ADDRESSES: You may submit comment as follows. Please note that late, untimely filed comments will not be considered.

Electronic Submissions: Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for docket number MSHA–2020–0037. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket, with no changes. Because your comment will be made public, you are responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as your or anyone else's Social Security number or confidential business information.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission.

Written/Paper Submissions: Submit written/paper submissions in the following way:

• *Mail/Hand Delivery:* Mail or visit DOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452.

• MSHA will post your comment as well as any attachments, except for information submitted and marked as confidential, in the docket at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Roslyn B. Fontaine, Deputy Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov*

(email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813(h), authorizes the Mine Safety and Health Administration (MSHA) to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811, authorizes the Secretary of Labor (Secretary) to develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal and metal and nonmetal mines.

MSHA works to prevent death, illness, and injury from mining and to promote safe and healthful workplaces for U.S. miners. Section 115 of the Mine Act, as amended, requires mine operators to have a health and safety training program. Under section 503 of the Mine Act, as amended, the Secretary may award grants to States to assist in developing and enforcing State mining laws and regulations, to improve State workers' compensation and mining occupational disease laws and programs, and to improve safety and health conditions in the Nation's mines through Federal-State coordination and cooperation.

Grantees are required by U.S. Department of Labor (DOL) regulations to submit project and final reports. Grantees are also required to submit final reports no later than 90 days after the end of the grant period.

Technical Project Reports: A grantee submits a technical project report to MSHA no later than 30 days after quarterly deadlines. Technical project reports provide both quantitative and qualitative information and a narrative assessment of performance for the preceding 3-month period. This includes a comparison of the current grant progress against the overall grant goals. Between reporting dates, the grantee informs MSHA of significant developments or problems affecting the organization's ability to accomplish the work.

Final Reports: At the end of the grant period, each grantee provides a project summary of its technical project reports, an evaluation report, and a close-out financial report. These final reports are due no later than 90 days after the end of the 12-month performance period.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Performance Reports for MSHA Grants. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Background documents related to this information collection request are available at *https://regulations.gov* and in DOL–MSHA located at 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice from the previous collection of information.

III. Current Actions

This information collection request concerns provisions for Performance Reports for MSHA Grants. MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request from the previous information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0154.

Affected Public: Business or other for-profit.

Number of Respondents: 50.

Frequency: On occasion.

Number of Responses: 250.

Annual Burden Hours: 625 hours.

Annual Respondent or Recordkeeper Cost: $0.

MSHA Forms: MSHA Performance Report Narratives; and MSHA Form 5000–50, MSHA State Grant Program Performance Report.

Comments submitted in response to this notice will be summarized in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and will be available at *https://www.reginfo.gov.*

Roslyn B. Fontaine,

Certifying Officer.

[FR Doc. 2020–27929 Filed 12–17–20; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Veterans' Employment and Training Service

Advisory Committee on Veterans' Employment, Training and Employer Outreach (ACVETEO): Meeting

AGENCY: Veterans' Employment and Training Service (VETS), Department of Labor (DOL).

ACTION: Notice of virtual open meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the ACVETEO. The ACVETEO will discuss the DOL core programs and services that assist veterans seeking employment and raise employer awareness as to the advantages of hiring veterans. There will be an opportunity for individuals or organizations to address the committee. Any individual or organization that wishes to do so should contact Mr. Gregory Green at *ACVETEO@dol.gov.* Additional information regarding the Committee, including its charter, current membership list, annual reports, meeting minutes, and meeting updates may be found at *https://www.dol.gov/agencies/vets/about/advisorycommittee.* This notice also describes the functions of the ACVETEO. Notice of this meeting is required under Section 10(a) (2) of the Federal Advisory Committee Act. This document is intended to notify the general public.

DATES: Thursday, January 14, 2021 beginning at 9:00 a.m. and ending at approximately 12:00 p.m. (EST).

ADDRESSES: This ACVETEO meeting will be held via WebEx video and teleconference. Meeting information will be posted at the link below under the Meeting Updates tab. *https://www.dol.gov/agencies/vets/about/advisorycommittee*

Notice of Intent To Attend the Meeting: All meeting participants should submit a notice of intent to attend by Monday, January 4, 2021, via email to Mr. Gregory Green at

ACVETEO@dol.gov, subject line ''January 2021 ACVETEO Meeting.''

Individuals who will need accommodations for a disability in order to attend the meeting (*e.g.,* interpreting services, assistive listening devices, and/or materials in alternative format) should notify the Advisory Committee no later than Monday, January 4, 2021 by contacting Mr. Gregory Green at *ACVETEO@dol.gov.* Requests made after this date will be reviewed, but availability of the requested accommodations cannot be guaranteed.

FOR FURTHER INFORMATION CONTACT: Mr. Gregory Green, Designated Federal Official for the ACVETEO, *ACVETEO@dol.gov,* (202) 693–4734.

SUPPLEMENTARY INFORMATION: The ACVETEO is a Congressionally mandated advisory committee authorized under Title 38, U.S. Code, Section 4110 and subject to the Federal Advisory Committee Act, 5 U.S.C. App. 2, as amended. The ACVETEO is responsible for: assessing employment and training needs of veterans; determining the extent to which the programs and activities of the U.S. Department of Labor meet these needs; assisting to conduct outreach to employers seeking to hire veterans; making recommendations to the Secretary, through the Assistant Secretary for Veterans' Employment and Training Service, with respect to outreach activities and employment and training needs of veterans; and carrying out such other activities necessary to make required reports and recommendations. The ACVETEO meets at least quarterly.

Agenda

9:00 a.m. Welcome and remarks, John Lowry, Assistant Secretary, Veterans' Employment and Training Service

9:10 a.m. Administrative Business, Gregory Green, Designated Federal Official

9:15 a.m. Discussion on Fiscal Year 2020 Report Recommendations, Committee Chairperson, Kayla Williams

9:30 a.m. Update to Fiscal Year 2019 Report Recommendations

10:00 a.m. Subcommittee Discussion/Assignments, Committee Chairperson, Kayla Williams

11:00 a.m. Briefing on Fiscal Year 2021 DOL/VETS Priorities

11:30 a.m. Public Forum, Gregory Green, Designated Federal Official

12:00 p.m. Adjourn

Signed in Washington, DC, this 14th day of December 2020.

John Lowry,

Assistant Secretary, Veterans' Employment and Training Service.

[FR Doc. 2020–27835 Filed 12–17–20; 8:45 am]

BILLING CODE 4510–79–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; National Science Foundation-Managed Honor Awards

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register**, and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAmain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Copies of the submission may be obtained by calling 703–292–7556.

SUPPLEMENTARY INFORMATION: NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Title of Collection: National Science Foundation-Managed Honor Awards.

OMB Number: 3145–0035.

Type of Request: Extension of approval of an information collection.

Proposed Project: The National Science Foundation (NSF) administers several external awards, among them the President's National Medal of Science, the Alan T. Waterman Award, the National Science Board (NSB) Vannevar Bush Award, the NSB Public Service Award, the Presidential Awards for Excellence in Science, Mathematics and Engineering Mentoring (PAESMEM) program, and the Presidential Awards for Excellence in Mathematics and Science Teaching (PAEMST) program.

In 2003, to comply with E-government requirements, the nomination processes were converted to electronic submission through NSF's FastLane system or via other electronic systems as described in the individual nomination process. Individuals can now prepare nominations and references through *www.fastlane.nsf.gov/honawards/* for all but the PAESMEM and PAEMST awards. First-time users must register on the Fastlane website using the link found in the upper right-hand corner above the ''Log In'' box before accessing all but the PAESMEM and PAEMST honorary award categories. For PAEMST nominations and applications are submitted on the PAEMST portal at *www.paemst.org.* For PAESMEM, nominations and applications are submitted on the PAESMEM portal at *www.paesmem.net.*

Use of the Information: The Foundation has the following honorary award programs:

• President's National Medal of Science. Statutory authority for the President's National Medal of Science is contained in 42 U.S.C. 1881 (P.L. 86–209), which established the award and stated that ''(t)he President shall . . . award the Medal on the recommendations received from the National Academy of Sciences or on the basis of such other information and evidence as . . . appropriate.''

Subsequently, Executive Order 10961 specified procedures for the Award by establishing a National Medal of Science Committee which would ''receive recommendations made by any other nationally representative scientific or engineering organization.'' On the basis of these recommendations, the Committee was directed to select its candidates and to forward its recommendations to the President.

In 1962, to comply with these directives, the Committee initiated a solicitation form letter to invite these nominations. In 1979, the Committee

initiated a nomination form as an attachment to the solicitation letter. A slightly modified version of the nomination form was used in 1980.

The Committee has established the following considerations for selection of candidates:

a. The impact of an individual's body of work on the current state of his or her field of science or engineering;

b. Whether the individual's achievements are of an unusually significant nature in relation to the potential effects on the development of thought in his or her field of science or engineering;

c. Whether the nominee has demonstrated unusually distinguished service in the general advancement of science and/or engineering for the Nation, especially when accompanied by substantial contributions to the content of science;

d. The recognition of the nominee by peers within his or her community, and whether s/he is recognized for substantial impact in fields in addition to his/her discipline;

e. If the nominee has made contributions to innovation and industry;

f. Whether the nominee has demonstrated sustained influence on education through publications, teaching activities, outreach, mentoring, etc., and;

g. Whether the nominee's contributions have created significant positive impact for the Nation.

In 2003, the Committee changed the active period of eligibility to three years, including the year of nomination. After that time, candidates must be renominated with a new nomination package for them to be considered by the Committee.

Narratives are now restricted to three pages of text, as stipulated in the guidelines at: *https://www.fastlane.nsf.gov/honawards/medalHome.do*

• *Alan T. Waterman Award.* Congress established the Alan T. Waterman Award in August 1975 (42 U.S.C. 1881a (P.L. 94–86) and authorized NSF to ''establish the Alan T. Waterman Award for research or advanced study in any of the sciences or engineering'' to mark the 25th anniversary of the National Science Foundation and to honor its first Director. The annual award recognizes an outstanding young researcher in any field of science or engineering supported by NSF. In addition to a medal, the awardee receives a grant of $1,000,000 over a five-year period for scientific research or advanced study in the mathematical, physical, medical, biological, engineering, social, or other sciences at the institution of the recipient's choice.

The Alan T. Waterman Award Committee was established by NSF to comply with the directive contained in Public Law 94–86. The Committee solicits nominations from members of the National Academy of Sciences, National Academy of Engineering, scientific and technical organizations, and any other source, public or private, as appropriate.

In 1976, the Committee initiated a form letter to solicit these nominations. In 1980, a nomination form was used which standardized the nomination procedures, allowed for more effective Committee review, and permitted better staff work in a short period of time. On the basis of its review, the Committee forwards its recommendation to the Director, NSF, and the National Science Board (NSB).

Candidates must be U.S. citizens or permanent residents and must be 40 years of age or younger or not more than ten years beyond receipt of the Ph.D. degree by December 31 of the year in which they are nominated. Candidates should have demonstrated exceptional individual achievements in scientific or engineering research of sufficient quality to place them at the forefront of their peers. Criteria include originality, innovation, and significant impact on the field.

• *Vannevar Bush Award.* The Vannevar Bush Award honors truly exceptional lifelong leaders in science and technology who have made substantial contributions to the welfare of the Nation through public service activities in science, technology, and public policy. The National Science Board established this award in 1980 in the memory of Vannevar Bush, who served as a science advisor to President Franklin Roosevelt during World War II, helped to establish Federal funding for science and engineering as a national priority during peacetime, and was behind the creation of the National Science Foundation.

The Vannevar Bush Award recipient is selected annually by the National Science Board's Subcommittee on Honorary Awards (AWD), which is established to solicit nominations from scientific, engineering, and educational societies and institutions, in both the public and private sectors.

Candidates for the Vannevar Bush Award should have demonstrated outstanding leadership and accomplishment in meeting at least two of the following selection criteria:

1. Candidates must be U.S. citizens.

2. Distinguished himself/herself through public service activities in science and technology.

3. Pioneered the exploration, charting, and settlement of new frontiers in science, technology, education, and public service.

4. Demonstrated leadership and creativity that have inspired others to distinguished careers in science and technology.

5. Contributed to the welfare of the Nation and humankind through activities in science and technology.

6. Demonstrated leadership and creativity that has helped mold the history of advancements in the Nation's science, technology, and education.

Nomination Submissions must include:

1. A current curriculum vita without publications (no more than 5 pages).

2. A narrative statement (no more than 8 pages) addressing the candidate's activities and contributions related to the selection criteria.

3. A proposed award citation addressing the candidate's activities in and contributions to national public service activities in science, technology, and public policy.

4. Contact information for award candidate and nominator (mailing address, email address, and phone number).

5. Two reference letters (no more than 2 pages each) from individuals familiar with the candidate's accomplishments, and not affiliated with the candidate's home institution. Letters should be submitted by email to *nsbawards@nsf.gov* on letterhead as a PDF file.

Nominations remain active for three years, including the year of nomination. After that time, candidates must be renominated with a new nomination for them to be considered by the selection committee.

• *NSB Public Service Award.* The National Science Board established the Public Service Award in November 1996 to honor individuals and groups that have made substantial contributions to increasing public understanding of science and engineering in the United States. These contributions may be in a wide variety of areas that have the potential of contributing to public understanding of and appreciation for science and engineering—including mass media, education and/or training programs, and entertainment.

Eligibility includes any individual or group (company, corporation or organization) that has increased the public understanding of science or engineering.

Candidates for the NSB Public Service Award should have demonstrated outstanding leadership and accomplishment in meeting the following selection criteria:

1. Increased the public's understanding of the processes of science and engineering through scientific discovery, innovation, and its communication to the public.
2. Encouraged others to help raise the public understanding of science and technology.
3. Promoted the engagement of scientists and engineers in public outreach and scientific literacy.
4. Contributed to the development of broad science and engineering policy and its support.
5. Influenced and encouraged the next generation of scientists and engineers.
6. Achieved broad recognition outside of the candidate's area of specialization.
7. Fostered awareness of science and technology among broad segments of the population.

Note: Members of the U.S. Government are not eligible for this award.

Nomination Procedures:

Nominations for an *individual* must include:

1. A current curriculum vita without publications (no more than 3 pages).
2. A narrative statement (no more than 5 pages) addressing the following:
   a. the candidate's public service activities in science and engineering, and
   b. the candidate's contributions to public understanding of science and engineering, as they relate to the selection criteria.
3. Contact information of candidate and nominator (mailing address, email address, phone number).

Nominations must be submitted by email to: *nsbawards@nsf.gov.*

Nominations for a *group* must include:

1. A narrative statement (no more than 5 pages) addressing the following:
   a. the group's activities, and how it accomplishes the selection criteria for the award,
   b. length of years of the program,
   c. number and type of individuals served by the group's activities; and
   d. data on the success of the program (if available).
2. Contact information of candidate and nominator (mailing address, email address, phone number).
3. Reference letters are optional, and up to 3 letters (no more than to 2 pages each) may be submitted on letterhead as a PDF file.

Nominations must be submitted by email to: *nsbawards@nsf.gov.*

Nominations remain active for three years, including the year of nomination. After that time, candidates must be re-nominated with a new nomination for them to be considered by the selection committee.

- *Presidential Awards for Excellence in Science, Mathematics and Engineering Mentoring (PAESMEM) program*

In 1996, the White House, through the National Science and Technology Council (NSTC) and the Office of Science and Technology Policy (OSTP), established the Presidential Awards for Excellence in Science, Mathematics and Engineering Mentoring (PAESMEM) program. The program, administered on behalf of the White House by the National Science Foundation, seeks to identify outstanding mentoring efforts or programs designed to enhance the participation of groups (women, minorities and persons with disabilities as well as groups from low socioeconomic regions) underrepresented in science, mathematics and engineering. The awardees will serve as exemplars to their colleagues and will be leaders in the national effort to more fully develop the Nation's human resources in science, mathematics and engineering. This award is managed at NSF by the Directorate for Education and Human Resources (EHR).

The award will be made to U.S. citizens or U.S. permanent residents based on the following: (1) An individual who has demonstrated outstanding and sustained mentoring and effective guidance to a significant number of early career STEM professionals, students at the K–12, undergraduate, or graduate education level or (2) to an organization that, through its programming, has enabled a substantial number of students underrepresented in science, mathematics and engineering to successfully pursue and complete the relevant degree programs as well as mentoring of early career STEM professionals. Nominees must have served in a mentoring role for at least five years. Nominations are reviewed for impact, significance of the mentoring throrganizational awards must demonstrate rigorous evaluation and/or assessment during the five-year period of the mentoring activity.

Award Ceremony

The awardees are hosted for two days in Washington, DC, for celebratory activities. Recipients of the PAESMEM award receive a monetary award in the amount of $10,000 from NSF and a commemorative Presidential certificate. If scheduling permits, the President meets with the mentors for a photo opportunity at the White House. The Director of OSTP and the Director of NSF present the awards to the mentors at an awards ceremony.

- Presidential Award for Excellence in Mathematics and Science Teaching

The Presidential Award for Excellence in Mathematics and Science Teaching (PAEMST) is the highest recognition that a kindergarten through 12th-grade mathematics or science teacher may receive for outstanding teaching in the United States. Enacted by Congress in 1983, this program authorizes the President to bestow 108 awards with two per state or jurisdiction, assuming there are qualified applicants. Awards are given in the science category, which includes science and engineering, and the mathematics category, which includes mathematics, technology and computer science. In even-numbered y]ears, nominations are accepted for elementary teachers (grades K–6); in odd-numbered years, secondary teachers (grades 7–12) are nominated. This award is managed at NSF by the Directorate for Education and Human Resources (EHR).

Nomination Criteria

A teacher may be nominated by a principal, another teacher, students, members of the community, or the general public. Self-nominations are allowed. Awardees must be either U.S. Citizens or U.S. Permanent Residents. A Nominee must meet the following criteria to apply:

- Teach science, technology, engineering, mathematics, and/or computer science as part of his or her contracted teaching responsibilities at the K–6 grade level in a public (including charter) or private school;
- hold at least a bachelor's degree from an accredited institution;
- be a full-time employee of his or her school or school district as determined by state and district policies, with responsibilities for teaching students no less than 50% of the school's allotted instructional time;
- have at least five years of full-time employment as a K–12 teacher prior to the academic school year in which they apply, with science, technology, engineering, mathematics, and/or computer science teaching duties each of the past five years;
- teach in one of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Department of Defense Education Activity schools, or the U.S. Territories

as a group (American Samoa, Guam, Commonwealth of the Northern Mariana Islands, and U.S. Virgin Islands);

• be a U.S. citizen or permanent resident; and

• not have received the PAEMST award at the national level in any prior competition or category.

Application Process

• Applicants complete a narrative on five dimensions of outstanding teaching (content knowledge, pedagogy, assessment, leadership and professional development), submit a video of one class, supplemental materials, and references cited. Three letters of reference including one from a school official are required, along with a resume or biographical sketch.

• The applicant completes an application and submits for state review during the academic year. The nomination period runs through the application cycle up to one month before the application deadline.

Review of Nominations

• State coordinators convene state selection committees of prominent mathematicians, scientists, mathematics and science educators, and past awardees to select up to three mathematics category and three science category finalists for recognition at the state level and for submission to NSF. To ensure consistency, state selection committees review their applications using the same criteria and scoring information that was approved by OSTP. Following the state review applicants are given two weeks to complete an addendum to the state application that addresses state reviewer comments.

• NSF (EHR) convenes a National Selection Committee of prominent mathematicians, scientists, mathematics and science educators, and past awardees that review the application packets of the state finalists including the addendum and make recommendations to NSF. NSF reviews the state selection committee recommendations and recommends to OSTP, when possible, one awardee in the mathematics category and one in the science category for all eligible states/jurisdictions. Alternatively, NSF may recommend two awardees from a discipline in a jurisdiction, when warranted.

Award Ceremony

The awardees are hosted for 3–4 days in Washington, DC, for a variety of professional development sessions and celebratory activities. Each awardee receives a citation signed by the President and $10,000 from NSF. If scheduling permits, the President meets the teachers for a photo opportunity at the White House. The Director of OSTP and the Director of NSF present the citations to the teachers at an awards ceremony. Awardees also have the opportunity to meet their congressional representatives and education representatives from other federal agencies.

Estimate of Burden: These are annual award programs with application deadlines varying according to the program. Public burden also may vary according to program; however, across all the programs, it is estimated that each submission will average 19 hours per respondent. If the nominator is thoroughly familiar with the disciplinary background of the nominee, time spent to complete the nomination may be considerably reduced.

Respondents: Individuals, businesses or other for-profit organizations, universities, non-profit institutions, and Federal and State governments.

Estimated Number of Responses per Award: 1800 responses, broken down as follows: For the President's National Medal of Science, 80; for the Alan T. Waterman Award, 70; for the Vannevar Bush Award, 20; for the Public Service Award, 30; for the PAESMEM, 200; and 1400 for the PAEMST.

Estimated Total Annual Burden on Respondents: 41,350 hours, broken down by 1,600 hours for the President's National Medal of Science (20 hours per 80 respondents); 1,400 hours for the Alan T. Waterman Award (20 hours per 70 respondents); 300 hours for the Vannevar Bush Award (15 hours per 20 respondents); 450 hours for the Public Service Award (15 hours per 30 respondents); 4,000 hours for the PAESMEM (20 hours per 200 respondents); and 33,600 hours for the PAEMST (24 hours per 1400 respondents).

Frequency of Responses: Annually.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: December 15, 2020.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2020–27984 Filed 12–17–20; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of December 14, 21, 28, 2020, January 4, 11, 18, 25, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of December 14, 2020

Thursday, December 17, 2020

2:30 p.m. Affirmation Session (Public Meeting) (Tentative)

a. Interim Storage Partners, LLC (WCS Consolidated Interim Storage Facility), Appeals of LBP–19–7: Fasken Proposed New Contention Based on Draft Environmental Impact Statement (Tentative)

(Contact: Denise McGovern: 301–415–0681)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live via teleconference. Details for joining the teleconference in listen only mode can be found at *https://www.nrc.gov/pmns/mtg.*

b. Interim Storage Partners, LLC (WCS Consolidated Interim Storage Facility), Sierra Club Appeal of LBP–19–9 (Denying Motion to Amend and Granting Motion to Dismiss), LBP–19–7 (Denial of Contentions)

(Tentative)

(Contact: Denise McGovern: 301–415–0681)

Additional Information: By a vote of 5–0 on December 15, 2020, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and 10 CFR 9.107 that the above referenced Affirmation Session be held with less than one week notice to the public. The meeting will be held on December 17, 2020. Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live via teleconference. Details for joining

the teleconference in listen only mode can be found at *https://www.nrc.gov/pmns/mtg.*

Week of December 21, 2020—Tentative

There are no meetings scheduled for the week of December 21, 2020.

Week of December 28, 2020—Tentative

There are no meetings scheduled for the week of December 28, 2020.

Week of January 4, 2021—Tentative

There are no meetings scheduled for the week of January 4, 2021.

Week of January 11, 2021—Tentative

There are no meetings scheduled for the week of January 11, 2021.

Week of January 18, 2021—Tentative

There are no meetings scheduled for the week of January 18, 2021.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* Braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or by email at *Tyesha.Bush@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: December 15, 2020.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2020–28027 Filed 12–16–20; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0266]

Replacement Energy Cost Estimates for Nuclear Power Plants: 2020–2030

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft NUREG–2242, ''Replacement Energy Cost Estimates for Nuclear Power Plants: 2020–2030.'' This guidance updates previous estimates of replacement energy costs for potential shutdowns of U.S. nuclear electricity-generating units.

DATES: Submit comments by February 16, 2021. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0266. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Pamela Noto, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6795, email: *Pamela.Noto@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0266 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0266.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The draft NUREG, ''Replacement Energy Cost Estimates for Nuclear Power Plants: 2020–2030,'' is available in ADAMS under Accession No. ML20342A132.
- *Attention:* The Public Document Room (PDR), where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2020–0266 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The NRC is developing new guidance to update replacement energy cost estimates for both short- and long-term nuclear power plant outages. The new guidance document, NUREG–2242, ''Replacement Energy Cost Estimates for Nuclear Power Plants: 2020–2030,'' when finalized, updates and replaces the information contained within NUREG/CR–4012, Volume 4, ''Replacement Energy Costs for Nuclear Electricity-Generating Units in the United States: 1997–2001,'' and NUREG/CR–6080, ''Replacement Energy, Capacity, and Reliability Costs for Permanent Nuclear Reactor Shutdowns'' (ADAMS Accession Nos. ML20073J435 and ML20076F500, respectively).

Replacement energy costs are estimated for the U.S. electricity wholesale market regions with nuclear electricity-generating units over the 2020–2030 study period. These estimates were developed to assist the NRC in evaluating proposed regulatory actions that (1) require safety modifications that might necessitate temporary reactor outages and (2) reduce the potential for extended outages resulting from a severe reactor accident. Estimates were calculated using ASEA Brown Boveri's PROMOD model and ICF's Integrated Planning Model for North America. The model simulates dispatching a collection of generating units in merit order (*i.e.,* lowest to highest incremental cost of dispatch) until the regional power demand is met. Each generating unit is characterized by the technology and fuel it uses to generate electricity, the unit's heat rate, and the variable and fixed costs incurred in owning and operating the unit. To estimate the replacement energy cost, the study models a Reference Case, in which all operational nuclear power plants are generating, and an Alternative Case, in which a nuclear generating unit is taken offline so that the next unit in merit order is dispatched to replace the lost generation. The difference in market clearing prices between the two cases is the replacement energy cost.

The resulting wholesale power price projections capture the dynamics and economics of the U.S. electricity markets, which provide short- and long-term replacement energy cost estimates on a market area basis. Factors that affect replacement energy costs, such as load growth, replacement sources of generation, fuel prices, air emission requirement outlooks, and seasonal variations were treated in the analysis.

On November 18, 2020, the NRC held a Category 3 public meeting (ADAMS Accession No. ML20336A181) to discuss the updated replacement energy cost estimates. The NRC appreciates feedback received from the November 18, 2020 public meeting and will consider comments received during the public comment period when developing the final NUREG–2242. After Commission approval and publication of the final NUREG–2242, the NRC plans to develop an appendix to NUREG/BR–0058, Revision 5, ''Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,'' (ADAMS Accession No. ML19261A278) to provide guidance for applying the replacement energy cost estimates.

Dated: December 15, 2020.

For the Nuclear Regulatory Commission.

John R. Tappert,

Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Materials Safety and Safeguards.

[FR Doc. 2020–27928 Filed 12–17–20; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2020–230; CP2020–246; CP2020–263; MC2021–46 and CP2021–48]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 22, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

1. *Docket No(s).:* CP2020–230; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 7 Negotiated Service Agreement; *Filing Acceptance Date:* December 14, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 22, 2020.

2. *Docket No(s).:* CP2020–246; *Filing Title:* Notice of the United States Postal

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Service of Filing Modification One to Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 8 Negotiated Service Agreement; *Filing Acceptance Date:* December 14, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 22, 2020.

3. *Docket No(s).:* CP2020–263; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 9 Negotiated Service Agreement; *Filing Acceptance Date:* December 14, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 22, 2020.

4. *Docket No(s).:* MC2021–46 and CP2021–48; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 182 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 14, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* December 22, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–27917 Filed 12–17–20; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2021–47; Order No. 5780]

Inbound Parcel Post (at UPU Rates)

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recent Postal Service filing of a change in rates not of general applicability to be effective January 1, 2021. This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 21, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Contents of Filing
III. Administrative Actions
IV. Ordering Paragraphs

I. Introduction

On December 11, 2020, the Postal Service filed notice announcing its intention to change prices not of general applicability for Inbound Parcel Post (at Universal Postal Union (UPU) Rates) effective January 1, 2021.[1]

II. Contents of Filing

To accompany its Notice, the Postal Service filed: a redacted copy of the UPU International Bureau (IB) Circular that contains the new prices, a copy of the certification required under 39 CFR 3035.105(c)(2), redacted Postal Service data used to justify any bonus payments, a copy of the Postal Service's submission to the UPU in support of an inflation-linked adjustment, and a redacted copy of Governors' Decision 19–1. Notice at 2–3; *see id.* Attachments 2–6. The Postal Service also filed redacted financial workpapers. Notice at 5.

Additionally, the Postal Service filed an unredacted copy of Governors' Decision 19–1, an unredacted copy of the new prices, and related financial information under seal. *See id.* The Postal Service filed an application for non-public treatment of materials filed under seal. Notice, Attachment 1.

The Postal Service states that it has provided supporting documentation as required by Order No. 2102 and Order No. 2310.[2] In addition, the Postal Service states that it provided citations and copies of relevant UPU IB Circulars and updates to inflation-linked adjustments.

[1] Notice of the United States Postal Service of Filing Changes in Rates Not of General Applicability for Inbound Parcel Post (at UPU Rates), and Application for Non-Public Treatment, December 11, 2020, at 1–2 (Notice).

[2] Notice at 4–5. *See* Docket No. CP2014–52, Order Accepting Price Changes for Inbound Air Parcel Post (at UPU Rates), June 26, 2014, at 6 (Order No. 2102); Docket No. CP2015–24, Order Accepting Changes in Rates for Inbound Parcel Post (at UPU Rates), December 29, 2014, at 4 (Order No. 2310).

III. Commission Action

The Commission establishes Docket No. CP2021–47 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, and 39 CFR part 3035. Comments are due no later than December 21, 2020. The public portions of the filing can be accessed via the Commission's website (*http://www.prc.gov*).

The Commission appoints Katalin K. Clendenin to serve as Public Representative in this docket.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2021–47 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than December 21, 2020.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2020–27843 Filed 12–17–20; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2020–173, CP2020–174, CP2020–188, CP2020–202; MC2021–44 and CP2021–45; MC2021–45 and CP2021–46]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 21, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

1. *Docket No(s).:* CP2020–173; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 2 Negotiated Service Agreement; *Filing Acceptance Date:* December 11, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* December 21, 2020.

2. *Docket No(s).:* CP2020–174; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 3 Negotiated Service Agreement; *Filing Acceptance Date:* December 11, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* December 21, 2020.

3. *Docket No(s).:* CP2020–188; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 4 Negotiated Service Agreement; *Filing Acceptance Date:* December 11, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* December 21, 2020.

4. *Docket No(s).:* CP2020–202; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 9 Negotiated Service Agreement; *Filing Acceptance Date:* December 11, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* December 21, 2020.

5. *Docket No(s).:* MC2021–44 and CP2021–45; *Filing Title:* USPS Request to Add Priority Mail Contract 683 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 11, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 21, 2020.

6. *Docket No(s).:* MC2021–45 and CP2021–46; *Filing Title:* USPS Request to Add Priority Mail, First-Class Package Service & Parcel Select Contract 2 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 11, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 21, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2020–27844 Filed 12–17–20; 8:45 am]
BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL SERVICE

Notice of Changes to Postal Service Standard 4C

AGENCY: Postal Service.

ACTION: Notice of Changes and Request for Comments.

SUMMARY: The Postal Service is updating the Postal Operations Manual (POM) to revise Standard 4C concerning apartment parcel locker ratios.

DATES: Comments must be received by January 19, 2021.

ADDRESSES: Email comments to *Delivery.Growth@usps.gov,* with a subject line of ''Postal Operations Manual-Standard 4C Revision.'' Faxed and mailed comments are not accepted. You may inspect and photocopy all written comments at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor N, Washington, DC by appointment only between the hours of 9 a.m. and 4 p.m., Monday through Friday by calling 1–202–268–2906 in advance.

FOR FURTHER INFORMATION CONTACT: The Growth Coordinator Administrator at *Delivery.Growth@usps.gov.*

SUPPLEMENTARY INFORMATION: The Postal Service is revising Postal Operations Manual (POM) section 632.622a. These changes revise the parcel locker ratio in apartment community buildings from 10:1 to 5:1. This change is necessary to accommodate an increase in package volume. While the Postal Service has made these changes to the POM, it is seeking, and intends to consider, comments from the public concerning these changes. You may view the changes to the POM at the following website: *https://about.usps.com/what-we-are-doing/current-initiatives/delivery-growth-management/section-632.pdf* (632.622a).

(Authority: 39 CFR 211.2)

Joshua J. Hofer,

Attorney, Federal Compliance.

[FR Doc. 2020–27886 Filed 12–17–20; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

(Release No. 34–90661; File No. SR–NYSE–2020–99)

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

December 14, 2020.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 1, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to (1) extend the Transition Period for member organizations to transition to the utilization of ports that connect to the Exchange using Pillar technology; (2) extend the Decommission Period that begins once the Transition Period ends; and (3) extend the effective date that the Exchange would prorate the monthly fee for ports activated on or after July 1, 2019. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to provide additional time for member organizations to transition from older to newer and more efficient Pillar technology. The Exchange is not proposing to adjust the amount of the port fees or the fees charged to offset the Exchange's continuing costs of supporting legacy ports, which will remain at the current level for all market participants.

Effective July 3, 2019, the Exchange introduced transition pricing designed to provide member organizations an extended transition period to connect to the Exchange using Pillar technology with no fee increase. Specifically, the Exchange (1) adopted a cap on monthly fees for the use of certain ports connecting to the Exchange for the billing months July 2019 through March 2020 (the ''Transition Period''); (2) adopted a Decommission Extension Fee applicable for the billing months April 2020 through September 2020 (the ''Decommission Period'') for legacy port connections; and (3) prorated the monthly fee for certain ports activated after July 1, 2019, effective April 1, 2020.[3]

Effective March 2, 2020, the Exchange (1) extended the end of the Transition Period from March 2020 to August 2020 for member organizations to transition to the utilization of ports that connect to the Exchange using Pillar technology; (2) shortened the Decommission Period from six months (April 2020-September 2020) to four months (September–December 2020); (3) extended the effective date that the Exchange would prorate the monthly fee for certain ports activated on or after July 1, 2019 from April 1, 2020 to September 1, 2020; and (4) revised the fees charged for legacy port connections during the Decommission Period.[4]

Effective August 1, 2020, the Exchange (1) extended the end of the Transition Period from August 2020 to October 2020; (2) extended the beginning of the Decommission Period from September 2020 to November 2020 and the end of the Decommission Period from December 2020 to February 2021; and (3) extended the effective date that the Exchange would prorate the monthly fee for ports activated on or after July 1, 2019 from September 1, 2020 to November 1, 2020.[5]

Effective October 1, 2020, the Exchange (1) extended the end of the Transition Period from October 2020 to December 2020; (2) extended the beginning of the Decommission Period from November 2020 to January 2021 and the end of the Decommission Period from February 2021 to April 2021; and (3) extended the effective date that the Exchange would prorate the monthly fee for ports activated on or after July 1, 2019 from November 1, 2020 to January 1, 2021.[6]

The Exchange proposes to:

- Extend the end of the Transition Period from December 2020 to February 2021;
- extend the beginning of the Decommission Period from January 2021 to March 2021 and the end of the Decommission Period from April 2021 to June 2021; and
- extend the effective date that the Exchange would prorate the monthly fee for ports activated on or after July 1, 2019 from January 1, 2021 to March 1, 2021.

The Exchange would continue to provide a cap on how much member organizations would be charged for ports during the proposed extra two months of the Transition Period so that they would not incur additional charges during the transition to Pillar communication protocols. Moreover, the Exchange would retain a four month period during which the few firms that do not transition during the proposed longer Transition Period would be charged fees to offset the Exchange's continuing costs of supporting legacy ports but proposes to extend the beginning and end dates for this period.

The Exchange proposes to implement these changes to its Price List effective December 1, 2020.

Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86360 (July 11, 2019), 84 FR 34210 (July 17, 2019) (SR–NYSE–2019–39).

[4] *See* Securities Exchange Act Release No. 88373 (March 12, 2020), 85 FR 15533 (March 18, 2020) (SR–NYSE–2020–14).

[5] *See* Securities Exchange Act Release No. 89591 (August 18, 2020), 85 FR 52159 (August 24, 2020) (SR–NYSE–2020–14).

[6] *See* Securities Exchange Act Release No. 90180 (October 14, 2020), 85 FR 66612 (October 20, 2020) (SR–NYSE–2020–82).

products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [7]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [8] Indeed, equity trading is currently dispersed across 16 exchanges,[9] 31 alternative trading systems,[10] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 16% of the market share of executed volume of equity trades (whether excluding or including auction volume).[11] The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, including ports, in response to fee changes. Accordingly, the Exchange's fees, including port fees, are reasonably constrained by competitive alternatives and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange is proposing these changes in the context of a competitive environment in which market participants can and do shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Because ports are used by member organizations to trade electronically on the Exchange, fees associated with ports are subject to these same competitive forces. The Exchange believes that the proposal represents a reasonable attempt to provide member organizations with additional time to effect an orderly transition to upgraded technology without incurring additional costs.

Proposed Rule Change

Member organizations enter orders and order instructions, and receive information from the Exchange, by establishing a connection to a gateway that uses communication protocols that map to the order types and modifiers described in Exchange rules. These gateway connections, also known as logical port connections, are referred to as ''ports'' on the Exchange's Price List. Legacy ports connect with the Exchange via a Common Customer Gateway (known as ''CCG'') that accesses its equity trading systems (''Phase I ports''). Beginning July 1, 2019, the Exchange began making available ports using Pillar gateways to its member organizations (''Phase II ports'').

Extension of the Date to Prorate Ports

The Exchange currently makes available ports that provide connectivity to the Exchange's trading systems (*i.e.,* ports for entry of orders and/or quotes (''order/quote entry ports'')) and charges $550 per port per month. Designated Market Makers (''DMMs'') are not charged for the first 12 ports per month that connect to the Exchange.[12] The Exchange also currently makes ports available for drop copies and charges $550 per port per month,[13] except that DMMs are not charged for drop copy ports that connect to the Exchange.

During the ongoing first phase of the Exchange's transition pricing, the fees charged for both order/quote entry and drop copy ports are, with certain exceptions, capped at—and thus not charged for more than—the total number of both order/quote entry and drop copy ports that the member organization has activated as of its June 2019 invoice.

Effective January 1, 2021, the Exchange will prorate fees for order/quote entry and drop copy ports activated after July 1, 2019, to the number of trading days that a port is eligible for production trading with the Exchange, including any scheduled early closing days.

The Exchange proposes to extend the effective date for the prorating of order/quote entry and drop copy ports to March 1, 2021 to coincide with the end of the proposed extended Transition Period in February 2021, discussed below.

Extension of the Transition Period

Currently, during the billing months of July 2019 through December 2020 (the ''Transition Period''), the total number of ports charged per member organization is capped at the total number of ports that the member organization activated as of the June 2019 invoice, which was the last full month prior to the introduction of the new gateways (the ''Transition Cap''). Transition Cap pricing is available until the earlier of (1) the end of the Transition Period, *i.e.,* December 2020, or (2) the billing month during which a member organization fully transitions to using only ports that communicate using Pillar phase II protocols. If during the Transition Period, a member organization increases the number of Phase I ports above the Transition Cap, those ports would be charged at the current rates for order/quote entry ports and drop copy ports. Finally, if during the Transition Period a member organization has a total number of ports below the Transition Cap, the Exchange would charge a member organization for their actual number of ports.

The Exchange proposes to extend the Transition Period by two months to February 2020 [sic]. As proposed, the charge per port (order/quote entry and drop copy) would remain at $550 per port per month. DMMs would continue not to be charged for drop copy ports and for their first 12 order/quote entry ports per month that connect to the Exchange, and then charged $550 per order/quote entry port that connects to the Exchange per month thereafter.

The purpose of Transition Period pricing is to cap port fees to allow member organizations additional time to implement technology changes necessary to connect to the Exchange using the Phase II ports without incurring additional Exchange fees. As of November 2020, only 67% of Phase I ports have been cancelled, a 1% increase over the 66% that had transitioned as of September 2020. Based on the Exchange's experience to date, the Exchange believes that an additional two months will be necessary to provide sufficient time for all member organizations, regardless of size, to be able to complete the necessary changes and transition fully to the Phase II ports.

[7] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[8] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[9] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.* See generally *https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[10] See FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is available at *https://www.sec.gov/foia/docs/atslist.htm.*

[11] See Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[12] DMMs completed the transition to Phase II ports last year.

[13] Only one fee per drop copy port applies, even if receiving drop copies from multiple order/quote entry ports.

Extension of the Decommission Period

Currently, member organizations that have not transitioned to Phase II ports and are still utilizing Phase I ports during the billing months of January 2021 through April 2021 (*i.e.,* the Decommission Period), would, in addition to the current port fees, be charged a Decommission Extension Fee of $1,000 per port per month, increasing by $1,000 per port for each month for any ports that communicate using Pillar phase I protocols. As per the Price List, ports using Pillar phase I protocols would no longer be available beginning May 1, 2021.

The Exchange proposes that the Decommission Period would begin in March 2021, after the end of the proposed longer Transition Period, and end four months later. As proposed, the Decommission Period would commence in March 2021 and end in June 2021. As a result, the Price List would also be amended to provide that ports using Pillar phase I protocols would no longer be available beginning July 1, 2021.

As noted above, the Exchange believes that extending the Transition Period would provide sufficient time for member organizations to fully transition to Phase II ports and eliminate their use of Phase I ports. To the extent that member organizations do not complete the transition during the Transition Period, the Exchange will offer member organizations the ability to choose to continue using Phase I ports until July 2021.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[15] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Changes Are Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [16]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [17] Indeed, equity trading is currently dispersed across 16 exchanges,[18] 31 alternative trading systems,[19] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 16% of the market share of executed volume of equity trades (whether excluding or including auction volume).[20] The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, including ports, in response to fee changes. Accordingly, the Exchange's fees, including port fees, are reasonably constrained by competitive alternatives and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

If a particular exchange charges excessive fees for connectivity, impacted members and non-members may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

Given this competitive environment, the proposal represents a fair and reasonable attempt to provide member organizations with additional time to make an orderly transition to upgraded technology without increasing their costs. As noted, as of November 2020, 33% of legacy ports have not been cancelled. If a member organization is unable to complete this transition within the additional time of the extended Transition Period, the pricing is designed so that only those few member organizations that may not transition within that time period would pay for the Exchange to continue to support their Phase I ports.

The Proposal is an Equitable Allocation of Fees

The Exchange believes its proposal equitably allocates its fees among its market participants. The Exchange is not proposing to adjust the amount of the port fees or the fees charged fees to offset the Exchange's continuing costs of supporting legacy ports, which will remain at the current level for all market participants. Rather, the proposal would provide additional time for member organizations to transition from older to newer and more efficient Pillar technology and would charge the same fee for those few member organizations that choose not to transition to Phase II ports during the extended Transition Period.

The Exchange believes that the proposal to pro-rate port fees beginning March 1, 2021, is also an equitable allocation of fees since it would apply equally to all member organizations that connect to the Exchange, who would equally receive the benefit of being charged only for the connectivity utilized during any trading month beginning in March 2021. As noted above, to the extent a member organization continues to use ports activated before July 1, 2019 to connect to the Exchange during the new March 1, 2021 date and any subsequent months, the Exchange believes it is fair and equitable to continue to charge flat fees for such ports until such time that connection to the Exchange through the

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(4) & (5).

[16] *See* Regulation NMS, 70 FR at 37499.

[17] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[18] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.* See generally *https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[19] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is available at *https://www.sec.gov/foia/docs/atslist.htm.*

[20] See Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

use of Phase I ports is no longer available beginning July 1, 2021.

The proposal constitutes an equitable allocation of fees because all similarly situated member organizations and other market participants that choose to connect to the Exchange through the use of Phase I ports during the Decommission Period would continue to be charged the same, unchanged Decommission Extension Fee. Moreover, as noted above, the Exchange proposes a longer transition period which the Exchange expects should be more than sufficient for all member organizations, regardless of size, to transition to Phase II ports before the Decommission Fee goes into effect.

The Proposal is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, member organizations are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value, and are free to discontinue to connect to the Exchange through its ports. As noted, the Exchange is offering upgraded connections in an effort to keep pace with changes in the industry and evolving customer needs as new technologies emerge and products continue to develop and change.

The proposal neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal does not permit unfair discrimination because the proposal would be applied to all similarly situated member organizations and other market participants would be charged the same rates, which will remain unchanged.

The Exchange believes that the proposal does not permit unfair discrimination because the Exchange will be making available both the Phase I and Phase II ports available to all member organizations during the extended Transition Period on an equal basis. Accordingly, no member organization already operating on the Exchange would be disadvantaged by this allocation of fees. For the same reasons, the Exchange believes that the proposal would not permit unfair discrimination between member organizations.

Similarly, the Decommission Extension Fee would apply equally to all member organizations that choose to connect to the Exchange through the use of such ports during the proposed Decommission Period. If a member organizations becomes subject to the Decommission Fee, it would only be because such firm chose not to complete its transition to the Phase II ports by the end of the proposed Transition Period. While the Exchange cannot predict with certainty whether any firms would be subject to the Decommission Fee, and if so, which ones, the Exchange anticipates that it would be a limited set of member organizations that would incur such fees.

The Exchange believes that the proposal to pro-rate port fees does not permit unfair discrimination because it would apply equally to all member organizations that connect to the Exchange, who would equally receive the benefit of being charged only for the connectivity utilized during any trading month beginning February 1, 2021. As noted, to the extent a member organization continues to use ports activated before July 1, 2019 to connect to the Exchange during March 2021 and any subsequent months, the Exchange believes it is fair, equitable and not unfairly discriminatory to continue to charge flat fees for such ports until such time that connection to the Exchange through the use of old ports is no longer available beginning July 1, 2021.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[21] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would provide additional time for member organizations to transition from older to newer and more efficient Pillar technology with no fee increase and offset the Exchange's continuing costs of supporting the Phase I ports for the few firms that do not transition to the new ports during the longer transition period without any change to the fees currently charged by the Exchange for the use of ports to connect to the Exchange's trading systems.

Intramarket Competition. The Exchange does not believe the proposed rule change would impose any burden on intramarket competition that is not necessary or appropriate because it would apply to all member organizations equally that connect to the Exchange. All member organizations, regardless of size, will be eligible for the transition pricing through the extended Transition Period ending February 2021 and will be eligible to connect via either Phase I or Phase II ports during this period. In addition, all member organizations will be subject to the Decommission Fee on an equal basis if they do complete the transition to Phase II ports by the end of the new February 2021 date. As noted, the Exchange anticipates that a low percentage of member organizations would be subject to the proposed Decommission Fee, and the firms likely to be subject to such fee would be larger firms that could more easily absorb the cost of that fee. The Exchange further believes that by extending the Transition Period, all member organizations have an equal opportunity to timely transition to Phase II ports before the Decommission Fee would take effect.

Intermarket Competition. The Exchange does not believe the proposed rule change would impose any burden on intermarket competition that is not necessary or appropriate because the Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. The Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets.

As noted, the no single exchange has more than 16% of the market share of executed volume of equity trades (whether excluding or including auction volume).[22] The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, including ports, in response to fee changes. Accordingly, the Exchange's fees, including port fees, are reasonably constrained by competitive alternatives and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange is proposing these changes in the context of a competitive environment in which market participants can and do shift order flow, or discontinue or reduce use of certain categories of products, in response to fee

[21] 15 U.S.C. 78f(b)(8).

[22] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/*.

changes. Because ports are used by member organizations to trade electronically on the Exchange, fees associated with ports are subject to these same competitive forces. The Exchange therefore believes that the proposal would not impose an undue burden on intermarket competition because the purpose of this filing is not to change the rates charged for ports or to offset the Exchange's continuing costs of supporting legacy ports but rather to provide member organizations with more time to effect an orderly transition to upgraded technology without needing to incur any additional costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [23] of the Act and subparagraph (f)(2) of Rule 19b-4 [24] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [25] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2020–99 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2020–99. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2020–99, and should be submitted on or before January 8, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–27842 Filed 12–17–20; 8:45 am]

BILLING CODE 8011–01–P

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b-4(f)(2).

[25] 15 U.S.C. 78s(b)(2)(B).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90659; File No. SR-CboeBZX–2020–070]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings to Determine Whether to Approve or Disapprove a Proposed Rule Change to List and Trade Shares of the –1x Short VIX Futures ETF, a Series of VS Trust, Under Rule 14.11(f)(4) (''Trust Issued Receipts'')

December 14, 2020.

I. Introduction

On September 4, 2020, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the –1x Short VIX Futures ETF (''Fund''), a series of VS Trust (''Trust''), under BZX Rule 14.11(f)(4) (Trust Issued Receipts). The proposed rule change was published for comment in the **Federal Register** on September 23, 2020.[3] On October 30, 2020, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] The Commission has received no comments on the proposed rule change. The Commission is publishing this order to solicit comments on the proposed rule change from interested persons and to institute proceedings pursuant to Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to list and trade Shares of the Fund [7] under BZX

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89901 (Sept. 17, 2020), 85 FR 59836 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 90292, 85 FR 70678 (Nov. 5, 2020). The Commission designated December 22, 2020, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] The Trust has filed a registration statement on Form S–1 under the Securities Act of 1933, dated August 26, 2020 (File No.333–248430) (''Registration Statement''). The Fund will not trade on the Exchange until the Registration Statement is effective.

Rule 14.11(f)(4), which governs the listing and trading of Trust Issued Receipts [8] on the Exchange. The Fund seeks to provide daily investment results (before fees and expenses) that correspond to the performance of the Short VIX Futures Index (SHORTVOL) (''Index'').[9]

Volatility Shares LLC (''Sponsor''), a Delaware limited liability company and a commodity pool operator, serves as the Sponsor of the Trust.[10] Tidal ETF Services LLC serves as the administrator; U.S. Bank National Association serves as custodian of the Fund and the Shares; U.S. Bancorp Fund Services, LLC serves as the sub-administrator and transfer agent; and Wilmington Trust Company is the sole trustee of the Trust.

The Index measures the daily inverse performance of a theoretical portfolio of first- and second-month futures contracts on the Cboe Volatility Index (''VIX'').[11] The Index is comprised of VIX futures contracts (''VIX Futures Contracts'').[12] Specifically, the Index components represent the prices of the two near-term VIX Futures Contracts, replicating a position that rolls the nearest month VIX Futures Contract to the next month VIX Futures Contract on a daily basis in equal fractional amounts, resulting in a constant weighted average maturity of approximately one month.[13] The Index seeks to reflect the returns that are potentially available from holding an unleveraged short position in first- and second- month VIX Futures Contracts.[14]

To pursue its investment objective, the Fund would primarily invest in VIX Futures Contracts based on components of the Index. The Fund would primarily acquire short exposure to the VIX through VIX Futures Contracts, such that the Fund has exposure intended to approximate the Index at the time of the net asset value (''NAV'') calculation of the Fund.[15] However, in the event that the Fund is unable to meet its investment objective solely through investment in VIX Futures Contracts, it may invest in over-the-counter swaps referencing the Index or referencing particular VIX Futures Contracts comprising the Index (''VIX Swap Agreements'') [16] or in listed VIX options contracts (''VIX Options Contracts,'' and, together with VIX Futures Contracts and VIX Swap Agreements, ''VIX Derivative Products''). The Fund may also invest in Cash or Cash Equivalents [17] that may serve as collateral to the Fund's investments in VIX Derivative Products.[18]

The Fund would not be actively managed but rather would seek to remain fully invested in VIX Derivative Products (and Cash and Cash Equivalents as collateral) that provide exposure to the Index consistent with its investment objective without regard to market conditions, trends or direction. The Fund's investment objective is a daily investment objective; that is, the Fund seeks to track the Index on a daily basis, not over longer periods.[19] Accordingly, each day, the Fund will position its portfolio so that it can seek to track the Index. The direction and extent of the Index's movements each day will dictate the direction and extent of the Fund's portfolio rebalancing. For example, if the level of the Index falls on a given day, net assets of the Fund would fall. As a result, exposure to the Index, through futures positions held by the Fund, would need to be decreased. The opposite would be the case if the level of the Index rises on a given day.

The time and manner in which the Fund would rebalance its portfolio is defined by the Index methodology but may vary from the Index methodology depending upon market conditions and other circumstances including the potential impact of the rebalance on the price of the VIX Futures Contracts. The Sponsor would seek to minimize the

[8] Rule 14.11(f)(4) applies to Trust Issued Receipts that invest in ''Financial Instruments,'' defined in Rule 14.11(f)(4)(A)(iv) as any combination of investments, including cash; securities; options on securities and indices; futures contracts; options on futures contracts; forward contracts; equity caps, collars and floors; and swap agreements.

[9] The Index is sponsored by Cboe Global Indexes. The Index sponsor is not a registered broker-dealer, but is affiliated with a broker-dealer and has implemented and will maintain a fire wall with respect to the broker-dealer affiliate regarding access to information concerning the composition of and/or changes to the Index. In addition, the Index Sponsor has implemented and will maintain procedures that are designed to prevent the use and dissemination of material, non-public information regarding the Index.

[10] The Sponsor is not a broker-dealer or affiliated with a broker-dealer. In the event that (a) the Sponsor becomes a broker-dealer or newly affiliated with a broker-dealer, or (b) any new sponsor is a broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the portfolio.

[11] The VIX is an index designed to measure the implied volatility of the S&P 500 over 30 days in the future. The VIX is calculated based on the prices of certain put and call options on the S&P 500. The VIX is reflective of the premium paid by investors for certain options linked to the level of the S&P 500.

[12] VIX Futures Contracts are measures of the market's expectation of the level of VIX at certain points in the future, and as such, will behave differently than current, or spot, VIX. While the VIX represents a measure of the current expected volatility of the S&P 500 over the next 30 days, the prices of VIX Futures Contracts are based on the current expectation of what the expected 30-day volatility will be at a particular time in the future (on the expiration date).

[13] The roll period usually begins on the Wednesday falling 30 calendar days before the S&P 500 option expiration for the following month (''Cboe VIX Monthly Futures Settlement Date'') and runs to the Tuesday prior to the subsequent month's Cboe VIX Monthly Futures Settlement Date.

[14] The Exchange states that because VIX Futures Contracts correlate to future volatility readings of VIX, while the VIX itself correlates to current volatility, the Index and the Fund should be expected to perform significantly different from the inverse of the VIX over all periods of time. Further, unlike the Index, the VIX, which is not a benchmark for the Fund, is calculated based on the prices of certain put and call options on the S&P 500. While the Index does not correspond to the inverse of the VIX, as it seeks short exposure to VIX, the value of the Index, and by extension the Fund, will generally rise as the VIX falls and fall as the VIX rises.

[15] The Exchange states the Fund's NAV will be calculated at 4:00 p.m. E.T.

[16] The VIX Swap Agreements in which the Fund may invest may or may not be cleared. The Fund would only enter into VIX Swap Agreements with counterparties that the Sponsor reasonably believes are capable of performing under the contract and will post collateral as required by the counterparty. The Fund would seek, where possible, to use counterparties, as applicable, whose financial status is such that the risk of default is reduced; however, the risk of losses resulting from default is still possible. The Sponsor would evaluate the creditworthiness of counterparties on a regular basis. In addition to information provided by credit agencies, the Sponsor would review approved counterparties using various factors, which may include the counterparty's reputation, the Sponsor's past experience with the counterparty and the price/market actions of debt of the counterparty. The Fund may use various techniques to minimize OTC counterparty credit risk including entering into arrangements with counterparties whereby both sides exchange collateral on a mark-to-market basis. Collateral posted by the Fund to a counterparty in connection with uncleared VIX Swap Agreements is generally held for the benefit of the counterparty in a segregated tri-party account at the custodian to protect the counterparty against non-payment by the Fund.

[17] For purposes of the proposal, ''Cash and Cash Equivalents'' are short-term instruments with maturities of less than 3 months, including the following: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

[18] The Fund would collateralize its obligations with Cash and Cash Equivalents consistent with the 1940 Act and interpretations thereunder.

[19] The Exchange states that return of the Fund for a period longer than a single day is the result of its return for each day compounded over the period and usually would differ in amount and possibly even direction from either the inverse of the VIX or the inverse of a portfolio of short-term VIX Futures Contracts for the same period. These differences can be significant.

market impact of Fund rebalances on the price of VIX Futures Contracts by limiting the Fund's participation, on any given day, in VIX Futures Contracts to no more than one-quarter of the contracts traded on Cboe Futures Exchange during any ''Rebalance Period'' (defined by the Index methodology as 3:45 p.m.–4 p.m., E.T.) (''VIX Futures Contracts Limitation''). If the Fund's portfolio rebalance exceeds one-quarter of the futures' volume between 3:45 p.m. and 4 p.m., E.T., the Sponsor would extend the rebalance period (the ''Extended Rebalance Period) to include, for example, the period between 4 p.m. and 4:15 p.m., E.T. and the Trade At Settlement market (''TAS'').

The Sponsor expects that allowing the Fund to participate in an Extended Rebalance Period would minimize the impact on the price of VIX Futures Contracts, and particularly minimize any impact of large Fund rebalances during periods of market illiquidity.[20] The Exchange states that defining an explicit rebalancing methodology and limiting the Fund's participation in the VIX Futures Contracts should reduce the impact of the Fund's rebalancing on the price of VIX Futures Contracts.

III. Proceedings To Determine Whether to Approve or Disapprove SR-CboeBZX–2020–070 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [21] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposal. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[22] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposal's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,'' and ''to protect investors and the public interest.'' [23]

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is consistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.[24]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by January 8, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by January 22, 2021.

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice,[25] in addition to any other comments they may wish to submit about the proposed rule change. In this regard, the Commission seeks commenters' views regarding whether the Exchange's proposal to list and trade the Shares, which seek to provide daily investment results that correspond to the performance of an index that measures the daily inverse performance of a theoretical portfolio of first- and second-month VIX Futures Contracts, is adequately designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and to protect investors and the public interest, and is consistent with the maintenance of a fair and orderly market under the Act. The Commission also seeks commenters' views regarding whether the Exchange has adequately described the potential impact of sudden fluctuations in market volatility on the Index and on the Fund's operation and performance for the Commission to make a determination under Section 6(b)(5) of the Act. In particular, the Commission seeks comment regarding the Fund's operation during periods with large percentage increases in volatility, and whether the Sponsor's proposed VIX Futures Contracts Limitation would sufficiently minimize the market impact of the Fund's daily rebalance.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2020–070 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2020–070. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are

[20] The Sponsor believes that the Fund would enter an Extended Rebalance Period most often during periods of extraordinary volatility or illiquidity in VIX futures contracts.

[21] 15 U.S.C. 78s(b)(2)(B).

[22] *Id.*

[23] 15 U.S.C. 78f(b)(5).

[24] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[25] *See supra* note 3.

cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2020–070 and should be submitted by January 8, 2021. Rebuttal comments should be submitted by January 22, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–27840 Filed 12–17–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90653; File No. SR–NYSE–2020–98]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Amend Its Rules To Prohibit Member Organizations From Seeking Reimbursement, in Certain Circumstances, From Issuers for Forwarding Proxy and Other Materials to Beneficial Owners

December 14, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 30, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules to prohibit member organizations from seeking reimbursement from issuers for forwarding proxy and other materials to beneficial owners who received shares from their broker at no cost or at a price substantially less than the market price in connection with a promotion by the broker. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE Rule 451 requires NYSE member organizations that hold securities for beneficial owners in street name to solicit proxies from, and deliver proxy and issuer communication materials to, beneficial owners on behalf of issuers.[4] For this service, issuers reimburse NYSE member organizations for out-of-pocket, reasonable clerical, postage and other expenses incurred for a particular distribution. This reimbursement structure stems from SEC Rules 14b–1 and 14b–2 under the Act,[5] which impose obligations on companies and nominees to ensure that beneficial owners receive proxy materials and are given the opportunity to vote. These rules require companies to send their proxy materials to nominees, *i.e.,* broker-dealers or banks that hold securities in street name, for forwarding to beneficial owners and to pay nominees for reasonable expenses, both direct and indirect, incurred in providing proxy information to beneficial owners. Similarly, Rule 465 requires member organizations to forward issuer communications to beneficial owners on behalf of issuers subject to receipt of reimbursement of expenses.

Recently, brokers providing retail brokerage services have developed a practice in which customers are given securities without charge as a commercial incentive (for example, upon opening a new account or referring a new customer to the broker). Typically, these incentives involve the transfer of a small number of shares to benefiting customers and result in the customer having a position in the company whose shares they receive that has a very small dollar value. Rule 451 does not distinguish between these beneficial owners and beneficial owners that have paid for their shares, so brokers are required to solicit proxies from these accounts and are entitled to reimbursement of their expenses under Rules 451 and 465, as well as pursuant to the applicable rules of any other national securities exchange or national securities association of which the NYSE member organization is a member.[6] As a consequence, issuers are billed under Exchange rules and the rules of other SROs for the reimbursement of expenses the broker incurs in making distributions to these beneficial owners who have very small positions, which they acquired from their broker without any payment by the customer. In certain cases, the issuer can experience a significant increase in its distribution reimbursement expenses solely due to its shares being included in these broker promotional schemes.

While the distribution of shares in these broker promotions may result in a significant increase in the number of beneficial owners of an issuer's stock, the generally very small size of each of these positions means that they usually represent a very small percentage of the voting power. As such, the costs the issuer incurs in reimbursing the broker for distributing proxies to these accounts is very disproportionate to the maximum potential vote such shares represent. By contrast, the broker using such a scheme chooses to engage in it because it believes that it will result in a commercial benefit to the broker. Consequently, the Exchange believes that it is more appropriate for the broker to bear these proxy distribution costs. Accordingly, the Exchange proposes new Rule 451A, which would provide that, notwithstanding the applicable provisions of Rules 451 or 465 or what may be permitted by the rules of any other national securities exchange or national securities association of which a member organization is also a

[26] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The ownership of shares in street name means that a shareholder, or ''beneficial owner,'' has purchased shares through a broker-dealer or bank, also known as a ''nominee.'' In contrast to direct ownership, where shares are directly registered in the name of the shareholder, shares held in street name are registered in the name of the nominee, or in the nominee name of a depository, such as the Depository Trust Company. For more detail regarding share ownership, *see* Securities Exchange Act Release No. 62495 (July 14, 2010), 75 FR 42982 (July 22, 2010) (Concept Release on the U.S. Proxy System) (''Proxy Concept Release'').

[5] 17 CFR 240.14b–1; 17 CFR 240.14b–2.

[6] *See,* for example, FINRA Rule 2251.

member, no member shall seek to be reimbursed for expenses incurred in connection with the distribution of proxies or other materials on behalf of issuers to the beneficial owners of shares or units of an issuer's securities in a nominee account if those shares or units were transferred to the account holder by the member organization at no cost or at a price substantially less than the market price.

As proposed, Rule 451A would not limit a broker's right to reimbursement for distributions to any beneficial owner if any part of that beneficial owner's position in an issuer's securities was received by any means other than a transfer without charge or at a price substantially less than the market price from the broker. Rules 451 and 465 would continue to apply to all distributions, so the broker would continue to be fully obligated to solicit votes from, and make other distributions on behalf of issuers to, all beneficial owners notwithstanding the limitations on reimbursement of expenses imposed by Rule 451A.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'') generally.[7] Section 6(b)(4)[8] requires that exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using the facilities of an exchange. Section 6(b)(5)[9] requires, among other things, that exchange rules are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect the public interest and the interests of investors, promote just and equitable principles of trade and that they are not designed to permit unfair discrimination between issuers, brokers or dealers.

The Exchange believes that the proposal is consistent with Sections 6(b)(4) and 6(b)(5) of the Act as it would only limit the reimbursement of distribution expenses in circumstances where a broker distributes the shares to its customers as part of a voluntary promotional strategy by the broker from which it derives a commercial benefit. The Exchange notes that the recipients of shares without charge or at a price substantially less than the market price from the broker as part of such schemes typically will not be given any choice as to which shares they receive and are therefore not making any investment decision. As the broker typically has sole control over the allocation of these shares to its customers and derives a commercial benefit from doing so, the Exchange believes that the proposal is not unfairly discriminatory and does not represent an inequitable allocation of the costs of the distribution of proxy and other issuer materials. The Exchange also notes that brokers will continue to be required to distribute proxy and other materials on behalf of issuers notwithstanding the fact that brokers will not be entitled to any reimbursement of expenses and believes that the proposal is therefore consistent with Rules 14b–1 and 14b–2 under the Act,[10] which impose obligations on companies and nominees to ensure that beneficial owners receive proxy materials and are given the opportunity to vote.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed limitation on distribution expense reimbursement would apply to any broker that adopts a commercial strategy of distributing shares to account holders free of charge or at a substantial discount to the market price. Brokers that adopt this strategy do so because they believe that they derive a commercial and competitive advantage from doing so. As such, the Exchange believes that any burden on competition associated with this proposal is appropriate in light of the fact that brokers will only be subject to any such burden as a consequence of voluntarily adopting a strategy that they believe is beneficial for their business. There would be no effect on the competition among issuers resulting from the proposed rule change, as all issuers would benefit from the proposed restriction in the same manner if their shares have been distributed without charge as part of such a commercial arrangement.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2020–98 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2020–98. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78f(b)(5).

[10] 17 CFR 240.14b–1; 17 CFR 240.14b–2.

provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2020–98 and should be submitted on or before January 8, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–27836 Filed 12–17–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90655; File No. SR–BX–2020–037]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing of Proposed Rule Change To Amend BX Options 7, Section 2 and Section 3

December 14, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 1, 2020, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BX Options 7, Section 2, ''BX Options Market—Fees and Rebates,'' and Options 7, Section 3, ''BX Options Market—Ports and other Services.''

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend BX's Pricing Schedule at Options 7, Section 2, ''BX Options Market—Fees and Rebates,'' and Options 7, Section 3, ''BX Options Market—Ports and other Services.'' Each change will be described in detail below.

Options 7, Section 2

The Exchange proposes to remove the options tier schedules applicable to Select Symbols[3] and SPY pricing. With this proposal, all pricing within Options 7, Section 2 would be subject to either the Penny Symbol or Non-Penny Symbol pricing tier schedules.

Today, the Exchange assesses fees and rebates for Penny Symbols and Non-Penny Symbols, excluding Select Symbols and SPY. Today, both Select Symbols and options overlying ''SPY'' are subject to alternative pricing as detailed below.

Today, the Exchange assesses fees and pays rebates for Penny and Non-Penny Symbols in accordance with the below table and corresponding Penny and Non-Penny tier schedules.

FEES AND REBATES

[per executed contract]

	Customer	BX options market maker	Non-customer [1]	Firm
Penny Symbols (Excluding Options in Select Symbols):				
Rebate to Add Liquidity	#	[2] $0.10	N/A	N/A
Fee to Add Liquidity	#	[3] 0.39	$0.45	$0.45
Rebate to Remove Liquidity	#	N/A	N/A	N/A
Fee to Remove Liquidity	N/A	#	0.46	0.46
Non-Penny Symbols:				
Rebate to Add Liquidity	*	N/A	N/A	N/A
Fee to Add Liquidity	*	[5] 0.50/0.95	0.98	0.98
Rebate to Remove Liquidity	*	N/A	N/A	N/A
Fee to Remove Liquidity	N/A	*	0.89	0.89

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The following are current Select Symbols within Options 7, Section 2: ASHR, DIA, DXJ, EEM, EFA, EWJ, EWT, EWW, EWY, EWZ, FAS, FAZ, FXE, FXI, FXP, GDX, GLD, HYG, IWM, IYR, KRE, OIH, QID, QLD, QQQ, RSX, SDS, SKF, SLV, SRS, SSO, TBT, TLT, TNA, TZA, UNG, URE, USO, UUP, UVXY, UYG, VXX, XHB, XLB, XLE, XLF, XLI, XLK, XLP, XLU, XLV, XLY, XME, XOP, XRT.

PENNY SYMBOLS TIER SCHEDULE

[Excluding select symbols options]

	Rebate to add liquidity	Fee to add liquidity	Rebate to remove liquidity	Fee to remove liquidity	Fee to remove liquidity
When:	Customer	Customer	Customer	BX options market maker	BX options market maker
Trading with:	Non-customer BX options market maker, or firm	Customer	Non-customer, BX options market maker, customer, or firm	Customer	Non-customer, BX options market maker, or firm
Tier 1. Participant executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month	$0.00	$0.39	$0.00	$0.39	$0.46
Tier 2. Participant executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month	0.10	0.39	0.25	0.39	0.46
Tier 3. Participant executes 0.15% or more of total industry customer equity and ETF option ADV contracts per month	0.20	0.39	0.35	0.30	0.46

* NON-PENNY SYMBOLS TIER SCHEDULE

	Rebate to add liquidity	Fee to add liquidity	Rebate to remove liquidity	Fee to remove liquidity	Fee to remove liquidity
When:	Customer	Customer	Customer	BX options market maker	BX options market maker
Trading with:	Non-customer BX options market maker, or firm	Customer	Non-customer, BX options market maker, customer, or firm	Customer	Non-customer, BX options market maker, or firm
Tier 1. Participant executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month	$0.00	$0.85	$0.80	$0.89	$0.89
Tier 2. Participant executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month	0.10	0.85	0.80	0.89	0.89
Tier 3. Participant executes 0.15% or more of total industry customer equity and ETF option ADV contracts per month	0.20	0.85	0.80	0.60	0.89

Select Symbols

With respect to Select Symbols Options, the following tier schedule [4] applies today:

[4] Volume from all products listed on BX Options applies to the Select Symbols Options Tiers.

SELECT SYMBOLS OPTIONS TIER SCHEDULE

	Rebate to add liquidity	Fee to add liquidity	Rebate to remove liquidity	Fee to remove liquidity	Fee to remove liquidity
When:	Customer	Customer	Customer	BX options market maker	BX options market maker
Trading with:	Non-customer BX options market maker, or firm	Customer	Non-customer, BX options market maker, customer, or firm	Customer	Non-customer, BX options market maker, or firm
Tier 1. Participant executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month	$0.00	$0.44	$0.00	$0.42	$0.14
Tier 2. Participant executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month	0.10	0.44	0.25	0.42	0.10
Tier 3. Participant executes 0.15% or more of total industry customer equity and ETF option ADV contracts per month	0.20	0.40	0.37	0.39	0.04
Tier 4. Participant executes greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month	0.25	0.29	0.37	0.25	0.00

The Exchange proposes to remove the Select Symbols Options Tier Schedule and corresponding notes and instead assess each Select Symbol as either a Penny [5] or Non-Penny Symbol.

Among the Select Symbols noted within Options 7, Section 2, the following are Penny Symbols: ASHR, DIA, EEM, EFA, EWJ, EWW, EWY, EWZ, FAS, FXI, GDX, GLD, HYG, IWM, IYR, KRE, OIH, QQQ, RSX, SDS, SLV, SSO, TBT, TLT, TNA, UNG, USO, UUP, UVXY, VXX, XLB, XLE, XLF, XLI, XLK, XLP, XLU, XLV, XLY, XME, XOP, and XRT. Among the Select Symbols noted within Options 7, Section 2, the following are Non-Penny Symbols: DXJ, EWT, FAZ, FXE, FXP, QID, QLD, SKF, SRS, SSO, TZA, URE, UYG, and XHB.

Select Symbols to be Priced as Penny Symbols

With respect to the impact on pricing for the above-referenced Select Symbols,[6] which would be priced as Penny Symbols with this proposal, the Exchange notes the below changes in pricing.

Customers

Today, Customers are paid Rebates to Add Liquidity in Select Symbols when trading against Non-Customers, BX Options Market Makers or Firms which range from $0.00 to $0.25 per contract.[7] Today, Customers are paid a Rebate to Remove Liquidity in Select Symbols when trading against Non-Customers, BX Options Market Makers, Customers or Firms which range from $0.00 to $0.37 per contract.[8] Today, the Customer Fee to Add Liquidity in Select Symbols when contra to another Customer is $0.33 per contract.

With this proposal, Customers would receive a Penny Symbol Rebate to Add Liquidity when trading against a Non-Customer, BX Options Market Maker or Firm which ranges from $0.00 to $0.20 per contract.[9] With this proposal, Customers would receive a Penny Symbol Rebate to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker, Customer or Firm which ranges from $0.00 to $0.35 per contract.[10] With this proposal,

[5] Penny Symbols must comply with the requirements for the Penny Interval Program within Supplementary Material .01 to Options 3, Section 3.

[6] Among the Select Symbols noted within Options 7, Section 2, the following are Penny Symbols: ASHR, DIA, EEM, EFA, EWJ, EWW, EWY, EWZ, FAS, FXI, GDX, GLD, HYG, IWM, IYR, KRE, OIH, QQQ, RSX, SDS, SLV, SSO, TBT, TLT, TNA, UNG, USO, UUP, UVXY, VXX, XLB, XLE, XLF, XLI, XLK, XLP, XLU, XLV, XLY, XME, XOP, and XRT.

[7] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month receive no Select Symbol Rebate to Add Liquidity for Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month receive a $0.10 per contract Select Symbol Rebate to Add Liquidity for Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month receive a $0.20 per contract Select Symbol Rebate to Add Liquidity for Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month receive a $0.25 per contract Select Symbol Rebate to Add Liquidity for Tier 4.

[8] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month receive no Select Symbol Rebate to Remove Liquidity for Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month receive a $0.25 per contract Select Symbol Rebate to Remove Liquidity for Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month receive a $0.37 per contract Select Symbol Rebate to Remove Liquidity for Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month receive a $0.37 per contract Select Symbol Rebate to Remove Liquidity for Tier 4.

[9] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Penny Symbol Rebate to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.10 per contract Penny Symbol Rebate to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would receive a $0.20 per contract Penny Symbol Rebate to Add Liquidity in Tier 3.

[10] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Penny Symbol Rebate to Remove Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.25 per contract Penny Symbol Rebate to Remove Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month will would receive a

Continued

Customers would pay a Penny Symbol Fee to Add Liquidity when trading against a Customer of $0.39 per contract, regardless of the tier.[11] With this proposal, Customers would not pay a Penny Symbol Fee to Remove Liquidity.

BX Options Market Makers

Today, BX Options Market Makers pay a Fee to Add Liquidity in Select Symbols when trading against a Customer which ranges from $0.44 to $0.29 per contract.[12] Today, BX Options Market Makers pay a Fee to Remove Liquidity in Select Symbols when trading against a Customer which ranges from $0.42 to $0.25 per contract.[13] Today, BX Options Market Makers pay a Fee to Remove Liquidity in Select Symbols when trading against a Firm, Non-Customer, or BX Options Market Maker of $0.46 per contract. Today, BX Options Market Makers pay a Fee to Add Liquidity in Select Symbols when trading against a Non-Customer, BX Options Market Maker or Firm which ranges from $0.14 to $0.00 per contract.[14]

With this proposal, BX Options Market Makers would receive a Penny Symbol Rebate to Add Liquidity of $0.10 per contract only when the BX Options Market Maker is contra to a Non-Customer, Firm, or BX Options Market Maker. With this proposal, BX Options Market Makers would receive no Penny Symbol Rebate to Remove Liquidity. With this proposal, BX Options Market Makers would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity only when the BX Options Market Maker is contra to a Customer. With this proposal, BX Options Market Makers would pay a Penny Symbol Fee to Remove Liquidity when trading against a Customer which ranges from $0.39 to $0.30 per contract.[15] With this proposal, BX Options Market Makers would pay a Penny Symbol Fee to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker or Firm of $0.46 per contract, regardless of the tier.[16]

Non-Customers

Today, Non-Customers pay a Fee to Add Liquidity and a Fee to Remove Liquidity in Select Symbols of $0.46 per contract, regardless of counterparty. Today, Non-Customers receive no Select Symbol rebates.

With this proposal, Non-Customers would receive no Penny Symbol Rebate to Add Liquidity and no Penny Symbol Rebate to Remove Liquidity. With this proposal, Non-Customers would pay a Penny Symbol Fee to Add Liquidity of $0.45 per contract. With this proposal, Non-Customers would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract.

Firms

Today, Firms pay a Select Symbol Fee to Add Liquidity and a Fee to Remove Liquidity of $0.37 per contract, regardless of counterparty. Today, Firms receive no Select Symbol rebates.

With this proposal, Firms would receive no Penny Symbol Rebate to Add Liquidity and no Penny Symbol Rebate to Remove Liquidity. With this proposal, Firms would pay a Penny Symbol Fee to Add Liquidity of $0.45 per contract. With this proposal, Firms would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract.

Select Symbols To Be Priced as Non-Penny Symbols

With respect to the impact on pricing for Select Symbols which would be priced as Non-Penny Symbols (DXJ, EWT, FAZ, FXE, FXP, QID, QLD, SKF, SRS, SSO, TZA, URE, UYG, and XHB) with this proposal, the Exchange notes the below changes in pricing.

Customers

Today, Customers are paid Rebates to Add Liquidity in Select Symbols when trading against Non-Customers, BX Options Market Makers or Firms which range from $0.00 to $0.25 per contract.[17] Today, Customers are paid a Rebate to Remove Liquidity in Select Symbols when trading against Non-Customers, BX Options Market Makers, Customers or Firms which range from $0.00 to

$0.35 per contract Penny Symbol Rebate to Remove Liquidity in Tier 3.

[11] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 3.

[12] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.44 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.44 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.40 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay a Select Symbol Fee to Add Liquidity of $0.29 per contract in Tier 4.

[13] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.42 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.42 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay a Select Symbol Fee to Remove Liquidity of $0.25 per contract in Tier 4.

[14] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.14 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.10 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.04 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay no Select Symbol Fee to Add Liquidity in Tier 4.

[15] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.30 per contract in Tier 3.

[16] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 3.

[17] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month receive no Select Symbol Rebate to Add Liquidity for Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month receive a $0.10 per contract Select Symbol Rebate to Add Liquidity for Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month receive a $0.20 per contract Select Symbol Rebate to Add Liquidity for Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month receive a $0.25 per contract Select Symbol Rebate to Add Liquidity for Tier 4.

$0.37 per contract.[18] Today, the Customer Fee to Add Liquidity in Select Symbols when contra to another Customer is $0.33 per contract.

With this proposal, Customers would receive a Non-Penny Symbol Rebate to Add Liquidity when trading against a Non-Customer, BX Options Market Maker or Firm which ranges from $0.00 to $0.20 per contract.[19] With this proposal, Customers would receive a Non-Penny Symbol Rebate to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker, Customer or Firm of $0.80 per contract, regardless of the tier.[20] With this proposal, Customers would pay a Non-Penny Symbol Fee to Add Liquidity when trading against a Customer of $0.85 per contract, regardless of the tier.[21] With this proposal, Customers would not pay a Non-Penny Symbol Fee to Remove Liquidity.

BX Options Market Makers

Today, BX Options Market Makers pay a Fee to Add Liquidity in Select Symbols when trading against a Customer which ranges from $0.44 to $0.29 per contract.[22] Today, BX Options Market Makers pay a Fee to Remove Liquidity in Select Symbols when trading against a Customer which ranges from $0.42 to $0.25 per contract.[23] Today, BX Options Market Makers pay a Fee to Remove Liquidity in Select Symbols when trading against a Firm, Non-Customer, or BX Options Market Maker of $0.46 per contract. Today, BX Options Market Makers pay a Fee to Add Liquidity in Select Symbols when trading against a Non-Customer, BX Options Market Maker or Firm which ranges from $0.14 to $0.00 per contract.[24]

With this proposal, BX Options Market Makers would receive no Non-Penny Symbol Rebate to Add Liquidity or Non-Penny Rebate to Remove Liquidity. With this proposal, BX Options Market Makers would pay a $0.50 per contract Non-Penny Symbol Fee to Add Liquidity when trading against a BX Options Market Maker, Non-Customer or Firm and a $0.95 per contract Non-Penny Symbol Fee to Add Liquidity when trading against a Customer. With this proposal, BX Options Market Makers would pay a Non-Penny Symbol Fee to Remove Liquidity when trading against a Customer which ranges from $0.89 to $0.60 per contract.[25] With this proposal, BX Options Market Makers would pay a Non-Penny Symbol Fee to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker, or Firm of $0.89 per contract, regardless of the tier.[26]

Non-Customers

Today, Non-Customers pay a Fee to Add Liquidity and a Fee to Remove Liquidity in Select Symbols of $0.46 per contract, regardless of counterparty. Today, Non-Customers receive no Select Symbol rebates.

With this proposal, Non-Customers would receive no Non-Penny Symbol Rebate to Add Liquidity or Non-Penny Symbol Rebate to Remove Liquidity. With this proposal, Non-Customers would pay a Non-Penny Symbol Fee to Add Liquidity of $0.98 per contract. With this proposal, Non-Customers would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract.

[18] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month receive no Select Symbol Rebate to Remove Liquidity for Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month receive a $0.25 per contract Select Symbol Rebate to Remove Liquidity for Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month receive a $0.37 per contract Select Symbol Rebate to Remove Liquidity for Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month receive a $0.37 per contract Select Symbol Rebate to Remove Liquidity for Tier 4.

[19] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Non-Penny Symbol Rebate to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.10 per contract Non-Penny Symbol Rebate to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month will would receive a $0.20 per contract Non-Penny Symbol Rebate to Add Liquidity in Tier 3.

[20] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive a Non-Penny Symbol Rebate to Remove Liquidity of $0.80 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a Non-Penny Symbol Rebate to Remove Liquidity of $0.80 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would receive a Non-Penny Symbol Rebate to Remove Liquidity of $0.80 per contract in Tier 3.

[21] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Add Liquidity of $0.85 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Add Liquidity of $0.85 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Add Liquidity of $0.85 per contract in Tier 3.

[22] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.44 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.44 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.40 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay a Select Symbol Fee to Add Liquidity of $0.29 per contract in Tier 4.

[23] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.42 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.42 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay a Select Symbol Fee to Remove Liquidity of $0.25 per contract in Tier 4.

[24] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.14 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.10 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.04 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay no Select Symbol Fee to Add Liquidity in Tier 4.

[25] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.60 per contract in Tier 3.

[26] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 3.

Firms

Today, Firms pay a Select Symbol Fee to Add Liquidity and a Fee to Remove Liquidity of $0.37 per contract, regardless of counterparty. Today, Firms receive no Select Symbol rebates.

With this proposal, Firms would receive no Non-Penny Symbol Rebate to Add Liquidity or Non-Penny Symbol Rebate to Remove Liquidity. With this proposal, Firms would pay a Non-Penny Symbol Fee to Add Liquidity of $0.98 per contract. With this proposal, Firms would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract.

SPY

Today, the SPY Options Tier Schedule is as follows:

SPY OPTIONS TIER SCHEDULE

	Rebate to remove liquidity (per contract)
Applied to:	Customer
Trading with:	Non-customer, BX options market maker, customer, or firm
Tier 1. Participant removes less than 500 SPY Options contracts per day in the customer range	$0.01
Tier 2. Participant removes 500 to not more than 999 SPY Options contracts per day in the customer range	0.10
Tier 3. Participant removes 1000 to not more than 1999 SPY Options contracts per day in the customer range	0.35
Tier 4. Participant removes 2000 to not more than 3999 SPY Options contracts per day in the customer range	0.43
Tier 5. Participant removes more than 3999 SPY Options contracts per day in the customer range	0.52

With respect to the impact on pricing for SPY, with this proposal, SPY would be priced as a Penny Symbol the Exchange notes the below changes in pricing.

Customers

Today, SPY pays Customer Rebates to Remove Liquidity ranging from $0.01 to $0.52 per contracts when trading against a Non-Customer, BX Options Market Maker, Customer or Firm.[27] Today, Customers pay SPY Fees to Add Liquidity of $0.38 per contract when contra to another Customer. Today, Customers pay no SPY fee or receive a SPY rebate for Customer SPY Options that add liquidity when contra to a Firm, BX Options Market Maker or Non-Customer.

With this proposal, Customers would receive a Penny Symbol Rebate to Add Liquidity when trading against a Non-Customer, BX Options Market Maker or Firm which ranges from $0.00 to $0.20 per contract.[28] With this proposal, Customers would receive a Penny Symbol Rebate to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker, Customer or Firm which ranges from $0.00 to $0.35 per contract.[29] With this proposal, Customers would pay a Penny Symbol Fee to Add Liquidity when trading against a Customer of $0.39 per contract, regardless of the tier.[30] With this proposal, Customers would not pay a Penny Symbol Fee to Remove Liquidity.

BX Options Market Makers

Today, with SPY, BX Options Marker Makers are paid no rebates. BX Options Market Makers pay a SPY Fee to Remove Liquidity of $0.44 per contract when trading against a Firm, Non-Customer, or BX Options Market Maker. Today, BX Options Market Makers pay a SPY Fee to Add Liquidity and a SPY Fee to Remove Liquidity of $0.39 per contract when trading against a Customer. Finally, today, BX Options Market Makers pay a SPY Fee to Add Liquidity of $0.14 per contract when trading against a Firm, BX Options Market Maker or Non Customer.

With this proposal, BX Options Market Makers would receive a Penny Symbol Rebate to Add Liquidity of $0.10 per contract only when the BX Options Market Maker is contra to a Non-Customer, Firm, or BX Options Market Maker. With this proposal, BX Options Market Makers would receive no Penny Symbol Rebate to Remove Liquidity. With this proposal, BX Options Market Makers would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity only when the BX Options Market Maker is contra to a Customer. With this proposal, BX Options Market Makers would pay a Penny Symbol Fee to Remove Liquidity when trading against a Customer which ranges from $0.39 to $0.30 per contract.[31] With this proposal, BX Options Market Makers would pay a Penny Symbol Fee to Remove Liquidity when trading against a Non-Customer,

[27] Tier 1 Participants that remove less than 500 SPY Options contracts per day in the customer range receive a $0.01 per contract rebate. Tier 2 Participants that remove 500 to not more than 999 SPY Options contracts per day in the customer range receive a $0.10 per contract rebate. Tier 3 Participants that removes 1000 to not more than 1999 SPY Options contracts per day in the customer range receive a $0.35 per contract rebate. Tier 4 Participants that remove 2000 to not more than 3999 SPY Options contracts per day in the customer range receive a $0.43 per contract rebate. Tier 5 Participants that remove more than 3999 SPY Options contracts per day in the customer range receive a $0.52 per contract rebate.

[28] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Penny Symbol Rebate to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.10 per contract Penny Symbol Rebate to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would receive a $0.20 per contract Penny Symbol Rebate to Add Liquidity in Tier 3.

[29] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Penny Symbol Rebate to Remove Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.25 per contract Penny Symbol Rebate to Remove Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month will would receive a $0.35 per contract Penny Symbol Rebate to Remove Liquidity in Tier 3.

[30] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 3.

[31] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.30 per contract in Tier 3.

BX Options Market Maker or Firm of $0.46 per contract, regardless of the tier.[32]

Non-Customers

Today, Non-Customers pay a SPY Fee to Add Liquidity and a SPY Fee to Remove Liquidity of $0.44 per contract, regardless of counterparty. Today, Non-Customers receive no SPY rebates.

With this proposal, Non-Customers would receive no Penny Symbol Rebate to Add Liquidity and no Penny Symbol Rebate to Remove Liquidity. With this proposal, Non-Customers would pay a Penny Symbol Fee to Add Liquidity of $0.45 per contract. With this proposal, Non-Customers would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract.

Firms

Today, Firms pay a SPY Fee to Add Liquidity and a SPY Fee to Remove Liquidity of $0.41 per contract, regardless of counterparty. Today, Firms receive no SPY rebates.

With this proposal, Firms would receive no Penny Symbol Rebate to Add Liquidity and no Penny Symbol Rebate to Remove Liquidity. With this proposal, Firms would pay a Penny Symbol Fee to Add Liquidity of $0.45 per contract. With this proposal, Firms would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract.

The Exchange believes that this proposal will simplify its transaction fees and rebates by classifying pricing for all options symbols as either Penny or Non-Penny Symbols.

Technical Amendments

The Exchange proposes to remove footnote 4, which is currently reserved, and renumber current footnote 5 as new footnote 4 within Options 7, Section 2. The Exchange also proposes to remove ''(excluding Select Symbols Options)'' from the Fees and Rebates table within Options 7, Section 2(1) and from the Penny Symbols Tier Schedule title as that exclusion is no longer necessary because this proposal removes that pricing.

Options 7, Section 3

The Exchange proposes to amend Options 7, Section 3, ''BX Options Market—Ports and other Services,'' to remove obsolete text which reflects timeframes which have passed.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[33] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[34] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed changes to its Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . ..''[35]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[36]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of sixteen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

Options 7, Section 2

Select Symbols To Be Priced as Penny Symbols

With respect to pricing certain Select Symbols,[37] which would be priced as Penny Symbols with this proposal, the Exchange believes that its proposal is reasonable, equitable and not unfairly discriminatory for the reasons which follow.

Customers

While this proposal would offer Customers lower Rebates to Add Liquidity in Select Symbols when trading against Non-Customers, BX Options Market Makers, Customer, or Firms which range from $0.00 to $0.20 per contract,[38] instead of ranging from $0.00 to $0.25 per contract[39] (no Tier 4

[32] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 3.

[33] 15 U.S.C. 78 f(b).

[34] 15 U.S.C. 78f(b)(4) and (5).

[35] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (DC Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca-2006–21)).

[36] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[37] Among the Select Symbols noted within Options 7, Section 2, the following are Penny Symbols: ASHR, DIA, EEM, EFA, EWJ, EWW, EWY, EWZ, FAS, FXI, GDX, GLD, HYG, IWM, IYR, KRE, OIH, QQQ, RSX, SDS, SLV, SSO, TBT, TLT, TNA, UNG, USO, UUP, UVXY, VXX, XLB, XLE, XLF, XLI, XLK, XLP, XLU, XLV, XLY, XME, XOP, and XRT.

[38] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Penny Symbol Rebate to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.10 per contract Penny Symbol Rebate to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would receive a $0.20 per contract Penny Symbol Rebate to Add Liquidity in Tier 3.

[39] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month receive no Select Symbol Rebate to Add Liquidity for Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month receive a $0.10 per contract Select Symbol Rebate to Add Liquidity for Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month

Continued

rebate of $0.25 per contract as was the case for Select Symbols with this proposal), as well as lower Rebates to Remove Liquidity in Select Symbols when trading against Non-Customers, BX Options Market Makers, or Firms which range from $0.00 to $0.35 per contract,[40] instead of $0.00 to $0.37 per contract,[41] (no Tier 3 and 4 rebate of $0.37 per contracts as it was for Select Symbols with this proposal), the Exchange believes that these rebates will continue to incentivize Participants to bring Customer liquidity to BX. While the Customer Fee to Add Liquidity in Select Symbols when contra to another Customer would increase from $0.33 to $0.39 per contract, regardless of the tier for Select Symbols,[42] the Exchange believes that the fee remains competitive and will continue to attract order flow to BX to the benefit of all market participants. With this proposal, Customers would continue to pay no Penny Symbol Fee To Remove Liquidity.[43]

All pricing would be uniformly assessed to Participants for Penny Symbols. Customers would continue to receive favorable pricing as compared to other market participants because Customer liquidity enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Customer liquidity benefits all market participants by providing more trading opportunities which attracts market makers. An increase in the activity of these market participants (particularly in response to pricing) in turn facilitates tighter spreads which may cause an additional corresponding increase in order flow from other market participants.

BX Options Market Makers

With this proposal, BX Options Market Makers would receive a Penny Symbol Rebate to Add Liquidity of $0.10 per contract only when the BX Options Market Maker is contra to a Non-Customer, Firm, or BX Options Market Maker. Today, BX Options Market Makers receive no Select Symbol Rebate to Add Liquidity. This rebate will incentivize Participants to send order flow to BX. With this proposal, BX Options Market Makers would continue to receive no Rebate to Remove Liquidity.[44] With this proposal, BX Options Market Makers would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity only when the BX Options Market Maker is contra to a Customer as compared to the Select Symbol Fee to Add Liquidity for BX Options Market Makers which ranges from $0.44 to $0.29 per contract,[45] as such some Participants will pay a higher Penny Symbol Fee to Add Liquidity while some Participants will pay a lower Penny Symbol Fee to Add Liquidity. The Exchange believes that the fee remains competitive and will continue to attract order flow to BX to the benefit of all market participants. With this proposal, BX Options Market Makers would pay a Penny Symbol Fee to Remove Liquidity when trading against a Customer which ranges from $0.39 to $0.30 per contract.[46] These fees are lower than the current Select Symbol Fees to Remove Liquidity when trading against a Customer which range from $0.42 to $0.25 per contract.[47] The Exchange believes that these lower fees will attract a greater amount of liquidity to BX. With this proposal, BX Options Market Makers would pay a Penny Symbol Fee to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker or Firm of $0.46 per contract, regardless of the tier.[48] This proposed Penny Symbol Fee to Remove Liquidity is the same as the current Fee to Remove Liquidity in Select Symbols when trading against a Firm, Non-Customer, or BX Options Market Maker of $0.46 per contract. With this proposal BX Options Market Makers pay no Penny Symbol Fee to Add Liquidity when contra to a Non-Customer, BX Options Market Maker or Firm. Today, BX Options Market Makers

receive a $0.20 per contract Select Symbol Rebate to Add Liquidity for Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month receive a $0.25 per contract Select Symbol Rebate to Add Liquidity for Tier 4.

[40] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Penny Symbol Rebate to Remove Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.25 per contract Penny Symbol Rebate to Remove Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month will would receive a $0.35 per contract Penny Symbol Rebate to Remove Liquidity in Tier 3.

[41] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month receive no Select Symbol Rebate to Remove Liquidity for Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month receive a $0.25 per contract Select Symbol Rebate to Remove Liquidity for Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month receive a $0.37 per contract Select Symbol Rebate to Remove Liquidity for Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month receive a $0.37 per contract Select Symbol Rebate to Remove Liquidity for Tier 4.

[42] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 3.

[43] Today, Customers pay no Select Symbol Fee To Remove Liquidity.

[44] Today, BX Options Market Makers receive no Select Symbol Rebate to Remove Liquidity.

[45] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.44 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.44 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.40 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay a Select Symbol Fee to Add Liquidity of $0.29 per contract in Tier 4.

[46] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.30 per contract in Tier 3.

[47] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.42 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.42 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay a Select Symbol Fee to Remove Liquidity of $0.25 per contract in Tier 4.

[48] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 3.

pay a Fee to Add Liquidity in Select Symbols when trading against a Non-Customer, BX Options Market Maker or Firm which ranges from $0.14 to $0.00 per contract [49] which would be reduced to no fee and attract further liquidity to BX.

All pricing would be uniformly assessed to Participants for Penny Symbols. BX Options Market Makers add value through continuous quoting [50] and are subject to additional requirements and obligations [51] that other market participants are not. Incentivizing Market Makers to provide greater liquidity benefits all market participants through the quality of order interaction.

Non-Customers

With this proposal, Non-Customers would receive no Penny Symbol Rebate to Add Liquidity and no Penny Symbol Rebate to Remove Liquidity, as is the case today under Select Symbol pricing. With this proposal, Non-Customers would pay a Penny Symbol Fee to Add Liquidity of $0.45 per contract, this fee is lower than the current Select Symbol Fee to Add Liquidity of $0.46 per contract, regardless of counterparty, and will attract liquidity to BX. With this proposal, Non-Customers would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract that is the same as the current Select Symbol Fee to Remove Liquidity in Select Symbols of $0.46 per contract, regardless of counterparty. All pricing would be uniformly assessed to Participants for Penny Symbols.

Firms

With this proposal, Firms would receive no Penny Symbol Rebate to Add Liquidity and no Penny Symbol Rebate to Remove Liquidity, as is the case today under Select Symbol pricing. With this proposal, Firms would pay a Penny Symbol Fee to Add Liquidity of $0.45 per contract which is higher than the current Select Symbol Firm Fee to Add Liquidity of $0.37 per contract, regardless of counterparty. With this proposal, Firms would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract which is higher than the current Select Symbol Firm Fee to Remove Liquidity of $0.37 per contract, regardless of counterparty. Despite the fact that the Penny Symbol Fees to Add and Remove Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. All pricing would be uniformly assessed to Participants for Penny Symbols.

Select Symbols To Be Priced as Non-Penny Symbols

With respect to pricing for Select Symbols that would be priced as Non-Penny Symbols (DXJ, EWT, FAZ, FXE, FXP, QID, QLD, SKF, SRS, SSO, TZA, URE, UYG, and XHB) with this proposal, the Exchange believes that its proposal is reasonable, equitable and not unfairly discriminatory for the reasons which follow. The Exchange notes that, today, Select Symbol pricing is aligned closer to Penny Symbol pricing because the Select Symbols noted above which are proposed to be priced as Non-Penny Symbols were once in the Penny Pilot Program and these symbols are currently not in the Penny Interval Program.

Customers

While this proposal would offer Customers lower Non-Penny Symbol Rebates to Add Liquidity when trading against a Non-Customer, BX Options Market Maker or Firm which would range from $0.00 to $0.25 per contract,[52] instead of ranging from $0.00 to $0.20 per contract [53] (no Tier 4 rebate of $0.25 per contract as was the case for Select Symbols with this proposal), the Exchange believes that these rebates will continue to incentivize Participants to bring Customer liquidity to BX. With this proposal, Customers would receive an increased Non-Penny Symbol Rebate to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker, Customer or Firm of $0.80 per contract, regardless of the tier,[54] as compared to the current Rebate to Remove Liquidity in Select Symbols when trading against Non-Customers, BX Options Market Makers, Customers or Firms which range from $0.00 to $0.37 per contract.[55] The Exchange believes that these rebates will continue to incentivize Participants to bring Customer liquidity to BX. With this proposal, Customers would pay an increased Non-Penny Symbol Fee to Add Liquidity when trading against a Customer of $0.85 per contract, regardless of the tier,[56] as compared to the current Customer Fee to Add Liquidity in Select Symbols when

[49] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.14 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.10 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.04 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay no Select Symbol Fee to Add Liquidity in Tier 4.

[50] *See* Options 2, Section 5.

[51] *See* Options 2, Section 4.

[52] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month receive no Select Symbol Rebate to Add Liquidity for Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month receive a $0.10 per contract Select Symbol Rebate to Add Liquidity for Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month receive a $0.20 per contract Select Symbol Rebate to Add Liquidity for Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month receive a $0.25 per contract Select Symbol Rebate to Add Liquidity for Tier 4.

[53] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Non-Penny Symbol Rebate to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.10 per contract Non-Penny Symbol Rebate to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month will would receive a $0.20 per contract Non-Penny Symbol Rebate to Add Liquidity in Tier 3.

[54] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive a Non-Penny Symbol Rebate to Remove Liquidity of $0.80 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a Non-Penny Symbol Rebate to Remove Liquidity of $0.80 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would receive a Non-Penny Symbol Rebate to Remove Liquidity of $0.80 per contract in Tier 3.

[55] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month receive no Select Symbol Rebate to Remove Liquidity for Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month receive a $0.25 per contract Select Symbol Rebate to Remove Liquidity for Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month receive a $0.37 per contract Select Symbol Rebate to Remove Liquidity for Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month receive a $0.37 per contract Select Symbol Rebate to Remove Liquidity for Tier 4.

[56] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Add Liquidity of $0.85 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Add Liquidity of $0.85 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Add Liquidity of $0.85 per contract in Tier 3.

contra to another Customer of $0.33 per contract. Despite the fact that the Non-Penny Symbol Fee to Add and Remove Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. With this proposal, Customers would continue not pay a Non-Penny Symbol Fee to Remove Liquidity.

All pricing would be uniformly assessed to Participants for Non-Penny Symbols. Customers would continue to receive favorable pricing as compared to other market participants because Customer liquidity enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Customer liquidity benefits all market participants by providing more trading opportunities which attracts market makers. An increase in the activity of these market participants (particularly in response to pricing) in turn facilitates tighter spreads which may cause an additional corresponding increase in order flow from other market participants.

BX Options Market Makers

With this proposal, BX Options Market Makers would receive no Non-Penny Symbol Rebate to Add Liquidity or Non-Penny Rebate to Remove Liquidity, as is the case today under Select Symbols as well. With this proposal, BX Options Market Makers would pay a $0.50 per contract Non-Penny Symbol Fee to Add Liquidity when trading against a BX Options Market Maker, Non-Customer or Firm and a $0.95 per contract Non-Penny Symbol Fee to Add Liquidity when trading against a Customer. Currently, BX Options Market Makers pay a Fee to Add Liquidity in Select Symbols when trading against a Non-Customer, BX Options Market Maker or Firm which ranges from $0.14 to $0.00 per contract [57] and BX Options Market Makers pay a Fee to Add Liquidity in Select Symbols when trading against a Customer which ranges from $0.44 to $0.29 per contract.[58] Despite the fact that the Non-Penny Symbol Fees to Add Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. With this proposal, BX Options Market Makers would pay a Non-Penny Symbol Fee to Remove Liquidity when trading against a Customer which ranges from $0.89 to $0.60 per contract.[59] This fee would be higher than the current BX Options Market Makers pay a Fee to Remove Liquidity in Select Symbols when trading against a Customer which ranges from $0.42 to $0.25 per contract.[60] Also, with this proposal, BX Options Market Makers would pay a Non-Penny Symbol Fee to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker, or Firm of $0.89 per contract, regardless of the tier.[61] This fee would be higher than the current BX Options Market Makers pay a Fee to Remove Liquidity in Select Symbols when trading against a Firm, Non-Customer, or BX Options Market Maker of $0.46 per contract. Despite the fact that the Non-Penny Symbol Fees to Remove Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants.

All pricing would be uniformly assessed to Participants for Non-Penny Symbols. BX Options Market Makers add value through continuous quoting [62] and are subject to additional requirements and obligations [63] that other market participants are not. Incentivizing Market Makers to provide greater liquidity benefits all market participants through the quality of order interaction.

Non-Customers

With this proposal, Non-Customers would receive no Non-Penny Symbol Rebate to Add Liquidity or Non-Penny Symbol Rebate to Remove Liquidity as is the case today for Select Symbols. With this proposal, Non-Customers would pay an increased Non-Penny Symbol Fee to Add Liquidity of $0.98 per contract as compared to the current Non-Customer Fee to Add Liquidity in Select Symbols of $0.46 per contract, regardless of counterparty. Also, with this proposal, Non-Customers would pay an increased Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract as compared to the current Non-Customer Fee to Remove Liquidity in Select Symbols of $0.46 per contract, regardless of counterparty. Despite the fact that the Non-Penny Symbol Fees to Add and Remove Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. All pricing would be uniformly assessed to Participants for Non-Penny Symbols.

Firms

With this proposal, Firms would receive no Non-Penny Symbol Rebate to Add Liquidity or Non-Penny Symbol Rebate to Remove Liquidity as is the

[57] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.14 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.10 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.04 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay no Select Symbol Fee to Add Liquidity in Tier 4.

[58] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.44 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.44 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Add Liquidity of $0.40 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay a Select Symbol Fee to Add Liquidity of $0.29 per contract in Tier 4.

[59] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.60 per contract in Tier 3.

[60] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.42 per contract in Tier 1. Participants that executes 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.42 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month pay a Select Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 3. Participants that execute greater than 10,000 PRISM Agency Contracts per month; or Participant executes BX Options Market Maker volume of 0.30% or more of total industry customer equity and ETF options ADV per month pay a Select Symbol Fee to Remove Liquidity of $0.25 per contract in Tier 4.

[61] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract in Tier 3.

[62] *See* Options 2, Section 5.

[63] *See* Options 2, Section 4.

case for Select Symbols. With this proposal, Firms would pay an increased Non-Penny Symbol Fee to Add Liquidity of $0.98 per contract as compared to the current Firm Fee to Add Liquidity in Select Symbols of $0.37 per contract, regardless of counterparty. With this proposal, Firms would pay an increased Non-Penny Symbol Fee to Remove Liquidity of $0.89 per contract as compared to the current Firm Fee to Remove Liquidity in Select Symbols of $0.37 per contract, regardless of counterparty. Despite the fact that the Non-Penny Symbol Fees to Add and Remove Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. All pricing would be uniformly assessed to Participants for Non-Penny Symbols.

SPY

With respect to the impact on pricing for SPY that would be priced as a Penny Symbol with this proposal, the Exchange believes that its proposal is reasonable, equitable and not unfairly discriminatory for the reasons which follow.

Customers

With this proposal Customers would receive higher Penny Symbol Rebates to Add Liquidity when trading against a Non-Customer, BX Options Market Maker or Firm which range from $0.00 to $0.20 per contract.[64] Today, Customers receive no rebate when add liquidity in SPY when trading against a Non-Customer, BX Options Market Maker or Firm. The Exchange believes that these increased rebates will incentivize Participants to bring Customer liquidity to BX. With this proposal, Customers would receive a lower Penny Symbol Rebate to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker, Customer or Firm which ranges from $0.00 to $0.35 per contract.[65] Today, Customers receive a SPY Rebate to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker, Customer or Firm which ranges from $0.01 to $0.52 per contracts when trading against a Non-Customer, BX Options Market Maker, Customer or Firm.[66] Despite the fact that the Penny Symbol Rebates to Remove Liquidity in will be lower, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. With this proposal, Customers would pay an increased Penny Symbol Fee to Add Liquidity when trading against a Customer of $0.39 per contract, regardless of the tier,[67] as compared to the current Customer SPY Fees to Add Liquidity of $0.38 per contract when contra to another Customer. Despite the fact that the Penny Symbol Fees to Add Liquidity when contra to another Customer will be higher than the SPY Fee to Add Liquidity when contra to a Customer, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. With this proposal, t will be no Fee to Add Liquidity when contra to Firm, BX Options Market Maker or Non Customer, as is the case today. With this proposal, Customers would not pay a Penny Symbol Fee to Remove Liquidity as is the case for SPY today.

All pricing would be uniformly assessed to Participants for Penny Symbols. Customers would continue to receive favorable pricing as compared to other market participants because Customer liquidity enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Customer liquidity benefits all market participants by providing more trading opportunities which attracts market makers. An increase in the activity of these market participants (particularly in response to pricing) in turn facilitates tighter spreads that may cause an additional corresponding increase in order flow from other market participants.

BX Options Market Makers

With this proposal, BX Options Market Makers would receive a new Penny Symbol Rebate to Add Liquidity of $0.10 per contract only when the BX Options Market Maker is contra to a Non-Customer, Firm, or BX Options Market Maker, while currently BX Options Market Makers receive no rebates in SPY. This new rebate will incentivize Participants to bring liquidity to BX. With this proposal, BX Options Market Makers would receive no Penny Symbol Rebate to Remove Liquidity, as is the case today for SPY. With this proposal, BX Options Market Makers would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity only when the BX Options Market Maker is contra to a Customer which is the same as the current BX Options Market Makers SPY Fee to Add Liquidity of $0.39 per contract when trading against a Customer. With this proposal, the Exchange would not assess a Penny Symbol Fee to Add Liquidity when trading against a Firm, BX Options Market Maker or Non Customer as compared to today, where a BX Options Market Maker pays a SPY Fee to Add Liquidity of $0.14 per contract when trading against a Firm, BX Options Market Maker or Non Customer. The removal of this fee should incentivize BX Participants to send order flow to BX.

With this proposal, BX Options Market Makers would pay a Penny Symbol Fee to Remove Liquidity when trading against a Customer which ranges from $0.39 to $0.30 per contract,[68] as compared to the current BX Options

[64] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Penny Symbol Rebate to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.10 per contract Penny Symbol Rebate to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would receive a $0.20 per contract Penny Symbol Rebate to Add Liquidity in Tier 3.

[65] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would receive no Penny Symbol Rebate to Remove Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would receive a $0.25 per contract Penny Symbol Rebate to Remove Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month will would receive a $0.35 per contract Penny Symbol Rebate to Remove Liquidity in Tier 3.

[66] Tier 1 Participants that remove less than 500 SPY Options contracts per day in the customer range receive a $0.01 per contract rebate. Tier 2 Participants that remove 500 to not more than 999 SPY Options contracts per day in the customer range receive a $0.10 per contract rebate. Tier 3 Participants that removes 1000 to not more than 1999 SPY Options contracts per day in the customer range receive a $0.35 per contract rebate. Tier 4 Participants that remove 2000 to not more than 3999 SPY Options contracts per day in the customer range receive a $0.43 per contract rebate. Tier 5 Participants that remove more than 3999 SPY Options contracts per day in the customer range receive a $0.52 per contract rebate.

[67] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a $0.39 per contract Penny Symbol Fee to Add Liquidity in Tier 3.

[68] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.39 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.30 per contract in Tier 3.

Market Maker Fee to Remove Liquidity in SPY Options of $0.39 per contract when trading with Customer. With this proposal, the fee will be lower in certain cases depending on the volume tier achieved and may attract higher volume to the Exchange in an effort to obtain the lower fee. With this proposal, BX Options Market Makers would pay an increased Penny Symbol Fee to Remove Liquidity when trading against a Non-Customer, BX Options Market Maker or Firm of $0.46 per contract, regardless of the tier,[69] as compared to the current BX Options Market Makers pay a SPY Fee to Remove Liquidity of $0.44 per contract when trading against a Firm, Non-Customer, or BX Options Market Maker. Despite the fact that the Penny Symbol Fee to Remove Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants.

All pricing would be uniformly assessed to Participants for Penny Symbols. BX Options Market Makers add value through continuous quoting[70] and are subject to additional requirements and obligations[71] that other market participants are not. Incentivizing Market Makers to provide greater liquidity benefits all market participants through the quality of order interaction.

Non-Customers

With this proposal, Non-Customers would receive no Penny Symbol Rebate to Add Liquidity and no Penny Symbol Rebate to Remove Liquidity, as is the case today for SPY. With this proposal, Non-Customers would pay an increased Penny Symbol Fee to Add Liquidity of $0.45 per contract as compared to the current Non-Customers SPY Fee to Add Liquidity of $0.44 per contract, regardless of counterparty. With this proposal, Non-Customers would pay an increased Penny Symbol Fee to Remove Liquidity of $0.46 per contract as compared to the current Non-Customers SPY Fee to Remove Liquidity of $0.44 per contract, regardless of counterparty. Despite the fact that the Penny Symbol Fees to Add and Remove Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. All pricing would be uniformly assessed to Participants for Penny Symbols.

Firms

With this proposal, Firms would receive no Penny Symbol Rebate to Add Liquidity and no Penny Symbol Rebate to Remove Liquidity, as is the case today with SPY. With this proposal, Firms would pay an increased Penny Symbol Fee to Add Liquidity of $0.45 per contract as compared to the current Firm SPY Fee to Add Liquidity of $0.41 per contract, regardless of counterparty. With this proposal, Firms would pay an increased Penny Symbol Fee to Remove Liquidity of $0.46 per contract as compared to the current Firm SPY Fee to Remove Liquidity of $0.41 per contract, regardless of counterparty. Despite the fact that the Penny Symbol Fees to Add and Remove Liquidity will be higher, the Exchange believes that the fees remain competitive and will continue to attract order flow to BX to the benefit of all market participants. All pricing would be uniformly assessed to Participants for Penny Symbols.

Technical Amendments

The Exchange's proposal to make technical amendments to footnote 4 and renumber current footnote within Options 7, Section 2, and remove ''(excluding Select Symbols Options)'' from Options 7, Section 2(1) are reasonable, equitable and not unfairly discriminatory.

Options 7, Section 3

The Exchange's proposal to amend Options 7, Section 3, ''BX Options Market—Ports and other Services,'' is reasonable, equitable and not unfairly discriminatory as the rule text is obsolete in that the text reflects timeframes which have passed.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants with another choice of where to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intra-market Competition

The proposed amendments do not impose an undue burden on intra-market competition.

Options 7, Section 2

Select Symbols To Be Priced as Penny Symbols

With respect to pricing certain Select Symbols,[72] which would be priced as Penny Symbols with this proposal, the Exchange believes that its proposal does not impose an undue burden on competition.

All pricing would be uniformly assessed to Participants for Penny Symbols. Customers would continue to receive favorable pricing as compared to other market participants because Customer liquidity enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Customer liquidity benefits all market participants by providing more trading opportunities which attracts market makers. An increase in the activity of these market participants (particularly in response to pricing) in turn facilitates tighter spreads which may cause an additional corresponding increase in order flow from other market participants. BX Options Market Makers add value through continuous quoting[73] and are subject to additional requirements and obligations[74] that other market participants are not. Incentivizing Market Makers to provide greater liquidity benefits all market

[69] Participants that executes less than 0.05% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 1. Participants that execute 0.05% to less than 0.15% of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 2. Participants that execute 0.15% or more of total industry customer equity and ETF option ADV contracts per month would pay a Penny Symbol Fee to Remove Liquidity of $0.46 per contract in Tier 3.

[70] *See* Options 2, Section 5.

[71] *See* Options 2, Section 4.

[72] Among the Select Symbols noted within Options 7, Section 2, the following are Penny Symbols: ASHR, DIA, EEM, EFA, EWJ, EWW, EWY, EWZ, FAS, FXI, GDX, GLD, HYG, IWM, IYR, KRE, OIH, QQQ, RSX, SDS, SLV, SSO, TBT, TLT, TNA, UNG, USO, UUP, UVXY, VXX, XLB, XLE, XLF, XLI, XLK, XLP, XLU, XLV, XLY, XME, XOP, and XRT.

[73] *See* Options 2, Section 5.

[74] *See* Options 2, Section 4.

participants through the quality of order interaction.

Select Symbols to be Priced as Non-Penny Symbols

With respect to pricing for Select Symbols which would be priced as Non-Penny Symbols (DXJ, EWT, FAZ, FXE, FXP, QID, QLD, SKF, SRS, SSO, TZA, URE, UYG, and XHB) with this proposal, the Exchange believes that its proposal does not impose an undue burden on competition.

All pricing would be uniformly assessed to Participants for Non-Penny Symbols. Customers would continue to receive favorable pricing as compared to other market participants because Customer liquidity enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Customer liquidity benefits all market participants by providing more trading opportunities which attracts market makers. An increase in the activity of these market participants (particularly in response to pricing) in turn facilitates tighter spreads which may cause an additional corresponding increase in order flow from other market participants. All pricing would be uniformly assessed to Participants for Non-Penny Symbols. BX Options Market Makers add value through continuous quoting [75] and are subject to additional requirements and obligations [76] that other market participants are not. Incentivizing Market Makers to provide greater liquidity benefits all market participants through the quality of order interaction.

SPY

With respect to the impact on pricing for SPY which would be priced as a Penny Symbol with this proposal, the Exchange believes that its proposal does not impose an undue burden on competition.

All pricing would be uniformly assessed to Participants for Penny Symbols. Customers would continue to receive favorable pricing as compared to other market participants because Customer liquidity enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Customer liquidity benefits all market participants by providing more trading opportunities which attracts market makers. An increase in the activity of these market participants (particularly in response to pricing) in turn facilitates tighter spreads which may cause an additional corresponding increase in order flow from other market participants. BX Options Market Makers add value through continuous quoting [77] and are subject to additional requirements and obligations [78] that other market participants are not. Incentivizing Market Makers to provide greater liquidity benefits all market participants through the quality of order interaction.

Technical Amendments

The Exchange's proposal to make technical amendments to footnote 4 and renumber current footnote within Options 7, Section 2, and remove ''(excluding Select Symbols Options)'' from Options 7, Section 2(1) do not impose an undue burden on competition.

Options 7, Section 3

The Exchange's proposal to amend Options 7, Section 3, ''BX Options Market—Ports and other Services,'' does not impose an undue burden on competition as the rule text is obsolete in that the text reflects timeframes which have passed.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[79]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2020–037 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2020–037. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2020–037 and should be submitted on or before January 8, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[80]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–27838 Filed 12–17–20; 8:45 am]

BILLING CODE 8011–01–P

[75] *See* Options 2, Section 5.

[76] *See* Options 2, Section 4.

[77] *See* Options 2, Section 5.

[78] *See* Options 2, Section 4.

[79] 15 U.S.C. 78s(b)(3)(A)(ii).

[80] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90654; File No. SR–NASDAQ–2020–084]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NOM's Pricing Schedule at Options 7, Section 2 and Options 7, Section 3

December 14, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 1, 2020, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend The NASDAQ Options Market LLC's (''NOM'') Pricing Schedule at Options 7, Section 2, ''Nasdaq Options Market Fees and Rebates'' and Options 7, Section 3, ''Nasdaq Options Market—Ports and Other Services.''

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NOM's Pricing Schedule at Options 7, Section 2, ''Nasdaq Options Market Fees and Rebates'' and Options 7, Section 3, ''Nasdaq Options Market—Ports and Other Services.'' Each change will be described below.

Options 7, Section 2

Today, the Exchange pays certain Rebates to Add Liquidity in Penny Symbols according to the below table.

REBATES TO ADD LIQUIDITY IN PENNY SYMBOLS

	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
Customer [1 8 9 10]	($0.20)	($0.25)	($0.42)	($0.43)	($0.45)	[7]($0.48)
Professional [1 9 10]	($0.25)	($0.42)	($0.43)	($0.45)	($0.48)	
Broker-Dealer	($0.10)	($0.10)	($0.10)	($0.10)	($0.10)	($0.10)
Firm	($0.10)	($0.10)	($0.10)	($0.10)	($0.10)	($0.10)
Non-NOM Market Maker	($0.10)	($0.10)	($0.10)	($0.10)	($0.10)	($0.10)
NOM Market Maker [3]	($0.20)	($0.25)	[4]($0.30)	[4]($0.32)	[11]($0.44)	($0.48)

Specifically, NOM Market Maker Rebates to Add Liquidity in Penny Symbols are paid according to the below tier qualifications.

Monthly Volume

Tier 1: Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of up to 0.10% of total industry customer equity and ETF option average daily volume (''ADV'') contracts per day in a month.

Tier 2: Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.10% to 0.20% of total industry customer equity and ETF option ADV contracts per day in a month.

Tier 3: Participant: (a) Adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.20% to 0.60% of total industry customer equity and ETF option ADV contracts per day in a month: Or (b)(1) transacts in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.70% or more of Consolidated Volume (''CV'') which adds liquidity in the same month on The Nasdaq Stock Market, (2) transacts in Tape B securities through one or more of its Nasdaq Market Center MPIDs that represent 0.18% or more of CV which adds liquidity in the same month on The Nasdaq Stock Market, and (3) executes greater than 0.01% of CV via Market-on- Close/Limit-on-Close (''MOC/LOC'') volume within The Nasdaq Stock Market Closing Cross in the same month.

Tier 4: Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month.

Tier 5: Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month and transacts in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (''CV'') which adds liquidity in the same month on The Nasdaq Stock Market.

Tier 6: Participant: (a)(1) Adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.95% of total industry customer equity and ETF option ADV contracts per day in a month, (2) executes Total Volume of 250,000 or more contracts per day in a month, of which 30,000 or more contracts per day in a month must be removing liquidity, and (3) adds Firm, Broker-Dealer and Non-NOM Market Maker liquidity in Non-Penny Symbols of 10,000 or more contracts per day in a month; or (b)(1) adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 1.50% of total industry customer equity and ETF option ADV contracts per day in a month, and (2) executes Total Volume of 250,000 or more contracts per day in a month, of which 15,000 or more contracts per day in a month must be removing liquidity.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The Exchange proposes to amend Penny Pilot NOM Market Maker Tier 4 which currently provides, ''Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month.'' [3] The Exchange proposes to amend Penny Pilot NOM Market Maker Tier 4 to provide, ''Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% of total industry customer equity and ETF option ADV contracts per day in a month.'' This proposed rule change will not impact NOM's pricing. Today, NOM Market Maker Rebates to Add Liquidity in Penny Symbols are paid per the highest tier achieved.[4] Current Penny Pilot NOM Market Maker Tier 5 requires Participants to add NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month and transact in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (''CV'') which adds liquidity in the same month on The Nasdaq Stock Market in order to achieve a rebate.[5] Therefore, a Participant that adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month volume would qualify for Penny Pilot NOM Market Maker Tier 4 today, and may qualify for Penny Pilot NOM Market Maker Tier 5 if the additional criteria was met. Penny Pilot NOM Market Maker Tier 6 requires, among other things, that a Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.95% of total industry customer equity and ETF option ADV contracts per day in a month.[6]

The Exchange believes that this proposal will bring greater clarity to the Penny Pilot NOM Market Maker tiers as any volume above 0.60% would qualify a Participant for Penny Pilot NOM Market Maker Tier 4, as is the case today unless the Participant qualified for Penny Pilot NOM Market Maker Tiers 5 or 6, as is also the case today. Stating, ''above 0.60%'' within the rule text will make the aforementioned opportunities clearer for all Participants.

Options 7, Section 3

The Exchange proposes to amend Options 7, Section 3, ''Nasdaq Options Market—Ports and Other Services,'' to remove obsolete text which reflects timeframes which have passed.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[8] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed changes to its Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . ..'' [9]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [10]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of sixteen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

Options 7, Section 2

The Exchange's proposal to amend Penny Pilot NOM Market Maker Tier 4 to change the current volume requirement from ''Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month'' to ''Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% of total industry customer equity and ETF option ADV contracts per day in a

[3] Penny Pilot NOM Market Maker Tier 4 pays a rebate of $0.43 per contract to Customers and Professionals, $0.10 per contract to Broker-Dealers, Firms and Non-NOM Market Makers and $0.32 per contract to NOM Market Makers. Further, pursuant to footnote 4, Participants who achieve the NOM Market Maker Tier 3 or Tier 4 Rebate to Add Liquidity will receive $0.40 per contract to add liquidity in the following symbols: AAPL, SPY, QQQ, IWM, and VXX.

[4] *See* note 3 of Options 7, Section 2.

[5] Penny Pilot NOM Market Maker Tier 5 pays a rebate of $0.45 per contract to Customers and Professionals, $0.10 per contract to Broker-Dealers, Firms and Non-NOM Market Makers and $0.44 per contract to NOM Market Makers. Further, pursuant to footnote 11, NOM Participants that qualify for the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Symbols and add NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month, will receive a $0.46 per contract rebate to add liquidity in Penny Symbols as Market Maker in lieu of the Tier 5 rebate.

[6] Penny Pilot NOM Market Maker Tier 6 provides, ''Participant: (a)(1) Adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.95% of total industry customer equity and ETF option ADV contracts per day in a month, (2) executes Total Volume of 250,000 or more contracts per day in a month, of which 30,000 or more contracts per day in a month must be removing liquidity, and (3) adds Firm, Broker-Dealer and Non-NOM Market Maker liquidity in Non-Penny Symbols of 10,000 or more contracts per day in a month; or (b)(1) adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 1.50% of total industry customer equity and ETF option ADV contracts per day in a month, and (2) executes Total Volume of 250,000 or more contracts per day in a month, of which 15,000 or more contracts per day in a month must be removing liquidity.''

[7] 15 U.S.C. 78 f(b).

[8] 15 U.S.C. 78f(b)(4) and (5).

[9] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (DC Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[10] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

month,'' is reasonable. This proposed rule change will not impact NOM's pricing. Today, NOM Market Maker Rebates to Add Liquidity in Penny Symbols are paid per the highest tier achieved.[11] Current Penny Pilot NOM Market Maker Tier 5 requires Participants to add NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month and transact in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of CV which adds liquidity in the same month on The Nasdaq Stock Market in order to achieve a rebate.[12] Therefore, a Participant that adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month volume would qualify for Penny Pilot NOM Market Maker Tier 4 today, and may qualify for Penny Pilot NOM Market Maker Tier 5 if the additional criteria was met. Penny Pilot NOM Market Maker Tier 6 requires, among other things, that a Participants adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.95% of total industry customer equity and ETF option ADV contracts per day in a month.[13] This proposal will make clear that any volume above 0.60% would qualify a Participant for Penny Pilot NOM Market Maker Tier 4, as is the case today, unless the Participant qualified for Penny Pilot NOM Market Maker Tiers 5 or 6, as is also the case today. Any NOM Market Maker may qualify for a NOM Market Maker Penny Pilot rebate provided the requisite criteria has been met.

The Exchange's proposal to amend Penny Pilot NOM Market Maker Tier 4 to change the current volume requirement from ''Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month'' to ''Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% of total industry customer equity and ETF option ADV contracts per day in a month,'' is equitable and not unfairly discriminatory as all NOM Market Makers may uniformly qualify for these NOM Market Maker Penny Pilot rebates, provided they submit the requisite qualifying criteria. NOM Market Makers add value through continuous quoting[14] and are subject to additional requirements and obligations[15] that other market participants are not. Incentivizing Market Makers to provide greater liquidity benefits all market participants through the quality of order interaction.

Options 7, Section 3

The Exchange's proposal to amend Options 7, Section 3, ''Nasdaq Options Market—Ports and Other Services,'' is reasonable, equitable and not unfairly discriminatory as the rule text is obsolete in that the text reflects timeframes which have passed.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants another choice of where to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intra-Market Competition

The proposed amendments do not impose an undue burden on intra-market competition.

The Exchange's proposal to amend Penny Pilot NOM Market Maker Tier 4 to change the current volume requirement from ''Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month'' to ''Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% of total industry customer equity and ETF option ADV contracts per day in a month,'' does not impose an undue burden on competition as all NOM Market Makers may uniformly qualify for these NOM Market Maker Penny Pilot rebates, provided they submit the requisite qualifying criteria. NOM Market Makers add value through continuous quoting[16] and are subject to additional requirements and obligations[17] that other market participants are not. Incentivizing Market Makers to provide greater liquidity benefits all market participants through the quality of order interaction.

Options 7, Section 3

The Exchange's proposal to amend Options 7, Section 3, ''Nasdaq Options Market—Ports and Other Services,'' does not impose an undue burden on competition as the rule text is obsolete in that the text reflects timeframes which have passed.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Uecessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

[11] *See* note 3 of Options 7, Section 2.

[12] *See* note 5.

[13] *See* note 6.

[14] *See* Options 2, Section 5.

[15] *See* Options 2, Section 4.

[16] *See* Options 2, Section 5.

[17] *See* Options 2, Section 4.

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–NASDAQ–2020–084 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number *SR–NASDAQ–2020–084.* This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number *SR–NASDAQ–2020–084* and should be submitted on or before January 8, 2021.

For the Commission, by the Division of Trading and Markets, pursuant todelegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–27837 Filed 12–17–20; 8:45 am]

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[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90660; File No. SR–MEMX–2020–15]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the Exchange's Fee Schedule

December 14, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 4, 2020, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the fee schedule applicable to Members[3] pursuant to Exchange Rules 15.1(a) and (c) in order to modify its pricing for transactions in securities priced below $1.00 per share that are executed on the Exchange. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify its fee schedule to modify the fees and rebates applicable to transactions in securities priced below $1.00 per share (''Sub-Dollar Securities'') that are executed on the Exchange, effective as of December 4, 2020.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 16% of the total market share of executed volume of equities trading.[4] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow.

The Exchange recently adopted a proposal[5] to charge a standard fee of 0.30% of the total dollar value of any transaction in Sub-Dollar Securities that removes liquidity from the Exchange (''Removed Sub-Dollar Volume'').[6] The Exchange also adopted pricing to provide a standard rebate of 0.30% of the total dollar value of any transaction in Sub-Dollar Securities that adds liquidity, displayed or non-displayed, to the Exchange (''Added Sub-Dollar Volume'').[7]

The current rebate for executions of Added Sub-Dollar Volume was adopted to increase order flow in Sub-Dollar Securities to the Exchange by incentivizing Members to increase the liquidity-providing orders in Sub-Dollar Securities they submit to the Exchange, which would support price discovery on the Exchange and provide additional liquidity for incoming orders. The current fee for executions of Removed Sub-Dollar Volume, in turn, was intended to be a direct offset of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] *See* Exchange Rule 1.5(p).

[4] Market share percentage calculated as of December 3, 2020. The Exchange receives and processes data made available through consolidated data feeds (*i.e.,* CTS and UTDF).

[5] *See* Securities Exchange Act Release No. 90555 (December 3, 2020) (SR–MEMX–2020–13) [sic].

[6] This pricing is referred to by the Exchange on the fee schedule under the existing description ''Removed volume from MEMX Book'' with a fee code of ''RB'' or ''RrB'', as applicable, assigned by the Exchange.

[7] This pricing is referred to by the Exchange on the fee schedule under ''Added displayed volume'', ''Added non-displayed volume'' or ''Added displayed volume, Retail Order'', as applicable, with a fee code of ''BB'', ''BrB'', ''DB'', ''DrB'', ''JB'', ''JrB'', ''HB'', ''HrB'', ''MB'' or ''MrB'', as applicable, assigned by the Exchange.

rebate provided for Added Sub-Dollar Volume so that the Exchange could remain revenue neutral with respect to such transactions while attempting to compete with other venues to attract this order flow. While the pricing adopted by the Exchange was successful in attracting liquidity, based on activity that has occurred on the Exchange in the first several days of such pricing, the Exchange believes that a rebate of 0.30% of the total dollar value of any transaction might provide an out-sized incentive to trade certain high-volume Sub-Dollar Securities, particularly those with a lower bid-ask spread. Accordingly, the Exchange is proposing to modify its rebate for Added Sub-Dollar Volume to provide a rebate of 0.05% of the total dollar value of any transaction. The Exchange still believes that providing a rebate is important to attract displayed liquidity in Added Sub-Dollar Volume but is reducing the amount of the rebate in order to further analyze the optimal way to attract on-exchange order flow in Sub-Dollar Securities. In connection with this change, the Exchange proposes to maintain a revenue-neutral fee structure for executions in Sub-Dollar Securities, and thus proposes to reduce the fee to for Removed Sub-Dollar Volume to 0.05% of the total dollar value of any transaction.

The proposed pricing for Removed Sub-Dollar Volume and Added Sub-Dollar Volume would only apply to transactions that are executed on the Exchange, and as such there would continue to be no fee charged or rebate provided for transactions in Sub-Dollar Securities that are routed to and executed at another market center. The proposed rule change does not include different fees or rebates for Sub-Dollar Securities that depend on the amount of orders submitted to, and/or transactions executed on or through, the Exchange. Accordingly, all fees and rebates described above are applicable to all Members, regardless of the overall volume of a Member's trading activities on the Exchange.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) of the Act,[8] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[9] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers.

As discussed above, the Exchange operates in a highly fragmented and competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient, and the Exchange represents only a small percentage of the overall market. The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [10]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, including with respect to transactions in Sub-Dollar Securities, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposed rule change reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members and investors. The Exchange notes that the proposal does not include different fees or rebates for transactions in Sub-Dollar Securities depending on the amount of orders submitted to, and/or transactions executed on or through, the Exchange. Accordingly, the proposed pricing structure is applicable to all Members, regardless of the overall volume of a Member's trading activities on the Exchange.

The Exchange believes that the proposed changes with respect to pricing for executions of transactions in Sub-Dollar Securities would continue to incentivize submission of additional liquidity in Sub-Dollar Securities to the Exchange through the proposed rebate of 0.05% of the total dollar value of any Added Sub-Dollar Volume transactions, thereby promoting price discovery and transparency, and enhancing order execution opportunities for all Members. The Exchange believes that the proposed rebate for Added Sub-Dollar Volume is reasonable because it would continue to incentivize Members to direct order flow in Sub-Dollar Securities to the Exchange. The Exchange notes that at least one other exchange provides tiered rebates for liquidity-adding transactions in Sub-Dollar Securities equal to and better than the proposed rebate.[11]

The Exchange also believes that the proposed fee for Removed Sub-Dollar Volume is reasonable because it is in lower than [12] or within the range of [13] fees charged by other exchanges for liquidity-removing transactions in Sub-Dollar Securities. The Exchange believes that, given the competitive environment in which the Exchange currently operates, the proposed pricing structure,

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4) and (5).

[10] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[11] *See* the NYSE Arca, Inc. (''NYSE Arca'') equities trading fee schedule on its public website (available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf*), which reflects a standard rebate of $0.00004 per share for liquidity-adding transactions in securities priced below $1.00 per share; the NYSE Arca equities trading fee schedule also permits participants to qualify for tiered rebates reflected as a percentage of the total dollar value of such transactions enabling participants to receive a rebate of 0.05% of the total dollar value per transaction (*i.e.,* the same rebate proposed by the Exchange) or higher rebates ranging from 0.10% to 0.15% of the total dollar value per transaction.

[12] *See, e.g.,* the Cboe EDGX Exchange, Inc. equities trading fee schedule on its public website (available at *https://markets.cboe.com/us/equities/membership/fee_schedule/edgx/*), which reflects a fee of 0.30% of the total dollar value of the transaction for liquidity-removing transactions in securities priced below $1.00 per share; the NYSE Arca equities trading fee schedule on its public website (available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf*), which reflects a fee of 0.295% of the total dollar value of the transaction for liquidity-taking transactions in securities priced below $1.00 per share.

[13] *See, e.g.,* the Cboe BYX Exchange, Inc. equities trading fee schedule on its public website (available at *https://markets.cboe.com/us/equities/membership/fee_schedule/byx/*), which reflects a fee of 0.10% of the total dollar value of the transaction for liquidity-removing transactions in securities priced below $1.00 per share; the Cboe EDGA Exchange, Inc. equities trading fee schedule on its public website (available at *https://markets.cboe.com/us/equities/membership/fee_schedule/edga/*), which reflects no fee or rebate for liquidity-removing transactions in securities priced below $1.00 per share; the NYSE National, Inc. equities trading fee schedule on its public website (available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf*), which reflects no fee or rebate for liquidity-removing transactions in securities priced below $1.00 per share.

with an offsetting fee and rebate with respect to executions of transactions in Sub-Dollar Securities, is a reasonable attempt to encourage liquidity in Sub-Dollar Securities on the Exchange while remaining revenue neutral with respect to such transactions.

The Exchange also believes that the proposed fee and rebate structure applicable to executions of transactions in Sub-Dollar Securities is equitably allocated and not unfairly discriminatory because it applies equally to all Members and is reasonably related to the value of the Exchange's market quality associated with higher volume. A number of Members currently transact in Sub-Dollar Securities and they, along with additional Members that choose to direct order flow in Sub-Dollar Securities to the Exchange, would all qualify for the proposed fee and rebate. The Exchange still believes that providing a rebate is important to attract displayed liquidity in Added Sub-Dollar Volume but is reducing the amount of the rebate in order to further analyze the optimal way to attract on-exchange order flow in Sub-Dollar Securities. The Exchange believes that maintaining competitive pricing for transactions in Sub-Dollar Securities would benefit all investors by deepening the Exchange's liquidity pool, which would support price discovery, promote market transparency and improve investor protection, further rendering the proposed changes reasonable and equitable.

In conclusion, the Exchange also submits that its proposed fee structure satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act for the reasons discussed above in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing, including with respect to transactions in Sub-Dollar Securities, is subject to significant competitive forces, and that the proposed fees and rebates described herein are appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change would encourage the continued submission of orders in Sub-Dollar Securities to the Exchange, thereby promoting market depth, enhanced execution opportunities, as well as price discovery and transparency for all Members. Furthermore, the Exchange believes that the proposed changes would allow the Exchange to continue to compete with other execution venues by providing competitive pricing for transactions in Sub-Dollar Securities, thereby making it a desirable destination venue for its customers. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [14]

Intramarket Competition

The Exchange believes that the proposed changes would continue to incentivize market participants to direct order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all Members. The proposed fees and rebates for transactions in Sub-Dollar Securities would be available to all market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange. As such, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow to, including 15 other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than approximately 16% of the total market share of executed volume of equities trading. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, including with respect to transactions in Sub-Dollar Securities, and market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As described above, the proposed changes are competitive proposals through which the Exchange is seeking to encourage certain order flow to be sent to the Exchange.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. SEC, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . ..''.[16] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[14] *See supra* note 10.

[15] *See supra* note 10.

[16] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (DC Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [17] and Rule 19b–4(f)(2) [18] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MEMX–2020–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2020–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2020–15 and should be submitted on or before January 8, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–27841 Filed 12–17–20; 8:45 am]

BILLING CODE 8011–01–P

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 240.19b–4(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90658; File No. SR–CBOE–2020–055]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 3, To Amend Rule 5.24

December 14, 2020.

I. Introduction

On June 12, 2020, Cboe Exchange, Inc. (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt Rule 5.24(e)(3) to make available an audio and video communication program to serve as a ''virtual trading floor'' in one or more option classes during regular trading hours if the physical trading floor is inoperable. The proposed rule change was published for comment in the **Federal Register** on June 29, 2020.[3] On July 23, 2020, the Exchange filed Amendment No. 1 to the proposed rule change.[4] On August 10, 2020, the Commission designated a longer period for Commission action on the proposed rule change, until September 27, 2020.[5] On August 21, 2020, the Exchange filed Amendment No. 2 to the proposed rule change, which replaced and superseded the proposed rule change, as modified by Amendment No. 1.[6] On September 21, 2020, the Commission published notice of Amendment No. 2 to the proposed rule change and instituted proceedings to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 2.[7] On November 2, 2020, the Exchange filed Amendment No. 3 to the proposed rule change, which replaced and superseded the proposed rule change, as modified by Amendment No. 2.[8] The Commission has received one comment letter on the proposal.[9] The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89131 (June 29, 2020), 85 FR 38951 (''Notice'').

[4] In Amendment No. 1, the Exchange revised the proposal to: (i) Clarify that if the virtual trading floor is available in a class, the temporary rules in CBOE Rule 5.24(e)(1) will not apply to that class and (ii) permit clerks to access the virtual trading floor. Amendment No. 1 is available at: *https://www.sec.gov/comments/sr-cboe-2020-055/srcboe2020055-7470763-221281.pdf.*

[5] *See* Securities Exchange Act Release No. 89514 (August 10, 2020), 85 FR 49696 (August 14, 2020).

[6] In Amendment No. 2, the Exchange revised the proposal to: (i) Eliminate access to the virtual trading floor when the physical trading floor is operating in a modified state; (ii) provide additional description of several aspects of the proposal, including access to the virtual trading floor, recordkeeping of all chats in the virtual trading floor, regulatory surveillance of the virtual trading floor; and (iii) make technical and conforming changes. Amendment No. 2 is available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-055/srcboe2020055-7741240-223109.pdf.*

[7] *See* Securities Exchange Act Release No. 89931 (September 21, 2020), 85 FR 60504 (September 25, 2020).

[8] In Amendment No. 3, the Exchange revised the proposal to: (i) Provide additional description on several aspects of the proposal, including operation of the multiple ''zones'' in the virtual trading floor, interaction of Floor Brokers and Maker Makers in the virtual trading floor, distribution and use of PAR workstations for purposes of participating in the virtual trading floor, market participant outreach and testing of the virtual trading floor, use of chat functionality in the virtual trading floor, regulatory surveillance of the virtual trading floor; and (ii) make technical and conforming changes. Amendment No. 3 is available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-055/srcboe2020055-7967230-225008.pdf.*

[9] *See* letter to Secretary, Commission, from Kevin Kennedy, Senior Vice President, North American Markets, Nasdaq, dated July 10, 2020, *available at https://www.sec.gov/comments/sr-cboe-2020-055/srcboe2020055-7409704-219196.pdf* (''Nasdaq Letter''). The Nasdaq Letter expressed support for CBOE's proposal as described in the Notice, but raised questions about whether options classes

Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 3, from interested persons and is approving the proposed rule change, as modified by Amendment No. 3, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 3

Rule 5.24(e) currently provides that if the Exchange trading floor becomes inoperable, the Exchange will continue to operate in a screen-based only environment using a floorless configuration of the system that is operational while the trading floor facility is inoperable. The Exchange would operate using that configuration only until the Exchange's trading floor facility became operational.[10] Open outcry on the physical trading floor would not be available in the event the trading floor becomes inoperable.[11] In the event that the trading floor becomes inoperable, CBOE Rule 5.24(e)(1) provides that trading will be conducted pursuant to all applicable system rules, except that open outcry rules would not be in force, including but not limited to the rules (or applicable portions) in Chapter 5, Section G,[12] and that all non-trading rules of the Exchange would continue to apply.[13]

On March 16, 2020, the Exchange suspended open outcry trading to help prevent the spread of COVID–19.[14] The Exchange operated in an all-electronic configuration until it reopened its trading floor on June 15, 2020, at which time the Exchange returned to operating as a hybrid exchange with electronic and open outcry trading.[15] However, given the uncertainty related to the ongoing pandemic, which includes the possibility of the Exchange having to close its trading floor again, and given the possibility that the Exchange's trading floor may be inoperable for other reasons in the future, the Exchange now has proposed to adopt Rule 5.24(e)(3) to permit it to make available an audio and video communication program to serve as a ''virtual trading floor'' in one or more option classes [16] if the physical trading floor is inoperable. The Exchange represents that if it were to determine to use the virtual trading floor in a more permanent manner for reasons other than business continuity purposes, the Exchange would submit a separate rule filing to the Commission.[17]

In the program, the Exchange would create ''virtual trading pits,'' in each of which the Exchange would determine which options class(es) would be available for trading.[18] TPHs would access virtual trading pits via ''zones.'' [19] Multiple classes may trade in a single virtual trading pit, available for trading in a single zone.[20] The Exchange may determine to divide a virtual trading pit for a single class into multiple zones given the number of TPHs generally present in the trading pit for that class on the physical trading floor.[21] The Exchange will assign each Floor Broker to a zone, and each Market-Maker may determine in which zone it will be present.[22] In each zone, the Exchange will make visible an electronic blotter containing a running list of unexecuted orders that have been represented by Floor Brokers in that zone.[23] The Exchange believes that the proposed configuration of the virtual trading pit is a practical replication of the structure of the physical trading floor that will allow market participants to interact in nearly the same manner as they do on the physical trading floor.[24]

In a virtual trading pit, each TPH authorized to access the virtual trading floor (as described below) that enters the virtual trading pit would be visible to all other TPHs in that virtual trading pit.[25] Additionally, all TPHs in a virtual trading pit may speak to each other through the proposed communication program.[26] The Exchange states that this will provide the same communication capabilities TPHs generally have on the physical trading floor so that they may conduct open outcry trading on the virtual trading floor in the same manner as they do on the physical trading floor.[27]

Proposed Rule 5.24(e)(3) states that if the Exchange makes a virtual trading floor available in a class, the rules in Rule 5.24(e)(1) will not apply to that class.[28] All rules related to open outcry trading, including those in Chapter 5, Section G,[29] will apply to open outcry trading on the virtual trading floor in the same manner as they apply to open outcry trading on the physical trading floor, except as the context otherwise requires and as set forth in proposed subparagraph (e)(3).[30] Proposed subparagraph (e)(3)(A) lists certain terms in the rules related to open outcry trading on the physical trading floor that would be deemed to refer to corresponding terms related to open outcry trading on the virtual trading floor. Specifically:

- References in the rules to the ''floor,'' ''trading floor,'' and ''Exchange floor'' (and any other terms with the same meaning) will be deemed to refer to the ''virtual trading floor.''

should be able to trade in both virtual and floor-based trading environments, whether the virtual trading floor should require the presence of a minimum number of Market-Makers to ensure liquidity, and whether access to the virtual trading floor is limited to current members on CBOE's floor. The description in the next section of the proposed rule change, as modified by Amendment No. 3, addresses the questions raised by the Nasdaq Letter by explaining that: (i) The proposal only allows access to the virtual trading floor when the physical trading floor is inoperable, (ii) there is no minimum number of Market-Makers required to be present on the virtual trading floor, consistent with the current operation on the physical trading floor, and (iii) current and future Trading Permit Holders (''TPHs'') may be authorized to receive access to the virtual trading floor.

[10] *See* CBOE Rule 5.24(e).

[11] *See id.*

[12] Chapter 5, Section G of the Exchange's rulebook sets forth the rules and procedures for manual order handling and open outcry trading on the Exchange.

[13] *See* CBOE Rule 5.24(e)(1). The Exchange recently adopted several rule changes that would apply during a time in which the trading floor in inoperable, which are effective until December 31, 2020. *See, e.g.,* Securities Exchange Act Release Nos. 88386 (March 13, 2020), 85 FR 15823 (March 19, 2020) (SR–CBOE–2020–019); 88447 (March 20, 2020) (SR–CBOE–2020–023); 88490 (March 26, 2020), 85 FR 18318 (April 1, 2020) (SR–CBOE–2020–026); 88530 (March 31, 2020), 85 FR 19182 (April 6, 2020) (SR–CBOE–2020–031); 88886 (May 15, 2020), 85 FR 31008 (May 21, 2020) (SR–CBOE–2020–047); 89307 (July 14, 2020), 85 FR 43938 (July 20, 2020) (SR–CBOE–2020–066); 89789 (September 8, 2020), 85 FR 56658 (September 14, 2020) (SR–CBOE–2020–081); and 90174 (October 14,2020), 85 FR 66617 (October 20, 2020) (SR–CBOE–2020–092).

[14] *See* Amendment No. 3, *supra* note 8, at 5.

[15] *See id.*

[16] Similar to open outcry trading on the physical trading floor, open outcry trading on the virtual trading floor will be available only during Regular Trading Hours. *See* proposed CBOE Rule 5.24(e)(3).

[17] *See* Amendment No. 3, *supra* note 8, at 7, n.7.

[18] The Exchange states that this is similar to the Exchange's authority with respect to open outcry trading on the physical trading floor. *See id.* at 7.

[19] *See* proposed CBOE Rule 5.24(e)(3)(D). A ''zone'' is a virtual room within the communication program in which a subset of participants on the virtual trading floor will be visible. *See* Amendment No. 3, *supra* note 8, at 7, n.9.

[20] *See* proposed CBOE Rule 5.24(e)(3)(D)(i).

[21] *See* proposed CBOE Rule 5.24(e)(3)(D)(ii). The Exchange states that it plans to have eight zones for the SPX pit. *See* Amendment No. 3, *supra* note 8, at 7. The Exchange represents that, similar to the arrangement of a physical trading pit, it will assign each Floor Broker to a zone, and each Market-Maker may determine in which zone it will be present. *See id.* at 7–8.

[22] *See* proposed CBOE Rule 5.24(e)(3)(D)(ii). The Exchange states that this arrangement is similar to the arrangement of a physical trading pit. *See* Amendment No. 3, *supra* note 8, at 8.

[23] *See* proposed CBOE Rule 5.24(e)(3)(D)(iii). The Exchange believes that the blotter will benefit virtual trading floor participants due to the limitations of communication software (such as limitations on how many people may be heard at the same time in a virtual pit or potential buffering or echoing). *See* Amendment No. 3, *supra* note 8, at 16. Additionally, the information that will be displayed in the blotter is already retained as part of the PAR order audit trail. *See id.* at 18, n.26.

[24] *See id.* at 9.

[25] *See id.*

[26] *See id.*

[27] *See id.*

[28] *See supra* note 13 and accompanying text.

[29] *See supra* note 12.

[30] *See* proposed CBOE Rule 5.24(e)(3).

• References in the rules to ''pit,'' ''trading station,'' and ''trading post'' (and any other terms with the same meaning) will be deemed to refer to a ''virtual trading pit.''

• References in the rules to ''physical presence'' (any other terms with the same meaning) in a pit or on the trading floor will be deemed to refer to ''presence'' in a virtual trading pit or on the virtual trading floor, respectively.

• The terms ''in-crowd market participant'' and ''ICMP'' mean a Market-Maker, a Designated Primary Market-Maker (''DPM'') or Lead Market-Maker (''LMM'') with an allocation in a class, or a Floor Broker or PAR Official representing an order in a virtual pit on the virtual trading floor.

• References to an ''on-floor DPM'' or ''on -floor LMM'' will be deemed to refer to a DPM or LMM, respectively, in a virtual pit for its allocated class(es).

In addition, proposed Rule 5.24(e) states that the temporary rules set forth in Rule 5.24(e)(1) will not be applicable to trading in classes in which the Exchange makes a virtual trading floor available when the physical trading floor is inoperable. As noted above, the temporary rules in Rule 5.24(e)(1) are intended to make electronic trading more similar to open outcry trading when open outcry trading is not available by replicating certain features of open outcry trading in an electronic environment. However, the virtual trading floor will permit open outcry trading to continue in a separate environment if the physical trading floor becomes inoperable. Therefore, trading opportunities that are generally only available in open outcry trading will continue to be available on the virtual trading floor, making the temporary rules in Rule 5.24(e)(1) unnecessary when the virtual trading floor is available.

The Exchange represents that access to the virtual trading floor will be substantially similar to access to the physical trading floor.[31] Proposed Rule 5.24(e)(3)(B) states that admission to the virtual trading floor is limited to TPHs, clerks,[32] Exchange employees, and any other persons the Exchange authorizes admission to the virtual trading floor.[33] The Exchange will provide access to the virtual trading floor to TPHs the Exchange has approved to perform a trading floor function (including Floor Brokers and Market-Makers).[34] Each authorized individual will receive one log-in to the virtual trading floor and may be present in only one virtual trading pit/zone at one time.[35] The Exchange will not require a minimum number of Market-Makers to be present for the virtual trading floor, which is consistent with the manner of operation on the physical trading floor.[36]

Proposed Rule 5.24(e)(3)(C) states that TPHs may use any equipment (*e.g.,* any hardware or software related to a phone, system, or other device, including an instant messaging system, email system, or similar device) to access the virtual trading floor and do not need to register devices they use while on the virtual trading floor.[37] TPHs must use Exchange-provided equipment to access PAR workstations while transacting on the virtual trading floor.[38] The Exchange states that the requirements in Rule 5.81(a) would otherwise apply in the same manner to the virtual trading floor as it does to the physical trading floor (to the extent the context requires).[39]

Proposed Rule 5.24(e)(3)(E) provides that the Exchange may determine to require any Market-Maker or Floor Broker in a virtual trading pit/zone that wants to trade against an order represented for execution to express its bid or offer in a chat available in the virtual trading pit.[40] Additionally, chats will be visible to all participants in a zone and will not be permitted directly between individual participants.[41]

Finally, if the virtual trading floor encounters issues that cause it to become unavailable, the Exchange will operate in an all-electronic configuration, pursuant to CBOE Rule 5.24(e), until the communication program is available again.[42]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 3, is consistent with the requirements of the Act,[43] and the rules and regulations thereunder applicable to a national securities exchange.[44] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 3, is consistent with Section 6(b)(5) of the Act,[45] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

[31] *See* Amendment No. 3, *supra* note 8, at 11. The Exchange states that, currently, admission to the physical trading floor is limited to TPHs, Exchange employees, clerks employed by TPHs and registered with the Exchange, service personnel, Exchange visitors that receive authorized admission to the trading floor pursuant to Exchange policy, and any other persons that the Exchange authorizes admission to the trading floor. *See id.* The proposed rule change excludes service personnel and visitors from accessing the virtual trading floor. *See id.* at 12.

[32] TPHs and clerks will not be required to display badges on the virtual trading floor. *See* proposed CBOE Rule 5.24(e)(3)(B). The virtual trading floor program will identify the TPH organization of each participant in a virtual trading pit. *See* Amendment No. 3, *supra* note 8, at 13, n.19.

[33] The Exchange states that it does not anticipate granting any other individuals with access to the virtual trading floor outside of TPHs and Exchange personnel; however, the Exchange believes the flexibility to permit Exchange personnel to access the virtual trading floor is appropriate, such as to permit access to make updates to the communication program. *See id.* at 12, n.15.

[34] *See* proposed CBOE Rule 5.24(e)(3)(B). This includes TPHs (and individuals that represent TPH organizations) that are currently authorized to perform trading floor functions, as well as any TPHs that receive such authorization in the future. *See* Amendment No. 3, *supra* note 8, at 12.

[35] *See* proposed CBOE Rule 5.24(e)(3)(B). The Exchange will track which individuals participate in the virtual trading floor, including when they log in and log out. *See id.*

[36] *See* Amendment No. 3, *supra* note 8, at 12.

[37] *See id.* at 15.

[38] The Exchange states that it has already distributed to TPHs the necessary equipment for accessing PAR for purposes of the virtual trading floor. *See id.* at 13–14. The Exchange represents that the PAR will be used and work in the same manner for the virtual trading floor as it is on the physical trading floor. *See id.* at 14. For more detail on the ways in which a Floor Broker may use a PAR workstation for the virtual trading floor in the same manner as it would on the physical trading floor, see pages 14–15 of Amendment No. 3.

[39] The Exchange states that this would include requirements related to audit trail and record retention, prohibition on using any device for the purpose of recording activities in the virtual trading pit or maintaining an open line of continuous communication whereby a non-associated person not located in the trading crowd may continuously monitor the activities in the trading crowd, and the prohibition on using devices to disseminate quotes or last sale reports. *See id.* at 15.

[40] The Exchange states that it will announce with sufficient advance notice to all TPHs any determination to require bids and offers to be expressed in a chat within the communication program pursuant to Rule 1.5 (such as by Exchange notice or regulatory circular). *See id.* at 16, n.25.

[41] The Exchange will retain records of all chats, participant logs, and any other records related to the virtual trading floor that are subject to the Exchange's record retention obligations under the Act. *See* proposed CBOE Rule 5.24(e)(3)(F). The Exchange states that it does not currently plan to make video recordings of the virtual trading floor; however, if the Exchange determines to make such recordings, it would retain those video recordings in accordance with its record retention obligations. *See* Amendment No. 3, *supra* note 8, at 18. Moreover, the Exchange represents that it will disable the ability of TPHs to record the virtual trading floor through the communication program. *See id.* at 18, n.28.

[42] *See id.* at 18–19.

[43] 15 U.S.C. 78f.

[44] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[45] 15 U.S.C. 78f(b)(5).

As discussed above, CBOE proposes to adopt rules for a virtual trading floor for when the physical trading floor is inoperable. Currently, Rule 5.24(e) provides that, if the physical trading floor becomes inoperable, the Exchange will operate in all-electronic screen-based only environment. The proposed virtual trading floor is designed to facilitate open outcry trading on the Exchange when the physical trading floor is inoperable, which would allow trading on the Exchange to occur more similarly to physical floor trading than the current rules for all-electronic trading. Among other things, the Exchange believes that the proposed enhancement to its business continuity plans through the implementation of a virtual trading floor environment would ameliorate some of the features in open outcry trading that are difficult to replicate in an all-electronic environment, particularly the small segment of trading strategies that benefit from human interactions to negotiate pricing and to facilitate executions of large orders and high-risk and complicated trading strategies.[46] The Exchange believes that the proposed rule change may facilitate continued trading of these orders if and when the trading floor is inoperable. As a result, the Exchange believes that providing continuous access to open outcry trading when the physical trading floor becomes inoperable will remove impediments to a free and open market and will ultimately benefit investors, particularly those executing high-risk and complex trading strategies.

The Commission finds that the proposed implementation of the virtual trading floor for business continuity purposes is consistent with the Act. The Commission believes that the proposed virtual trading floor will allow the Exchange to provide a trading environment to TPHs that is reasonably designed to facilitate open outcry trading when circumstances prevent physical human interaction. The Commission notes that the Exchange has conducted several town halls with TPHs on the virtual trading floor and made the functionality available for testing so that the Exchange will be ready to implement it if necessary. The Exchange states that it has received positive feedback from TPHs regarding the tool and will continue to make updates as necessary and appropriate in response to member feedback.[47] As a result, the Commission finds that the virtual trading floor is reasonably designed to allow continuous access to open outcry trading, which will remove impediments to a free and open market and will ultimately benefit investors, particularly those facilitating executions of large orders and complex trading strategies.

Additionally, the design of the virtual trading zones to closely replicate the arrangement of the physical trading floor will facilitate the rollout of the virtual trading floor to TPHs and help remove impediments to a free and open market when the physical trading floor is inoperable. Virtual trading zones will provide flexibility for a Market-Maker to enter and exit zones for particular trading interest, which may make it easier for a Market-Maker to trade with Floor Brokers that are otherwise too far away on the physical trading floor for them to trade (as movement inside a trading pit is practically not possible, and is currently not permitted while the physical trading floor operates in a modified state).

Furthermore, the Commission finds that the design of the virtual trading floor will help prevent fraudulent and manipulative acts and practices, and promote just and equitable principles of trade by requiring that the Rules and regulatory requirements apply in the substantially the same manner as open outcry of the physical trading floor. Specifically, the Exchange represents that all Rules related to open outcry trading, including those in Chapter 5, Section G, will apply to open outcry trading on the virtual trading floor.[48] In addition, all risk controls and price protection mechanisms in Rule 5.34 that currently apply to open outcry trading will apply in the same manner on the virtual trading floor.[49] TPHs participating on the virtual trading floor will be subject to the same regulatory requirements on the virtual trading floor as they are on the physical trading floor, including those set forth in Chapters 8 and 9 of the Rules.[50] Orders on the virtual trading floor will be systematized and represented, and transactions reported, in the same manner as on the physical trading floor.[51] CBOE's Regulatory Division staff will continue to utilize preexisting floor surveillances to surveil for the activity occurring on the virtual trading floor and will access the virtual trading floor as necessary and appropriate, including records of any chats, participant logs, and any other records related to the virtual trading floor consistent with the Exchange's record retention obligations under the Act.[52] Finally, Floor Officials will also have access to all zones in the virtual trading floor and will retain the same authority to act in the virtual trading floor as they do on the physical trading floor.[53]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 3 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2020–055 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2020–055. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[46] The Exchange states that, while the recent amendments to Rule 5.24(e)(1) allowed all-electronic trading to occur more similarly to open outcry trading, an all-electronic trading environment cannot fully replicate open outcry trading. *See* Amendment No. 3, *supra* note 8, at 5. The Exchange states that from January 2 through March 13, 2020 (the last day on which the trading floor was open), complex orders for SPX options with more than six legs represented approximately 5.3% of the total SPX complex order average daily volume (''ADV'') during that timeframe. *See id.* at 6. However, from March 16, 2020 (the first day on which the trading floor was closed) through April 30, 2020, complex orders for SPX options with more than six legs represented only approximately 2.2% of the total SPX complex order ADV during that similar timeframe. *See id.* Similarly, the corresponding ADV percentages for VIX options complex orders were approximately 6.2% (prior to the trading floor closing) and 1.8% (after the trading floor closing), respectively. *See id.*

[47] *See id.* at 19.

[48] *See* Amendment No. 3, *supra* note 8, at 9.

[49] *See id.* at 19.

[50] *See id.* at 20

[51] *See id.*

[52] *See id.*

[53] *See id.* at 18. The Exchange represents that an Exchange employee will be available in each zone to provide technical and operational support (in addition to regular Exchange support staff for floor operations) if participants in the virtual trading floor need assistance. *See id.*

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2020–055 and should be submitted by January 8, 2021. Rebuttal comments should be submitted by January 22, 2021.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 3

The Commission finds good cause for approving the proposed rule change, as amended by Amendment No. 3, prior to the 30th day after the date of publication of notice in the **Federal Register**. Amendment No. 3 provided additional detail and clarity on several points.[54] Specifically, the Exchange revised the proposal to provide additional description on several aspects of the proposal, including operation of the multiple ''zones'' in the virtual trading floor, interaction of Floor Brokers and Maker Makers in the virtual trading floor, distribution and use of PAR workstations for purposes of participating in the virtual trading floor, market participant outreach and testing of the virtual trading floor, use of chat functionality in the virtual trading floor, regulatory surveillance of the virtual trading floor, and make technical and conforming changes. Amendment No. 3 does not change the substance of the proposed rule change, but merely adds detail and clarification to several items of the proposal. Accordingly, the Commission finds good cause for approving the proposed rule change, as amended, on an accelerated basis, pursuant to Section 19(b)(2) of the Act.[55]

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[56] that the proposed rule change, as modified by Amendment No. 3 (SR–CBOE–2020–055), be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[57]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–27839 Filed 12–17–20; 8:45 am]

BILLING CODE 8011–01–P

[54] *See* Amendment No. 3, *supra* note 8.

[55] 15 U.S.C. 78s(b)(2).

[56] *Id.*

[57] 17 CFR 200.30–3(a)(57) and (58).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16710 and #16711; Oregon Disaster Number OR–00111]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Oregon

AGENCY: Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of OREGON (FEMA–4562–DR), dated 10/20/2020. Incident: Wildfires and Straight-line Winds. Incident Period: 09/07/2020 through 11/03/2020.

DATES: Issued on 12/11/2020.

Physical Loan Application Deadline Date: 01/13/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 07/20/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Oregon, dated 10/20/2020, is hereby amended to extend the deadline for filing applications for physical damage as a result of this disaster to 01/13/2021.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2020–27920 Filed 12–17–20; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11282]

Designation of Saraya al-Mukhtar as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with sections 1(a)(ii)(A) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, Executive Order 13284 of January 23, 2003, and Executive Order 13886 of September 9, 2019, I hereby determine that the person known as Saraya al-Mukhtar, also known as Saraya al-Mokhtar, also known as SaM, also known as al-Mukhtar Brigades, also known as AMB, also known as Al-Mukhtar Companies, also known as Bahraini Islamic Resistance Al-Mukhtar Companies, also known as Bahraini Islamic Resistance, also known as Al-Muqawama al-Islamiyya al-Bahrania, is a foreign person who poses a significant risk of committing acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: December 9, 2020.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2020–27849 Filed 12–17–20; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 11280]

Designation of Ashraf al-Qizani as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(a)(ii)(B) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, Executive Order 13284 of January 23, 2003, and Executive Order 13886 of September 9, 2019, I hereby determine that the person known as Ashraf al-Qizani, also known as Ashraf al-Gizani, also known as Abu 'Ubaydah al-Kafi, also known as Achref Ben Fethi Ben Mabrouk Guizani, also known as Achraf Ben Fathi Ben Mabrouk Guizani, is a foreign person who is a leader of leader of Jund al-Khilafah in Tunisia (JAK–T), a group whose property and interests in property are blocked pursuant to a prior determination by the Secretary of State pursuant to Executive Order 13224.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: November 27, 2020.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2020–27846 Filed 12–17–20; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 11281]

Rescission of Determination Regarding Sudan

In accordance with sections 1754 (c) and 1768(c) of the National Defense Authorization Act for Fiscal Year 2019 (50 U.S.C. 4813(c) and 4826(c)), I hereby rescind the Determination of August 12, 1993, regarding Sudan, effective December 14, 2020. This action is based upon the considerations contained in the memorandum accompanying the Presidential Report of October 26, 2020, regarding Sudan.

This rescission shall also satisfy the provisions of section 620A(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2371(c)), and section 40(f) of the Arms Export Control Act (22 U.S.C. 2780(f), and, to the extent applicable, section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), and as continued in effect by Executive Order 13222 of August 17, 2001).

This notice shall be published in the **Federal Register**.

Dated: December 8, 2020.

Michael Pompeo,

Secretary of State.

[FR Doc. 2020–27848 Filed 12–17–20; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

Call for Expert Reviewers To Submit Comments on the Intergovernmental Panel on Climate Change (IPCC) Working Group II Contribution to the Sixth Assessment Report.

AGENCY: Department of State.

ACTION: Call for Expert Reviewers to Submit Comments on the Intergovernmental Panel on Climate Change (IPCC) Working Group II Contribution to the Sixth Assessment Report

SUMMARY: The Department of State, in cooperation with the United States Global Change Research Program *(USGCRP),* requests expert review of the second-order draft of the IPCC Working Group II (WGII) contribution to the Sixth Assessment Report cycle (AR6), including the first draft of the Summary for Policymakers (SPM).

The *United Nations Environment Programme (UNEP)* and the *World Meteorological Organization (WMO)* established the IPCC in 1988. As reflected in its governing documents, the role of the IPCC is to assess on a comprehensive, objective, open, and transparent basis the scientific, technical, and socio-economic information relevant to understanding the scientific basis of risk of human-induced climate change, its potential impacts, and options for adaptation and mitigation. IPCC reports should be neutral with respect to policy, although they may need to deal objectively with scientific, technical, and socio-economic factors relevant to the application of particular policies. The principles and procedures for the IPCC and its preparation of reports can be found at: *https://www.ipcc.ch/site/assets/uploads/2018/09/ipcc-principles.pdf* and *https://www.ipcc.ch/site/assets/uploads/2018/09/ipcc-principles-appendix-a-final.pdf.* In accordance with these procedures, IPCC documents undergo peer review by experts and governments. The purpose of these reviews is to ensure the reports present a comprehensive, objective, and balanced view of the subject matter they cover.

As part of the U.S. government review—starting December 4, 2020—experts wishing to contribute to the U.S. government review are encouraged to register via the USGCRP Review and Comment System (*https://review.globalchange.gov).* Instructions and the second-order draft will be available for download via the system. *In accordance with IPCC policy, drafts of the report are provided for review purposes only and are not to be cited or distributed.* All technical comments received that are relevant to the text under review will be forwarded to the IPCC authors for their consideration. To be considered for inclusion in the U.S. government submission, comments must be received by January 8, 2021.

Experts may choose to provide comments directly through the IPCC's expert review process, which occurs in parallel with the U.S. government review: *https://apps.ipcc.ch/comments/ar6wg1/sod/.* To avoid duplication, experts are requested to submit comments via either the USGCRP or IPCC review websites, not both.

This notice will be published in the **Federal Register**.

Andrew Griffin,

Deputy Director, Office of Global Change, Department of State.

[FR Doc. 2020–27969 Filed 12–17–20; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 290 (Sub–No. 5) (2021–1)]

Quarterly Rail Cost Adjustment Factor

AGENCY: Surface Transportation Board.

ACTION: Approval of rail cost adjustment factor.

SUMMARY: The Board has approved the first quarter 2021 Rail Cost Adjustment Factor (RCAF) and cost index filed by the Association of American Railroads. The first quarter 2021 RCAF (Unadjusted) is 1.040. The first quarter 2021 RCAF (Adjusted) is 0.434. The first quarter 2021 RCAF–5 is 0.410.

DATES: *Applicability Date:* January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez, (202) 245–0333. Assistance for the hearing impaired is

available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision, which is available on our website, *http://www.stb.gov.* Copies of the decision may be purchased by contacting the Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238.

Decided: December 14, 2020.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2020–27968 Filed 12–17–20; 8:45 am]

BILLING CODE 4915–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Actions Taken at December 11, 2020, Meeting

AGENCY: Susquehanna River Basin Commission

ACTION: Notice.

SUMMARY: As part of its regular business meeting held on December 11, 2020, from Harrisburg, Pennsylvania, the Commission approved the applications of certain water resources projects, and took additional actions, as set forth in the Supplementary Information below.

DATES: December 11, 2020.

ADDRESSES: Susquehanna River Basin Commission, 4423 N Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary, telephone: (717) 238–0423, ext. 1312, fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address. See also Commission website at *www.srbc.net.*

SUPPLEMENTARY INFORMATION: In addition to the actions taken on projects identified in the summary above and the listings below, the following items were also presented or acted upon at the business meeting: (1) Tabled action on a policy to incentivize the use of impaired waters; (2) adoption of an updated regulatory program fee schedule; (3) adoption of a general permit for groundwater remediation projects; (4) ratification/approval of contracts/grants; (5) a report on delegated settlements; and (6) Regulatory Program projects.

The Commission is also making its draft Comprehensive Plan available for public comment. The draft plan can be obtained by visiting the Commission's website, *https://www.srbc.net/our-work/programs/planning-operations/comprehensive-plan.html,* or by contacting Paula Ballaron, Manager of Policy Implementation and Outreach. The Commission will hold a public hearing on the Comprehensive Plan on February 4, 2021 via telephone. The Commission will also host two webinars on January 25 and 27, 2021. Written public comments may be sent to John Balay, Manager of Planning & Operations.

The deadline for written public comments is February 19, 2021.

Project Applications Approved

1. *Project Sponsor and Facility:* Cabot Oil & Gas Corporation (Susquehanna River), Susquehanna Depot Borough, Susquehanna County, Pa. Application for renewal of surface water withdrawal of up to 1.500 mgd (peak day) (Docket No. 20161202).

2. *Project Sponsor and Facility:* Chesapeake Appalachia, L.L.C. (Towanda Creek), Monroe Borough and Monroe Township, Bradford County, Pa. Application for surface water withdrawal of up to 1.500 mgd (peak day).

3. *Project Sponsor and Facility:* Denver Borough, Lancaster County, Pa. Application for renewal of groundwater withdrawal of up to 0.120 mgd (30-day average) from Well 4 (Docket No. 19960102).

4. *Project Sponsor and Facility:* Elmira Water Board, City of Elmira, Chemung County, N.Y. Applications for renewal of groundwater withdrawals (30-day averages) of up to 0.958 mgd from Well PW–40, 1.656 mgd from Well PW–41, and 0.389 mgd from Well PW–42, for a total wellfield limit of 3.000 mgd (Docket No. 19901105).

5. *Project Sponsor:* Goodyear Lake Hydro, LLC. Project Facility: Colliersville Hydroelectric Project, Town of Milford, Otsego County, N.Y. Application for an existing hydroelectric facility.

6. *Project Sponsor:* Borough of Middletown. Project Facility: SUEZ/Middletown Water System, Middletown Borough, Dauphin County, Pa. Application for renewal of groundwater withdrawal of up to 0.219 mgd (30-day average) from Well 5 (Docket No. 19890701), as well as recognizing historic withdrawals from Wells 1, 2, 3, and 4.

7. *Project Sponsor and Facility:* Seneca Resources Company, LLC (Cowanesque River), Deerfield Township, Tioga County, Pa. Application for renewal of surface water withdrawal of up to 0.999 mgd (peak day) (Docket No. 20161218–2).

Project Scheduled for Action Involving a Diversion

8. *Project Sponsor:* JKLM Energy, LLC. Project Facility: Goodwin and Son's Sand and Gravel Quarry, Roulette Township, Potter County, Pa. Application for renewal of an into-basin diversion from the Ohio River Basin of up to 1.100 mgd (peak day) from the Goodwin and Son's Sand and Gravel Quarry (Docket No. 20161221).

Commission Initiated Project Approval Modifications

9. Project Sponsor: Lycoming County Recreation Authority. Project Facility: White Deer Golf Courses, Brady Township, Lycoming County, Pa. Conforming the grandfathered amount with the forthcoming determination for a groundwater withdrawal of up to 0.169 mgd (30-day average) from Well 2 (Docket No. 20020806).

Project Applications Tabled

10. *Project Sponsor and Facility:* Hastings Municipal Authority, Elder Township, Cambria County, Pa. Application for groundwater withdrawal of up to 0.260 mgd (30-day average) from Mine Spring No. 1 Well.

11. *Project Sponsor:* New York State Office of Parks, Recreation and Historic Preservation. Project Facility: Indian Hills State Golf Course (Irrigation Pond), Towns of Erwin and Lindley, Steuben County, N.Y. Applications for an existing surface water withdrawal of up to 0.940 mgd (peak day) and consumptive use of up to 0.850 mgd (peak day).

Authority: Pub.L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: December 15, 2020.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2020–27962 Filed 12–17–20; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: November 1–30, 2020.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries May be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22 (e) and 18 CFR 806.22 (f) for the time period specified above:

Water Source Approval—Issued Under 18 CFR 806.22(f)

1. LPR Energy, LLC; Pad ID: Davis Drilling Pad #1; ABR–201007067.R2; West Clair Township, Bedford County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: November 11, 2020.

2. Pennsylvania General Energy Company, L.L.C.; Pad ID: COP Tract 729 Pad D; ABR–201008052.R2; Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: November 11, 2020

3. Pennsylvania General Energy Company, L.L.C.; Pad ID: COP Tract 729 Pad C; ABR–201008051.R2; Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: November 11, 2020.

4. Repsol Oil & Gas USA, LLC; Pad ID: ROY (03 062) L; ABR–201008089.R2; Wells Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 11, 2020.

5. Rockdale Marcellus, LLC; Pad ID: Swingle 725; ABR–201007129.R2; Canton Township, Bradford County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 11, 2020.

6. Seneca Resources Company, LLC; Pad ID: Bauer 849; ABR–201008032.R2; Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 11, 2020.

7. Seneca Resources Company, LLC; Pad ID: Fuleihan 417; ABR–201008073.R2; Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 11, 2020.

8. Repsol Oil & Gas USA, LLC; Pad ID: DETWEILER (02 100) R; ABR–201008023.R2; Covington Township, Tioga County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 16, 2020.

9. Repsol Oil & Gas USA, LLC; Pad ID: DCNR 594 (02 205); ABR–201008040.R2; Bloss Township, Tioga County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 16, 2020.

10. Repsol Oil & Gas USA, LLC; Pad ID: DCNR 587 (02 019); ABR–201008072.R2; Ward Township, Tioga County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 16, 2020.

11. Seneca Resources Company, LLC; Pad ID: Sticklin 510; ABR–201007113.R2; Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 16, 2020.

12. Epsilon Energy USA, Inc.; Pad ID: Harold Craige Pad; ABR–202011002; Rush Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 19, 2020.

13. SWN Production Company, LLC; Pad ID: Chamberlin; ABR–201008008.R2; Stevens Township, Bradford County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: November 19, 2020.

14. ARD Operating, LLC; Pad ID: Nevin L. Smith Pad A; ABR–201008115.R2; Gamble Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 19, 2020.

15. Rockdale Marcellus, LLC; Pad ID: Hedrick 702; ABR–201007092.R2; Union Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 19, 2020.

16. Cabot Oil & Gas Corporation.; Pad ID: WarrinerR P4; ABR–201008123.R2; Dimock Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 19, 2020.

17. Repsol Oil & Gas USA, LLC; Pad ID: AYERS (05 005) K; ABR–201008129.R2; Orwell Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 20, 2020.

18. Repsol Oil & Gas USA, LLC; Pad ID: STROPE (05 026) G; ABR–201008152.R2; Warren Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 20, 2020.

19. Repsol Oil & Gas USA, LLC; Pad ID: CARPENTER (03 023) K; ABR–201008141.R2; Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 20, 2020.

20. ARD Operating, LLC; Pad ID: Brooks Family Pad A; ABR–201508002.R1; Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 20, 2020.

21. Cabot Oil & Gas Corporation; Pad ID: StockholmK P2; ABR–201008134.R2; Rush Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 20, 2020.oval Date: November 16, 2020.

22. Cabot Oil & Gas Corporation; Pad ID: Maiolini P3; ABR–201008114.R2; Dimock and Auburn Townships, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 20, 2020.

23. Cabot Oil & Gas Corporation; Pad ID: Teel P2; ABR–201508004.R1; Dimock Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 20, 2020.

24. Cabot Oil & Gas Corporation; Pad ID: KingD P1; ABR–201009010.R2; Dimock Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 20, 2020.

25. Rockdale Marcellus, LLC; Pad ID: Yaggie 704; ABR–201006113.R2; Union Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 24, 2020.

26. Repsol Oil & Gas USA, LLC; Pad ID: Sparrow Hawk ; ABR–201009044.R2; Covington Township, Tioga County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 24, 2020.

27. Cabot Oil & Gas Corporation; Pad ID: CosnerW P1; ABR–201009047.R2; Springville Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 24, 2020.

28. Greylock Production, LLC; Pad ID: Coldstream Affiliates #1MH; ABR–201007051.R2; Goshen Township, Clearfield County, Pa.; Consumptive Use of Up to 3.0200 mgd; Approval Date: November 25, 2020.

29. Greylock Production, LLC; Pad ID: Whitetail #1–5MH; ABR–201008112.R2; Goshen Township, Clearfield County, Pa.; Consumptive Use of Up to 3.0200 mgd; Approval Date: November 25, 2020.

30. ARD Operating, LLC; Pad ID: COP Tr 685 Pad C; ABR–201009013.R2; Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 25, 2020.

31. BKV Operating, LLC; Pad ID: Baker 2H; ABR–201008137.R2; Forest Lake Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 27, 2020.

32. Chesapeake Appalachia, L.L.C.; Pad ID: Tama; ABR–201010057.R2; North Towanda Township, Bradford

County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 27, 2020.

33. Seneca Resources Company, LLC; Pad ID: Hotchkiss 472; ABR–201009045.R2; Charleston Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 27, 2020.

34. Chesapeake Appalachia, L.L.C.; Pad ID: Folta; ABR–201010044.R2; Tuscarora Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2020.

35. Cabot Oil & Gas Corporation; Pad ID: FraserE P1; ABR–201009052.R2; Forest Lake Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 30, 2020.

36. Seneca Resources Company, LLC; Pad ID: Klettlinger 294; ABR–201009054.R2; Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 30, 2020.

37. Chesapeake Appalachia, L.L.C.; Pad ID: Norton; ABR–201011008.R2; Elkland Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2020.

38. Chesapeake Appalachia, L.L.C.; Pad ID: Penecale; ABR–201011060.R2; North Branch Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2020.

39. Chesapeake Appalachia, L.L.C.; Pad ID: Taylor; ABR–201011034.R2; Orwell Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2020.

40. Chesapeake Appalachia, L.L.C.; Pad ID: Zaleski; ABR–201011021.R2; Asylum Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2020.

(Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.)

Dated: December 15, 2020.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2020–27960 Filed 12–17–20; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in ''**DATES**.''

DATES: October 1–31, 2020.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries May be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22 (e) and 18 CFR 806.22 (f) for the time period specified above:

Water Source Approval—Issued Under 18 CFR 806.22(f)

1. Seneca Resources Company, LLC; Pad ID: Barbine 292; ABR–20100614.R2; Charleston Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 1, 2020.

2. Repsol Oil & Gas USA, LLC; Pad ID: SHEDDEN (01 075) L; ABR–201007004.R2; Granville Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 1, 2020.

3. LPR Energy, LLC; Pad ID: Lightner East Drilling Pad #1; ABR–201009087.R2; Juniata Township, Blair County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: October 2, 2020.

4. Seneca Resources, LLC; Pad ID: Covington Pad L; ABR–201008065.R2; Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 14, 2020.

5. Seneca Resources, LLC; Pad ID: COP Pad C; ABR–201008027.R2; Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: October 14, 2020.

6. Seneca Resources, LLC; Pad ID: Doan 893; ABR–20100670.R2; Deerfield Township, Tioga County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: October 14, 2020.

7. Seneca Resources, LLC; Pad ID: Anthony 564; ABR–201006111.R2; Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: October 14, 2020.

8. Seneca Resources, LLC; Pad ID: Hauswirth 516; ABR–20100688.R2; Richmond Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 14, 2020.

9. Seneca Resources, LLC; Pad ID: Matz 824; ABR–201007010.R2; Chatham Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 14, 2020.

10. Seneca Resources, LLC; Pad ID: Frost 573; ABR–201007013.R2; Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 14, 2020.

11. Seneca Resources, LLC; Pad ID: Sorensen 876; ABR–201007021.R2; Osceola Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 14, 2020.

12. Chesapeake Appalachia, L.L.C.; Pad ID: Hopson; ABR–201010004.R2; Asylum Township, Bradford County, Pa.; Consumptive Use of Up to 7.50000 mgd; Approval Date: October 14, 2020.

13. Chesapeake Appalachia, L.L.C.; Pad ID: Yvonne; ABR–201010015.R2; Rush Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.50000 mgd; Approval Date: October 14, 2020.

14. Diversified Production, LLC; Pad ID: Phoenix E; ABR–201008130.R2; Duncan Township, Tioga County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: October 14, 2020.

15. Chief Oil & Gas, LLC; Pad ID: Warburton North Drilling Pad; ABR–201510003.R1; Forks Township, Sullivan County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: October 14, 2020.

16. Cabot Oil & Gas Corporation; Pad ID: ArnoneJ P1; ABR–201507004.R1; Brooklyn Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 14, 2020.

17. Cabot Oil & Gas Corporation; Pad ID: BistisM P1; ABR–201507005.R1; Lathrop Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 14, 2020.

18. Eclipse Resources-PA, LP; Pad ID: Abplanalp; ABR–201510001.R1; Westfield Township, Tioga County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 14, 2020.

19. Eclipse Resources-PA, LP; Pad ID: Painter; ABR–201510002.R1; Westfield Township, Tioga County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 14, 2020.

20. SWN Production Company, LLC; Pad ID: Ball; ABR–201007060.R2; Stevens Township, Bradford County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: October 28, 2020.

21. Repsol Oil & Gas USA, LLC; Pad ID: FEUSNER (03 044) J; ABR–201007094.R2; Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 28, 2020.

22. Repsol Oil & Gas USA, LLC; Pad ID: WARNER VALLEY FARM LLC (05 002); ABR–201007130.R2; Pike Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 28, 2020.

23. Repsol Oil & Gas USA, LLC; Pad ID: WATSON (03 051) B; ABR–201007084.R2; Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 28, 2020.

24. Cabot Oil & Gas Corporation; Pad ID: LambertR P1; ABR–201507006.R1; Gibson Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 28, 2020.

25. Cabot Oil & Gas Corporation; Pad ID: AdamsJ P1; ABR–201007121.R2; Harford Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 28, 2020.

26. Cabot Oil & Gas Corporation; Pad ID: DavisG P1; ABR–201007120.R2; Gibson Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 28, 2020.

27. Seneca Resources, LLC; Pad ID: Wood 874; ABR–201007069.R2; Deerfield Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 28, 2020.

28. Seneca Resources, LLC; Pad ID: Hamblin 860; ABR–201007117.R2; Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 28, 2020.

29. Frontier Natural Resources, Inc.; Pad ID: Winner 4H; ABR–201009094.R2; West Keating Township, Clinton County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 28, 2020.

30. SWN Production Company, LLC; Pad ID: NR–19-Walker Diehl; ABR–201507003.R1; Oakland Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: October 28, 2020.

31. Cabot Oil & Gas Corporation; Pad ID: PlonskiJ P1; Brooklyn Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 28, 2020.

32. Seneca Resources Company, LLC; Pad ID: Gee 848V; ABR–201007093.R2; Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 28, 2020.

33. ARD Operating, LLC; Pad ID: COP Tr 285 Pad D; ABR–201008013.R2; Chapman Township, Clinton County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 28, 2020.

34. Repsol Oil & Gas USA, LLC; Pad ID: YOUNG (05 080); ABR–201007080.R2; Warren Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 30, 2020.

35. EOG Resources, Inc.; Pad ID: KINGSLEY 2H; ABR–20100692.R2; Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: October 30, 2020.

36. EOG Resources, Inc.; Pad ID: KINGSLEY 3H; ABR–20100698.R2; Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: October 30, 2020.

37. Repsol Oil & Gas USA, LLC; Pad ID: CUMMINGS LUMBER (01 081); ABR–201007088.R2; Troy Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 30, 2020.

38. ARD Operating, LLC; Pad ID: COP Tr 356 Pad H; ABR–201008020.R2; Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 30, 2020.

39. ARD Operating, LLC; Pad ID: COP Tr 290 Pad B; ABR–201008029.R2; McHenry Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 30, 2020.

40. ARD Operating, LLC; Pad ID: Brian K. Frymire Pad A; ABR–201008056.R2; Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 30, 2020.

41. Seneca Resources Company, LLC; Pad ID: Clark 392; ABR–201008004.R2; Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 30, 2020.

42. Seneca Resources Company, LLC; Pad ID: Fish 301; ABR–201008034.R2; Richmond Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 30, 2020.

43. EXCO Resources (PA), LLC; Pad ID: COP Tract 706 (Pad B); ABR–201008059.R2; Burnside Township, Centre County, Pa.; Consumptive Use of Up to 8.0000 mgd; Approval Date: October 30, 2020.

44. Chief Oil & Gas, LLC; Pad ID: SGL–12 L SOUTH UNIT PAD; ABR–202010001; Leroy Township, Bradford County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: October 30, 2020

Approval By Rule—Revoked Under 18 CFR 806.22(f)

1. Seneca Resources Company, LLC, Pad ID: Wolfinger Pad A, ABR–201008064.R1; City of Saint Mary's, Elk County; and Shippen Township, Cameron County; Pa.; Revocation Date: May 21, 2020.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: December 15, 2020.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2020–27957 Filed 12–17–20; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Grandfathering (GF) Registration Notice

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Grandfathering Registration for projects by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: November 1–30, 2020.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries May be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists GF Registration for projects, described below, pursuant to 18 CFR 806, Subpart E for the time period specified above: *Grandfathering Registration Under 18 CFR part 806, subpart E:*

1. Shippensburg University, GF Certificate No. GF–202011127, Shippensburg Township, Cumberland County, Pa.; Wells 1, 2, 3, and 5; Issue Date: November 4, 2020.

2. West Earl Water Authority—Public Water Supply System, GF Certificate No. GF–202011128, West Earl Township, Lancaster County, Pa.; Nolt Well; Issue Date: November 4, 2020.

3. Biglerville Borough Authority—Biglerville Borough Water Company, GF Certificate No. GF–202011129, Biglerville Borough and Butler Township, Adams County, Pa.; Wells 5 and 6; Issue Date: November 5, 2020.

4. Greenfield Township Municipal Authority—Public Water Supply System, GF Certificate No. GF–202011130, Greenfield Township, Blair County, Pa.; Wells 1 and 3; Issue Date: November 5, 2020.

5. City of Cortland—Cortland Water Department, GF Certificate No. GF–202011131, City of Cortland, Cortland

County, N.Y.; Wells 3, 4, and 5; Issue Date: November 5, 2020.

6. New Freedom Borough—New Freedom Borough Water, GF Certificate No. GF–202011132, New Freedom Borough, York County, Pa.; Wells 1, 3, 4, and 8; Issue Date: November 5, 2020.

7. Clinton County Recreation Authority—Belles Springs Golf Course, GF Certificate No. GF 202011133, Lamar Township, Clinton County, Pa.; Spring Fed Pond; Issue Date: November 24, 2020.

8. Village of McGraw—Public Water Supply System, GF Certificate No. GF–202011134, Village of McGraw, Cortland County, N.Y.; Academy St. Well 1 (original) and Academy St. Well 1 (replacement); Issue Date: November 24, 2020.

9. Conagra Brands—Milton, Pa., GF Certificate No. GF–202011135, Milton Borough, Northumberland County, Pa.; Wells 1 and 2 and consumptive use; Issue Date: November 24, 2020.

(Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.)

Dated: December 15, 2020.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2020–27958 Filed 12–17–20; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Minor Modifications

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the minor modifications approved for a previously approved project by the Susquehanna River Basin Commission during the period set forth in ''DATES.''

DATES: November 1–30, 2020.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists previously approved projects, receiving approval of minor modifications, described below, pursuant to 18 CFR 806.18 or to Commission Resolution Nos. 2013–11 and 2015–06 for the time period specified above:

Minor Modification Issued Under 18 CFR 806.18

1. Northeast Marcellus Aqua Midstream I, LLC, Docket No. 20200919, Tunkhannock Township, Wyoming County, Pa.; approval to change intake design to add a temporary intake structure to allow withdrawals during low flow conditions when the existing permanent intake is inoperable; Approval Date: November 12, 2020.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: December 15, 2020.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2020–27959 Filed 12–17–20; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0799]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Certification: Mechanics, Repairman, Parachute Riggers.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on August 19, 2020. The collection involves 14 CFR part 65 requirements for mechanics, repairmen, parachute riggers, and inspection authorization. The information to be collected will be used to determine applicant eligibility for certification or authorization.

DATES: Written comments should be submitted by January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Tanya Glines by email at: *Tanya.glines@faa.gov;* phone: 202–380–5869

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0022.

Title: Certification: Mechanics, Repairman, Parachute Riggers.

Form Numbers: FAA Form 8610–1, FAA Form 8610–2, FAA Form 8610–3.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on August 19, 2020 (85 FR 51144). 14 CFR part 65 prescribes, among other things, rules governing the issuance of certificates and associated ratings for mechanics, repairmen, parachute riggers, and the issuance and renewal of inspection authorizations.

The information is collected on forms submitted by applicants for mechanic, repairman, or parachute rigger certificates, or applicants for an initial or renewed inspection authorization. The information is used for evaluation by the FAA, and is necessary for determining eligibility for issuance of a certificate, rating, or authorization.

Applicants for a light-sport repairman certificate must complete a prescribed number of training hours, based on the repairman rating and class of aircraft being applied for. Parachute riggers must maintain records of the packing, maintenance, and alteration of parachutes performed or supervised by the parachute rigger. Applicants who fail a required certification test, and who test within 30 days of that test failure, must present a signed statement certifying that the applicant has received additional instruction in each of the subjects failed.

A new FAA form is being proposed for repairman applications. In lieu of repairman applicant information being collected on FAA Form 8610–2 as currently required, it will be collected on a new FAA Form 8610–3.

Respondents: 36,000 mechanic, parachute rigger, and repairman applicants.

Frequency: On occasion.

Estimated Average Burden per Response: 20 minutes.

Estimated Total Annual Burden: 40,000 hours.

Issued in Washington, DC on December 15, 2020.

Tanya A. Glines,

Aviation Safety Inspector, Safety Standards, General Aviation Maintenance Branch.

[FR Doc. 2020–27922 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2020–0409]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Commercial Air Tour Operator Reports

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 8, 2020. The collection involves information from commercial air tour operators on the numbers and types of air tours over national park units. The information to be collected will be used by the FAA and the National Park Service to track air tour operations over national parks and as background information in the development of air tour management plans and voluntary agreements for purposes of addressing any potential significant impacts from commercial air tour operations on the natural or cultural resources or visitor experience at the parks.

DATES: Written comments should be submitted by January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Keith Lusk by email at: *Keith.Lusk@faa.gov;* phone: 424–405–7017

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0750.

Title: Commercial Air Tour Operator Reports.

Form Numbers: There are no FAA forms associated with this collection of information.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 8, 2020 (85 FR 27506). The FAA Modernization and Reform Act of 2012 included amendments to the National Parks Air Tour Management Act (NPATMA) of 2000, which applies to commercial air tour operators who conduct tours over or within a half mile of a national park unit. One of these amendments requires commercial air tour operators conducting tours over national park units to provide the FAA and National Park Service with certain information on these operations. The information collected includes the date and time of day of the tour operation, the make and model of aircraft the tour was taken in, and the name of tour route flown. The information allows the agencies to track air tour activity over national park units and provides background information that the agencies can utilize when developing an air tour management plan or voluntary agreement for a national park unit. Respondents are the commercial air tour operators currently authorized to conduct tours over national parks. Operators provide the information on a reporting template and either email it or mail it in to the agencies.

Respondents: 48 commercial air tour operators nationwide.

Frequency: Information is collected semi-annually (twice a year), or annually for park units with 50 or fewer tours per year.

Estimated Average Burden per Response: 11.83 hours.

Estimated Total Annual Burden: 1,136 hours.

Issued in El Segundo, CA, on December 15, 2020.

Keith Lusk,

Program Manager,Special Programs Office, FAA Western-Pacific Region.

[FR Doc. 2020–27940 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Notice of Final Federal Agency Actions on Proposed Highway Projects in Texas

AGENCY: Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), U.S. Department of Transportation.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by TxDOT and Federal Agencies.

SUMMARY: This notice announces actions taken by TxDOT and Federal agencies that are final. The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT pursuant to an assignment agreement executed by FHWA and TxDOT. The actions relate to various proposed highway projects in the State of Texas. These actions grant licenses, permits, and approvals for the projects.

DATES: By this notice, TxDOT is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of TxDOT and Federal agency actions on the highway projects will be barred unless the claim is filed on or before the deadline. For the projects listed below, the deadline is 150 days from the date of publication. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such a claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Carlos Swonke, Environmental Affairs Division, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701; telephone: (512) 416–2734; email: *carlos.swonke@txdot.gov.* TxDOT's normal business hours are 8:00 a.m.–5:00 p.m. (central time), Monday through Friday.

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 9, 2019, and executed by FHWA and TxDOT.

Notice is hereby given that TxDOT and Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway projects in the State of Texas that are listed below.

The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion (CE), Environmental Assessment (EA), or Environmental Impact Statement (EIS) issued in connection with the projects and in other key project documents. The CE, EA, or EIS and other key documents for the listed projects are available by contacting TxDOT at the address provided above.

This notice applies to all TxDOT and Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 300101 *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)-11]; Archeological and Historic Preservation Act [54 U.S.C. 312501 *et seq.*]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)-2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1251–1377](Section 404, Section 401, Section 319); Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)-300(j)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; TEA–21 Wetlands Mitigation [23 U.S.C. 103(b)(6)(m), 133(b)(11)]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species. (Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

The projects subject to this notice are:

1. FM 1515 from Masch Branch Street to Bonnie Brae Street in Denton County, Texas. The proposed project would reconstruct the existing undivided two-lane roadway to a median separated six-lane roadway. The proposed project would include replacement of the existing bridge structures over Dry Fork Hickory Creek, the KCS railroad, and IH 35W. The total project length is approximately 2.1 miles. The purpose of the proposed project to enhance safety and mobility and mitigate future increases in traffic associated with projected growth. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on August 4, 2020, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E. Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

2. Rudeloff Road from SH 46 to Huber Road, Guadalupe County, Texas. The project would expand the existing two-lane roadway to a four-lane roadway with a continuous center left turn lane and bicycle and pedestrian accommodations. The project is approximately 1.5 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on August 13, 2020 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone: (210) 615–5839.

3. Bonnie Brae Street from Windsor Drive to US 77 in Denton County, Texas. The proposed project would widen the existing two/four-lane undivided roadway to a four-lane divided roadway. Near the northern limit of the proposed project, from approximately 1,670 feet south of US 77 to US 77, the roadway would be widened from a two-lane undivided roadway to a four-lane divided roadway. The total project length is approximately one mile. The purpose of the proposed project to improve operations of the roadway, increase mobility, and enhance safety. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in, the Categorical Exclusion Determination issued on August 18, 2020, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E. Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

4. State Highway (SH) 72 from Farm to Market (FM) 237 to United States (US) 87 in DeWitt County, Texas. The proposed project would widen SH 72 from a two-lane roadway to a four-lane highway between the towns of Yorktown and Cuero in DeWitt County, Texas. The project would be approximately 14.0 miles long. The purpose of the project is to provide a safer corridor for the traveling public through the area. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on August 24, 2020, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Yoakum District Office at 403 Huck St., Yoakum, TX 77995; telephone: (361) 293–4436.

5. Interstate Highway (IH) 10 from Farm to Market (FM) 2761 to United States (US) 90, in Colorado County, Texas. The proposed project would expand IH 10 to a six-lane roadway, which includes: three 12-foot wide main lanes in each direction, 12-foot inside and outside shoulders, and two 12-foot wide, one-way frontage lanes in each direction. The project would extend for approximately 11 miles east of the city of Columbus in Colorado County, Texas.

The purpose of the project is to increase the capacity of the roadway to alleviate traffic congestion and provide a safer traveling corridor for the public. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 24, 2020, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Yoakum District Office at 403 Huck St., Yoakum, TX 77995; telephone: (361) 293–4436.

6. Gattis School Road from Via Sonoma Trail to Red Bud Lane, in Williamson County, Texas. The project will widen Gattis School Road from an existing 4-lane undivided roadway to a 6-lane divided urban roadway with a raised median. The project is approximately 1.01 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on October 20, 2020 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Austin District Office at 7901 North I–35, Austin, TX 78753; telephone: (512) 832–7000.

7. IH 10 Widening, from 0.22 miles west of FM 1905 (Antonio St.) to SH 20 (Mesa St.), in El Paso County, Texas. The proposed widening project is approximately 11.2 miles in length. The Texas Department of Transportation El Paso District proposes to reconstruct and widen the existing roadway to improve capacity, operation, circulation, and safety on IH 10. The proposed project would reconstruct, upgrade, and widen IH 10 from a 4-lane divided roadway to a 6-lane divided roadway. The frontage roads between State Loop 375 and Mesa Street would be reconstructed in place to meet urban design criteria. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on October 22, 2020, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT El Paso District Office at 13301 Gateway West, El Paso, TX 79928; telephone: (915) 790–4341.

8. SL 288 From IH 35W to IH 35 in Denton County, Texas. The proposed project would construct a four-lane new location frontage road system for SL 288 from IH 35W south of Denton to IH 35 north of Denton. SL 288 currently does not exist west of IH 35 where the proposed project is located. The proposed project would consist of two frontage road lanes in each direction and sidewalks along both sides of the road, with a median that would accommodate the future construction of an ultimate mainlane facility. The distance of the proposed project is approximately 9.0 miles. The purpose of the proposed project is to address local policies, improve mobility, accommodate future traffic demand, and improve safety in and around the west side of Denton. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on August 21, 2020, Finding of No Significant Impact (FONSI) issued on September 25, 2020 and other documents in the TxDOT project file. The EA, FONSI, and other documents are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E. Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

9. SH 31 from SL 323 to FM 1639 in Gregg and Smith Counties, Texas. The purpose of the proposed project is to improve safety and connectivity on SH 31 between the cities of Tyler and Kilgore by widening the road to a four-lane highway with two 12-foot travel lanes in each direction, a variable center median, shoulders, and curb and gutter in portions of the project. The proposed project length is approximately 20 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on October 13, 2020, the Finding of No Significant Impact (FONSI) issued on October 15, 2020, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Tyler District Office at 2709 W. Front St., Tyler, TX 75702; telephone: (903) 510–9100.

10. Loop 88 Segments 1 and 2, from US 84 in Shallowater to US 62/82, in Lubbock County, Texas. TxDOT plans to construct Loop 88 by converting existing rural roadways to an access-controlled six-lane freeway with frontage roads and ramps. Interchanges will be developed at designated cross streets. For Segment 1, the frontage roads would start at US 84 while the mainlanes would begin approximately 0.97 mile west of US 84. Segment 2 would end approximately 0.48 mile northwest of US 62/82. This project is approximately 16 miles in length and will improve transportation infrastructure to current design standards and improve mobility in western and southwestern Lubbock and Lubbock County. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on September 18, 2020, the Finding of No Significant Impact (FONSI) issued on October 26, 2020, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Lubbock District Office at 135 Slaton Road, Lubbock, Texas 79404, telephone: (806) 748–4472.

11. Loop 88 Segment 4, from 0.5 miles east of US 87 to US 84 in Slaton, in Lubbock County, Texas. TxDOT plans to construct Loop 88 by converting existing rural roadways to an access-controlled six-lane freeway with frontage roads and ramps. Portions of the proposed project will follow existing facilities, including FM 1585 for approximately 0.96 mile, and CR 7500 for 3.98 miles. The remainder of the proposed project is on new location. Interchanges will be developed at designated cross streets. This project is approximately 8.8 miles in length and will improve transportation infrastructure to current design standards and improve mobility in southeastern Lubbock County. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on September 18, 2020, the Finding of No Significant Impact (FONSI) issued on October 26, 2020, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Lubbock District Office at 135 Slaton Road, Lubbock, Texas 79404, telephone: (806) 748–4472.

(Authority: 23 U.S.C. 139(l)(1))

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2020–27611 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0144]

Hours of Service of Drivers: Mountain Blade Runner Helicopters, LLC; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA requests public comment on Mountain Blade Runner Helicopters, LLC's (MBR Helicopters) application for an exemption from two provisions of the hours-of-service (HOS) regulations for its ground support equipment operators. MBR Helicopters requested relief from the 14-hour rule and the requirement that drivers have 10 consecutive hours off duty at the end of the work shift. The exemption would allow MBR Helicopters' ground support equipment operators a 16-hour window within which to complete all driving and enable these operators to use an 8-consecutive hour off-duty break, combined with at least 2 other off-duty hours during the 16-hour window within which driving would be completed, in lieu of taking 10 consecutive hours off duty.

DATES: Comments must be received on or before January 19, 2021.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2020–0144 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Send comments to Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Deliver comments to Dockets Operations, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Dockets Operations, Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: (202) 366–4225. Email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2020–0144), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number, ''FMCSA–2020–0144'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Under 49 CFR 395.3(a)(1), a driver may not drive without first taking 10 consecutive hours off duty, and 49 CFR 395.3 (a)(2) provides that a driver may drive only during a period of 14 consecutive hours after coming on duty following 10 consecutive hours off duty. The driver may not drive after the end of the 14-consecutive-hour period, without first taking 10 consecutive hours off duty.

MBR Helicopters requested relief from the 14-hour rule and the requirement that drivers have 10 consecutive hours off duty at the end of the work shift. The exemption would allow MBR Helicopters' ground support equipment operators a 16-hour window within which to complete all driving and enable these operators to use an 8-consecutive hour off-duty break, combined with at least 2 other off-duty hours during the 16-hour window

within which driving would be completed, in lieu of taking 10 consecutive hours off duty. If granted, the exemption would cover MBR Helicopters' commercial motor vehicle (CMV) operators only when they are responding to or returning from an active incident as requested by an officer of a safety agency or public utility commission or service. A copy of the application is included in the docket referenced at the beginning of this notice.

Request for Comments

In accordance with 49 U.S.C. 31315, FMCSA requests public comment from all interested persons on MBR's application for an exemption. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–27966 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0173]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Netradyne, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition; grant of exemption.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to grant Netradyne, Inc's. (Netradyne) application for a limited 5-year exemption to allow its Driveri® Dash Cam to be mounted lower in the windshield on commercial motor vehicles (CMV) than is currently permitted. The Agency has determined that lower placement of the Driveri® Dash Cam would not have an adverse impact on safety and that adherence to the terms and conditions of the exemption would likely achieve a level of safety equivalent to, or greater than, the level of safety provided by the regulation.

DATES: This exemption is effective December 18, 2020. The exemption expires December 15, 2025.

FOR FURTHER INFORMATION CONTACT: Mr. José R. Cestero, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–5541, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC, 20590–0001. If you have questions regarding viewing or submitting material to the docket, contact Docket Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request. The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305).

The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

Netradyne's Application for Exemption

Netradyne applied for an exemption from 49 CFR 393.60(e)(1) to allow its Driveri® Dash Cam to be mounted lower in the windshield than is currently permitted by the Agency's regulations to utilize a mounting location that allows optimal functionality of the advance safety system supported by the device. A copy of the application is included in the docket referenced at the beginning of this notice. Section 393.60(e)(1)(i) of the FMCSRs prohibits obstruction of the driver's field of view by devices mounted at the top of the windshield. Antennas and similar devices must not be mounted more than 152 mm (6 inches) below the upper edge of the windshield, and must be outside the driver's sight lines to the road and highway signs and signals. However, § 393.60(e)(1)(i) does not apply to vehicle safety technologies, as defined in § 390.5, that include ''a fleet related incident management system, performance or behavior management system, speed management system, forward collision warning or mitigation system, active cruise control system, and transponder.''

Section 393.60(e)(1)(ii) requires devices with vehicle safety technologies to be mounted (1) not more than 100 mm (4 inches) below the upper edge of the area swept by the windshield wipers, or (2) not more than 175 mm (7 inches) above the lower edge of the area swept by the windshield wipers, and (3) outside the driver's sight lines to the road and highway signs and signals.

Netradyne states that the functionality of its Driveri® Dash Cam includes the ability to capture and analyze distracted driving events along with providing in-cab audio alerts, following distance management, and detection of stop signs and traffic signals. Netradyne states that the proposed exemption will increase safety by providing these advance safety features on its customers' CMVs. Netradyne notes that it conducted pilot tests of the devices' functionality and found that there was no noticeable obstruction to the driver's normal sightlines to the road ahead, highway signs and, signals, or any mirrors.

The Driveri® Dash Cam, four-camera version housing, is approximately 190 mm (7.4 inches) wide by 118 mm (4.6 inches) tall and the two-camera version housing is 126 mm (4.9 inches) wide by 71 mm (2.8 inches) tall. The devices will be mounted in the approximate center of the top of the windshield such that the bottom edge of the camera housing is approximately 204 mm (8 inches) below the upper edge of the windshield wipers, outside of the driver's and passenger's normal sight lines to the road ahead, highway signs and signals, and all mirrors. This location will allow for optimal functionality of the advanced safety systems supported by the device. Without the proposed exemption, Netradyne states that its customers will not be able to install these devices in an optimal location on the windshield to

maximize the effectiveness of the safety features of the technology. The exemption would apply to all CMVs equipped with Netradyne's Driveri® Dash Cam mounted on the windshield. Netradyne believes that mounting the system as described will maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

Comments

FMCSA published a notice announcing receipt of the exemption application in the **Federal Register** on August 20, 2020, and requested public comment on the application (85 FR 51545).

The Agency received no comments addressing the exemption application.

FMCSA Decision

FMCSA has evaluated the Netradyne exemption application. The Driveri® Dash Cam, four-camera housing version, is approximately 4.6 inches tall while the two-camera housing version is 2.8 inches tall. Both camera versions are mounted near the top of the center of the windshield, with the bottom of the camera housing located approximately 8 inches below the top of the area swept by the windshield wipers. The Driveri® Dash Cam needs to be mounted in this location for optimal functionality of the advance safety system. The size of the Driveri® Dash Cam precludes mounting it (1) higher in the windshield, and (2) within 4 inches from the top of the area swept by the windshield wipers to comply with § 393.60(e)(1)(ii)(A).

The Agency believes that granting the temporary exemption to allow placement of the Driveri® Dash Cam lower than currently permitted by Agency regulations will provide a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption because (1) based on the technical information available, there is no indication that the Driveri® Dash Cam would obstruct drivers' views of the roadway, highway signs and signals surrounding traffic; (2) generally, trucks and buses have an elevated seating position that greatly improves the forward visual field of the driver, and any impairment of available sight lines would be minimal; and (3) the mounting location 8 inches below the upper edge of the windshield and out of the driver's normal sightline will be reasonable and enforceable at roadside. In addition, the Agency believes that use of Driveri® Dash Cam by fleets is likely to improve the overall level of safety for the motoring public. This action is consistent with previous Agency action permitting the placement of similarly-sized devices on CMVs outside the driver's sight lines to the road, and highway signs and signals. FMCSA is not aware of any evidence showing that installation of other vehicle safety technologies mounted on the interior of the windshield has resulted in any degradation in safety.

James W. Deck,

Deputy Administrator.

[FR Doc. 2020–27967 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2020–0027–N–28]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, this notice announces that FRA is forwarding the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On July 22, 2020, FRA published a notice providing a 60-day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or before January 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed ICR should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find the particular ICR by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Hodan Wells, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, Federal Railroad Administration, telephone (202) 493–0440, email: *Hodan.wells@dot.gov.*

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On July 22, 2020, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICR for which it is now seeking OMB approval. *See* 85 FR 44359. FRA received no comments in response to this notice.

Before OMB decides whether to approve the proposed collection of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summaries below describe the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Safety Appliance Standards Guidance Checklist Forms.

OMB Control Number: 2130–0565.

Abstract: Title 49 Code of Federal Regulations (CFR) part 231, *Railroad Safety Appliance Standards,* was supplemented and expanded in 2013 to include the industry standard established by the Association of American Railroads (AAR), *Standard 2044 or S–2044,* which prescribed safety appliance arrangements for 11 new types of cars. As a result of the inclusion, FRA developed Forms FRA F6180.161(a)–(k) as guidance checklist forms to facilitate railroad, rail car owner, and rail equipment manufacturer compliance with S–2044 and 49 CFR part 231.

AAR has since updated S–2044 to include seven new types of cars. In

response, FRA is proposing to add seven new forms, Forms FRA F6180.161(l)–(r), to the safety appliance standards guidance checklists to cover these new types of cars.

Additionally, FRA is updating the existing 11 forms to reflect editorial changes that were made to S–2044.

Type of Request: Revision of a currently approved collection.

Affected Public: Businesses.

Form(s): 11 forms (FRA F6180.161(a)–(k)), plus seven new forms (FRA F 6180.161(l)–(r)).

Respondent Universe: Car manufacturers/state inspectors.

Frequency of Submission: On occasion.

Total Estimated Annual Responses: 142.

Total Estimated Annual Burden: 142 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $8,694.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that a respondent is not required to respond to, conduct, or sponsor a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Deputy Chief Counsel.

[FR Doc. 2020–27871 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2020–0027–N–33]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) abstracted below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in the ICR.

DATES: Interested persons are invited to submit comments on or before February 16, 2021.

ADDRESSES: Submit comments and recommendations for the proposed ICR to Ms. Hodan Wells, Information Collection Clearance Officer at email: *hodan.wells@dot.gov* or telephone: (202) 493–0440. Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, FRA reasons that comments received will advance three objectives: (1) reduce reporting burdens; (2) organize information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Occupational Noise Exposure for Railroad Operating Employees.

OMB Control Number: 2130–0571.

Abstract: Title 49 CFR part 227 contains requirements for occupational noise exposure. FRA uses the collection of information to ensure that railroads covered by this rule establish and implement noise monitoring, hearing conservation, and audiometric testing programs to protect their employees against the harmful effects of excessive noise in the workplace. Additionally, railroads must maintain testing and training records on noise and hearing conservation. Further, railroads must make exposure measurement records for specific locations available to regional or national labor representatives upon request.

Type of Request: Extension with change (estimates) of a currently approved collection.

Affected Public: Businesses (Railroads, railroads equipment manufacturers).

Form(s): N/A.

Respondent Universe: 512 railroads.

Frequency of Submission: On occasion.

Reporting Burden:

CFR Section [1]	Respondent universe (railroads)	Total Annual responses	Average time per response	Total annual burden hours	Total cost equivalent [2]
227.13—Waivers	512 railroads	.3 petition letters	1 hour	.3	$23
227.103(a)-(f)—Noise monitoring program—Development and implementation.	512 railroads	5 programs	30 hours	150	18,000
—(g) Reporting of monitoring results—Notification of employee of monitoring.	512 railroads	5 lists	30 minutes	3	231
227.107(a)—Hearing Conservation Program (HCP)—Development of programs.	512 railroads	3 HCPs	31 hours	93	11,160
—Revised hearing conservation programs (HCPs).	512 railroads	3 HCPs	1.75 hours	5	385
227.109(e)—Audiometric testing program—Baseline audiograms—New and existing employees.	76,244 employees	6,862 records of tests	30 seconds	57	4,389

CFR Section [1]	Respondent universe (railroads)	Total Annual responses	Average time per response	Total annual burden hours	Total cost equivalent [2]
—(f) Periodic audiograms	76,244 employees	25,415 records of tests	30 seconds	212	16,324
—(g)(1)-(2) Evaluation of audiograms	76,244 employees	2,330 ratings + 93 records of retests.	6 minutes + 30 seconds.	234	18,018
—(g)(3) Review of problem audiograms	8,000 employees	45 documents	10 minutes	8	616
— (h)(1) Follow-up procedures—notifications.	8,000 employees	93 notices	5 minutes	8	616
—(h)(2)(i)-(ii) Fitting/training of employees: hearing protectors.	240 employees	240 documenting training sessions.	5 minutes	20	1,540
— (h)(2)(iii) Referrals for clinical/otological exam.	240 employees	20 referrals	1 hour	20	1,540
— (h)(2)(iv) Notification to employee of need for otological examination.	240 employees	20 notices	5 minutes	2	154
— (h)(3) New audiometric interpretation	240 employees	20 notices	5 minutes	2	154
227.111—Audiometric test requirements	1,000 mobile vans	1,000 records of tests	30 seconds	8	616
227.117(a)—Hearing protection attenuation— evaluation.	512 railroads	50 evaluations	30 minutes	25	1,925
— (d) Reevaluations of adequacy of hearing protection attenuation when employee noise exposure increases.	512 railroads	10 documented re-evaluations.	30 minutes	5	385
227.119—Hearing Conservation Training Program—Development.	512 railroads	3 training program modifications.	60 minutes	3	231
—Employee HCP training	512 railroads	26,000 records of trainings.	2 minutes	867	66,759
—Periodic training	512 railroads	6,862 records of trainings.	2 minutes	229	17,633
227.121(a)(1)(i)-(ii)—Recordkeeping—Availability of records upon request.	512 railroads	30 requests + 30 responses.	10 minutes + 15 minutes.	13	1,001
—(a)(1)(iv) Availability of exposure measurement records to regional or national labor representatives upon request.	512 railroads	150 requests + 150 responses.	21 minutes + 45 minutes.	165	12,705
—(a)(2)-(3) Electronic records—Maintenance and transfer of records.	512 railroads	10 records	24 minutes	4	308
—(c) Audiometric test records	512 railroads	26,000 records	2 minutes	867	66,759
—(d) Positions and person designated records.	512 railroads	54,000 records	45 seconds	675	51,975
229.121(a)—Locomotive Cab Noise—Performance standards for locomotives—Records and certification.	3 equipment manufacturers	610 records + 90 certifications.	5 minutes + 40 minutes.	111	8,547
—(b)(3) Maintenance of locomotives—Excessive noise reports.	494 railroads	3,000 reports + 3,000 records.	1 minute + 1 minute	100	7,700
—(b)(4) Recordkeeping—Written or electronic records.	494 railroads	3,750 records	1 minute	63	4,851
—(b)(4)(iii) Internal auditable monitoring systems—Records.	494 railroads	22 systems + 2 systems.	36 min + 8.25 hours	30	2,310
Appendix H(IV)—Static noise test protocols—Records for retest.	500 locomotives	2 retest records	5 minutes	.2	15
Total	512 railroads	159,927 responses	N/A	3,980	316,871

Total Estimated Annual Responses: 159,927.

Total Estimated Annual Burden: 3,980 hours.

[1] The current inventory exhibits a total burden of 28,311 hours while the total burden of this notice is 3,980 hours. FRA determined some of the estimates were not derived from PRA requirements, thus leading to the increased figures in the current inventory, which were decreased accordingly in this notice. Also, totals may not add due to rounding.

[2] The dollar equivalent cost is derived from the Surface Transportation Board's Full Year Wage A&B data series using the appropriate employee group hourly wage rate that includes a 75-percent overhead charge.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $316,871.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that a respondent is not required to respond to, conduct, or sponsor a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Deputy Chief Counsel.

[FR Doc. 2020–27925 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0089]

National Emergency Medical Services Advisory Council; Solicitation of Applications

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

ACTION: Solicitation of Nominations for Appointment to the National Emergency

Medical Services Advisory Council (NEMSAC).

SUMMARY: NHTSA is soliciting applications for appointment/reappointment to the U.S. Department of Transportation's (DOT) NEMSAC. The purpose of NEMSAC is to serve as a nationally recognized council of Emergency Medical Services (EMS) representatives and consumers to provide advice and recommendations regarding EMS to DOT. Through NHTSA, NEMSAC's advice is provided to the Federal Interagency Committee on EMS (FICEMS).

DATES: Applications for membership must be received by NHTSA on or before 5 p.m. EST, January 15, 2021.

ADDRESSES: If you wish to apply for membership, your application should be submitted to:

- *Email: NEMSAC@dot.gov.*
- Mail: *Use only overnight mail such as UPS or FedEx to:* U.S. Department of Transportation, National Highway Traffic Safety Administration, Office of Emergency Medical Services, Attn: NEMSAC, 1200 New Jersey Avenue SE, NTI–140, Washington, DC 20590.

Additional information on NEMSAC, including the current roster, charter, and previous meeting minutes can be found at: *https://www.ems.gov/nemsac.html.*

FOR FURTHER INFORMATION CONTACT: Clary Mole, EMS Specialist, National Highway Traffic Safety Administration, U.S. Department of Transportation, *Clary.Mole@dot.gov* or 202–366–2795. Any committee related questions should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

Background:

NEMSAC is an advisory council established by DOT in accordance with the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.) and DOT Order 1120.3C NEMSAC provides information, advice, and recommendations to the Secretary via the Administrator of NHTSA, and through NHTSA to FICEMS on matters relating to all aspects of development and implementation of EMS.

Description of Duties:

Consistent with Sections 3 and 5, NEMSAC is authorized to:

a. Consider information on EMS issues to define, develop positions, and make recommendations on such issues for the Secretary of Transportation and/or FICEMS.

b. Provide recommendations or advice relating to EMS on such topics as:

- Improved coordination and support of EMS systems among Federal programs;
- Strategic planning;
- EMS standards, guidelines, performance benchmarks, and other guidelines;
- Guidelines for conducting needs assessments for improving community-based EMS systems at State and local levels;
- Enhancing the National EMS Information System (NEMSIS) through adoption, utilization and revision of the NEMSIS standard and supporting EMS systems with new uses of EMS data and information; and
- Strengthening EMS systems through enhanced workforce development, education, training, exercises, sustainability, equipment, medical oversight, and other areas.

c. Respond to requests for consultation and advice on EMS issues from the Secretary of Transportation (via the National Highway Traffic Safety Administration's (NHTSA) Designated Federal Officer (DFO)) and/or from FICEMS.

d. NEMSAC shall prepare an annual report to the Secretary of Transportation, with copies sent to the Secretary of Health and Human Services and Secretary of Homeland Security, and to FICEMS, regarding NEMSAC's actions and recommendations.

Membership

In accordance with the NEMSAC charter, members should represent a cross-section of the diverse agencies, organizations, and individuals involved in EMS activities and programs in the United States. NEMSAC consists of 25 members, each of whom shall be appointed by the Secretary of Transportation, in coordination with the U.S. Departments of Homeland Security and Health and Human Services through their respective representatives on FICEMS. The NEMSAC members shall collectively be representative of all sectors of the EMS community.

The NEMSAC's broad-based membership will ensure that it has sufficient EMS system expertise and geographic and demographic diversity to accurately reflect the whole EMS community.

To the extent practical, the final NEMSAC membership shall ensure representation from the following sectors of the EMS community:

- Volunteer EMS
- Fire-based (career) EMS
- Private (career non-fire) EMS
- Hospital-based EMS
- Tribal EMS
- Air Medical EMS
- Local EMS service directors/administrators
- EMS Medical Directors
- Emergency Physicians
- Trauma Surgeons
- Pediatric Emergency Physicians
- State EMS Directors
- State Highway Safety Directors
- EMS Educators
- Public Safety Call-taker/Dispatcher (911)
- EMS Data Managers
- EMS Quality Improvement
- EMS Researchers
- Emergency Nurses
- Hospital Administration
- Public Health
- Emergency Management
- EMS Practitioners
- Consumers (not directly affiliated with an EMS or healthcare organization)
- State or local legislative bodies (*e.g.,* city/county councils; state legislatures)

Members serve in a ''representative'' capacity on NEMSAC and not as Special Government Employees. The Secretary of Transportation shall appoint each member for up to a 2-year term and members may be reappointed but may not serve more than two consecutive terms unless the Secretary determines that additional terms are permitted to ensure representation of all sectors of EMS. NEMSAC members will not receive pay or other compensation from NHTSA for their NEMSAC service, but are entitled to reimbursement of their travel expenses, including per diem. The NEMSAC meets in plenary session approximately three to four times per year.

Qualifications

Members will be selected for their ability to reflect a balanced representation of interests from across the EMS community, but no member will represent a specific organization.

Materials To Submit

Qualified individuals interested in serving on the NEMSAC are invited to apply for appointment by submitting a resume or CV along with letters of recommendation to one of the locations listed in the **ADDRESSES** section by the deadline listed in the **DATES** section. Each applicant must identify the EMS sector or discipline that he or she seeks to represent. Current NEMSAC members whose terms are ending should notify the person listed in the **FOR FURTHER INFORMATION CONTACT** section of their interest in reappointment in lieu of submitting a new application, and should provide an updated resume or

CV and a restatement of the current sector they represent by the deadline. Nominations are open to all individuals without regard to race, color, religion, sex, national origin, age, mental or physical disability, marital status, or sexual orientation. Evaluations will be based on the materials submitted.

Authority: 42 U.S.C. 300d–4(b); 49 CFR 1.95(i)(4).

Issued in Washington, DC.

Nanda Narayanan Srinivasan,

Associate Administrator, Research and Program Development.

[FR Doc. 2020–27942 Filed 12–17–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the OCC, the Board, and the FDIC (the agencies) may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The Federal Financial Institutions Examination Council (FFIEC), of which the agencies are members, has approved the agencies' publication for public comment of a proposal to revise and extend the Consolidated Reports of Condition and Income (Call Reports) (FFIEC 031, FFIEC 041, and FFIEC 051), which are currently approved collections of information. The agencies are requesting comment on a change to the Call Report forms and instructions (FFIEC 031 and FFIEC 041 only) to implement the FDIC's proposed amendments to the deposit insurance assessment system applicable to all large insured depository institutions (IDIs), including highly complex IDIs, to address the temporary deposit insurance assessment effects resulting from certain optional regulatory capital transition provisions relating to the implementation of the current expected credit losses (CECL) methodology. The change to the Call Reports would enable the FDIC to remove the double counting of a specified portion of the CECL transitional amount or the modified CECL transitional amount, as applicable (collectively, the CECL transitional amounts), in certain financial measures that are calculated using the sum of Tier 1 capital and reserves and that are used to determine assessment rates for large and highly complex IDIs.

DATES: Comments must be submitted on or before February 16, 2021.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the ''Call Report Deposit Insurance Assessment-Related Revisions,'' will be shared among the agencies.

OCC: You may submit comments, which should refer to ''Call Report Deposit Insurance Assessment-Related Revisions,'' by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Office of the Comptroller of the Currency, Attention: 1557–0081, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, suite 3E–218, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''1557–0081'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the following method:

- *Viewing Comments Electronically: Go to www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0081.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

Board: You may submit comments, which should refer to ''Call Report Deposit Insurance Assessment-Related Revisions,'' by any of the following methods:

- *Agency website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at: *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include ''Call Report Deposit Insurance Assessment-Related Revisions'' in the subject line of the message.
- *Fax:* (202) 395–6974.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available on the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information.

FDIC: You may submit comments, which should refer to ''Call Report Deposit Insurance Assessment-Related Revisions,'' by any of the following methods:

- *Agency website: https://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC's website.
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: comments@FDIC.gov.* Include ''Call Report Deposit Insurance Assessment-Related Revisions'' in the subject line of the message.
- *Mail:* Manuel E. Cabeza, Counsel, Attn: Comments, Room MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building

(located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

• *Public Inspection:* All comments received will be posted without change to *https://www.fdic.gov/regulations/laws/federal/* including any personal information provided. Paper copies of public comments may be requested from the FDIC Public Information Center by telephone at (877) 275–3342 or (703) 562–2200.

Additionally, commenters may send a copy of their comments to the OMB desk officer for the agencies by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503; by fax to (202) 395–6974; or by email to *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about the proposed revisions to the information collections discussed in this notice, please contact any of the agency staff whose names appear below. In addition, copies of the report forms for the Call Reports can be obtained at the FFIEC's website (*https://www.ffiec.gov/ffiec_report_forms.htm*).

OCC: Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649–5490.

Board: Nuha Elmaghrabi, Federal Reserve Board Clearance Officer, (202) 452–3884, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Manuel E. Cabeza, Counsel, (202) 898–3767, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

I. Report Summary

The agencies propose to extend for three years, with revision, their information collections associated with the FFIEC 031, FFIEC 041, and FFIEC 051 Call Reports.

Report Title: Consolidated Reports of Condition and Income (Call Report).

Form Number: FFIEC 031 (Consolidated Reports of Condition and Income for a Bank with Domestic and Foreign Offices), FFIEC 041 (Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only), and FFIEC 051 (Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only and Total Assets Less Than $5 Billion).

Frequency of Response: Quarterly.

Affected Public: Business or other for-profit.

Type of Review: Revision and extension of currently approved collections.

OCC

OMB Control No.: 1557–0081.

Estimated Number of Respondents: 1,111 national banks and federal savings associations.

Estimated Average Burden per Response: 41.92 burden hours per quarter to file.

Estimated Total Annual Burden: 186,292 burden hours to file.

Board

OMB Control No.: 7100–0036.

Estimated Number of Respondents: 739 state member banks.

Estimated Average Burden per Response: 45.40 burden hours per quarter to file.

Estimated Total Annual Burden: 134,202 burden hours to file.

FDIC

OMB Control No.: 3064–0052.

Estimated Number of Respondents: 3,263 insured state nonmember banksand state savings associations.

Estimated Average Burden per Response: 39.96 burden hours per quarter to file.

Estimated Total Annual Burden: 521,558 burden hours to file.

The estimated average burden hours collectively reflect the estimates for the FFIEC 031, the FFIEC 041, and the FFIEC 051 reports for each agency. When the estimates are calculated by type of report across the agencies, the estimated average burden hours per quarter are 85.85 (FFIEC 031), 55.20 (FFIEC 041), and 35.27 (FFIEC 051). The change to the FFIEC 031 and FFIEC 041 Call Report forms and instructions proposed in this notice would not have a material impact on the existing burden estimates. This notice does not propose any changes to the FFIEC 051. The estimated burden per response for the quarterly filings of the Call Report is an average that varies by agency because of differences in the composition of the institutions under each agency's supervision (*e.g.,* size distribution of institutions, types of activities in which they are engaged, and existence of foreign offices).

Type of Review: Extension and revision of currently approved collections.

Legal Basis and Need for Collections

The Call Report information collections are mandatory: 12 U.S.C. 161 (national banks), 12 U.S.C. 324 (state member banks), 12 U.S.C. 1817 (insured state nonmember commercial and savings banks), and 12 U.S.C. 1464 (federal and state savings associations). At present, except for selected data items and text, these information collections are not given confidential treatment.

Banks and savings associations submit Call Report data to the agencies each quarter for the agencies' use in monitoring the condition, performance, and risk profile of individual institutions and the industry as a whole. Call Report data serve a regulatory or public policy purpose by assisting the agencies in fulfilling their shared missions of ensuring the safety and soundness of financial institutions and the financial system and protecting consumer financial rights, as well as agency-specific missions affecting national and state-chartered institutions, such as conducting monetary policy, ensuring financial stability, and administering federal deposit insurance. Call Reports are the source of the most current statistical data available for identifying areas of focus for on-site and off-site examinations. Among other purposes, the agencies use Call Report data in evaluating institutions' corporate applications, including interstate merger and acquisition applications for which the agencies are required by law to determine whether the resulting institution would control more than 10 percent of the total amount of deposits of insured depository institutions in the United States. Call Report data also are used to calculate institutions' deposit insurance assessments and national banks' and federal savings associations' semiannual assessment fees.

II. Current Action

A. Background

Upon adoption of the CECL methodology, an institution will record a one-time adjustment to its credit loss allowances as of the beginning of its fiscal year of adoption equal to the difference, if any, between the amount of credit loss allowances required under the incurred loss methodology and the amount of credit loss allowances required under CECL. An institution's implementation of CECL will affect its retained earnings, deferred tax assets, credit loss allowances, and, as a result, its regulatory capital ratios.

In recognition of the potential for the implementation of CECL to affect regulatory capital ratios, on February 14, 2019, the agencies issued a final rule that revised certain regulations, including the agencies' regulatory

capital regulations (capital rule),[1] to account for the aforementioned changes to credit loss accounting under U.S. generally accepted accounting principles (GAAP), including CECL (2019 CECL rule).[2] The 2019 CECL rule includes a transition provision that allows institutions to phase in over a three-year period the day-one adverse effects of CECL on their regulatory capital ratios.

As part of the efforts to address the disruption of economic activity in the United States caused by the spread of the coronavirus disease 2019 (COVID–19), on March 31, 2020, the agencies adopted a second CECL transition provision through an interim final rule.[3] The agencies subsequently adopted a final rule (2020 CECL rule) on September 30, 2020, that is consistent with the interim final rule, with some clarifications and adjustments related to the calculation of the transition and the eligibility criteria for using the 2020 CECL transition provision.[4] The 2020 CECL rule provides that only institutions that adopt CECL for a fiscal year that begins during the 2020 calendar year, have the option to delay for up to two years an estimate of CECL's effect on regulatory capital, followed by a three-year transition period (*i.e.,* a five-year transition period in total). The 2020 CECL rule does not replace the three-year transition provision in the 2019 CECL rule, which remains available to any institution at the time that it adopts CECL.[5]

Certain financial measures that are used to determine assessment rates for large and highly complex institutions[6] are calculated using both Tier 1 capital and reserves. For institutions that elect either the three-year transition provision contained in the 2019 CECL rule or the five-year transition provision contained in the 2020 CECL rule, the amount of Tier 1 capital reported in Call Report Schedule RC–R, Part I, item 26, includes (due to adjustments to the amount of retained earnings reported on the Call Report balance sheet) the applicable portion of the CECL transitional amount (or the modified CECL transitional amount). For deposit insurance assessment purposes, reserves are calculated using the amount of the allowance for loan and lease losses reported in Call Report Schedule RC, item 4.c. For all institutions that have adopted CECL, Schedule RC, item 4.c, reflects the allowance for credit losses on loans and leases. The issue of double counting arises in certain financial measures used to determine assessment rates for large and highly complex institutions that are calculated using both Tier 1 capital and reserves because the allowance for credit losses on loans and leases is included during the transition period in both reserves and, as a portion of the CECL or modified CECL transitional amount, Tier 1 capital.

For institutions that elect either the three-year transition provision contained in the 2019 CECL rule or the five-year transition provision contained in the 2020 CECL rule, the CECL transitional amounts, as defined in the regulatory capital rules,[7] additionally include the effect on retained earnings, net of tax effect, of establishing allowances for credit losses in accordance with the CECL methodology on held-to-maturity (HTM) debt securities, other financial assets measured at amortized cost, and off-balance sheet credit exposures as of the beginning of the fiscal year of adoption. The applicable portions of the CECL transitional amounts attributable to allowances for credit losses on HTM debt securities, other financial assets measured at amortized cost, and off-balance sheet credit exposures are included in Tier 1 capital only and are not double counted with reserves for deposit insurance assessment purposes.

To address the temporary deposit insurance assessment effects resulting from certain optional regulatory capital transition provisions under the 2019 and 2020 CECL rules, the FDIC proposed amendments to the deposit insurance assessment system applicable to all large and highly complex IDIs on December 7, 2020.[8] Under these proposed amendments to the assessment system, the FDIC would remove the double counting of the applicable portion of the CECL transitional amounts that is added to retained earnings for regulatory capital purposes and is attributable to the allowance for credit losses on loans and leases held for investment in certain financial measures that are calculated using the sum of Tier 1 capital and reserves, and also from the loss severity measure, which are used to determine assessment rates for large and highly complex institutions.

B. Proposed New Memorandum Item To Remove Double Counting

In calculating certain financial measures used in the scorecards for determining deposit insurance assessment rates for large and highly complex institutions, the FDIC has proposed to remove a portion of the CECL transitional amounts added to retained earnings for regulatory capital purposes under the transitions provided for under the 2019 or 2020 CECL rules. Specifically, in certain measures used in the scorecard approach for determining assessment rates for large and highly complex institutions, the applicable portion of the CECL transitional amount (or modified CECL transitional amount) that is added to retained earnings for regulatory capital purposes and is attributable to the allowance for credit losses on loans and leases held for investment would be removed under the FDIC's proposal. However, large and highly complex institutions that have elected a CECL transition provision do not currently report these specific portions of the CECL transitional amounts in the Call Report. Thus, implementing the FDIC's proposed amendments to the risk-based deposit insurance assessment system applicable to large and highly complex institutions requires a new, temporary memorandum item and corresponding changes to the FFIEC 031 and FFIEC 041 versions of the Call Report forms and instructions.

In this regard, the CECL effective dates assigned by the Financial Accounting Standards Board's Accounting Standards Update (ASU) No. 2016–13, Financial Instruments—Credit Losses, Topic 326, Measurement of Credit Losses on Financial Instruments (ASU 2016–13) as most recently amended by ASU No. 2019–10, the optional temporary relief from complying with CECL afforded by the CARES Act, and the transitions under the 2019 CECL rule and 2020 CECL rule provide that, at present, all institutions will have completely reflected in regulatory capital the day-one effects of CECL (plus, if applicable, an estimate of CECL's effect on regulatory capital, relative to the incurred loss methodology's effect on regulatory capital, during the first two years of CECL adoption) by December 31, 2026. As a result, the reporting change for large and highly complex institutions would be required only while the temporary relief under the 2019 and 2020 CECL rules is reflected in institutions' Call Reports. The agencies would remove the proposed new Call Report item when all large and highly

[1] 12 CFR part 3 (OCC); 12 CFR part 217 (Board); 12 CFR part 324 (FDIC).

[2] 84 FR 4222 (Feb. 14, 2019).

[3] 85 FR 17723 (Mar. 31, 2020).

[4] *See* 85 FR 61577 (Sept. 30, 2020).

[5] See 85 FR 61578 (Sept. 30, 2020).

[6] *See* 12 CFR 327.8 and 12 CFR 327.16(f).

[7] *See* 12 CFR 3.301 (OCC); 12 CFR 217.301 (Board); 12 CFR 324.301 (FDIC).

[8] 85 FR 78794 (Dec. 7, 2020).

complex institutions are no longer using a CECL transition.

Specifically, the agencies propose to add a new Memorandum item 5 to Schedule RC–O, Other Data for Deposit Insurance Assessments, in the FFIEC 031 and the FFIEC 041 Call Reports, only in order to quantify the applicable portions of the CECL transitional amounts added to retained earnings for regulatory capital purposes and attributable to the allowance for credit losses on loans and leases held for investment. The removal of this portion of the CECL transitional amounts is needed because, for large and highly complex institutions that have adopted CECL, the measure of reserves used in the scorecard is limited to the allowance for credit losses on loans and leases.

To adjust the calculations of certain financial measures used to determine deposit insurance assessment rates for large and highly complex institutions, the FDIC would remove the amount reported in the new Schedule RC–O Memorandum item from scorecard measures that are calculated using the sum of Tier 1 capital and reserves and also from the loss severity measure in the scorecards.

C. Timing

Beginning with the June 30, 2021, Call Report, Schedule RC–O, Memorandum item 5, ''Applicable portion of the CECL transitional amount or modified CECL transitional amount that has been added to retained earnings for regulatory capital purposes as of the report date and is attributable to loans and leases held for investment,'' would be completed only by large and highly complex institutions that have adopted ASU 2016–13 and reported having a CECL transition election in effect as of the quarter-end report date.

The specific wording of the caption for the proposed new Schedule RC–O Memorandum item discussed in this proposal and the numbering of this Memorandum item should be regarded as preliminary.

III. Request for Comment

Public comment is requested on all aspects of this joint notice. Comment is specifically invited on:

(a) Whether the proposed revisions to the collections of information that are the subject of this notice are necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

(b) The accuracy of the agencies' estimates of the burden of the information collections as they are proposed to be revised, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this joint notice will be shared among the agencies.

Bao Nguyen,

Principal Deputy Chief Counsel,Office of the Comptroller of the Currency.Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

Dated at Washington, DC, on or about December 14, 2020.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2020–27847 Filed 12–17–20; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P

DEPARTMENT OF VETERANS AFFAIRS

VA High Risk List Action Plan, Managing Risks, and Improving VA Health Care

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Notice is given that the Department of Veteran Affairs (VA) High Risk List Action Plan—Managing Risks and Improving VA Health Care report to the U.S. Government Accountability Office (GAO) is available for public review at *https://www.va.gov/performance/.* The March 2020 document is VA's action plan for addressing the five broad management issues described by the GAO in its 2015 High Risk Series Update, which include: policy and processes, oversight and accountability, information technology (IT), adequate training, and resource allocation.

FOR FURTHER INFORMATION CONTACT: Karen Rasmussen, M.D., Director for GAO–OIG Accountability Liaison at (202) 461–6643 or *VHA10BGOALGAOHRL@va.gov.*

SUPPLEMENTARY INFORMATION: VA's commitment to addressing the management functions GAO highlighted in its report will ensure large initiatives are reinforced by sound policy; are implemented by staff with the right knowledge, skills, and abilities; receive the right IT support; identify and secure essential human and financial resources; have management oversight; and are accountable throughout planning, implementation, and reinforcement. To that end, VA's 2020 plan includes over 250 actions underway and other measures to monitor progress toward achieving the outcomes described in Chapter 2. The plan also identifies key transformational initiatives from the Veterans Health Administration's Plan for Modernization that complement or contribute to resolution of the areas of concern (Chapter 1).

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Brooks D. Tucker, Assistant Secretary for Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, Department of Veterans Affairs, approved this document on December 14, 2020, for publication.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2020–27939 Filed 12–17–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 435, 438, et al.

45 CFR Parts 156 and 170

Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 435, 438, 440, and 457

Office of the Secretary

45 CFR Parts 156 and 170

[CMS–9123–P]

RIN 0938–AT99

Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would place new requirements on state Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs) to improve the electronic exchange of health care data, and streamline processes related to prior authorization, while continuing CMS' drive toward interoperability, and reducing burden in the health care market. In addition, on behalf of the Department of Health and Human Service (HHS), the Office of the National Coordinator for Health Information Technology (ONC) is proposing the adoption of certain specified implementation guides (IGs) needed to support the proposed Application Programming Interface (API) policies included in this rule. Each of these elements plays a key role in reducing overall payer and provider burden and improving patient access to health information.

DATES: 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–9123–P.

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–9123–P, 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–9123–P, 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:

Alexandra Mugge, (410) 786–4457, for general issues related to this rule and CMS interoperability initiatives.

Denise St. Clair, (410) 786–4599, for the API policies, implementation guides (IGs), general issues related to this rule, and CMS interoperability initiatives.

Lorraine Doo, (443) 615–1309, for prior authorization process policies and CMS interoperability initiatives.

Amy Gentile, (410) 786–3499, for issues related to Medicaid managed care.

Kirsten Jensen, (410) 786–8146, for issues related to Medicaid fee for service (FFS).

Cassandra Lagorio, (410) 786–4554, for issues related to the Children's Health Insurance Program (CHIP).

Russell Hendel, (410) 786–0329, for issues related to the Collection of Information and Regulatory Impact Analysis.

Rebecca Zimmermann, (301) 492–4396, for issues related to Qualified Health Plans (QHPs).

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://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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I. Background and Summary of Provisions

A. Purpose

In the May 1, 2020 **Federal Register**, we published the first phase of CMS interoperability rulemaking in the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, state Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges and Health Care Providers'' final rule (85 FR 25510) (hereinafter referred to as the ''CMS Interoperability and Patient Access final rule'').

This proposed rule emphasizes improving health information exchange

and achieving appropriate and necessary access to complete health records for patients, providers, and payers, while simultaneously reducing payer, provider, and patient burden by improving prior authorization processes, and helping to ensure that patients remain at the center of their own care. In this rule, we are proposing to enhance certain policies from the CMS Interoperability and Patient Access final rule, as described below, and add several new proposals to increase data sharing and reduce overall payer, provider, and patient burden through proposed changes to prior authorization practices. ''Prior authorization'' refers to the process through which a provider must obtain approval from a payer before providing care and prior to receiving payment for delivering items or services. In some programs, this may be referred to as ''pre-authorization'' or ''pre-claim review.'' Prior authorization requirements are established by payers to help control costs and ensure payment accuracy by verifying that an item or service is medically necessary, meets coverage criteria, and is consistent with standards of care before the item or service is provided rather than undertaking that review for the first time when a post-service request for payment is made.

We are taking an active approach to move participants in the health care market toward interoperability and reduced burden by proposing policies for the Medicaid program; the Children's Health Insurance Program (CHIP); and qualified health plan (QHP) issuers on the individual market Federally-facilitated Exchanges (FFEs).

For purposes of this proposed rule, references to QHP issuers on the FFEs exclude issuers offering only stand-alone dental plans (SADPs). Likewise, we are also excluding QHP issuers only offering QHPs in the Federally-facilitated Small Business Health Options Program Exchanges (FF–SHOPs) from the proposed provisions of this rule. We believe that the proposed standards would be overly burdensome to both SADP and SHOP issuers, as their current enrollment numbers and premium intake from QHP enrollment are unlikely to support the costs of the requirements that this proposed rule would impose, and could result in those issuers no longer participating in the FFEs, which would not be in the best interest of enrollees. We note that, in this proposed rule, FFEs include those Exchanges in states that perform plan management functions. State-based Exchanges on the Federal Platform (SBE–FPs) are not FFEs, even though consumers in these states enroll in coverage through *HealthCare.gov*, and QHP issuers in SBE–FPs would not be subject to the requirements in this proposed rule. We encourage states operating Exchanges to consider adopting similar requirements for QHPs on the State-based Exchanges (SBEs).

In the CMS Interoperability and Patient Access final rule (85 FR 25510), we finalized policies impacting Medicare Advantage organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs. The policies finalized in that rule requiring those impacted payers to build and maintain application programing interfaces (APIs) were critical and foundational policies, increasing patient access and data exchange and improving interoperability in health care. In this proposed rule, we are proposing certain policies to expand upon those foundational policies for state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs. As further addressed later in this section of the preamble, starting with this payer population is a critical first step for these new proposals. For instance, state Medicaid and CHIP FFS programs were excluded from the payer-to-payer data exchange policies finalized in the CMS Interoperability and Patient Access final rule (85 FR 25564 through 25569). In our first phase of interoperability policy, we chose to limit the burden on these programs so they could focus their attention and resources on implementing the Patient Access and Provider Directory APIs. This proposed rule is a critical step in proposing to require state Medicaid and CHIP FFS programs to similarly exchange patient health information in a more efficient and interoperable way, as discussed in section II.D. of this proposed rule, leveraging the technology and experience gained from implementing the initial set of API policies to these new proposed policies.

''Churn'' in health care refers to the movement of patients between payers and in and out of health care coverage. Churn occurs when a patient moves between payer types and plans or dis-enrolls from coverage (voluntarily or involuntarily) for a period of time. Patients enrolled in Medicaid, CHIP, and QHPs in particular may move between and among these payers due to a change in their eligibility status, or a change in the availability of subsidies in the case of QHP enrollees. Medicaid beneficiaries who churn in and out of Medicaid tend to have higher utilization of emergency services. Overall, these patients face more coverage instability than those enrolled in Medicare. Several of the API proposals outlined in this proposed rule would particularly benefit patients enrolled in Medicaid, CHIP, and QHPs by allowing them to retain their health information in an electronic form, and have their health information move with them from payer to payer and provider to provider.

Our authority to regulate Medicaid and CHIP FFS, Medicaid and CHIP managed care, and QHP issuers on the FFEs puts us in a unique position to be able to align policies across these programs to the benefit of patients across the nation. Patients enrolled in these programs may churn from payer to payer within a given program, as well as from program to program. For example, a Medicaid enrollee may change eligibility status for Medicaid and enroll with a QHP issuer and back in a given year. For this reason, our API proposals discussed in the following sections are particularly valuable because they allow patients to maintain an electronic copy of their health information (Patient Access API discussed in section II.A.), share data directly with their providers (Provider Access API discussed in section II.B. of this proposed rule), and to bring their health information with them as they move from one payer to another (Payer-to-Payer API discussed in section II.D.), which is especially valuable to patients covered by Medicaid and QHPs who experience churn both within and between programs, and may also experience churn in and out of coverage.

While we are not making any proposals for MA organizations at this time, we acknowledge that payers with multiple lines of business may choose to implement these polices for their MA lines of business to support better internal alignment as well as to create more efficiencies and transparency for their patients. Neither the provisions in the CMS Interoperability and Patient Access final rule nor the proposed provisions here would preclude any payer from implementing these proposed policies regardless of whether the payer is directly impacted by the rule. We believe aligning these policies across all payers would benefit all payers alike. However, we do not believe our approach to start with state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs will have a negative impact on patients. We believe these policies would provide a net benefit to these patients, bringing these programs closer in alignment with one another. We are aware that these proposals, if finalized,

would create misalignments between Medicaid and Medicare that could affect dually eligible individuals enrolled in both a Medicaid managed care plan and an MA plan. While we currently do not believe it is necessary to apply these policies to Medicare Advantage organizations at this time, we intend to further evaluate the implementation of these policies to determine whether they would also be appropriate to apply to Medicare Advantage organizations for future rulemaking. In this proposed rule, when we refer to ''impacted payers,'' we are referring to state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs.

Throughout this proposed rule, we refer to terms such as ''patient'', ''consumer'', ''beneficiary'', ''enrollee'', and ''individual.'' We note that every reader of this proposed rule is a patient and has or will receive medical care at some point in their life. In this proposed rule, we use the term ''patient'' as an inclusive term, but because we have historically referred to patients using the other terms noted above in our regulations, we use specific terms as applicable in sections of this proposed rule to refer to individuals covered under the health care programs that we administer and regulate. We also note that when we discuss patients, the term includes a patient's personal representative. Per the privacy regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, enacted on August 21, 1996), as modified, at 45 CFR 164.502(g), a personal representative, generally, is someone authorized under state or other applicable law to act on behalf of the individual in making health care-related decisions (such as a parent, guardian, or person with a medical power of attorney).[1] A patient's personal representative could address policies in this proposed rule that require a patient's action.

We also use terms such as ''payer'', ''plan'', and ''issuer'' in this proposed rule. Certain portions of this proposed rule are applicable to state Medicaid FFS programs, state CHIP FFS programs, Medicaid managed care plans (managed care organizations (MCOs)), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs)), CHIP managed care entities (MCOs, PIHPs, and PAHPs), and QHP issuers on the FFEs. We use the term ''payer'' in the preamble of this proposed rule as an inclusive term for all these programs and (in the case of plans) plan types, but we also use specific terms as applicable in sections of this proposed rule.

We reference ''items and services'' when discussing prior authorization. Throughout this proposed rule, when we discuss ''items and services,'' this does not include prescription drugs and/or covered outpatient drugs. We did not include information about prescription drugs and/or covered outpatient drugs in any of the proposals in this rule.

Finally, we use the terms ''provider'' and ''supplier'' too, as inclusive terms comprising individuals, organizations, and institutions that provide health services, such as clinicians, hospitals, skilled nursing facilities, home health agencies, hospice settings, laboratories, suppliers of durable medical equipment (such as portable X-ray services), community based organizations, etc., as appropriate in the context used.

B. Summary of Major Proposals

To drive interoperability, improve care coordination, reduce burden on providers and payers, and empower patients, we are proposing several initiatives that would impact state Medicaid FFS programs, Medicaid managed care plans, state CHIP FFS programs, CHIP managed care entities, and QHP issuers on the FFEs. We are also including several Requests for Information (RFIs) to gather information that may support future rulemaking or other initiatives. As with the CMS Interoperability and Patient Access rulemaking, our proposals provide for program requirements to cross-reference technical specifications in HHS regulations codified at 45 CFR part 170; in this rule, ONC is proposing the adoption of certain specified implementation guides (IGs) needed to support the proposed new API policies we are proposing here for impacted payers.

In the CMS Interoperability and Patient Access final rule, we required certain payers to implement and maintain standards-based Patient Access and Provider Directory application programming interfaces (APIs).[2] The Patient Access API must allow patients to easily access their claims and encounter information and a specified sub-set of their clinical information as defined in the US Core for Data Interoperability (USCDI) version 1 data set through third-party applications of their choice (85 FR 25558 through 25559). The Provider Directory API must make provider directory information publicly available to third-party applications (85 FR 25563 through 25564). Additionally, in the same final rule we required certain payers, with the approval and at the direction of a patient, to exchange specified clinical data (specifically the USCDI version 1 data set) through a Payer-to-Payer Data Exchange (85 FR 25568 through 25569).

In this proposed rule, we are proposing to enhance the Patient Access API for impacted payers by requiring the use of specific IGs, proposed for adoption by ONC on behalf of HHS, and by proposing payers include information about pending and active prior authorization decisions. In addition, we are proposing to require that impacted payers establish, implement, and maintain a process to facilitate requesting an attestation from a third-party app developer requesting to retrieve data via the Patient Access API that indicates the app adheres to certain privacy provisions. We are also proposing to require these impacted payers to report certain metrics about patient data requests via the Patient Access API quarterly to CMS. In addition, we are proposing to require use of a specific IG for the Provider Directory API. And, we are proposing to extend the patient-initiated Payer-to-Payer Data Exchange requirements to state Medicaid and CHIP FFS programs.

We also propose to enhance and expand the Payer-to-Payer Data Exchange, and to require this exchange be conducted via a specified Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR)-based API. We are proposing that impacted payers must implement and maintain a Payer-to-Payer API to facilitate the exchange of patient information between impacted payers, both with the approval and at the direction of the patient and when a patient moves from one payer to another as permitted, and in accordance with applicable law. Specifically, we are proposing that impacted payers implement the Payer-to-Payer API in accordance with the specified HL7 FHIR version 4.0.1 IGs, as well as the HL7

[1] See OCR guidance regarding personal representatives at *https://www.hhs.gov/hipaa/for-professionals/faq/2069/under-hipaa-when-can-a-family-member/index.html* and *https://www.hhs.gov/hipaa/for-professionals/faq/personal-representatives-and-minors/index.html.*

[2] Impacted payers under that rule include MA organizations, state Medicaid FFS programs, Medicaid managed care plans, state CHIP FFS programs, CHIP managed care entities, and QHP issuers on the FFEs for the Patient Access API. The Provider Directory API requirement applies to all those impacted payers except the QHP issuers on the FFEs. The Payer-to-Payer Data Exchange applies to all those impacted payers except state Medicaid and CHIP FFS programs.

FHIR Bulk Data Access (Flat FHIR) specification, to support exchanging patient data including but not limited to: Adjudicated claims and encounter data (not including cost information), clinical data as defined in the USCDI, and information related to pending and active prior authorization decisions.

To better facilitate the coordination of care across the care continuum and in support of a move to value-based care, we are proposing to require that impacted payers implement and maintain a Provider Access API that, consistent with the APIs finalized in the Interoperability and Patient Access final rule (85 FR 25510), utilizes HL7 FHIR version 4.0.1 to facilitate the exchange of current patient data from payers to providers, including adjudicated claims and encounter data (not including cost information), clinical data as defined in the USCDI, and information related to pending and active prior authorization decisions.

In an effort to improve patient experience and access to care, we are proposing several policies associated with the prior authorization process that may ultimately reduce burden on patients, providers, and payers. As described in the CMS Interoperability and Patient Access proposed rule published on March 4, 2019 (84 FR 7610, 7613), we partnered with industry stakeholders to build a FHIR-based web service that would enable providers to search documentation and prior authorization requirements for Medicare FFS directly from their electronic health records (EHRs). This has significant potential to decrease the burden associated with providers determining which items and services need a prior authorization and what documentation is needed to submit the prior authorization request. And, this could reduce burden on payers who would receive fewer incomplete prior authorization requests and fewer denied and appealed requests simply as the result of missing or incorrect documentation. In this second phase of interoperability proposals, we are proposing to require impacted payers to implement and maintain a similar prior authorization Documentation Requirement Lookup Service (DRLS) API. To further streamline the process of submitting a prior authorization request, and reduce processing burden on both providers and payers, we are also proposing to require impacted payers to implement and maintain a FHIR-based Prior Authorization Support (PAS) API that would have the capability to accept and send prior authorization requests and decisions, and could be integrated within a provider's workflow, while maintaining alignment with, and facilitating the use of, HIPAA transaction standards. Provider use of the PAS API would be voluntary and payers may maintain their existing methods for processing prior authorization requests.

We are also proposing several policies that would require impacted payers, with the exception of QHP issuers on the FFEs, to respond to prior authorization requests within certain timeframes. And, we are proposing that impacted payers publicly report certain metrics about prior authorization processes for transparency.

Finally, on behalf of HHS, the Office of the National Coordinator for Health IT (ONC) is proposing to adopt the implementation specifications described in this regulation at 45 CFR 170.215—Application Programming Interfaces—Standards and Implementation Specifications as standards and implementation specifications for health care operations. ONC is proposing these implementation specifications for adoption by HHS as part of a nationwide health information technology infrastructure that supports reducing burden and health care costs and improving patient care. By ONC proposing these implementation specifications in this way, CMS and ONC are together working to ensure a unified approach to advancing standards in HHS that adopts all interoperability standards in a consistent manner, in one location, for HHS use. Once adopted for HHS use, these specifications would facilitate implementation of the proposed API policies in this rule if finalized.

Although Medicare FFS is not directly impacted by this rule, we do note that we are targeting to implement these proposed provisions, if finalized. In this way, the Medicare implementations would conform to the same requirements that apply to the impacted payers under this rulemaking, as applicable, so that Medicare FFS beneficiaries would also benefit. And, we encourage other payers not directly impacted by this rule to join us in moving toward reduced burden and greater interoperability.

We are also including several RFIs to gather information that may support future rulemaking or other initiatives. Specifically, we are seeking input for potential future rulemaking on whether patients and providers should have the ability to selectively control the sharing of data in an interoperable landscape. We request comment on whether patients and/or providers should be able to dictate which data elements from a medical record are shared when and with whom.

We are additionally seeking comment on how CMS might leverage APIs (or other solutions) to facilitate electronic data exchange between and with behavioral health care providers, and also community based organizations, who have lagged behind other provider types in adoption of EHRs.

We are also seeking comment on how to reduce barriers, and actively encourage and enable greater use of electronic prior authorization, particularly among providers who could benefit most by being able to engage in the prior authorization process directly from their workflows. And, we request comment specifically on including an Improvement Activity under the Merit-based Incentive Payment System (MIPS) to support the use of the Prior Authorization Support (PAS) API.

We are continually looking for ways to facilitate efficient, effective, and secure electronic data exchange to help ensure timely, better quality, and highly coordinated care. We believe one way to do this is to generally reduce or eliminate the use of facsimile (fax) technology across CMS programs, as possible and appropriate. The use of fax technology limits the ability of the health care sector to reach true interoperability. To work toward this goal and enable electronic data exchange, we request information on how CMS can reduce or eliminate the use of fax technology across programs where fax technology is still in use.

Finally, we request information on barriers to adopting standards, and opportunities to accelerate adoption of standards, related to social risk data. We recognize that social risk factors (for example, housing instability and food insecurity) influence patient health and health care utilization. In addition, we understand that providers in value-based arrangements rely on comprehensive, high-quality social risk data. Given the importance of these data, we look to understand how to better standardize and liberate these data.

II. Provisions of the Proposed Rule

A. Patient Access API

1. Background

Claims and encounter data, used in conjunction with clinical data, can offer a more complete picture of an individual's health care experience. In the CMS Interoperability and Patient Access final rule (85 FR 25523), we noted examples of how claims data can be used to benefit patients, as well as providers. For example, inconsistent

benefit utilization patterns in an individual's claims data, such as a failure to fill a prescription or receive recommended therapies, can indicate to a provider or a payer that the individual has had difficulty financing a treatment regimen, may require less expensive prescription drugs or therapies, or may need additional explanation about the severity of their condition. Claims data can also include other information that could be used to understand care utilization and create opportunities for future services or care coordination or management. These are a few examples of how access to these data can improve patient care.

Patients tend to access care from multiple providers throughout their lifetime, leading to fractured patient health records in which various pieces of an individual's data are locked in disparate, siloed data systems. With patient data scattered among these segregated systems, it can be challenging for providers to get a clear picture of the patient's care history, and patients may forget or be unable to provide critical information to their provider during an office visit. This lack of comprehensive patient data can impede care coordination efforts and access to appropriate care. Through the FHIR-based Patient Access API, finalized in the CMS Interoperability and Patient Access final rule (85 FR 25558 through 25559), we required certain impacted payers to share, among other things, patient claims and encounter data and a sub-set of clinical data with the third-party apps of a patient's choice so that patients could get their health information in a way that was most meaningful and useful to them. We noted that this FHIR-based API could also allow the patient to facilitate their data moving from their payer to their provider, and discussed the benefits of sharing patient claims and encounter data with providers, which we discuss in more detail in section II.B. of this proposed rule.

2. Enhancing the Patient Access API

In the CMS Interoperability and Patient Access final rule that certain payers, specifically MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs, must permit third-party applications to retrieve, with the approval and at the direction of a current enrollee, data specified at 42 CFR 422.119, 431.60, 457.730, and 45 CFR 156.221, respectively. We required that the Patient Access API must, at a minimum, make available adjudicated claims (including provider remittances and enrollee cost-sharing); encounters with capitated providers; and clinical data, including laboratory results when maintained by the payer. We required that data must be made available no later than one (1) business day after a claim is adjudicated or encounter data are received. And, that these payers make available through the Patient Access API the specified data they maintain with a date of service on or after January 1, 2016.

a. Patient Access API Implementation Guides (IGs)

When we finalized the Patient Access API, we provided a link to a CMS website that identified IGs and related reference implementations demonstrating use of these IGs available to support implementation (85 FR 25529): *https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index.* On this website, we provide links and information about certain IGs, including:

- HL7 Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG: Version STU 1.0.0 to facilitate the exchange of the claims and encounter data; [3]
- HL7 FHIR US Core IG: Version STU 3.1.0 or HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG: Version STU 1.0.0 to facilitate the exchange of the clinical information as defined in the USCDI; [4] [5] and
- HL7 FHIR Da Vinci Payer Data Exchange (PDex) US Drug Formulary IG: Version STU 1.0.1 to facilitate the exchange of current formulary information.[6]

On this website, we explain how these IGs can help payers meet the requirements of the final rule efficiently and effectively in a way that reduces burden on them and ensures patients are getting timely access to their health information in a way that they can best make use of these data so that they can make informed decisions about their health. Although these IGs were available for payers and third-party app vendors, we did not require payers to use these IGs in the CMS Interoperability and Patient Access final rule. We did not specifically propose these IGs for possible finalizing in the final rule as general practice had been to include such information in sub-regulatory guidance. However, the June 3, 2019 *Azar* v. *Allina Health Services,* 139 S. Ct. 1804 (2019) decision held that under section 1871 of the Act, CMS must undertake notice-and-comment rulemaking for any rule, requirement, or other statement of policy that establishes or changes a ''substantive legal standard'' for the Medicare Program. IGs are considered a ''substantive legal standard'' per this decision. As such, we are now officially proposing to finalize these IGs through notice-and-comment rulemaking to ensure that all impacted payers are using these IGs in order to support true interoperability. If these IGs remain optional, there is a chance that the required APIs could be built in such a way that creates misalignment between and among payer APIs and with third-party apps. For example, where there is optionality in the technical build of the API, if that optionality is interpreted differently by the payer and a third-party app, that app may be unable to access and use the data as needed. By removing this optionality in the technical implementation, we better ensure that the APIs can support true interoperability and facilitate the desired data exchange. Additionally, as these same IGs are proposed for use for other APIs proposed in this rule, it would mean that providers (see section II.B. of this proposed rule) and payers (see section II.D. of this proposed rule) would also not be able to access and use the data as needed if misalignment is introduced during implementation. Proposing these IGs be required removes the current optionality resulting from only suggested use of the IGs, which could be a barrier to interoperability.

We are proposing to require these specific IGs for the Patient Access API, by amending 42 CFR 431.60(c)(3)(iii) for state Medicaid FFS programs, 42 CFR 457.730(c)(3)(iii) for state CHIP FFS programs, and 45 CFR 156.221(c)(3)(iii) for QHP issuers on the FFEs. These requirements would be equally applicable to Medicaid managed care plans and CHIP managed care entities based on cross-references to the state Medicaid and CHIP FFS requirements at 42 CFR 438.242(b)(5) for Medicaid managed care plans and 42 CFR 457.1233(d)(2) for CHIP managed care entities. If finalized, beginning January 1, 2023, impacted payers would be required to ensure their APIs are

[3] HL7 International. (n.d.). Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide Publication (Version) History. Retrieved from *http://hl7.org/fhir/us/carin-bb/history.html.*

[4] HL7 International. (n.d.). US Core Implementation Guide (FHIR IG) Publication (Version) History. Retrieved from *http://hl7.org/fhir/us/core/history.html.*

[5] HL7 International. (n.d.). Da Vinci Payer Data Exchange (FHIR IG) Publication (Version) History. Retrieved from *http://hl7.org/fhir/us/davinci-pdex/history.html.*

[6] HL7 International. (n.d.). US Drug Formulary (FHIR IG) Publication (Version) History. Retrieved from *http://hl7.org/fhir/us/Davinci-drug-formulary/history.html.*

conformant with these IGs (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023). The CARIN IG for Blue Button, the PDex IG, and the PDex US Drug Formulary IG are proposed for HHS use at 45 CFR 170.215(c). The US Core IG was adopted by HHS at 45 CFR 170.215(a)(2) in the ONC 21st Century Cures Act final rule.

We recognize that while we have proposed to require compliance with the specific IGs noted above, the need for continually evolving IGs typically outpaces our ability to amend regulatory text. Therefore, we propose to amend 431.60(c)(4), 438.242(b)(5), 457.730(c)(4), 457.1233(d)(2), and 45 CFR 156.221(c)(4) to provide that, if finalized, regulated entities would be permitted to use an updated version of any or all IGs proposed for adoption in this rule if use of the updated IG does not disrupt an end user's ability to access the data through any of the specified APIs discussed in this rule. This would then amend the process to allow payers to use new standards as they are available, as we finalized in the CMS Interoperability and Patient Access final rule to these proposed IGs.

In making these proposals, we note that these IGs are publicly available at no cost to a user (see section IV. of this proposed rule for more information). All HL7 FHIR IGs are developed through an industry-led, consensus-based public process. HL7 is an American National Standards Institute (ANSI)-accredited standards development organization. HL7 FHIR standards are unique in their ability to allow disparate systems that otherwise represent data differently and speak different languages to exchange such information in a standardized way that all systems can share and consume via standards-based APIs. HL7 FHIR IGs are also open source, so any interested party can go to the HL7 website and access the IG. Once accessed, all public comments made during the balloting process as well as the IG version history are available for review. In this way, all stakeholders can fully understand the lifecycle of a given IG. Use of IGs developed through such a public process would facilitate a transparent and cost-effective path to interoperability that ensures the IGs are informed by, and approved by, industry leaders looking to use technology to improve patient care.

We request comment on these proposals.

We finalized in the CMS Interoperability and Patient Access final rule that the Patient Access API at 42 CFR 422.119(b)(1)(iii), 431.60(b)(3), and 457.730(b)(3), and 45 CFR 156.221(b)(1)(iii) must make available clinical data, including laboratory results. We specified at 42 CFR 422.119(c)(3)(i), 431.60(c)(3)(i), and 457.730(c)(3)(i), and 45 CFR 156.221(c)(3)(i) that such clinical data must comply with the content and vocabulary standards at 45 CFR 170.213, which is the USCDI version 1. Through a cross-reference to 45 CFR 170.215(a)(2) and (c)(6), at 42 CFR 431.60(c)(3)(iii) for state Medicaid FFS programs, 42 CFR 457.730(c)(3)(iii) for state CHIP FFS programs, and 45 CFR 156.221(c)(3)(iii) for QHP issuers on the FFEs, we propose that payers would be allowed to conform with either the US Core IG or the PDex IG to facilitate making the required USCDI data available via the Patient Access API. In section II.E. of this proposed rule, ONC, on behalf of HHS, proposes to adopt the PDex IG at 45 CFR 170.215(c)(6); currently, the US Core IG is adopted at 45 CFR 170.215(a)(2). These proposed new requirements to conform with either IG would be equally applicable to Medicaid managed care plans and CHIP managed care entities based on cross-references to the state Medicaid and CHIP FFS requirements at 42 CFR 438.242(b)(5) for Medicaid managed care plans and 42 CFR 457.1233(d)(2) for CHIP managed care entities. When we first finalized the CMS Interoperability and Patient Access final rule and suggested IGs payers could use to implement the APIs, we only suggested the US Core IG; however, some payers informed us that they preferred to leverage the PDex IG because it offered additional resources for payer-specific use cases and was compatible with the US Core IG ensuring interoperable data regardless of which IG was used (see *https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index* for additional information). We seek comment on the pros and cons of requiring the use of either one of these IGs or if only one of the two proposed IGs should ultimately be required and why.

b. Additional Information

In addition to enhancing the Patient Access API by proposing to require that the API be conformant with the specified IGs, we are also proposing to require that information about prior authorization decisions be made available to patients through the Patient Access API in addition to the accessible content finalized in the CMS Interoperability and Patient Access final rule (85 FR 25558 through 25559). The primary goal of the Patient Access API is to give patients access to and use of their health information. By ensuring patient access to this additional information, we intend to help patients be more informed decision makers and true partners in their health care.

In section II.C. of this proposed rule, we advance a number of proposals focused on making the prior authorization process less burdensome for payers and providers, and in turn, avoiding care delays for patients, which we anticipate would also improve patient outcomes. Patients can only truly be informed if they understand all aspects of their care. We believe that more transparency would help ensure that patients better understand the prior authorization process. By having access to their pending and active prior authorization decisions via the Patient Access API, a patient could see, for instance, that a prior authorization is needed and has been submitted for a particular item or service, and might better understand the timeline for the process and plan accordingly. If a patient can see the supporting documentation shared with their payer they might better understand what is being evaluated and even potentially help providers get the best and most accurate information to payers to facilitate a successful prior authorization request, thus potentially avoiding unnecessary delays in care and reducing burden on providers and payers. As a result, we are proposing to require impacted payers to provide patients access to information about the prior authorization requests made on their behalf through the Patient Access API. Specifically, we are proposing at 431.60(b)(5) for state Medicaid FFS programs, at 438.242(b)(5) for Medicaid managed care plans, at 457.730(b)(5) for state CHIP FFS programs, at 457.1233(d)(2) for CHIP managed care entities, and at 45 CFR 156.221(b)(1)(iv) for QHP issuers on the FFEs to require these payers to make available to patients information about any pending and active prior authorization decisions (and related clinical documentation and forms) for items and services via the Patient Access API conformant with the HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG no later than one (1) business day after a provider initiates a prior authorization request or there is a change of status for the prior authorization. We believe one (1) business day is appropriate because in order for patients to have true transparency into the process, they need to see the information timely. As discussed more in section II.C. of this proposed rule, we are proposing expedited prior authorization

timeframes. If this information is provided any later, it would be of less value in supporting the process. We propose that this requirement begin January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023).[7]

By ''active prior authorization decisions,'' we mean prior authorizations that are currently open and being used to facilitate current care and are not expired or no longer valid. By ''pending prior authorization decisions,'' we mean prior authorizations that are under review, either pending submission of documentation from the provider, or being evaluated by the payer's medical review staff, or for another reason have not yet had a determination made. As discussed in section I.B. of this proposed rule, for the purposes of this rule, when we say ''items and services,'' we are talking about items and services excluding prescription drugs and/or covered outpatient drugs. And, ''status'' of the prior authorization means information about whether the prior authorization is approved, denied, or if more information is needed to complete the request. We also note that the required information and documentation through the API would include the date the prior authorization was approved, the date the authorization ends, the units and services approved, and those used to date.

Similarly, as further discussed in section II.B. of this proposed rule, we are proposing to require impacted payers to share the same information about prior authorization decisions with a patient's provider via the Provider Access API upon a provider's request, and, in section II.D. of this rule, we are proposing that the same information about prior authorization decisions be made available via the Payer-to-Payer API. In this way, if a patient authorizes their new payer to access data from their old payer, this data exchange would include information about pending and active prior authorizations, if such information is applicable.

We did not include information about denied or expired prior authorization decisions in this proposed requirement because this could result in a significant amount of information being shared that may or may not be clinically relevant at the moment in time the data are exchanged. Pending and active prior authorizations are much more likely to be clinically relevant and important for patients, providers, and payers to know in order to support treatment and care coordination, as well as efficient and effective payer operation that can lead to the best possible outcomes for patients. We do note that if a prior authorizations is ''pending,'' and the status changes to ''denied,'' that information would be shared as a ''change in status.'' As a result, a patient would have access to that information via the API per this proposal.

We anticipate that requiring payers to share prior authorization information through the Patient Access API, with their patient's approval and at their direction, might help patients better understand the items and services that require prior authorization, the information being considered and specific clinical criteria being reviewed to determine the outcome of that prior authorization, and the lifecycle of a prior authorization request. This proposed requirement could provide patients with an opportunity to better follow the prior authorization process and help their provider and payer by producing missing documentation or information when needed. The proposed requirement might also help to reduce the need for patients to make repeated calls to the provider and payer to understand the status of a request, or to inquire why there is a delay in care. We therefore believe this proposal would help give patients more agency in their health care journey and reduce burden on both the providers and the payers working through prior authorization requests, allowing them to more simply and efficiently administer the prior authorization process. As with all information being made available via the Patient Access API, we believe industry is in the best position to develop applications, or apps, that patients can use to most effectively use this information, and we look to innovators in industry to produce apps that would help patients understand this information and access it in a way that is useful to them.

In addition, we believe it would be highly valuable for payers to share pending and active prior authorization decisions with providers, as proposed in section II.B. of this proposed rule, and other payers, as proposed in section II.D. of this proposed rule. Currently, providers know which prior authorizations they have initiated for a patient, but they may not be able to see pending and active prior authorizations other providers have outstanding or in place for the patient. Having this information could support care coordination and more informed decision making. Additionally, if a new payer has information from a previous payer about pending and active prior authorization decisions, it could support improved care coordination and continuity of care, also potentially improving patient outcomes.

We request comment on this proposal.

We also request comment for possible future consideration on whether or not impacted payers should be required to include information about prescription drug and/or covered outpatient drug pending and active prior authorization decisions with the other items or services proposed via the Patient Access API, the Provider Access API, or the Payer-to-Payer API. We did not include information about prescription drugs and/or covered outpatient drugs in any of the proposals in this rule. However, we are interested in better understanding the benefits and challenges of potentially including drug information in future rulemaking. For example, what specific considerations should we take into account? Are there unique considerations related to the role Pharmacy Benefit Managers (PBMs) play in this process? Overall, we do think it would be very valuable to payers, providers, and patients to have information about a patient's prescription drug and/or covered outpatient drug pending and active prior authorization decisions, and we would like to better understand how to most efficiently and effectively consider including this information in these API provisions in the future.

c. Privacy Policy Attestation

As we discussed in detail throughout the CMS Interoperability and Patient Access final rule, one of the most important aspects of unleashing patient data is protecting the privacy and security of patient health information, especially appreciating that once a patient's data is received by a third-party app, it is no longer protected under HIPAA. Throughout the final rule, we noted the limitations to our authority to directly regulate third-party applications. We previously finalized a provision that payers could deny Patient Access API access to a third-party app that a patient wished to use only if the payer determined that such access would pose a risk to the PHI on their system. See 42 CFR 422.119(e) for Medicare Advantage organizations, 431.60(e) for state Medicaid FFS programs, 438.242(b)(5) for Medicaid managed care plans, 457.730(e) for state CHIP FFS programs, and 45 CFR 156.221(e) for QHP issuers on the FFEs.

[7] HL7 International. (n.d.). Da Vinci Payer Data Exchange (FHIR IG) Publication (Version) History. Retrieved from *http://hl7.org/fhir/us/davinci-pdex/history.html.*

In the ONC 21st Century Cures Act final rule (85 FR 25814 through 25815), ONC noted that it is not information blocking to provide information that is factually accurate, objective, unbiased, fair, and non-discriminatory to inform a patient about the advantages and disadvantages and any associated risks of sharing their health information with a third party. We previously finalized provisions at 42 CFR 422.119(g) for Medicare Advantage organizations, at 431.60(f) for state Medicaid FFS programs, at 438.242(b)(5) for Medicaid managed care plans, at 457.730(f) for state CHIP FFS programs, at 457.1233(d)(2) for CHIP managed care entities, and at 45 CFR 156.221(g) for QHP issuers on the FFEs, requiring that impacted payers share educational resources with patients to help them be informed stewards of their health information and understand the possible risk of sharing their data with third-party apps. In response to comments on the CMS Interoperability and Patient Access proposed rule, we noted in the final rule (85 FR 25549 through 25550) commenters' beliefs that it is a risk when patients do not understand what happens after their data are transmitted to a third-party app and are no longer protected by the HIPAA Rules. Commenters were specifically concerned about secondary uses of data, such as whether or not their data would be sold to an unknown third-party for marketing purposes or other uses. In the final rule, we noted that a clear, plain language privacy policy is the primary way to inform patients about how their information will be protected and how it will be used once shared with a third-party app.

Taking into consideration comments indicating strong public support for additional privacy and security measures, we encouraged, but did not require, impacted payers to request an attestation from third-party app developers indicating the apps have certain privacy provisions included in their privacy policy prior to the payer providing the app access to the payer's Patient Access API (85 FR 25549 through 25550). We are now proposing to make it a requirement that impacted payers request a privacy policy attestation from third party app developers when their app requests to connect to the payer's Patient Access API.

We are proposing at 42 CFR 431.60(g) for state Medicaid FFS programs, at 42 CFR 438.242(b)(5) for Medicaid managed care plans, at 42 CFR 457.730(g) for state CHIP FFS programs, at 42 CFR 457.1233(d)(2) for CHIP managed care entities, and at 45 CFR 156.221(h) for QHP issuers on the FFEs that beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023), that impacted payers must establish, implement, and maintain a process for requesting an attestation from a third-party app developer requesting to retrieve data via the Patient Access API that indicates the app adheres to certain privacy provisions.

We recognize that there are many ways that an impacted payer could meet this proposed requirement and we do not wish to be overly prescriptive regarding how each payer could implement this process. For instance, a reliable private industry third party may offer a pathway for apps to attest that they have established a minimum set of privacy provisions to be in compliance with this proposed requirement. A payer could work with such an organization to meet this requirement. Or, an impacted payer could establish its own process and procedures to meet this proposed requirement. This process could be automated.[8] We believe it is important to allow the market to develop and make available innovative solutions, and we do not look to preclude use of such options and services. Regardless of this proposed flexibility, impacted payers must not discriminate in implementation of this proposed requirement, including for the purposes of competitive advantage. Whatever method a payer might choose to employ to meet this proposed requirement, the method must be applied equitably across all apps requesting access to the payer's Patient Access API.

At a minimum, we propose that the requested attestation include whether:

- The app has a privacy policy that is publicly available and accessible at all times, including updated versions, and that is written in plain language,[9] and the third-party app developer has affirmatively shared this privacy policy with the patient prior to the patient authorizing the app to access their health information. To ''affirmatively share'' means that the patient had to take an action to indicate they saw the privacy policy, such as click or check a box or boxes.
- The app's privacy policy includes, at a minimum, the following important information:
  - ++ How a patient's health information may be accessed, exchanged, or used by any person or other entity, including whether the patient's health information may be shared or sold at any time (including in the future);
  - ++ A requirement for express consent from a patient before the patient's health information is accessed, exchanged, or used, including receiving express consent before a patient's health information is shared or sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction);
  - ++ If an app will access any other information from a patient's device; and
  - ++ How a patient can discontinue app access to their data and what the app's policy and process is for disposing of a patient's data once the patient has withdrawn consent.

As we discussed in the CMS Interoperability and Patient Access final rule (85 FR 25550), payers can look to industry best practices, including the CARIN Alliance's Code of Conduct and the ONC Model Privacy Notice for other provisions to include in their attestation request that best meet the needs of their patient population.[10] [11] In particular, we believe that explaining certain practices around privacy and security in a patient-friendly, easy-to-read privacy policy would help inform patients about an app's practices for handling their data. It helps patients understand if and how the app will protect their health information and how they can be an active participant in the protection of their information. Also, as explained in the CMS Interoperability and Patient Access final rule (85 FR 25517), if an app has a written privacy policy and does not follow the policies as written, the Federal Trade Commission (FTC) has authority to take action.

We propose that impacted payers must request the third-party app developer's attestation at the time the third-party app engages the API. Under our proposal, the payer must inform the patient within 24 hours of requesting the attestation from the app developer of the status of the attestation—positive, negative, or no response, with a clear explanation of what each means. The patient would then have 24 hours to respond to this information. For

[8] See Example 1 in ONC's 21st Century Cures at final rule (85 FR 25816).

[9] Plain Language Action and Information Network. (2011, May). Federal Plain Language Guidelines. Retrieved from *https://www.plainlanguage.gov/media/FederalPLGuidelines.pdf.*

[10] See *https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/.*

[11] See *https://www.healthit.gov/topic/privacy-security-and-hipaa/model-privacy-notice-mpn.*

instance, if the app developer cannot attest that the app meets these provisions, or if there is no response to the payer's request for the attestation, the payer can inform the patient there may be risk associated with sharing their health information with the app. The patient may choose to change his or her mind and, at that point, the payer would no longer be obligated to release the patient's data via the API. However, if the patient does not respond or the patient indicates they would like their information made available regardless, the payer would be obligated to make the data available via the API. The patient would have already authorized the app to access their data, as the request from the payer for an attestation could only happen after the patient has already authorized the app to access their information and provided information about their payer to the app. As a result, the patient's original request must be honored. Because the patient has already consented to the app receiving their data, it is important that this process not overly delay the patient's access to their health information via the app of their choice. However, we are interested in comments from the public that discuss this process, and the payer's obligation to send the data regardless of whether or not the patient responds to the payer after notification of the app's attestation results, specifically notification if the app does not attest to meeting the above privacy provisions.

We believe it is important for patients to have a clear understanding of how their health information may be used by a third party, as well as how to stop sharing their health information with a third party, if they so choose. We believe the use of this required attestation, if finalized as proposed, in combination with patient education,[12] would help patients be as informed as possible. Therefore, we propose that the payer must include information about the specific content of their privacy policy provisions included in the attestation in the required enrollee resources. The enrollee resources must also include, at a minimum, the timeline for the attestation process, the method for informing enrollees about the app developer's attestation response or non-response. The enrollee resources would also have to include the enrollee's role and rights in this process, such as what actions the enrollee may take when a payer informs the enrollee about the status of the attestation, and information about an enrollee's right to access their data via a third-party app of their choice no matter what the status of the attestation request is. Together, this privacy policy attestation framework and the requirement for payers to provide patients with educational resources would help ensure a more secure data exchange environment and more informed patients. And, this would help build patient trust in apps, therefore encouraging them to take advantage of this opportunity to access their health information through a third-party app.

Privacy and security remain a critical focus for CMS, and we look forward to continuing to work with stakeholders to keep patient privacy and data security a top priority. Accordingly, we request comment on additional content requirements for the attestation that impacted payers must request and additional required enrollee resources that impacted payers must make available related to the attestation in this proposal. We are particularly interested in hearing feedback on how best to engage available industry-led initiatives, as well as the level of flexibility payers think is appropriate for defining the process for requesting, obtaining, and informing patients about the attestation. For instance, would payers prefer that CMS require the specific types of communication methods payers can use to inform patients about the attestation result, such as via email or text or other electronic communication only? How should CMS account for third-party solutions that present a list of apps that have already attested? In this situation a payer would not need to take action for these apps, but would need to have a process in place for apps not included on such a list.

We also request comment on whether the request for the app developer to attest to certain privacy provisions should be an attestation that all provisions are in place, as it is currently proposed, or if the app developer should have to attest to each provision independently. We wish to understand the operational considerations of an ''all or nothing'' versus ''line-item'' approach to the attestation for both the app developers and the payers who would have to communicate this information to patients. And, we wish to understand the value to patients of the two possible approaches.

We request comment on the proposal to require impacted payers to request a privacy policy attestation from third-party app developers.

d. Patient Access API Metrics

We are proposing to require impacted payers to report metrics about patient use of the Patient Access API to CMS.[13] We believe this is necessary to better understand whether the Patient Access API requirement is efficiently and effectively ensuring that patients have the required information and are being provided that information in a transparent and timely way. We would be better able to evaluate whether policy requirements are achieving their stated goals by having access to aggregated, patient de-identified data on the use of the Patient Access API from each payer. With this information, we expect that we would be better able to support payers in making sure patients have access to their data and can use their data consistently across payer types. As a first step in evaluating the adoption of the Patient Access API, we propose to require states operating Medicaid and CHIP FFS programs at the state level, Medicaid managed care plans at the plan level, CHIP managed care entities at the entity level, and QHP issuers on the FFEs at the issuer level to report to CMS. We also seek comment on whether we should consider requiring these data be reported to CMS at the contract level for those payers that have multiple plans administered under a single contract or permit Medicaid managed care plans, CHIP managed care entities, or QHP issuers on the FFEs to aggregate data for the same plan type to higher levels (such as the payer level or all plans of the same type in a program).

Specifically, we propose that these payers report quarterly:

- The total number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app; and
- The number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app more than once.

Tracking multiple transfers of data would indicate repeat access showing patients are either using multiple apps or are allowing apps to update their information over the course of the quarter.

We are proposing these new reporting requirements at 42 CFR 431.60(h) for state Medicaid FFS programs, at 42 CFR 438.242(b)(5) for Medicaid managed

[12] In the CMS Interoperability and Patient Access final rule, we required impacted payers to make available enrollee resources regarding privacy and security on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former patients at 42 CFR 422.119(g), 42 CFR 431.60(f), 42 CFR 457.30(f), and 45 CFR 156.221(g).

[13] We note that the regulation text for QHP issuers on the FFEs in part 156 refers to HHS. In the regulation text for QHPs on the FFEs, we propose the reporting to HHS for consistency, noting that CMS is a part of HHS.

care plans, at 42 CFR 457.730(h) for state CHIP FFS programs, at 42 CFR 457.1233(d)(2) for CHIP managed care entities, and at 45 CFR 156.221(i) for QHP issuers on the FFEs. Under this proposal, we would redesignate existing paragraphs as necessary to codify the new proposed text. We do not intend to publicly report these data at the state, plan, or issuer level at this time, but may reference or publish them at an aggregate, de-identified level. We are proposing that by the end of each calendar quarter, payers would report the previous quarter's data to CMS starting in 2023. In the first quarter the requirement would become applicable, payers would be required to report, by the end of the first calendar quarter of 2023, data for the fourth calendar quarter of 2022. Therefore, beginning March 31, 2023 all impacted payers would need to report to CMS the first set of data, which would be the data for October, November, and December 2022.

We request comment on this proposal.

We are proposing a quarterly data collection. We seek comment on the burden associated with quarterly reporting versus annual reporting, as well as stakeholder input on the benefits and drawbacks of quarterly versus annual reporting. In addition, we request comment on what other metrics CMS might require payers to share with CMS, and potentially the public, on Patient Access API use, so that CMS can consider this information for possible future rulemaking.[14] In particular, we seek comment on the potential burden if payers were required to report the names of the unique apps that access the payer's API each quarter or each year. We are considering collecting this information to help identify the number of apps being developed, potentially review for best practices, and evaluate consumer ease of use.

e. Patient Access API Revisions

We note that to accommodate the proposed requirements regarding the use of the Patient Access API, we are proposing two minor changes to the requirements finalized in the CMS Interoperability and Patient access final rule.

First, we are proposing to revise language about the clinical data to be made available via the Patient Access API 42 CFR 431.60(b)(3) for state Medicaid FFS programs, 42 CFR 457.730(b)(3) for state CHIP FFS programs, and 45 CFR 156.221(b)(1)(iii) for QHP issuers on the FFEs. In the CMS Interoperability and Patient Access final rule, these specific provisions require payers to make available ''clinical data, including laboratory results.'' We are proposing to revise these paragraphs to read, ''clinical data, as defined in the USCDI version 1.'' Lab results are part of the USCDI, and clinical data were operationalized as the USCDI version 1 under the ''technical requirements'' where the content standard at 45 CFR 170.213 is adopted. Specifically calling out the USCDI here would help avoid unnecessary confusion, as it would be explicitly noted that the clinical data that must be available through the Patient Access API is the USCDI version 1 data elements.

Second, we are proposing to revise the language previously finalized for denial or discontinuation of access to the API to require that the payer make such a determination to deny or discontinue access to the Patient Access API using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which *parties* seek EHI. We are proposing to change the terms ''enrollees'' and ''beneficiaries'' to ''parties'' as we are proposing to apply this provision to the Provider Access API, Payer-to-Payer API, and the prior authorization APIs discussed further in sections II.B., II.C., and II.D. of this proposed rule. As other parties may be accessing these APIs, such as providers and payers, we believe it is more accurate to use the term ''parties'' rather than ''enrollees'' or ''beneficiaries.'' We are proposing these revisions 431.60(e)(2), 457.730(e)(2), and 45 CFR 156.221(e)(2).

We request comment on these proposals.

Although Medicare FFS is not directly impacted by this rule, we do note that we are targeting to implement the provisions, if finalized. In this way, the Medicare FFS implementation would conform to the same requirements that apply to the impacted payers under this rulemaking, so that Medicare FFS beneficiaries would also benefit from this data sharing. CMS started to liberate patients' data with Blue Button 2.0, which made Parts A, B, and D claims data available via an API to Medicare beneficiaries. In an effort to align with the API provisions included in the CMS Interoperability and Patient Access final rule, we are updating the Blue Button 2.0 API to FHIR R4, and will begin use of the CARIN IG for Blue Button.[15] If the provisions in this rule are finalized, we will work to align and enhance Blue Button accordingly, as possible.

f. Provider Directory API Implementation Guide

We are also proposing to require that the Provider Directory API finalized in the CMS Interoperability and Patient Access final rule (85 FR 25563 through 25564) be conformant with a specified IG. The Provider Directory API provision requires impacted payers to ensure provider directory information availability to third-party applications. Specifically, payers need to make, at a minimum, provider names, addresses, phone numbers, and specialties available via the public-facing API. All directory information must be available through the API within 30 calendar days of a payer receiving the directory information or an update to the directory information. We are proposing a new requirement at 42 CFR 431.70(d) for Medicaid state agencies, and at 42 CFR 457.760(d) for CHIP state agencies that the Provider Directory API be conformant with the implementation specification at 45 CFR 170.215(c)(8) beginning January 1, 2023. Therefore, we are proposing that the Provider Directory API be conformant with the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0.[16] Currently, because QHP issuers on the FFEs are already required to make provider directory information available in a specified, machine-readable format, the Provider Directory API proposal does not include QHP issuers.[17]

Currently, because of the existing cross-references at 42 CFR 438.242(b)(6) (cross referencing the Medicaid FFS Provider Directory API requirement at 42 CFR 431.70) and 42 CFR 457.1233(d)(3) (cross referencing the CHIP FFS Provider Directory API requirement at 42 CFR 457.760), Medicaid managed care plans and CHP managed care entities must also implement and maintain Provider Directory APIs. We are proposing here that Medicaid managed care plans and CHIP managed care entities must comply with the implementation specification at 45 CFR 170.215(c)(8) (that is, the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0) by the rating period that begins on or after January 1, 2023. Because of the different compliance deadline for the managed care programs, we are also proposing

[14] We note that the regulation text for QHP issuers on the FFEs in Part 156 refers to HHS. In the regulation text for QHP issuers on the FFEs, we propose the reporting to HHS for consistency, noting that CMS is a part of HHS.

[15] *https://bluebutton.cms.gov/blog/FHIR-R4-coming-to-the-blue-button-api.html.*

[16] HL7 International. (n.d.). Da Vinci Payer Data Exchange PlanNet (FHIR IG) Publication (Version) History. Retrieved from *http://www.hl7.org/fhir/us/davinci-pdex-plan-net/history.cfml.*

[17] Available at *http://cmsgov.github.io/QHP-provider-formulary-APIs/developer/index.html.*

additional revisions at 42 CFR 438.242(b)(6) and 42 CFR 457.1233(d)(3). We request comment on these proposals.

3. Statutory Authorities for the Patient Access and Provider Directory API Proposals

a. Medicaid and CHIP

For the reasons discussed below, our proposed requirements in this section for Medicaid managed care plans and Medicaid state agencies fall generally under our authority in section 1902(a)(4) of the Act, which requires that a state Medicaid plan provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the state Medicaid plan. The proposals in this section are also authorized under section 1902(a)(8) of the Act, which requires states to ensure that Medicaid services are furnished with reasonable promptness to all eligible individuals. Additionally, they are authorized by section 1902(a)(19) of the Act, which requires states to ensure that care and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

We are proposing to require that state Medicaid agencies and Medicaid managed care plans implement the Patient Access and Provider Directory APIs finalized in the CMS Interoperability and Patient Access final rule conformant with specific IGs, as discussed in section II.A.2. above in this proposed rule. In sections II.B.3., II.B.5., II.C.3., II.C.4., and II.D.2. of this proposed rule, we are also proposing that these payers be required to implement new APIs, specifically the Provider Access APIs, the DRLS API, the PAS API, and the Payer-to-Payer API, in a manner that is conformant with specific IGs. Use of these APIs would support more efficient administration of the state plan, because, as discussed in more detail below, CMS expects that the APIs would improve the flow of information relevant to the provision of Medicaid services among beneficiaries, providers, and the state Medicaid program and its contracted managed care plans. Improving the flow of that information could also help states to ensure that Medicaid services are provided with reasonable promptness and in a manner consistent with simplicity of administration and the best interests of the beneficiaries, as discussed in the CMS Interoperability and Patient Access final rule related to the Patient Access and Provider Directory APIs and the Payer-to-Payer data exchange (for Medicaid managed care) (see 85 FR 25526). The state is also required to make provider directory data for the FFS program available per section 1902(a)(83) of the Act; Medicaid managed care plans are similarly required to make a provider directory available under 42 CFR 438.10(g). Making provider directory information available via a standards-based API, and updating this information through this API, again adds efficiencies to administration of this process and our proposal here is intended to further standardize implementation of the Provider Directory API. The DRLS API and the PAS API both have the potential to significantly improve the efficiency and response time for Medicaid prior authorization processes, making them more efficient in many ways, including limiting the number of denials and appeals or even eliminating requests for additional documentation. In all of these ways, the APIs are expected to make administration of the Medicaid program more efficient.

Proposing to require these APIs be conformant with specific IGs is expected to simplify the process of implementing and maintaining each API, including preparing the information that must be shared via each specific API, and ensuring data are provided as quickly as possible to beneficiaries (in the case of the Patient Access API and the Provider Directory API), to providers (in the case of the Provider Access API), and to other payers (in the case of the Payer-to-Payer API). Implementing these APIs across payers using the same IGs, as would be the case via the Payer-to-Payer API, would ensure these APIs are functioning as intended, and are able to perform the data exchanges specified in a way that is interoperable and of value to both the sender and receiver of the information, and thus could help to ensure the APIs would improve the efficient operation of the state Medicaid program, consistent with section 1902(a)(4) of the Act. These IGs, by further ensuring that each API is built and implemented in a consistent and standardized way, transmitting data that are mapped and standardized as expected by both the sending and receiving parties, would further increase the efficiency of the APIs. It would help ensure that the data sent and received are usable and valuable to the end user, whether that is the patient looking to have timely access to their records or the provider or payer looking to ensure efficient care and increased care coordination to support the timely administration of services. As a result, proposing to adopt these IGs would further contribute to proper and efficient operation of the state plan, and is expected to facilitate data exchange in a way that is consistent with simplicity of administration of the program and the best interest of the participants. Requiring that the APIs be conformant with these IGs is therefore expected to make the APIs more effective in terms of improving the efficient operation of the Medicaid state plan and Medicaid managed care plans. If the APIs operate more efficiently, that, in turn, may help to ensure that beneficiaries and enrollees receive care with reasonable promptness and in a manner consistent with simplicity of administration and beneficiaries' and enrollees' best interests.

The proposed requirement to make available information about pending and active prior authorization decisions and associated documentation through the Patient Access API is expected to allow beneficiaries to more easily obtain the status of prior authorization requests submitted on their behalf, so that they could ultimately use that information to make more informed decisions about their health care, improve the efficiency of accessing and scheduling services, and if needed, provide missing information needed by the state to reach a decision. Receiving missing information more quickly could allow states to respond more promptly to prior authorization requests, thus improving providers' and beneficiaries' experience with the process by facilitating more timely and successful prior authorizations, which would help states fulfill their obligations to provide care and services in a manner consistent with simplicity of administration and the best interests of the recipients, and to furnish services with reasonable promptness to all eligible individuals. Improving the prior authorization process could also help states improve the efficient operation of the state plan. In these ways, these proposals are consistent with our authorities under section 1902(a)(4), (8), and (19) of the Act.

We also propose that payers would be required to ask app developers to attest to whether they have certain privacy policy provisions in place prior to making a beneficiary's or enrollee's data available via the Patient Access API. Proposing to require state Medicaid agencies and Medicaid managed care plans to implement a privacy policy attestation process is expected to help ensure beneficiaries be informed about how their information would be protected or not protected when it is provided by the state Medicaid agency

or Medicaid managed care plan to a third-party app at their request. This attestation process is expected to help a beneficiary or enrollee better understand how their data would be used, and what they can do to further control how and when their data is shared by other entities associated with the app. Taking additional steps to protect patient privacy and security would help to ensure that the Medicaid program, whether through FFS or managed care, is providing Medicaid-covered care and services in a manner consistent with the best interests of beneficiaries and enrollees. In this way, it is within our authority under section 1902(a)(19) of the Act to propose to require this privacy policy attestation.

We are also proposing to require state Medicaid agencies and Medicaid managed care plans to report Patient Access API metrics to CMS quarterly. We believe that having these metrics would support CMS' oversight, evaluation, and administration of the Medicaid program, as it would allow us to evaluate beneficiary and enrollee access to the Patient Access API. Use of the API could indicate that the policy is supporting program efficiencies and ensuring access to information in a timely and efficient way and in the best interest of beneficiaries, as intended. Section 1902(a)(6) of the Act authorizes CMS to request reports in such form and containing such information as the Secretary from time to time may require. These metrics would serve as a report to evaluate the implementation and execution of the Patient Access API.

For CHIP, we propose these requirements under the authority in section 2101(a) of the Act, which sets forth that the purpose of title XXI is to provide funds to states to provide child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage. This provision provides us with authority to adopt these requirements for CHIP because the proposed requirements increase access to patient data, which can improve the efficacy of CHIP programs, allow for more efficient communication and administration of services, and promote coordination across different sources of health benefits coverage.

As discussed above for Medicaid programs, requiring that the APIs finalized in the CMS Interoperability and Patient Access final rule, as well as those APIs proposed in this rule, be conformant with specific IGs would support program efficiency. By ensuring that these APIs are implemented in a consistent, standardized way, use of the IGs is expected to help support patient, provider, and payer access to data they can best use to make informed decisions, support care coordination, and for the state, support efficient operations.

We believe that requiring CHIP agencies, as well CHIP managed care entities, to make CHIP enrollees' prior authorization data and other standardized data available through standards-based APIs would ultimately lead to these enrollees accessing that information in a convenient, timely, and portable way. This improved access would help to ensure that services are effectively and efficiently administered in the best interests of beneficiaries, consistent with the requirements in section 2101(a). We believe making patient data available in this format would result in better health outcomes and patient satisfaction and improve the cost effectiveness of the entire health care system, including CHIP. Allowing beneficiaries or enrollees easy and simple access to certain standardized data can also facilitate their ability to detect and report fraud, waste, and abuse—a critical component of an effective program.

These proposals align with section 2101(a) in that they also improve the efficiency of CHIP programs. For example, adding information about pending and active prior authorization decisions to the Patient Access API allows beneficiaries to easily obtain the status of prior authorization requests made on their behalf. This allows patients to make scheduling decisions, and provide any missing information needed by a payer to reach a decision, which makes the prior authorization process more efficient, ultimately streamlining the prior authorization process.

Additionally, proposing to require the CHIP programs (FFS and managed care) to put a process in place to ask third-party app developers to attest to whether they have certain privacy provisions in place would allow CHIP to provide services in a way that is in the beneficiary's best interest by providing additional information to them about how they can best protect the privacy and security of their health information.

Finally, proposing to require state CHIP agencies and CHIP managed care plans report Patient Access API metrics to CMS quarterly would help states and CMS understand how this API can be used to continuously improve the effectiveness and efficiency of state CHIP operations by providing information about its use, which is an indication of the effectiveness of the API. The more we understand about the use of the Patient Access API, the better we can assess that the API is leading to improved operational efficiencies and providing information to beneficiaries in a way that supports their best interests.

Regarding the requiring the use of the PlanNet IG for the Provider Directory API under CHIP, we note that 42 CFR 457.1207 requires CHIP managed care entities to comply with the provider directory (and other information disclosure) requirements that apply to Medicaid managed care plans under 42 CFR 438.10.

b. QHP Issuers on the FFEs

For QHP issuers on the FFEs, we propose these new requirements under our authority in section 1311(e)(1)(B) of the Affordable Care Act, which affords the Exchanges the discretion to certify QHPs if the Exchange determines that making available such health plans through the Exchange is in the interests of qualified individuals in the state in which the Exchange operates.

Existing and emerging technologies provide a path to make information and resources for health care and health care management universal, integrated, equitable, more accessible, and personally relevant. Requiring the APIs discussed in this rule, including the Patient Access API, the Provider Access API, the DRLS API, the PAS API, and the Payer-to-Payer API be conformant with specific IGs would permit QHP issuers on the FFEs to meet the proposed requirements of this rulemaking efficiently by simplifying the process of implementing and maintaining each API, including preparing the needed information to be shared via each specific API, and ensuring data, and ultimately services, are provided to enrollees as quickly as possible. These IGs, by further ensuring that each API is built and implemented in a consistent and standardized way, transmitting data that are mapped and standardized as expected by both the sending and receiving parties, would further increase the efficiency of the APIs. It would help ensure that the data sent and received are usable and valuable to the end user, whether that is the patient looking to have timely access to their records or the provider or payer looking to ensure efficient care and increased care coordination to support the timely administration of services. This could add significant operational efficiencies for QHP issuers on the FFEs. This would help each proposed policy be most effective, the API solutions to be truly interoperable, and for QHP issuers on the FFEs to meet

these requirements in a way that ensures enrollees' needs are best met.

We believe generally that certifying only health plans that take steps to make enrollees' pending and active prior authorization decisions and related clinical documentation available through interoperable technology would ultimately lead to these enrollees having access to that information in a convenient, timely, and portable way, which is in the best interests of enrollees. Having simple and easy access, without special effort, to their health information also facilitates enrollees' ability to detect and report fraud, waste, and abuse—a critical component of an effective program. Adding information about pending and active prior authorization decisions to the Patient Access API would allow enrollees to easily obtain the status of prior authorization requests submitted on their behalf and use that information effectively to make more informed decisions about their health care, improve the efficiency of accessing and scheduling services, and if needed, provide missing information needed by the issuer to reach a decision. This could allow QHP issuers on the FFEs to more promptly address prior authorization requests, streamlining this process, and thus simplifying prior authorization processes, and enrollees' experience with the process, by facilitating timelier and potentially more successful initial prior authorization requests. We encourage State-based Exchanges (SBEs) to consider whether a similar requirement should be applicable to QHP issuers.

Proposing to require QHP issuers on the FFEs to implement a privacy policy attestation process would ensure enrollees are informed about how their information would be protected and how it would be used, and would add an additional opportunity for issuers to promote the privacy and security of their enrollees' information. This again ensures enrollees' needs are best met.

Finally, proposing to require QHP issuers on the FFEs report Patient Access API metrics to CMS quarterly would help CMS understand the impact this API is having on enrollees and would inform how CMS could either enhance the policy or improve access or use through such things as additional consumer education. These data could help CMS understand how best to leverage this API, and consumer access to it, to ensure this requirement is being met efficiently and adding value to CMS operations, including leading to the efficiencies intended.

B. Provider Access APIs

1. Background

As mentioned in the CMS Interoperability and Patient Access final rule, the Patient Access API (85 FR 25558 through 25559) could allow the patient to facilitate their data being accessible to their provider. A patient could use their mobile phone during a visit with their provider to show the provider their data to help inform their discussion. In the CMS Interoperability and Patient Access final rule (85 FR 25555), we discussed the benefits of sharing patient health information with providers. We also encouraged payers to consider an API solution to allow providers to access patient health information through payer APIs, such as for treatment purposes, and received comments in support of this type of data exchange. We sought comment for possible consideration in future rulemaking on the feasibility of providers being able to request information on a shared patient population using a standards-based API. Among the comments we received, some comments stated that allowing providers to receive data directly from payers would allow the FHIR-based data exchange to be significantly more valuable for patients, providers, and payers, as the data would be available at the moment of care when providers need it most, affording patients the maximum benefit from the data exchange. We also received some comments that having providers receive information about prior authorization decisions would reduce burden on providers and their staff (85 FR 25541).

While the use of the Patient Access API is a significant first step in facilitating sharing individual patient health information, we believe the benefits of making patient data available via a standards-based API would be greatly enhanced if providers had direct access to their patients' data. As discussed later in this section we are now working to get providers direct access to data through certain CMS programs, and based on this experience to date, we believe it would benefit providers if they were allowed ongoing access to information about their patients, particularly if they could access that information directly from clinical workflows in their EHRs or other health IT systems. We further believe provider access to patient information would improve both the provider and patient experience. Ensuring that providers have access to comprehensive patient data at the point of care could potentially reduce the burden on patients to recall certain information during an appointment, and might provide an additional way for both the provider and patient to confirm that the patient's recollection of a prior care episode is accurate. If providers could access information about the care their patient received outside of the provider's care network prior to a patient's visit, the information might improve clinical efficiency and provide a more comprehensive understanding of the patient's health, thus potentially saving time during appointments and potentially improving the quality of care delivered.

While we have no data, we anticipate that putting patient data in the hands of the provider at the point of care would reduce provider burden and improve patient care. Providers would be empowered to view their patient's claims history and available clinical data, including the identity of other providers who are working, or have worked, with the patient. This proposal might also improve a patient's care experience as it may lessen the burden on patients not only in relation to recall, as noted above, but it may spare patients from having to fill out the same medical history forms repeatedly. Used wisely, the data available to providers under these proposals might give patients and providers more time to focus on the patient's needs. In addition, if a patient's entire care team has access to the same information, this may help improve the efficiency and effectiveness of patient care.

2. HIPAA Disclosures and Transaction Standards

As reflected in our proposals below, providers would be allowed to request the claims and encounter data for patients to whom they provide services for treatment purposes. The HIPAA Privacy Rule, at 45 CFR 164.502, generally permits a covered entity to use or disclose protected health information (PHI) for treatment, payment, or health care operations without individual authorization. Covered entities must reasonably limit their disclosures of, and requests for, PHI for payment and health care operations to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request (45 CFR 164.502(b)). However, covered entities are not required to apply the minimum necessary standard to disclosures to or requests by a health care provider for treatment purposes (45 CFR 164.502(b)(2)(i)).[18]

[18] See, Office for Civil Rights. (2013, July 26). Uses and Disclosures for Treatment, Payment, and Health Care Operations (45 CFR 164.506). Retrieved from *https://www.hhs.gov/hipaa/for-professionals/*

HIPAA also identifies specific transactions for which the Secretary must adopt standards and specifies a process for updating those standards. A HIPAA transaction is an electronic exchange of information between two parties to carry out financial or administrative activities related to health care (for example, when a health care provider sends a claim to a health plan to request payment for medical services). Under HIPAA, HHS has adopted multiple standards for transactions involving the exchange of electronic health care data, including:

- Health care claims or equivalent encounter information.
- Health care electronic funds transfers (EFT) and remittance advice.
- Health care claim status.
- Eligibility for a health plan.
- Enrollment and disenrollment in a health plan.
- Referrals certification and authorization.
- Coordination of benefits.
- Health plan premium payments.
- Medicaid pharmacy subrogation.

We note that the HHS Secretary has not adopted an applicable HIPAA transaction standard for communications of claims or encounter data that are not sent for the purpose of requesting payment. Although our proposals detailed below would facilitate payers sharing claims data with providers, this would not be done for the purpose of obtaining (or making) payment (as described under 45 CFR 162.1101(a)). We are not proposing to report health care encounters in connection with a reimbursement contract that is based on a mechanism other than charges or reimbursement rates for specific services (as described under 45 CFR 162.1101(b)). Therefore, the use of a HIPAA transaction standard is not required for our proposals in this section, or for our proposals regarding data sharing in sections II.C. and II.D. of this proposed rule, because the Secretary has not adopted a HIPAA transaction applicable to communications of claims or encounter information for a purpose other than requesting payment.[19]

In this section, we propose to require that certain payers implement a standards-based Provider Access API that makes patient data available to providers both on an individual patient basis and for one or more patients at once using a bulk specification, as permitted by applicable law, so that providers could use data on their patients for such purposes as facilitating treatment and ensuring their patients receive better, more coordinated care. As noted, the HIPAA Privacy Rule generally permits HIPAA covered entities to use and disclose PHI for these purposes without need of an individual's authorization.[20] However, under other federal, state, local, or tribal laws (for example, the ''part 2'' regulations addressing substance use disorder data at 42 CFR part 2), payers and providers may need to obtain some specified form of patient consent to request or disclose behavioral health, certain substance use disorder treatment, or other sensitive health-related information, or they may have to use specified transactions to carry out certain defined data transfers between certain parties for specific purposes. We note these proposals do not in any way alter a payer's or a provider's obligations under all existing federal, state, local, or tribal laws.

3. Proposed Requirements for Payers: Provider Access API for Individual Patient Information Access

In the CMS Interoperability and Patient Access final rule (85 FR 25558 through 25559), we required impacted payers to make certain health information available to third–party apps with the approval and at the direction of a patient though the Patient Access API for patient use. We believe there would be value to providers having access to the same patient data through a FHIR-based API that allows the provider to request data for a single patient as needed. And, we recognize that the impacted payers under this proposed rule will have largely prepared the necessary infrastructure and implemented the FHIR standards to support the Patient Access API finalized in the CMS Interoperability and Patient Access final rule (85 FR 25558 through 25559) by January 1, 2021 (for QHP issuers on the FFEs, for plan years beginning on or after January 1, 2021). As a result, we are now proposing to require impacted payers to implement a Provider Access API.

Both this proposed Provider Access API and the Patient Access API would facilitate the FHIR-based exchange of claims and encounter data, as well as the same set of clinical data as defined in the USCDI version 1, where such clinical data are maintained by the payer, and formulary data or preferred drug list data, where applicable. Both APIs also require the sharing of pending and active prior authorization decisions (and related clinical documentation and forms) for items and services. One difference is that the Provider Access API would not include remittances and beneficiary cost-sharing information. Another key difference is that in the case of the Provider Access API proposals, the provider, not the patient, requests and ultimately receives the patient's information, and would typically make such a request for treatment or care coordination purposes. Where a patient would receive this data via a third-party app for use on a mobile device, in the case of the Provider Access API, the provider would receive the data directly from the payer and incorporate it into their EHR or other practice management system.

Through a proposed cross-reference to the Patient Access API requirements, the Provider Access API also requires adherence to the same technical standards, API documentation requirements, and discontinuation and denial of access requirements. For a complete discussion of these requirements, we refer readers to the CMS Interoperability and Patient Access final rule (85 FR 25526 through 25550) and to section II.A. of this proposed rule.

We are proposing two approaches to the Provider Access API. First, we are proposing a Provider Access API that allows providers to have access to an individual patient's information. Second, we are proposing that the Provider Access API allow access to multiple patients' information at the same time; this is discussed in section II.B.5. of this proposed rule. The individual request approach may be better suited for situations such as, but not limited to, when the provider needs ''real-time'' access to a patient's data prior to or even during a patient visit or for small practices with limited server bandwidth. In these situations, providers may wish to gain access to patient data through an API that yields the data through an individual patient request.

To support this individual patient use case, we are proposing to require state Medicaid and CHIP FFS programs at 42 CFR 431.61(a)(1)(i) and 457.731(a)(1)(i) respectively; and QHP issuers on the FFEs at 45 CFR 156.222(a)(1)(i), to implement and maintain a Provider Access API conformant with the requirements at 45 CFR 170.215, as detailed in section II.A.2. of this proposed rule for the Patient Access API. This proposed Provider Access API would leverage the same IGs in the same way as proposed for the Patient Access API. These requirements would be equally applicable to Medicaid managed care plans and CHIP managed care

privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html.

[19] See 45 CFR 162.923(a).

[20] See 45 CFR 164.506.

entities based on cross-references to the state Medicaid and CHIP FFS requirements at 42 CFR 438.242(b)(7) for Medicaid managed care plans other than Non-Emergency Medical Transportation (NEMT) PAHPs [21] and 42 CFR 457.1233(d)(4) for CHIP managed care entities. We propose that payers implement this Provider Access API individual patient data approach for data maintained by the payer with a date of service on or after January 1, 2016 by January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023). We note that providers may or may not have a provider agreement with or be in- or out-of-network with the payer that is providing the information, as we believe providers should have access to their patients' data regardless of their relationship with the payer. Therefore, our proposal does not permit a payer to deny use of or access to the Provider Access API based on whether the provider using the API is under contract with the payer. A provider that is not in network would need to demonstrate to the patient's payer that they do have a care relationship with the patient.

In the context of Medicaid managed care, we are proposing that NEMT PAHPs, as defined at 42 CFR 438.9(a), would not be subject to the requirement to establish a Provider Access API. MCOs, PIHPs, and non-NEMT PAHPs are subject to this proposed rule. We believe that the unique nature and limited scope of the services provided by NEMT PAHPs is not consistent with the proposed purposes of the Provider Access API proposed at 42 CFR 431.61(a). Specifically, we do not believe that providers have any routine need for NEMT data nor that having NEMT PAHPs implement and maintain a Provider Access API would help achieve the goals of the proposal, namely to help avoid patients needing to recall prior services, ensure that providers are able to spend time with patients focusing on care versus collecting redundant information, or improve patient care through enhanced care coordination. However, we include NEMT PAHPs in the scope of some of our other requirements that apply to all other Medicaid managed care plans under proposed 42 CFR 438.242(b)(5) through (8). Currently, NEMT PAHPs are exempt from compliance with requirements in 42 CFR part 438 unless the provision is listed in § 438.9(b), which does currently apply 42 CFR 438.242 to NEMT PAHPs. We are therefore proposing to revise 42 CFR 438.9(b)(7) to require compliance with the requirements in 42 CFR 438.242(b)(5) through (8) other than the reference to 42 CFR 431.61(a) and (c) at 438.242(b)(7).

We request public comment on this proposal for impacted payers to implement a Provider Access API for individual patient information access.

4. The MyHealthEData Initiative Experience With Sharing Patient Data With Providers

Understanding the benefits of provider access to patient information discussed above, as part of the MyHealthEData initiative, we launched the Beneficiary Claims Data API (BCDA), which enables Accountable Care Organizations (ACOs) participating in the Shared Savings Program to retrieve Medicare Part A, Part B, and Part D claims data for their prospectively assigned or assignable beneficiaries.[22] To better facilitate the coordination of care across the care continuum and in support of a move to value-based care, the BCDA utilizes the HL7 FHIR Bulk Data Access (Flat FHIR) specification to allow us to respond to requests for large amounts of patient-level Medicare FFS claims data on behalf of ACO participating practices.[23] Using a bulk data exchange reduces burden for ACOs and CMS, and adds a number of efficiencies for ACOs and their participating practices by facilitating the exchange of data for many patients at once. It also gets data to providers when and where they need it most.

In addition, in July 2019, we announced a pilot program called ''Data at the Point of Care'' (DPC) [24] in support of our mission to transform the health care system. Also part of the MyHealthEData initiative, DPC—utilizing the HL7 FHIR Bulk Data Access (Flat FHIR) specification—allows health care providers to access synthetic Medicare FFS claims data, either by integrating with their EHR or with the health IT system they utilize to support care, without requiring access to other applications. Currently, approximately 1,000 organizations representing over 130,000 providers have engaged with the synthetic data in the pilot. Participants include a diversity of practice types including primary care practices, single or small office specialist practices, academic medical centers, non- and for-profit health systems, and dialysis centers. The provider organization is the official demonstration participant, but each organization is taking part with its EHR vendor.

Both BCDA and DPC have started to demonstrate the value of exchanging data on multiple patients at once via FHIR. The HL7 FHIR Bulk Data Access (Flat FHIR) specification can reduce the number of API requests and support a secure connection for third-party application access to specified data stored in EHRs and data warehouse environments.[25] CMS has developed our projects leveraging the HL7 FHIR Bulk Data Access (Flat FHIR) specification using open source programming. The documentation, specifications, and reference implementations are available at *https://github.com/CMSgov/bcda-app* and *https://github.com/CMSgov/dpc-app.*

When leveraged, the HL7 FHIR Bulk Data Access (Flat FHIR) specification permits the efficient retrieval of data on entire patient populations or defined cohorts of patients via the bulk transfer of data using standard data exchanges. Providers who are responsible for managing the health of multiple patients may need to access large volumes of data. Exchanging patient data for large numbers of patients may require large exports, which would usually require multiple requests and a number of resources to manage the process that can overburden organizations and be time consuming and costly. Even using more efficient methods of data exchange like secure APIs can present challenges for a large number of patient records. For example, for a health system with thousands of Medicaid patients, accessing those patients' claims data one by one would require thousands of API calls.[26] We believe that providing a streamlined means of accessing this information via FHIR-based APIs utilizing the HL7 FHIR Bulk Data Access (Flat FHIR) specification greatly improves providers' ability to deliver quality, value-based care, and ultimately better manage patient health.

[21] See 42 CFR 438.9(b)(7).

[22] Centers for Medicare and Medicaid Services. (n.d.). Beneficiary Claims Data API. Retrieved from *https://bcda.cms.gov/.*

[23] HL 7 International. (n.d.). FHIR Bulk Data Access (Flat FHIR). Retrieved from *https://hl7.org/fhir/uv/bulkdata/history.html.*

[24] Data at the Point of Care. (n.d.). Retrieved from *https://dpc.cms.gov/.*

[25] Office of the National Coordinator, Computational Health Informatics Program, & Boston Children's Hospital. (2017, December 15). The Intersection of Technology and Policy: EHR Population Level Data Exports to Support Population Health and Value. Retrieved from *https://smarthealthit.org/an-app-platform-for-healthcare/meetings/bulk-data-export-meeting-and-report/.*

[26] A 'call' is an interaction with a server using an API to deliver a request and receive a response in return.

5. Proposed Requirements for Payers: Bulk Data Provider Access API

We believe that the benefits of data sharing would be greatly enhanced if other payers were sharing health information about their patients with health care providers for multiple patients at once, as CMS is now beginning to do under BCDA and as we are also further testing through the DPC pilot, for instance. As a result, we are proposing a second approach to require impacted payers to implement payer-to-provider data sharing using the HL7 FHIR Bulk Data Access (Flat FHIR) specification—a Bulk Data Provider Access API.

Given the many benefits of giving providers efficient access to their patients' data, and the relative ease of doing so by leveraging the HL7 FHIR Bulk Data Access (Flat FHIR) specification, we are proposing to require that all Medicaid and CHIP FFS programs at 42 CFR 431.61(a)(1)(ii) and 457.731(a)(1)(ii), Medicaid managed care plans at 42 CFR 438.242(b)(7), CHIP managed care entities at 42 CFR 457.1233(d)(4), and QHP issuers on the FFEs at 45 CFR 156.222(a)(1)(ii) implement and maintain a standards-based Provider Access API using the HL7 FHIR Bulk Data Access (Flat FHIR) specification at 45 CFR 170.215(a)(4) to allow providers to receive the same information as indicated above for the individual patient request Provider Access API—their patients' claims and encounter data (not including cost information such as provider remittances and enrollee cost-sharing); clinical data as defined in the USCDI version 1, where such clinical data are maintained; and formulary data or preferred drug list data, where applicable; as well as information on pending and active prior authorization decisions. The regulations for Medicaid managed care plans and CHIP managed care entities are cross-referenced and incorporate the regulations we propose for state Medicaid and CHIP FFS programs.

We are proposing that payers would be required to implement this Bulk Data Provider Access API approach for data maintained by the payer with a date of service on or after January 1, 2016, by January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023). We request public comment on whether this timeline is feasible and whether the benefits would out weight the costs of this Bulk Data Provider Access API proposal.

We understand and acknowledge that payers and developers may view these proposed requirements as burdensome, as they could involve building multiple APIs to share data between payers and providers. We invite public comment on the benefits of having the Provider Access API available with and without the use of the HL7 FHIR Bulk Data Access (Flat FHIR) specification. As we look to balance providing this flexibility with the burden of potentially implementing and maintaining multiple APIs, we invite input on whether we should require payers to implement just one API that leverages the HL7 FHIR Bulk Data Access (Flat FHIR) specification for when they are requesting data for just one patient, or for more than one patient, or should we finalize as we are proposing here to have payers implement one API solution that does not leverage the Bulk specification for a single patient request (as discussed in section II.B.3. above in this proposed rule), and a second solution that uses the Bulk specification for requests for more than one patient. We believe both proposed functionalities offer necessary benefits to providers depending on the specifics of the situations in which they would need patient data. For example, a large health system or large group practice may benefit from using the bulk specification if it is updating records annually. We also believe that requiring payers to have both API approaches available gives providers flexibility. For example, a provider practicing within a large health system, such as in the example above, may want quick access to a specific patient's information right before that patient's scheduled appointment.

We request comment on this proposal.

States operating Medicaid and CHIP programs may be able to access federal matching funds to support their implementation of this Provider Access API, because the API is expected to help the state administer its Medicaid and CHIP state plans properly and efficiently, consistent with sections 1902(a)(4) and 2101(a) of the Act, as discussed in more detail in section II.B.7.a. of this proposed rule.

We do not consider state expenditures for implementing this proposal to be attributable to any covered item or service within the definition of ''medical assistance.'' Thus, we would not match these expenditures at the state's regular federal medical assistance percentage. However, federal Medicaid matching funds under section 1903(a)(7) of the Act, at a rate of 50 percent, for the proper and efficient administration of the Medicaid state plan, might be available for state expenditures related to implementing this proposal for their Medicaid programs, because use of the Provider Access API would help ensure that providers can access data that could improve their ability to render Medicaid services effectively, efficiently, and appropriately, and in the best interest of the patient, and thus help the state more efficiently administer its Medicaid program.

States' expenditures to implement these proposed requirements might also be eligible for enhanced 90 percent federal Medicaid matching funds under section 1903(a)(3)(A)(i) of the Act if the expenditures can be attributed to the design, development, or installation of mechanized claims processing and information retrieval systems. Additionally, 75 percent federal matching funds under section 1903(a)(3)(B) of the Act may be available for state expenditures to operate Medicaid mechanized claims processing and information retrieval systems to comply with this proposed requirement.

States request Medicaid matching funds under section 1903(a)(3)(A)(i) or (B) of the Act through the Advance Planning Document (APD) process described in 45 CFR part 95, subpart F. States are reminded that 42 CFR 433.112(b)(12) and 433.116(c) require them to ensure that any system for which they are receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act aligns with and incorporates the ONC Health Information Technology standards adopted in accordance with 45 CFR part 170, subpart B. The Provider Access API, and all APIs proposed in this rule, complement this requirement because these APIs further interoperability through the use of HL7 FHIR standards proposed for adoption by ONC for HHS use at 45 CFR 170.215.[27] In addition, states are reminded that 42 CFR 433.112(b)(10) explicitly supports exposed APIs as a condition of receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act.

Similarly, 42 CFR 433.112(b)(13) requires the sharing and re-use of Medicaid technologies and systems as a condition of receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act. CMS would interpret that sharing and re-use requirement also to apply to technical documentation associated with a technology or system, such as technical documentation for connecting to a state's APIs. Making the needed

[27] See SHO #20–003, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho20003.pdf.*

technical documentation publicly available so that systems that need to connect to the APIs proposed in this rule can do so would be required as part of the technical requirements at 42 CFR 431.60(d) for all proposed APIs in this rule, including the Provider Access API.

Separately, for CHIP agencies, section 2105(c)(2)(A) of the Act, limiting administrative costs to no more than 10 percent of CHIP payments to the state, would apply in developing the APIs proposed in this rule.

We note that the temporary federal medical assistance percentage (FMAP) increase available under section 6008 of the Families First Coronavirus Response Act (Pub. L. 116–127) does not apply to administrative expenditures.

6. Additional Proposed Requirements for the Provider Access APIs

In general, the proposals discussed in this section would align with the requirements for the Patient Access API finalized in the CMS Interoperability and Patient Access final rule (85 FR 25558 through 25559) and as proposed in section II.A.2. of this rule with respect to the data that are available through the API and the technical specifications (other than the proposed use of the Bulk specification). We anticipate that this alignment would provide consistency and help ensure that payers could build on the foundation of work done to meet the final Patient Access API requirements to meet the proposed requirements related to the Provider Access API. The accessible content, technical standards, API documentation requirements, and discontinuation and denial of access requirements would generally be consistent between the Patient Access API and the Provider Access API proposals, and thus we will not repeat the details of these requirements here. There are additional proposed requirements specific to the Provider Access API proposals related to attribution, patient opt-in, and provider resources. These are discussed in this section.

a. Attribution

Data sharing between the payer and provider via the Provider Access API starts with a request from the provider for one or more patients' health information. Data sharing via the Provider Access API would be possible only if the patients for whom the provider is requesting information can be identified, especially if the provider is requesting data for more than one patient at a time using the proposed Bulk specification. We do not believe there is only one approach to identifying the patients whose information would be requested, and we look to provide impacted payers with the opportunity to establish a process that will work best for them in light of their existing provider relationships.

As discussed in the CMS Interoperability and Patient Access final rule, use of a standards-based FHIR API consistent with the privacy and security technical standards required provides a base level of protections (see 85 FR 25515 through 25519 and 85 FR 25544 through 25547). For instance, use of the API would allow payers to determine if the provider who is requesting the data is who they say they are by leveraging the required authorization and authentication protocols at 45 CFR 170.215. And, as mentioned above, the existing HIPAA Privacy and Security Rules apply. As a covered entity under HIPAA, it is the provider's responsibility to use and disclose data in accordance with these existing rules.

As part of the DPC pilot, as one example, we are planning to test a process that allows for the provider to add their active patients to a roster through self-attestation, which is further checked against claims to verify the provider has furnished services to the patient. The provider must attest electronically that they have an active treatment need for the data, and the provider must agree to the DPC terms of use for each roster submitted or updated.[28] This approach was identified given the specific goals of the DPC pilot and the provider and patient population involved. For new patients, payers could consider a process for confirming a patient has an upcoming appointment scheduled to facilitate data sharing when there is not a claims history to use to verify a care relationship.

We recognize that the payers impacted by this proposed rule have a variety of provider relationships to consider. We are therefore proposing that each payer establish, implement, and maintain for itself, a process to facilitate generating each provider's current patient roster to enable this proposed payer-to-provider data sharing via the Provider Access API.

We are proposing this at 42 CFR 431.61(a)(2) for state Medicaid FFS, at 42 CFR 438.242(b)(7) (to comply with the requirement at 42 CFR 431.61(a)) for Medicaid managed care plans other than non-emergency transportation (NEMT) PAHPs, at 42 CFR 457.731(a) for state CHIP FFS, at 42 CFR 457.1233(d)(4) (to comply with the requirement at 42 CFR 457.731(a)) for CHIP managed care, and at 45 CFR 156.222(a)(2) for QHP issuers on the FFEs. To facilitate this data sharing, it is necessary that providers give payers a list of the patients whose data they are requesting. We do not wish to be overly prescriptive about how to generate this list for all payers. But, we note that it would be necessary for payers to put a process in place that is compliant with existing HIPAA Privacy and Security Rules and provides the information they need to complete their payer-specific compliance processes.

We request comments on this proposal. And, we also seek comment on whether payers would like to maintain the option to define their own process or if they would prefer us to require a process across payers, such as the one we plan to test as part of the DPC pilot.

b. Opt-In

We are proposing that impacted payers would be permitted to put a process in place for patients to opt-in to use of the Provider Access API for data sharing between their payer and their providers. As with the attribution process discussed above, we did not want to be overly prescriptive regarding how this opt-in process might be implemented. However, we are considering whether to suggest a specific process for all payers who choose to implement this opt-in. One possible approach might be for CMS to have all payers engaging in an opt-in approach to include information about the ability to opt-in to this data sharing as part of their annual notice or regular communication with patients—such as when they communicate with patients about claims, and to permit opt-in via a variety of options, including by phone, via a website, or using an app, for instance.

Currently the HIPAA Privacy Rule does not require health plans to obtain patient consent to share data with health care providers for treatment purposes or care coordination, for instance. However, we believe it is important to honor patient privacy preferences, and thus see value in possibly providing patients with options regarding which providers have access to their information as it relates to this proposed policy. We do note, as discussed above, that all existing applicable laws and regulations apply. This opt-in option is only specific to using the Provider Access API as the means to share data that the payer otherwise has authority to share with the provider. Therefore, we are specifically proposing at 42 CFR

[28] Data at the Point of Care. (n.d.). Terms of Service. Retrieved from *https://dpc.cms.gov/terms-of-service.*

431.61(a)(3) for state Medicaid FFS, at 42 CFR 438.242(b)(7) (to comply with the requirement at 42 CFR 431.61(a)(3)) for Medicaid managed care, at 42 CFR 457.731(a)(3) for state CHIP FFS, at 42 CFR 457.1233(d)(4) (to comply with the requirement at 42 CFR 457.731(a)(3)) for CHIP managed care, and at 45 CFR 156.222(a)(3) for QHP issuers on the FFEs that payers may put a process in place to allow a patient to opt-in to the Provider Access API data exchange for each provider from whom they are currently receiving care or are planning to receive care.

We request comment on this proposal. In addition, we seek comment on whether payers would like to maintain the option to define their own process or if they would prefer CMS to suggest a process, such as the examples provided above, for all payers who would be required to implement and maintain the Provider Access API. We do note that we also considered the following alternatives: (1) Permit an opt-out process, (2) default to data sharing without patient engagement in the process consistent with the HIPAA Privacy Rule, and require an opt-out process. We seek comment on whether stakeholders would prefer we finalize an opt-out versus an opt-in approach, and whether either opt-out, or as currently proposed—opt-in, be permitted but not required. We request comment on the associated benefits and burdens with these different approaches, and any other considerations we should take into consideration as we consider a final policy.

c. Provider Resources

We are proposing that payers make educational resources available to providers that describe how a provider can request patient data using the payer's Provider Access APIs in non-technical, simple, and easy-to-understand language. This requirement would be codified at 42 CFR 431.61(a)(4) for Medicaid FFS, at 42 CFR 438.242(b)(7) (to comply with the requirement at 42 CFR 431.61(a)) for Medicaid managed care other than NEMT PAHPs as defined at 42 CFR 438.2, at 42 CFR 457.731(a)(4) for CHIP FFS, at 42 CFR 457.1233(d)(4) (to comply with the requirement at 42 CFR 457.731(a)) for CHIP managed care, and at 45 CFR 156.222(a)(4) for QHP issuers on the FFEs. As proposed, this would include information on using both the individual patient request function as well as the bulk data request function. We are proposing that these resources be made available on the payer's website and through other appropriate mechanisms through which the payer ordinarily communicates with providers. We believe these resources would help providers understand how they can leverage the available APIs to access patient data, thus helping to ensure that the full value of the proposed APIs is realized and that providers gain access to needed patient data for use at the moment of care.

We request comment on this proposal.

d. Extensions and Exemptions for Medicaid and CHIP FFS Programs

If our proposals regarding the Provider Access API are finalized, we would strongly encourage state Medicaid and CHIP FFS programs to implement the Provider Access API as soon as possible understanding the many benefits of the API as discussed previously in this section.

However, we also recognize that state Medicaid or CHIP FFS agencies could face certain unique circumstances that would not apply to other impacted payers, as discussed in more detail later in this section. As a result, a few states might need to seek an extension of the compliance deadline or an exemption from these requirements. To address this concern, we are proposing a process through which states may seek an extension of and, in specific circumstances, an exemption from, the Provider Access API requirements if they are unable to implement these API requirements. Providing for these flexibilities might allow these states to continue building technical capacity in support of overall interoperability goals consistent with their needs. We therefore propose the following.

Extension. At 42 CFR 431.61(e)(1) and 42 CFR 457.731(e)(1), respectively, we propose to provide states—for Medicaid FFS and CHIP FFS—the opportunity to request a one-time extension of up to one (1) year for implementation of the Provider Access API specified at 42 CFR 431.61(a) and 42 CFR 457.731(a). Unique circumstances that might present a challenge to specific states to meet the proposed compliance date could include resource challenges, such as funding. Depending on when the final rule is published in relation to a state's budget process and timeline, some states may not be able to secure the needed funds in time to both develop and execute implementation of the API requirements by the proposed compliance date. A one-year extension could help mitigate this issue. And, some states may need to initiate a public procurement process to secure contractors with the necessary skills to support a state's implementation of these proposed API policies. The timeline for an open, competed procurement process, together with the time needed to onboard the contractor and develop the API, could require additional time as well. Finally, a state might need to hire new staff with the necessary skillset to implement this policy. Again, the time needed to initiate the public employee hiring process, vet, hire, and onboard the new staff may make meeting the proposed compliance timeline difficult, because, generally speaking, public employee hiring processes include stricter guidelines and longer time-to-hire periods than other sectors.[29] In all such situations, a state might need more time than other impacted payers to implement the requirements.

If a state believes it can demonstrate the need for an extension, its request must be submitted and approved as a part of its annual Advance Planning Document (APD) for Medicaid Management Information System (MMIS) operations costs and must include the following: (1) A narrative justification describing the specific reasons why the state cannot reasonably satisfy the requirement(s) by the compliance date, and why those reasons result from circumstances that are unique to states operating Medicaid or CHIP FFS programs, (2) a report on completed and ongoing implementation activities to evidence a good faith effort toward compliance, and (3) a comprehensive plan to meet implementation requirements no later than one year after the initial compliance date.

An extension would be granted if CMS determines based on the information provided in the APD that the request adequately establishes a need to delay implementation, a good faith effort to implement the proposed requirements as soon as possible, and a clear plan to implement no later than one year after the proposed compliance date. We would expect states to explain why the request for an extension results from circumstances that are unique to states operating Medicaid or CHIP FFS programs. We also solicit comment on whether our proposal would adequately address the unique circumstances that affect states, and that might make timely compliance with the proposed API requirement sufficiently difficult for states and thus justify an extension. In particular, we seek comment on

[29] State hiring processes are comparable with federal hiring processes. According to OMB, the average time-to-hire for federal employees was 98.3 days in 2018, significantly higher than the private sector average of 23.8 days. See: *https://www.opm.gov/news/releases/2020/02/opm-issues-updated-time-to-hire-guidance/.*

whether we should require or use additional information on which to base the determination or whether we should establish different standards in the regulation text for evaluating and granting the request.

Exemption. At 42 CFR 431.61(e)(2) and 42 CFR 457.731(e)(2), respectively, we propose two circumstances that would permit state requests for exemption; namely, (1) when at least 90 percent of all covered items and services are provided to Medicaid or CHIP beneficiaries through Medicaid or CHIP managed care contracts with MCOs, PIHPs, or PAHPs, rather than through a FFS delivery system; or (2) when at least 90 percent of the state's Medicaid or CHIP beneficiaries are enrolled in Medicaid or CHIP managed care organizations as defined in 42 CFR 438.2 for Medicaid and 42 CFR 457.10 for CHIP. In both circumstances, the time and resources that the state would need to expend to implement the API requirements may outweigh the benefits of implementing and maintaining the API. Unlike other impacted payers, state Medicaid and CHIP FFS programs do not have a diversity of plans to balance implementation costs for those plans with low enrollment. If there is low enrollment in a state Medicaid or CHIP FFS program, there is no potential for the technology to be leveraged for additional beneficiaries as states, unlike other payers, do not maintain additional lines of business.

We acknowledge that the proposed exemption could mean that a few Medicaid or CHIP FFS systems would not receive the benefits of having this API available to facilitate health information exchange. To address this, we propose that states meeting the above thresholds would be expected to employ an alternative plan to enable the electronic exchange and accessibility of health information for those beneficiaries who are served under the FFS program.

A state meeting the above criteria would be permitted to submit a request for an exemption to the requirements for the Provider Access API once per calendar year for a one (1) year exemption. The state would be required to submit this annual request as part of a state's annual APD for MMIS operations costs. The state would be required to include in its request documentation that it meets the criteria for the exemption using data from any one of the three most recent and complete calendar years prior to the date the exemption request is made. We note we propose that this request be made annually as from year-to-year the nature of the FFS population could change and so it is important that the state provide the most current information for CMS' consideration.

Exemptions would be granted for a one-year period if a state establishes to CMS' satisfaction that it meets the criteria for the exemption and has established a plan to ensure that providers will have efficient electronic access to the same information through alternative means.

We request comment on the proposed extension and exemption.

For Medicaid and CHIP managed care, we are not proposing an extension process at this time because we believe that managed care plans are actively working to develop the necessary IT infrastructure to be able to comply with the existing requirements in 42 CFR part 438 and part 457 and also benefit from efficiencies resulting from their multiple lines of business impacted by these interoperability policies. Many managed care plans are part of parent organizations that maintain multiple lines of business, including Medicaid managed care plans and plans sold on the Exchanges. As discussed in the CMS Interoperability and Patient Access final rule (85 FR 25607, 25612, 25620), work done by these organizations can benefit all lines of business and, as such, we do not believe that the proposals in this rule impose undue burden or are unachievable by the compliance date. We are soliciting comment on whether our belief concerning the scope of resources and ability of managed care parent organizations to achieve economies of scale is well-founded. Further, we seek comment on whether an extension process is warranted for certain managed care plans to provide additional time for the plan to comply with the requirement at 42 CFR 438.61(a) (which cross references 42 CFR 438.242(b)(7)) for Medicaid managed care plans and at proposed 42 CFR 457.731(a) (which cross references 42 CFR 457.1223(d)(4)) for CHIP managed care entities. While we are not proposing such a process for managed care plans and entities and do not believe one is necessary for the reasons outlined here, we are open to considering one if necessary. If we adopt an extension process for these managed care plans and entities, what criteria would a managed care plan or entity have to meet to qualify for an extension? Should the process consider, for example, enrollment size, plan type, or some unique characteristic of certain plans that could hinder their achievement of the proposed requirements by the proposed compliance date? Also, we seek comment on whether, if finalized such a process for Medicaid managed care plans or CHIP managed care entities, the state or CMS should manage the process and whether states could successfully adopt and implement the process on the timeline necessary to fulfill the goals and purposes of the process. Consistent with the exception process proposed for QHP issuers on the FFEs at 45 CFR 156.222(d), we would expect any extension request to include, at a minimum, a narrative justification describing the reasons why a plan or entity cannot reasonably satisfy the requirements by the proposed compliance date, the impact of non-compliance upon enrollees, the current or proposed means of providing electronic health information to providers, and a corrective action plan with a timeline to achieve compliance.

e. Exception for QHP issuers

For QHP issuers on the FFEs, we propose an exception at 45 CFR 156.222(d) to these Provider Access API proposals. We propose that if an issuer applying for QHP certification to be offered through a FFE believes it cannot satisfy the proposed requirements in 45 CFR 156.222(a) for the Provider Access APIs, the issuer must include as part of its QHP application a narrative justification describing the reasons why the issuer cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance upon providers and enrollees, the current or proposed means of providing health information to providers, and solutions and a timeline to achieve compliance with the requirements of this section. We propose that the FFE may grant an exception to the requirements in 45 CFR 156.222(a) for the Provider Access APIs if it determines that making such health plan available through such FFE is in the interests of qualified individuals in the state or states in which such FFE operates. This proposal would be consistent with the exception for QHP issuers on the FFEs we finalized for the Patient Access API in the Interoperability and Patient Access final rule (85 FR 25552 through 25553). For instance, as noted in that final rule, that exception could apply to small issuers, issuers who are only in the individual or small group market, financially vulnerable issuers, or new entrants to the FFEs who demonstrate that deploying standards based API technology consistent with the required interoperability standards would pose a significant barrier to the issuer's ability to provide coverage to consumers, and not certifying the issuer's QHP or QHPs would result in consumers having few

or no plan options in certain areas. We believe that having a QHP issuer offer QHPs through an FFE is in the best interest of consumers and would not want consumers to have to go without access to QHP coverage because the issuer is unable to implement this API timely.

As mentioned in section II.A. of this proposed rule, although Medicare FFS is not directly impacted by this rule, we do note that we are targeting to implement a Provider Access API, if finalized. In this way, the Medicare FFS implementation would conform to the same requirements that apply to the impacted payers under this rulemaking, as applicable, so that Medicare FFS beneficiaries would also benefit from this data sharing.

7. Statutory Authorities for Provider Access API Proposals

a. Medicaid and CHIP

As is discussed in more detail below, our proposed requirements in this section for Medicaid managed care plans and Medicaid state agencies fall generally under the authority in the following provisions of the statute.

- Section 1902(a)(4) of the Act, which requires that a state Medicaid plan provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the state Medicaid plan.
- Section 1902(a)(8) of the Act, which requires states to ensure that Medicaid services are furnished with reasonable promptness to all eligible individuals.
- Section 1902(a)(19) of the Act, which requires states to ensure that care and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

We note statutory authority for proposals to require specific IGs for this and all APIs proposed in this rule is discussed in section II.A.3. of this proposed rule.

We believe these proposals are generally consistent with all these provisions of the Act, because they would help ensure that providers can access data that could improve their ability to render Medicaid services effectively, efficiently, and appropriately. The proposals are thus expected to help states fulfill their obligations to operate their state plans efficiently and to ensure that Medicaid services are furnished with reasonable promptness and in a manner consistent with the best interest of patients.

Proposing to require states to implement a Provider Access API to share data about certain claims, encounter, and clinical data, including data about pending and active prior authorization decisions, for a specific individual beneficiary or for more than one beneficiary at a time could improve the efficiency of and simplify how states ensure the delivery of Medicaid services. This API would enable providers to easily access accurate and complete beneficiary utilization and authorization information at the time of care, or prior to a patient encounter, and that, in turn, would enable the provider to spend more time on direct care. This would support efficient and prompt delivery of care as well as care in the best interest of patients. These proposals also are expected to allow for better access to other providers' prior authorization decisions. This would give a provider a more holistic view of a patient's care that could reduce the likelihood of ordering duplicate or misaligned services. This could also facilitate easier and more informed decision making by the provider and would therefore support efficient provision of care in the best interest of patients. Additionally, because the data could be incorporated into the provider's EHR or other practice management system, the proposal is expected to support efficient access to and use of the information. The proposal is expected to make it more likely that a more complete picture of the patient could be available to the provider at the point of care, which could result in the provision of more informed and timely services. These process efficiencies may ultimately improve practice efficiency and make more of providers' time available for appointments. These outcomes and process efficiencies would help states fulfill their obligations to ensure prompt access to services in a simpler manner and in a manner consistent with the best interest of beneficiaries, consistent with section 1902(a)(8) and (19) of the Act, and the efficiencies created for providers might help the state to administer its Medicaid program more efficiently, consistent with section 1902(a)(4) of the Act.

The proposal related to the Bulk specification for the Provider Access API would help facilitate data sharing about one or more beneficiaries at once. This could further improve the efficiency and simplicity of operations because it would eliminate the need for a provider to make individual API calls when seeking information about a large number of beneficiaries, taxing both the payer's and provider's systems. The ability to receive beneficiary data in bulk would also permit practices to analyze practice and care patterns across patient populations, thus helping them to improve processes and maximize efficiencies that could lead to better health outcomes. All of these expected positive outcomes could help states fulfill their obligations to ensure prompt access to services in a simpler manner and in a manner consistent with the best interest of beneficiaries, consistent with section 1902(a)(8) and (19) of the Act, and the efficiencies created for providers might help the state to administer its Medicaid program more efficiently, consistent with section 1902(a)(4) of the Act.

For CHIP, we are proposing these requirements under the authority in section 2101(a) of the Act, which states that the purpose of title XXI is to provide funds to states to provide child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage. We believe this proposed rule could strengthen states' ability to fulfill these title XXI statutory obligations in a way that recognizes and accommodates the use of electronic information exchange in the health care industry today and would facilitate a significant improvement in the delivery of quality health care to CHIP beneficiaries.

When providers have access to patient utilization and authorization information directly from their EHRs or other health IT systems, they can provide higher quality care. Improving the quality of care aligns with section 2101(a), which requires states to provide CHIP services in an effective and efficient manner. The more information a provider has to make informed decisions about a patient's care, the more likely it is that patients will receive care that best meets their needs. Additionally, providers can be more effective and efficient in their delivery of CHIP services by having direct access to patient utilization and authorization information. If a provider has information about a patient prior to or at the point of care, the provider will be able to spend more time focused on the patient versus on their need to collect information. And, the information they do collect will not be based solely on patient recall. As noted above for Medicaid, this could save time, improve the quality of care, and increase the total amount of direct care provided to CHIP beneficiaries. When data are standardized, and able to be incorporated directly into the provider's EHR or practice management system, they can be leveraged as needed at the point of care by the provider, but also be used to support coordination across

providers and payers. This is inherently more efficient, and ultimately, more cost effective, as the information does not have to be regularly repackaged and reformatted to be shared or used in a valuable way. As such, the Provider Access API proposals also align with section 2101(a) in that these proposals could improve coordination between CHIP and other health coverage. For these reasons, we believe this proposal is in the best interest of the beneficiaries and within our authorities.

b. QHP Issuers on the FFEs

For QHP issuers on the FFEs, we are proposing these new requirements under our authority in section 1311(e)(1)(B) of the Affordable Care Act, which affords the Exchanges the discretion to certify QHPs if the Exchange determines that making available such health plans through the Exchange is in the interests of qualified individuals in the state in which the Exchange operates. We note statutory authority for proposals to require specific IGs for this and all APIs proposed in this rule are discussed in section II.A.3. of this proposed rule.

We believe that certifying only health plans that make enrollees' health information available to their providers via the Provider Access API is in the interests of enrollees. Giving providers access to their patients' information supplied by QHP issuers on the FFEs would ensure that providers are better positioned to provide enrollees with seamless and coordinated care, and helps to ensure that QHP enrollees on the FFEs are not subject to duplicate testing and procedures, and delays in care and diagnosis. Access to the patients' more complete medical information may also maximize the efficiency of an enrollee's office visits. We encourage SBEs to consider whether a similar requirement should be applicable to QHP issuers participating in their Exchanges.

We also believe that requiring QHP issuers on the FFEs to use the Bulk specification for the Provider Access API would improve the efficiency and simplicity of data transfers by allowing the provider to get all the info for a full panel of patients at once.

C. Reducing the Burden of Prior Authorization Through APIs

1. Background

Improving the prior authorization process is an opportunity to reduce burden for payers, providers, and patients. The proposals in this rule build on the foundation set out in the CMS Interoperability and Patient Access final rule to improve health information exchange and increase interoperability in the health care system. Proposals in this section were developed based on industry input from CMS sponsored listening sessions, stakeholder meetings, and reports.

We use the term ''prior authorization'' to refer to the process through which a provider must obtain approval from a payer before providing care and prior to receiving payment for delivering items or services. In some programs, this may be referred to as ''pre-authorization'' or ''pre-claim review.'' Prior authorization requirements are established by payers to help control costs and ensure payment accuracy by verifying that an item or service is medically necessary, meets coverage criteria, and is consistent with standards of care before the item or service is provided rather than undertaking that review for the first time when a post-service request for payment is made. However, stakeholders have stated that diverse payer policies, provider workflow challenges, and technical barriers have created an environment in which the prior authorization process is a primary source of burden for both providers and payers, a major source of burnout for providers, and a health risk for patients when it causes their care to be delayed.

The policies in this proposed rule would apply to any formal decision-making process by which impacted payers render an approval or disapproval determination, or decision, regarding payment for clinical care based on the payer's coverage guidelines and policies before services are rendered or items provided.

We have been studying prior authorization and its associated burden to identify the primary issues that stakeholders believe need to be addressed to alleviate that burden. To advance the priorities of the 21st Century Cures Act,[30] specifically the aim to reduce burden, ONC and CMS created a working group to investigate the prior authorization ecosystem and identify opportunities for potential solutions. Burdens associated with prior authorization include difficulty in determining payer-specific requirements related to items and services that require prior authorization; inefficient use of provider and staff time to submit and receive prior authorization requests through burdensome channels such as fax, telephone, and various web portals; and unpredictable and lengthy amounts of time to receive payer decisions.

In 2018, the American Medical Association (AMA) conducted a physician survey that indicated a weekly per-physician average of 31 prior authorization requests, consuming an average of 14.9 hours of practice time per workweek for physicians and their staff. Additionally, 36 percent of physicians have staff that work exclusively on prior authorizations.[31] In 2019, CMS conducted a number of listening sessions with payers, providers, patients, and other industry representatives to gain insight into issues with prior authorization processes and to identify potential areas for improvement. While both providers and payers agreed that prior authorization provides value to the health care system through cost control, utilization management, and program integrity measures, some stakeholders expressed concerns that certain steps in the prior authorization processes are burdensome. For example, the information required from payers to receive prior authorization can be inconsistent from payer to payer, and it can be difficult for providers to determine the rules for items or services that require prior authorization or what documentation is needed to obtain approval. Furthermore, the documentation requirements are not centralized because the rules vary for each payer, and access to those requirements may require the use of proprietary portals. These challenges were described in the ONC 2020 report on reducing electronic health record burdens, which stated, ''Each payer has different requirements and different submission methods, and clinicians report finding it burdensome and time-consuming trying to determine whether prior authorization requirements exist for a given patient, diagnosis, insurance plan, or state.'' [32]

In the CMS listening sessions, as well as the surveys and reports referenced throughout this section, stakeholders suggested that payers should disclose their prior authorization requirements in a standard format. Stakeholders raised concerns that once a provider has identified the appropriate prior authorization requirement for a given

[30] ONC Strategy to reduce provider burden. Report required under the 21st Century Cures Act: *https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs.*

[31] American Medical Association. (2019, February). 2018 AMA Prior Authorization (PA) Physician Survey. Retrieved from *https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf.*

[32] Office of the National Coordinator for Health Information Technology. (n.d.) Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs [PDF file]. Retrieved from *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

patient, payer, and item or service, the process of submitting a prior authorization request relies on an array of cumbersome submission channels, including payer-specific web-based portals, telephone calls, and fax exchange technology. In addition, after a provider has completed the process of submitting a prior authorization request and received approval for an item or service from a particular payer, the provider may need to re-submit a new prior authorization request for the same, already approved, item or service should the patient experience a change in health coverage, which could include switching payers, or switching between private coverage and public coverage. Should this occur, the provider must start the prior authorization process anew with the patient's new payer, which may have different documentation requirements and submission formats.

In 2017, a coalition of 16 provider organizations collaborated with payer associations to develop a set of principles to identify ways to reduce administrative burdens related to prior authorizations and improve patient care. The coalition published a consensus paper identifying 21 specific opportunities for improvement in prior authorization programs and processes and specifically called out the need for industry-wide adoption of electronic prior authorization to improve transparency and efficiency.[33] Nonetheless, industry is still at a point where payers and IT developers have addressed prior authorization in an ad hoc manner with the implementation of unique interfaces that reflect their own technology considerations, lines of business, and customer-specific constraints.[34] The proposals in this proposed rule reflect several principles cited in the industry consensus statement, including transparency and communication regarding prior authorization to encourage effective communication between health plans, providers, and patients to minimize care delays and articulate prior authorization requirements, as well as automation to improve transparency, through the adoption and implementation of electronic prior authorization with the potential to streamline and improve the process for all stakeholders.

There is increasing demand from providers, with support from the payer and vendor community, as well as the Secretary's advisory committees, to address the burdens associated with the prior authorization process. In March and November of 2019, the Health IT Advisory Committee (HITAC) and National Committee on Vital and Health Statistics (NCVHS) held joint hearings with stakeholders to discuss the ongoing challenges with prior authorization workflow, standards, and payer policies. During these hearings, payers and providers agreed that solutions to address prior authorization issues may not rest with one single action, but, rather, they believed that the opportunity to use new standards and/or technology, coupled with the movement towards more patient focused policies, would provide substantial relief and progress. At the November 13, 2019 NCVHS Full Committee meeting,[35] ONC joined NCVHS and invited six industry experts to discuss ongoing challenges with prior authorization standards, policies, and practices. The themes from panelists were consistent with information provided elsewhere in this proposed rule, that changes are still needed in technology, payer policies, and payer/provider workflow. America's Health Insurance Plans (AHIP) reported the results of its 2019 fall plan survey, which included both AHIP and non-AHIP members, and reported that plans were evaluating opportunities for prior authorization policy changes to address issues. AHIP launched a pilot of alternative prior authorization strategies with several plans in 2020.[36] In early 2020, NCVHS and HITAC convened another task force, the Intersection of Clinical and Administrative Data (ICAD), which met weekly to address an overarching charge to convene industry experts and produce recommendations related to electronic prior authorizations.[37] The task force report was presented to HITAC in November 2020.[38] Several recommendations pertaining to the use of FHIR based APIs for prior authorization were included in the ICAD report, and are consistent with proposals in this proposed rule. Those recommendations and others are described in more detail in the section II.E. of this proposed rule.

In a November 4, 2019 letter to the CMS Administrator, the American Hospital Association (AHA) described the ongoing impact of prior authorization on patient care, health system costs, and burdens.[39] In the letter, the AHA shared results from the previously referenced 2018 AMA survey of more than 1,000 physicians, which indicated that 90 percent of respondents stated prior authorization had a significant or somewhat negative clinical impact on care.[40] Furthermore, 27 percent of survey respondents stated that delays in the provision of care due to prior authorization processes had led to a serious adverse event such as a death, hospitalization, disability, or permanent bodily damage. The AHA's letter affirmed what we have stated above—prior authorization is a burden that can lead to patient harm. According to the AHA, hospitals and provider offices have many full-time employees whose sole role is to manage payer prior authorization requests. One hospital system spends $11 million annually just to comply with payer prior authorization requirements. Operational costs such as these are often factored into negotiated fees or charges to patients to ensure financial viability for health care organizations including providers and facilities, and we believe this to be the case for small and large organizations. We believe our proposals in the following sections would make meaningful progress in alleviating the burdens described above and facilitating more efficient and prompt health care service delivery to patients.

2. Electronic Options for Prior Authorization

To mitigate provider burden, and improve care delivery to patients, we are proposing requirements for payers to implement APIs that are conformant with certain implementation guides that

[33] American Medical Association. (2018). Consensus Statement on Improving the Prior Authorization Process. Retrieved from *https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.*

[34] Office of the National Coordinator for Health Information Technology. (2020, February). Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs. Retrieved from *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

[35] National Committee on Vital and Health Statistics. (2019, November 13). Committee Proceedings [Transcript]. Retrieved from *https://ncvhs.hhs.gov/wp-content/uploads/2019/12/Transcript-Full-Committee-Meeting-November-13-2019.pdf.*

[36] America's Health Insurance Plans. (2020, January 6). New Fast PATH Initiative Aims to Improve Prior Authorization for Patients and Doctors. Retrieved from *https://www.ahip.org/new-fast-path-initiative-aims-to-improve-prior-authorization-for-patients-and-doctors/.*

[37] *See https://www.healthit.gov/hitac/committees/intersection-clinical-and-administrative-data-task-force.*

[38] Final report from ICAD Task Force November 17, 2020: *https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf.*

[39] American Hospital Association. (2019, November 4). RE: Health Plan Prior Authorization [PDF file]. Retrieved from *https://www.aha.org/system/files/media/file/2019/11/aha-to-cms-health-plan-prior-authorization-11-4-19.pdf.*

[40] American Medical Association. (2019, February). 2018 AMA Prior Authorization (PA) Physician Survey. Retrieved from *https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf.*

would facilitate the exchange of information between payers and providers and allow providers to more effectively integrate the prior authorization process within their clinical workflow. We believe, and stakeholder input has confirmed, that payers and providers do not take advantage of standards that are currently available for the exchange of electronic prior authorization transactions and resort to proprietary interfaces and web portals supplemented by inefficient and time consuming manual processes such as phone calls or faxes. However, if payers made the requirements for prior authorization more accessible and understandable through APIs, and providers had access to the tools to initiate a prior authorization from within their workflow, providers would be more likely to submit the request and necessary documentation to the payer using electronic standards.

In section II.B.2. of this proposed rule, we reference transactions for which the Secretary must adopt electronic standards for use by covered entities (health plans, health care clearinghouses, and certain health care providers), and list the transactions there. The two standards adopted for referrals certifications and authorizations (hereafter referred to as the prior authorization transaction standard) under HIPAA (45 CFR 162.1302) include:

- NCPDP Version D.0 for retail pharmacy drugs; and
- X12 Version 5010x217 278 (X12 278) for dental, professional, and institutional request for review and response for items and services.

Though payers are required to use the X12 278 standard for electronic prior authorization transactions, and providers have been encouraged to conduct the transaction electronically, the prior authorization standard transaction has not achieved a high adoption rate by covered entities. The Council for Affordable and Quality Health Care (CAQH) releases an annual report called the CAQH Index, which includes data on payer and provider adoption of HIPAA standard transactions. In the 2019 report, among the seven transactions benchmarked, prior authorization using the X12 278 standard was the least likely to be supported by payers, practice management systems, vendors, and clearinghouse services.[41] According to this report, 14 percent of the respondents indicated that they were using the adopted standard in a fully electronic way while 54 percent responded that they were conducting electronic prior authorization using web portals, Integrated Voice Response (IVR) and other options, and 33 percent were fully manual (phone, mail, fax, and email). Reported barriers to use of the HIPAA standard include lack of vendor support for provider systems, inconsistent use of data content from the transaction, and lack of an attachment standard to submit required medical documentation (CAQH Index). The proposed PAS API could support increased use of the HIPAA standard through its capability to integrate with a provider's system directly, automation, and improved timeliness for obtaining a response to a prior authorization request, particularly when paired with the DRLS API. However, we are interested in hearing from commenters if there are other steps CMS could take to further implementation of the X12 278 standard and what challenges would remain if the standard was more widely utilized.

HIPAA also requires that HHS adopt operating rules for the HIPAA standard transactions. Operating rules are defined at 45 CFR 162.103 as the ''necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of HIPAA Administrative Simplification.'' The NCVHS reviews potential HIPAA operating rules and advises the Secretary as to whether HHS should adopt them (section 1173(g) of the Act). The Secretary adopts operating rules in regulations in accordance with section 1173(g)(4) of the Act. To date, HHS has adopted operating rules for three of the HIPAA standard transactions: Eligibility for a health plan and health care claim status (76 FR 40458), health care electronic funds transfers (EFT), and remittance advice (77 FR 48008). In February 2020, CAQH, which develops operating rules for HIPAA standards, submitted two operating rules for the HIPAA referral certification and authorization transaction for consideration to NCVHS, which held a hearing to discuss those operating rules in August 2020. Should HHS adopt operating rules for the HIPAA referral certification and authorization transaction, we would evaluate them to determine their effect, if any, on proposals in this proposed rule.

3. Proposed Requirement for Payers: Documentation Requirement Lookup Service (DRLS) API

Based on information from the listening sessions and non-governmental surveys, we believe one of the most highly burdensome parts of the prior authorization process for payers and providers include identifying the payer rules and determining what documentation is required for an authorization. As described earlier, this issue is one of the key principles in the industry consensus paper[42] under transparency and communication, in which the parties agreed to ''encourage transparency and easy accessibility of prior authorization requirements, criteria, rationale, and program changes to contracted health care providers and patients/enrollees.'' In concert with this effort towards collaboration, the AMA launched an outreach campaign called #fixpriorauth[43] to drive awareness to the scope of the challenges of the prior authorization process. Industry input underscores the fact that while there is no single solution to improving the prior authorization process, some action on certain burdens could be transformative. Therefore, we propose to streamline access to information about prior authorization and related documentation requirements to potentially reduce this burden. To that end, at 42 CFR 431.80(a)(1), 438.242(b)(7), 457.732(a)(1), 457.1233(d)(4), and 45 CFR 156.223(a)(1), we propose to require that, beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023), state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs, implement and maintain a FHIR-based DRLS API conformant with the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) IG: Version STU 1.0.0[44] and the HL7 FHIR Da Vinci Documentation Templates and Rules (DTR): Version STU 1.0.0[45] IG, populated with their list of covered items and services, not

[41] CAQH. (2019). 2019 CAQH Index: A Report of Healthcare Industry Adoption of Electronic Business Transactions and Cost Savings [PDF file]. Retrieved from *https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf?token=SP6YxT4u.*

[42] Consensus Statement for Improving Prior Authorization: *https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.*

[43] AMA website link with resources regarding the prior authorization challenges: *https://fixpriorauth.org/resources.*

[44] HL7 International. (n.d.). Da Vinci Coverage Requirements Discovery (CRD) FHIR Implementation Guide. Retrieved from *http://hl7.org/fhir/us/davinci-crd/history.html.*

[45] HL7 International. (n.d.). Da Vinci Documentation Templates and Rules. Retrieved from *http://hl7.org/fhir/us/davinci-dtr/history.html.*

including prescription drugs and/or covered outpatient drugs, for which prior authorization is required, and with the organization's documentation requirements for submitting a prior authorization request, including a description of the required documentation.

Through a proposed cross-reference to the Patient Access API requirements at 42 CFR 431.80(a)(1) for Medicaid FFS; at 42 CFR 438.242(b)(7) (to comply with the requirement at 42 CFR 431.80) for Medicaid managed care; at 42 CFR 457.732(a)(1) for CHIP FFS; at 42 CFR 457.1233(d)(4) (to comply with the requirement at 42 CFR 457.732) for CHIP managed care; and at 45 CFR 156.223(a)(1) for QHP issuers on the FFEs, we are proposing to require that the DRLS API comply with the same technical standards, API documentation requirements, and discontinuation and denial of access requirements as apply to the Patient Access API (and as proposed for the Provider Access API in section II.B. of this proposed rule). For a complete discussion of these requirements, we refer readers to the CMS Interoperability and Patient Access final rule (85 FR 25526 through 25550).

We believe payer implementation of DRLS APIs conformant with the CRD and DTR IGs which are proposed at 45 CFR 170.215(c)(1) and (2) in section II.E. of this proposed rule, would make prior authorization requirements and other documentation requirements electronically accessible and more transparent to health care providers at the point of care. As explained, because each payer has different rules to determine when a prior authorization is required, and what information is necessary to obtain approval, providers must use different methods to keep track of the rules and requirements, which is often time consuming and cumbersome. The payer's DRLS API would enable a query to their prior authorization requirements for each item and service and identify in real time the specific rules and documentation requirements. Based on the information, the provider could be prepared to submit any necessary documentation to the payer based on those requirements, and complete any available electronic forms or templates, which would be incorporated into the API. For example, once the payer has built a DRLS API and made it available, a provider could initiate a query to the payer's DRLS API to determine if a prior authorization and documentation is required. If the response is affirmative, the DLRS API would indicate what is required, and might provide a link to submit the required documentation. In some cases, certain patient data available in the provider's system could be used to meet documentation requirements.

Payers who implement and maintain a DRLS API could see improvements and efficiencies in the prior authorization process within their own organization, by reducing the number of unnecessary requests, minimizing follow up, and through fewer denials or appeals. For similar reasons, this could contribute to burden reduction for providers as well. We believe that requiring impacted payers to implement the API would increase provider demand for this functionality if offered by these payers. Providers would want access to the API if the payer does offer it. We are interested in comments on steps that HHS could take to encourage development of these functions within provider EHR systems. We are also interested in comments for consideration for future policies to require or incentivize providers to use the payer DRLS API in their workflows.

By the time this proposed DRLS API would be required to be implemented beginning January 1, 2023 should this proposal be finalized as proposed, impacted payers would have the technology needed to support a FHIR API, because they would have implemented the Patient Access API as adopted in the CMS Interoperability and Patient Access final rule (85 FR 25558 through 25559). We intend to enforce the requirement for a Patient Access API, as adopted in that rule, starting July 1, 2021, taking into account the 6 months of enforcement discretion we are exercising due to the public health emergency.[46] In order to implement the Patient Access API, payers will have installed the FHIR servers, mapped claims and clinical data for data exchange via FHIR, and implemented a FHIR API. We believe the experience of implementing the Patient Access API, including having made upgrades to their computer systems and trained or hired staff to support its use, would enable impacted payers under this proposed rule to implement the DRLS API by January 1, 2023 (or, for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023). We considered whether it would be beneficial for payers to implement the proposed DRLS APIs in phases. For example, we considered whether payers should implement the DRLS API via an incremental approach, incorporating the top 10 percent or top 10 highest volume prior authorization rules in the first year, and continue adding to the DRLS API over a 2- or 3-year period before the DRLS is fully implemented. However, we believe that fully implementing the DRLS API in year one of such a phased timeline, by January 1, 2023, would be critical to streamlining the prior authorization process, and would be instrumental in moving towards increased use of electronic prior authorization.

We request comments on this proposal for impacted payers to implement a DRLS API. We also request input on a potential short-term solution to address the challenge of accessing payer requirements for prior authorizations. We solicit feedback on how payers currently communicate prior authorization requirements, and on the potential for payers to post, on a public-facing website, their list of items and services for which prior authorization is required, populate the website with their associated documentation rules as in interim step while they implement the DRLS. This is not intended to harmonize prior authorization requests, but rather to quickly address the issue identified by stakeholders regarding access to prior authorization information. If payers could post their prior authorization requirements on a website, how could that information be presented and organized for providers to easily identify the services and items which require prior authorization? Finally, we request comments on how the posting of this information on payer websites would provide a satisfactory interim solution to the challenge of accessing payer requirements for prior authorizations in advance of implementing the DRLS API.

4. Proposed Requirement for Payers: Implementation of a Prior Authorization Support API

Electronic prior authorizations are not used consistently between payers and providers, even with the availability of an adopted HIPAA standard. The burden of navigating the various submission mechanisms falls on the provider and can detract from providing care to patients. Additionally, many provider administrative practice management systems and vendors do not support the adopted HIPAA standard. To help address this issue, we are proposing that impacted payers implement a Prior Authorization Support (PAS) API that facilitates a HIPAA compliant prior authorization request and response, including any forms or medical record documentation

[46] For more information, visit: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index.*

required by the payer for items or services for which the provider is seeking authorization.

Specifically, we propose to require that Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs implement and maintain a PAS API conformant with the HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023). We propose to codify this requirement at 42 CFR 431.80(a)(2) and 457.732(a)(2), and 45 CFR 156.223(a)(2) and, as with our proposal for the Provider Access API (discussed in section II.B. of this proposed rule), we propose to use cross-references in 42 CFR 438.242(b)(7) and 42 CFR 457.1233(d)(4) to impose this new PAS API requirement on Medicaid managed care plans and CHIP managed care entities. The API would be required to be conformant with the implementation specification at 45 CFR 170.215(c)(3). If this provision is finalized as proposed, the payer would be required to implement the API, and, when sending the response, include information regarding whether the organization approves (and for how long), denies, or requests more information for the prior authorization request, along with a reason for denial in the case of a denial. The PAS API would provide an opportunity to leverage the convenience of API technology, while maintaining compliance with the adopted HIPAA transaction standard. Furthermore, use of the PAS API would accelerate adoption and use of electronic prior authorization transactions by impacted payers and by providers, particularly when coupled with implementation of the DRLS API, increasing efficiencies for both parties.

We are aware that the flow of the payer API may not be intuitive to all readers, therefore, please refer to the implementation guides for payer API flow details. We also provide a high-level description here. The payer would make a PAS API available for providers. When a patient needs authorization for a service, the payer's PAS API would enable the provider, at the point of service, to send a request for an authorization. The API would send the request through an intermediary (such as a clearinghouse) that would convert it to a HIPAA compliant X12 278 request transaction for submission to the payer. It is also possible that the payer converts the request to a HIPAA compliant X12 278 transaction, and thus the payer acts as the intermediary. The payer would receive and process the request and include necessary information to send the response back to the provider through its intermediary, where the response would be transformed into a HIPAA compliant 278 response transaction. The response through the API would indicate whether the payer approves (and for how long), denies, or requests more information related to the prior authorization request, along with a reason for denial in the case of a denial.

We believe it would be valuable for payers to implement the PAS API for prior authorizations, because doing so would enhance the overall process generally, and, specifically, would increase the uptake of electronic prior authorizations by providers. Implementation of the PAS API would also maintain compliance with the adopted HIPAA standards, so other legacy system changes may not be necessary. We also believe that existing business arrangements with intermediaries or clearinghouses would remain in place to support transmission of the X12 transaction. Payers who implement the PAS API would likely see an improvement in efficiencies, particularly when coupled with implementation of the DRLS API because when providers know clearly what documentation is required to support a prior authorization request, they do not need to call or fax for additional instructions. Fewer phone calls or errors would decrease administrative costs for a payer. Use of the PAS API could facilitate a real time exchange of the authorization request, so that payers could provide a real time response.

In particular, we expect that our proposals to require payers to implement the DRLS and PAS APIs would improve the electronic data exchange landscape between the impacted payers and providers once providers' practice management system or EHR make the connection to the payer's API. That is why it is important for the payers to make the APIs available first. It is burdensome and time-consuming for providers to use multiple mechanisms—including numerous payer-specific web portals and fax numbers—to submit prior authorization requests and receive prior authorization decisions. Our outreach and industry research show that providers are eager for the opportunity to have access to this technology to reduce burden.

We request comment on these proposals.

We believe that requiring the impacted payers to implement the FHIR based APIs that would be available for providers might ultimately result in broader industry-wide changes to address the prior authorization issues identified by stakeholders and discussed above. Similarly, if the APIs are successfully implemented by the impacted payers as proposed, the demand for this functionality would motivate EHR vendors to invest in integrating a PAS API directly into a provider's workflow, which might ultimately result in APIs becoming the preferred and primary method to facilitate prior authorization processes. As with the proposed DRLS API, we note that functionality to interact with the proposed PAS API is not standardized across provider systems today, but that industry interest in this initiative is extremely high. Industry participation is increasing in the HL7 work groups developing and testing the IGs for these APIs, including increased participation by providers, payers, and vendors. We believe that EHR developers would increasingly make this functionality available to their customers to support increased use of the payer APIs should this proposed rule be finalized. We request comment on steps that HHS could take to educate providers on the benefits of these APIs and incentive their use. We also request comment on opportunities to encourage health IT developers to implement these functions within EHRs, including the potential future addition of certification criteria in the ONC Health IT Certification Program.

a. Requirement To Provide a Reason for Denial

When a provider has submitted an electronic prior authorization request, there is an expectation for a response to indicate that an item or service is approved (and for how long), denied, or if there is a request for more information. Regardless of the mechanism through which a prior authorization request is received and processed, in the case of a denial, providers need to know why the request has been denied, so that they can either re-submit it with updated information, identify alternatives, appeal the decision, or communicate the decision to their patients. A payer might deny a prior authorization because the items or services are not covered, because the items or services are not medically necessary, or because documentation to support the request was missing or inadequate. However, payers do not always provide consistent communication about the reasons for denials or information about what is required for approval.

To improve the timeliness, clarity, and consistency of information for providers regarding prior authorization status, specifically denials, we are proposing that impacted payers send certain response information regarding the reason for denying a prior authorization request. Based on the surveys referenced above, stakeholders agree that payers do not provide consistent information about the status of a prior authorization or the reasons for a denial, nor do they use the adopted X12 278 HIPAA standard transaction to communicate prior authorization status information. Therefore, we propose at 42 CFR 431.80(a)(2)(iii) for Medicaid FFS, at 42 CFR 438.242(b)(7) (to comply with the requirement at 42 CFR 431.80) for Medicaid managed care, at 42 CFR 457.732(a)(2)(iii) for CHIP FFS, at 42 CFR 457.1233(d)(4) (to comply with the requirement at 42 CFR 457.732) for CHIP managed care, and at 45 CFR 156.223(a)(2)(iii) for QHP issuers on the FFEs that impacted payers transmit, through the proposed PAS API, information regarding whether the payer approves (and for how long), denies, or requests more information related to the prior authorization request. In addition, we propose at 42 CFR 431.80(a)(2)(iv) for Medicaid FFS, at 42 CFR 438.242(b)(7) (to comply with the requirement at 42 CFR 431.80) for Medicaid managed care, at 42 CFR 457.732(a)(2)(iv) for CHIP FFS, at 42 CFR 457.1233(d)(4) (to comply with the requirement at 42 CFR 457.732) for CHIP managed care, and at 45 CFR 156.223(a)(2)(iv) for QHP issuers on the FFEs that impacted payers include a specific reason for denial with all prior authorization decisions, regardless of the method used to send the prior authorization decision.

Under our proposal, impacted payers would be required to provide a specific reason a prior authorization request is denied, such as indicating necessary documentation was not provided, the services are not determined to be medically necessary, or the patient has exceeded limits on allowable (that is, covered) care for a given type of item or service, so that a provider is notified why a request was denied and can determine what their best next steps may be to support getting the patient the care needed in a timely manner. A clear and specific reason for a denial would help ensure both providers and payers have the opportunity to benefit from consistent communication, and supports our drive to reduce payer, provider, and even patient burden.

States operating Medicaid and CHIP programs may be able to access federal matching funds to support their implementation of the DRLS and PAS APIs, because these APIs are expected to help the state administer its Medicaid and CHIP state plans properly and efficiently by supporting a more efficient prior authorization process, consistent with sections 1902(a)(4) and 2101(a) of the Act, as discussed in more detail in section II.C.7.a. of this proposed rule.

We do not consider state expenditures for implementing this proposal to be attributable to any covered item or service within the definition of ''medical assistance.'' Thus, we would not match these expenditures at the state's regular federal medical assistance percentage. However, federal Medicaid matching funds under section 1903(a)(7) of the Act, at a rate of 50 percent, for the proper and efficient administration of the Medicaid state plan, might be available for state expenditures related to implementing this proposal for their Medicaid programs, because use of the DRLS and PAS APIs would help the state more efficiently administer its Medicaid program by increasing the efficiencies in the prior authorization process. For instance, use of these APIs would allow administrative efficiencies by making the process more timely, and by helping reduce the number of denied and appealed prior authorization decisions, making the process more clear and transparent via the APIs.

States' expenditures to implement these proposed requirements might also be eligible for enhanced 90 percent federal Medicaid matching funds under section 1903(a)(3)(A)(i) of the Act if the expenditures can be attributed to the design, development, or installation of mechanized claims processing and information retrieval systems. Additionally, 75 percent federal matching funds under section 1903(a)(3)(B) of the Act may be available for state expenditures to operate Medicaid mechanized claims processing and information retrieval systems to comply with this proposed requirement.

States request Medicaid matching funds under section 1903(a)(3)(A)(i) or (B) of the Act through the APD process described in 45 CFR part 95, subpart F. States are reminded that 42 CFR 433.112(b)(12) and 433.116(c) require them to ensure that any system for which they are receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act aligns with and incorporates the ONC Health Information Technology standards adopted in accordance with 45 CFR part 170, subpart B. The DRLS and PAS APIs, and all APIs proposed in this rule, would complement this requirement because these APIs further interoperability through the use of HL7 FHIR standards proposed for adoption by ONC for HHS use at 45 CFR 170.215.[47] And, states are reminded that 42 CFR 433.112(b)(10) explicitly supports exposed APIs as a condition of receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act.

Similarly, 42 CFR 433.112(b)(13) requires the sharing and re-use of Medicaid technologies and systems as a condition of receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act. CMS would interpret that sharing and re-use requirement also to apply to technical documentation associated with a technology or system, such as technical documentation for connecting to a state's APIs. Making the needed technical documentation publicly available so that systems that need to connect to the APIs proposed in this rule can do so would be required as part of the technical requirements at 42 CFR 431.60(d) for all proposed APIs in this rule, including the DRLS and PAS APIs.

Separately, for CHIP agencies, section 2105(c)(2)(A) of the Act, limiting administrative costs to no more than 10 percent of CHIP payments to the state, would apply in developing the APIs proposed in this rule.

We note that the temporary federal medical assistance percentage (FMAP) increase available under section 6008 of the Families First Coronavirus Response Act (Pub. L. 116–127) does not apply to administrative expenditures.

b. Program Specific Notice Requirements To Accompany Prior Authorization Denial Information—Medicaid and CHIP Managed Care

Some of the payers impacted by this proposed rule are required by existing regulations to notify providers and patients when they have made an adverse decision regarding a prior authorization. The proposal above to send a denial reason would not reduce or replace such existing notification requirements. Rather, the proposed requirement to use the PAS API to provide a notification whether the authorization has been approved (and for how long) or denied (along with a reason for the denial) would supplement current notice requirements for those payers, and offer an efficient method of providing such information for those payers who currently do not have a requirement to notify providers of the decision on a prior authorization request. We believe use of the proposed

[47] See SHO # 20–003, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho20003.pdf.*

denial reasons in addition to the notification requirements provides enhanced communication which increases transparency and would reduce burden and improve efficiencies for both payers and providers.

For Medicaid managed care plans and CHIP managed care entities,[48] existing regulations at 42 CFR 438.210(c) requires notice to the provider without specifying the format or method while 42 CFR 438.210(c) and 42 CFR 438.404(a) require written notice to the enrollee of an adverse benefit determination. As part of our proposal, we intend that an indication of whether the payer approves, denies, or requests more information for the prior authorization request, if transmitted to providers via the PAS API, and a denial reason in the case of denial, would be sufficient to satisfy the current requirement for notice *to providers* at 42 CFR 438.210(c) and (d). Therefore, the payer would not be required to send the response via the PAS API and a denial reason, as well as a separate notice in another manner to the provider with duplicate information. We remind managed care plans that their obligations to provide these required notices would not be reduced or eliminated regardless of the proposals included in this rule. We acknowledge that some providers may need more time to adapt to submitting prior authorization requests via an API and until such time, we encourage managed care plans to comply with other applicable regulations to ensure that their prior authorization practices and policies do not lead to impeding timely access to care or affect network adequacy. Lastly, we note that the proposal to electronically transmit information through the PAS API about whether the payer approves, denies, or requests more information for the prior authorization request is about notice to the provider and is limited to transmission to a provider's EHR or practice management system. This proposal would have no effect on the requirements for notice to an enrollee at 42 CFR 438.210(c) and (d) and 438.404.

We would like to hear from the provider community how current notifications are received and whether the proposed communication via the PAS API could be more useful than the current notification process. For instance, are the current notifications integrated into EHRs and could this proposal improve communications?

[48] CHIP managed care entities are required to comply with these standards by 42 CFR 57.1230(d).

5. Seeking Comment on Prohibiting Post-Service Claim Denials for Items and Services Approved Under Prior Authorization

During the listening sessions, stakeholders raised concerns about denials of claims for approved prior authorizations explaining that provider staff spend significant time on appeals to resolve these denials, and in some cases, patients receive unexpected bills for the services, after the fact. Generally, a prior authorization is currently only a determination by a payer that an item or service is medically necessary, and is not a promise of payment. However, when a valid claim for an approved service is denied, this creates inefficiencies in processes for both payers and providers and could affect patient care. We wish to learn how new policies could help improve this process, and therefore request input from payers and other industry stakeholders, on the issues that could inform a future proposal to prohibit impacted payers from denying claims for covered items and services for which a prior authorization has been approved.

We are requesting input on the criteria that could be included in a new policy, and the potential costs of such a policy on payers. Specifically we are soliciting input on what requirements would be appropriate to include in a policy to ensure that claims that meet certain guidelines for approved authorizations are not denied. In addition, we seek comment on whether it would be important that the patient be enrolled with the payer at the time the items or services were provided, or that certain conditions exist for the provider's contract status with the payer. And, we seek comment on what other requirements would be appropriate to include in a policy to ensure that the claims that meet certain guidelines for approved authorizations are not denied.

We would also like input on the criteria payers could use to deny claims once they are submitted to the claims processing system. For example, do payers deny claims when there is reliable evidence of technical errors, a duplicate claim for the approved item or service, or evidence that an approved prior authorization was procured based on material inaccuracy or by fraud? We believe payers have program integrity practices through which they determine if a prior authorization was procured by fraud, and coordinate investigations under relevant programmatic authorities or state laws. Commenters are encouraged to provide examples of program integrity practices used by payers to identify and address fraudulent claims.

We also seek comment on whether all payer types should be required to comply with a policy to prohibit payers from denying a claim for payment after approving a prior authorization for covered items and services, or if any payer types should be excluded, and for what reasons. Finally, we would like input on the unintended consequences, cost implications, and cost estimates related to prohibiting a prior authorized claim from being denied, to the extent data can be provided. We are interested in what legitimate reasons for denial could be restricted by the adoption of specific criteria. We also invite payers to comment on whether such a policy could increase improper payments or program costs, decrease state use of prior authorization, or impact enforcement of third-party liability.

If we were to address these topics, we would do so in a future notice and proposed rulemaking.

6. Requirements for Prior Authorization Decision Timeframes and Communications

a. Overview of Decision Timeframe Issue

We also heard from providers that excessive wait times for prior authorization decisions often caused delays in the delivery of services to patients. One risk of the time burden associated with some of the prior authorization processes is the potential patient harm resulting from delays in responses to prior authorization requests—whether for the approval of the initial request, or delays in the resolution of the request—for example, waiting for a payer's review and decision based on required documentation for the request. The AMA study reported that 28 percent of physicians stated that delays in care due to the prior authorization process, specifically the wait for approval, led to serious, life-threatening adverse events, including death, for their patients.[49] In addition, 91 percent of physicians reported that delays related to prior authorization have had other negative impacts on their patients.[50] As described earlier, in 2019 CMS conducted outreach with external

[49] American Medical Association. (n.d.). 2017 AMA Prior Authorization Physician Survey. Retrieved from *https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf.*

[50] American Medical Association. (n.d.). 2017 AMA Prior Authorization Physician Survey. Retrieved from *https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf.*

stakeholders through listening sessions, interviews, observational visits, RFIs and a special email box, to obtain information about how to improve the transparency, efficiency, and standardization of the prior authorization process. From the high volume of comments we received on the subject of timeframes for processing prior authorizations, it is apparent that delays in securing approvals for prior authorization directly affect patient care by, for example, delaying access to services, transfers between hospitals and post-acute care facilities, treatment, medication, and supplies. These delays occur, in part, because of the variation in processes used by each payer to review prior authorization requests, inconsistent use of available technologies to process prior authorizations, and the ongoing reliance on manual systems such as phone, fax, and mail, which require more labor-intensive human interactions. Some commenters noted that the large variations in payer prior authorization policies for the same items and services and the difficulty discovering each payer's policies—which requires substantial staff research and time—contribute to delays in care.

In this proposed rule, we use the term ''standard'' prior authorization to refer to non-expedited request for prior authorization and the term ''expedited'' prior authorization to indicate an urgent request. This is consistent with the provisions at 42 CFR 438.210(d) (for Medicaid managed care plans). A standard prior authorization is for non-urgent items and services. An expedited prior authorization is necessary when failure to decide could jeopardize the health or life of the patient.

b. Current Regulations Establishing Timeframes for Certain Payers for Standard and Expedited Prior Authorization Requests

We have regulated in this area previously and have established timeframes for certain payers to make decisions and provide notice regarding prior authorizations as well as time requirements for certain decisions on appeals. Specifically, in the Medicaid managed care program, and for CHIP managed care entities, payers must, for standard authorization decisions, make a decision, and send notice of that decision, as expeditiously as the enrollee's condition requires and within state-established timeframes that may not exceed 14 calendar days following receipt of the request for items or services (42 CFR 438.210(d)(1), 457.495(d), and 457.1230(d)). For cases in which a provider indicates or the payer determines that following the standard timeframe could seriously jeopardize the enrollee or beneficiary's life, health or ability to attain, maintain, or regain maximum function, the Medicaid managed care plan, or CHIP managed care entity must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request (42 CFR 438.210(d)(2) and 457.1230(d)).

In addition, under these existing regulations, the enrollee or the provider may request an extension of up to 14 additional calendar days from the standard timeframe to make a decision on a prior authorization request for an item or service, or the payer may also initiate the extension up to 14 additional calendar days if the payer can justify a need for additional information and how the extension is in the enrollee or beneficiary's interest (42 CFR 438.210(d)(2) and 457.1230(d)). For example, a payer may need to gather additional information by consulting with additional providers with expertise in treating a particular condition to enable the payer to make a more informed decision.

Under existing CHIP regulations, prior authorization of health services must be completed within 14 days after receipt of a request for services or in accordance with existing state law regarding prior authorization of health services (42 CFR 457.495(d)). This means the CHIP managed care entities must decide, and send notice of that decision within 14 calendar days following receipt of the request for a medical item or service by the provider. An extension of 14 days may be permitted if the enrollee requests the extension or if the physician or health plan determines that additional information is needed (42 CFR 457.495(d)(1)). For cases in which a provider indicates, or the payer determines, that the standard timeframe of 14 days could seriously jeopardize the enrollee's life; health; or ability to attain, maintain, or regain maximum function, the CHIP managed care entity must make an expedited authorization decision and provide notice no later than 72 hours after receiving the request (42 CFR 457.1230(d)).

c. Proposals To Address Timeframes for Standard Prior Authorization Requests

Given our interest in patient health outcomes, we are proposing to require that state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities provide notice of prior authorization decisions as expeditiously as a beneficiary's health condition requires and under any circumstances not later than 72 hours of receiving a request for expedited decisions. Notice should be provided no later than 7 calendar days after receiving a request for standard decisions. For Medicaid managed care plans, we are also proposing to maintain that an extension of 14 days is authorized if the enrollee requests it or a health plan determines additional information is needed.

We are not proposing at this time to change timeframes for prior authorization (pre-service) claims processes for QHP issuers on the FFEs, as further discussed below.

We are not proposing that a prior authorization would be automatically approved should the impacted payer fail to meet the required timeframe. If the deadline is missed, providers may need to contact the payer to determine the status of the request and whether additional information is needed. Further, under the Medicaid managed care rules (at 42 CFR 438.404(c)(5)), a payer's failure to decide within the required timeframe is considered a denial and the right to appeal that denial is available to the enrollee or provider. We are not proposing to change this existing rule. In addition to these proposals, we request comments on the impact of proposing a policy whereby a payer would be required to respond to a prior authorization request within the regulated timeframes, and if the payer failed to meet the required timeframe, the prior authorization would be automatically approved. We are interested in stakeholder feedback on the potential volume of such occurrences, the costs to payers in increasing prior authorization staffing levels or inappropriate items and services and the benefits to providers and patients in terms of reduced burden and faster access to necessary items and services.

We propose at 42 CFR 440.230(d)(1)(i) for Medicaid FFS, at 42 CFR 457.495(d) for CHIP FFS, at 42 CFR 438.210(d) for Medicaid managed care, at 42 CFR 457.1233 for CHIP managed care (through the existing requirement to comply with 42 CFR 438.210), that impacted payers must meet these timeframes beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023). We are not proposing to change the timeframes that apply to expedited authorization decisions made by Medicaid managed care plans and CHIP managed care entities under 42 CFR 438.210(d)(2) and 457.1230(d), which already apply a 72 hour

timeframe, with an opportunity to extend the timeframe by up to 14 days under certain conditions.

d. Requirements for Notifications Related to Prior Authorization Decision Timeframes

This section addresses current requirements for certain impacted payers to maintain communications about prior authorization decisions with patients through notifications, in concert with our proposals to improve the timeliness of prior authorization decisions.

For Medicaid, we are proposing a new paragraph (d)(1)(i) at 42 CFR 440.230 to specify regulatory timeframes for providing notice of both expedited and standard prior authorization requests. The new requirements would be applied to prior authorization decisions beginning January 1, 2023.

Under this proposal for Medicaid, notice of the state Medicaid program's decision regarding an expedited request for prior authorization would have to be communicated as expeditiously as a beneficiary's health condition requires, and in any event not later than 72 hours after receiving a provider's request for an expedited determination. Notice of a decision on a standard request for a prior authorization would have to be communicated to the requesting provider as expeditiously as a beneficiary's health condition requires, and under any circumstance, within 7 calendar days. If the state determines that it needs additional information from a provider to make a decision, or if the beneficiary or provider requests an extension, this proposed decision-making and communication timeframe could be extended by up to 14 calendar days. State Medicaid FFS programs must also comply with the requirements in section 1927 of the Act regarding coverage and prior authorization of covered outpatient drugs. Nothing in this proposed rule would change these requirements.

This proposal is consistent with section 1902(a)(19) of the Act, which requires that care and services be provided in a manner consistent with simplicity of administration and the best interests of recipients, because it is expected to help make the prior authorization process less burdensome for the state, providers, and beneficiaries. The proposed requirements and standards could result in more prompt prior authorization decisions, improve delivery of covered services, reduce burden on providers, and improve efficiency of operations for the program, thereby serving the best interest of Medicaid beneficiaries.

Under current Medicaid notice and fair hearing regulations, notice and fair hearing rights already apply to state decisions about Medicaid fee-for-service prior authorization requests. Specifically, Medicaid notice and fair hearing regulations apply to all prior authorization decisions, including partial or total denials of prior authorization requests, failures to make prior authorization decisions in a timely fashion, and terminations, suspensions of, and reductions in benefits or services for which there is a current approved prior authorization. We propose the following changes in regulation text to make it explicit that existing Medicaid notice and fair hearing rights apply to Medicaid fee-for-service prior authorization decisions. First, we propose a new paragraph (1)(ii) in 42 CFR 440.230(d) to specify that states must provide beneficiaries with notice of the Medicaid agency's prior authorization decisions and fair hearing rights in accordance with 42 CFR 435.917 and part 431, subpart E. Second, we propose to revise the definition of an ''action'' at 42 CFR 431.201 to include termination, suspension of, or reduction in benefits or services for which there is a current approved prior authorization. We also propose to revise the definition of the term ''action'' to improve readability. Third, to align with our proposal at 42 CFR 431.201 (definition of ''action'') and 42 CFR 440.230(d)(1)(ii), we propose to modify 42 CFR 431.220(a)(1) to add a new paragraph (vi) to add a prior authorization decision to the list of situations in which a state must provide the opportunity for a fair hearing. Fourth, we propose a modification to 42 CFR 435.917(b)(2) to add a notice of denial or of change in benefits or services to the types of notices that need to comply with the requirements of 42 CFR 431.210. Finally, we propose modifications to the headers at 42 CFR 435.917(a) and (b) to clarify that the information contained in 42 CFR 435.917 relates broadly to eligibility, benefits, and services notices. Specifically, we propose to remove the word ''eligibility'' from the headers of paragraphs (a) and (b) of 42 CFR 435.917 to more accurately reflect the content of these paragraphs.

These proposed changes are intended to make it explicit in regulation text how existing Medicaid fair hearing regulations apply to states' prior authorization decisions. As noted above, the partial or total denial of a prior authorization request is appealable through a state fair hearing under current regulations. Even though current regulations at 42 CFR 431.220(a)(1) do not expressly refer to denials of prior authorization requests, a denial of a prior authorization request is a denial of benefits or services as described in that section because a prior authorization denial results in denial of coverage of a benefit or service requested by the beneficiary. Therefore, the state must provide a beneficiary who receives a partial or total denial of a prior authorization request the opportunity to have a fair hearing.[51]

Similarly, under current regulations at 42 CFR 431.220(a)(1), the state must provide beneficiaries the opportunity to request a fair hearing if the state fails to act on a claim with reasonable promptness. Just as states must furnish medical assistance to eligible individuals with reasonable promptness under section 1902(a)(8) of the Act, states must also provide individuals with access to a fair hearing if the state fails to act on a claim for medical assistance with reasonable promptness under section 1902(a)(3) of the Act. Therefore, for example, after January 1, 2023, the failure to render a prior authorization decision within the timeframe at proposed 42 CFR 440.230(d)(1)(i) would be considered a failure to act with reasonable promptness and subject to fair hearing rights available to individuals under 42 CFR part 431, subpart E. Finally, existing regulations require that states grant Medicaid beneficiaries the opportunity for a fair hearing whenever a state takes an action as defined in 42 CFR 431.201. This definition includes ''a termination, suspension of, or reduction in covered benefits or services.'' Therefore, under the current definition of ''action'' at 42 CFR 431.201, any termination, suspension of, or reduction in benefits or services for which there is a current approved prior authorization is considered an action for which the state must afford a beneficiary the opportunity for a fair hearing in accordance with 42 CFR 431.220(a)(1).

The proposed changes at 42 CFR 440.230(d)(1)(ii) are also intended to make it explicit in regulation text that existing Medicaid notice regulations apply to states' prior authorization

[51] *See* discussion in the ''Medicaid and Children's Health Insurance Programs: Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP'' final rule (hereinafter ''Eligibility and Appeals Final Rule''), published in the **Federal Register** on November 30, 2016 (81 FR 86382, 86395)(approvals of prior authorization requests for an amount, duration, or scope that is less than what the beneficiary requested are subject to fair hearing requirements in 42 CFR 431, subpart E).

decisions. Under 42 CFR 435.917(a), a state must provide timely and adequate written notice of its prior authorization decisions, consistent with 42 CFR 431.206 through 431.214. This notice must include information about the beneficiary's fair hearing rights. Under our proposals, a state would be required to provide notice of a decision within the timeframes in 42 CFR 440.230(d)(1)(i) when the state approves or partially or totally denies a prior authorization request after January 1, 2023. However, whenever a state makes a prior authorization decision that is considered an action, including the termination, suspension of, or reduction in benefits or services for which there is a current approved prior authorization, the state must provide the individual at least 10 days advance notice consistent with 42 CFR 431.211 prior to taking the action and afford the beneficiary the right to the continuation of services pending the resolution of the state fair hearing, in accordance with 42 CFR 431.230. Under 42 CFR 431.206(c)(2), the state must inform the beneficiary in writing whenever a fair hearing is required per 42 CFR 431.220(a), which includes when a state has not acted upon a claim with reasonable promptness. For example, after January 1, 2023, this would mean that a state must also provide notice to the beneficiary when it fails to reach a decision on a prior authorization request within the timeframes in proposed 42 CFR 440.230(d)(1)(i).

To enhance beneficiary notice, we are proposing to explicitly link the required notice content in 42 CFR 431.210 to denials of or changes in benefits or services for beneficiaries receiving medical assistance by proposing amendments to 42 CFR 435.917(b)(2) to include a reference to denials of or changes in benefits and services for beneficiaries receiving medical assistance. The notice content requirements at 42 CFR 431.210 include a requirement that notices include a clear statement of the specific reasons supporting the intended action, so this proposed amendment would ensure that individuals receiving medical assistance who are denied benefits or services receive a notice clearly explaining the reasons for a denial. As we explained above, because a denial of a prior authorization request is a denial of a benefit or service, this change would also apply to notices for denials of prior authorization decisions.

We note that the current application of existing notice and fair hearing requirements to Medicaid fee-for-service prior authorization decisions, which we propose to make explicit in regulation text, is consistent with current regulations for notice and appeal rights for managed care prior authorization decisions (sometimes referred to as service authorizations or adverse benefit determinations). *See* 42 CFR 438.400 (definition of adverse benefit determination), 42 CFR 438.404 (timely and adequate notice for adverse benefit determination), and 42 CFR 438.420 (continuation of benefits while managed care plan appeal and the state fair hearing process are pending).

As noted above, these proposed modifications generally apply existing regulations to prior authorization decisions and do not generally change Medicaid notice or fair hearing policy. As such, we propose that the revisions to 42 CFR 431.201, 431.220, 431.917, and 440.230(d)(1)(ii) would be effective upon publication of the final rule, with the understanding that any notice or fair hearing rights based solely on new provisions proposed in this rulemaking would take effect in accordance with the proposed effective date for the proposed new provisions, including the proposed timeframes for notifications about prior authorization decisions. We seek comment both on how states apply these notice and fair hearing rights to prior authorization decisions currently and on our proposals. We also seek comment on whether we should change this policy through future rulemaking, and not require fair hearing rights for prior authorization denials.

To implement the proposed authorization timeframes for Medicaid managed care, we also propose to revise 42 CFR 438.210(d)(1). Under our proposal, the new timeframes for Medicaid managed care plans to issue decisions on prior authorization requests would apply beginning with the rating period on or after January 1, 2023. Therefore, we propose to add at the end of the current regulation that, beginning with the rating period that starts on or after January 1, 2023, the state-established timeframe that a decision may not exceed 7 calendar days following the plan's receipt of the request for service would go into effect. This effectively would limit the period of time that a Medicaid managed care plan must make and provide notice of an authorization decision to a maximum of 7 days (or fewer if the state establishes a shorter timeline) unless there is an extension. We propose that the authority to extend that timeframe by up to 14 additional calendar days would continue to apply. Our proposal would not change the current provisions for how failure to issue a decision within the required time frame constitutes an adverse benefit determination that can be appealed under 42 CFR 438.404(c)(5). Section 438.404 and the other regulations governing appeal rights in 42 CFR part 438, subpart F, would continue to apply. This is also consistent with how the definition of ''adverse benefit determination'' in 42 CFR 438.400(b) includes a failure of a Medicaid managed care plan to make an authorization decision within the regulatory timeframes. We also note that under current regulations at 42 CFR 438.3(s)(1) and (s)(6) and 438.210(d)(3), Medicaid managed care plans must also comply with the requirements in section 1927 of the Act regarding coverage and prior authorization of covered outpatient drugs. Nothing in this proposed rule would change these requirements. We also note that Medicaid managed care plans that are applicable integrated plans as defined in 42 CFR 438.2 would continue to follow the decision timeframes defined in 42 CFR 422.631(d).

We believe implementing these proposed prior authorization timeframes for Medicaid FFS and managed care programs would help states to ensure that they are furnishing medical assistance services with reasonable promptness as described in section 1902(a)(8) of the Act and with reasonable program safeguards to ensure that services would be provided in the best interests of the recipients, in accordance with section 1902(a)(19) of the Act. In addition, this proposal would implement section 1932(b)(4) of the Act, which provides that each Medicaid managed care organization must establish an internal grievance procedure under which an enrollee who is eligible for medical assistance may challenge the denial of coverage of or payment for such assistance. Reducing plan response time for prior authorizations should enable enrollees to file appeals timelier, when needed, and receive faster resolution. The prior authorization proposals in this rule, particularly the proposal to reduce the maximum amount of time for a managed care plan to make a standard prior authorization decision from 14 days to 7 days, are consistent with how section 1932(c)(2)(A) of the Act indicates that timely access to care should be assured for enrollees. Currently, and under our proposal, 42 CFR 438.210 applies the same appeal and grievance requirements for PIHPs and PAHPs as for MCOs; for this proposal, we rely on our authority in section 1902(a)(4) to adopt these standards for PIHPs and PAHPs. This is consistent with our prior practice for adopting standards for Medicaid

managed care plans (81 FR 27507). We believe that the proposal to shorten the maximum amount of time for a plan to make a prior authorization decision from 14 days to 7 days would improve the efficient operation of the Medicaid program by facilitating faster receipt of services or filing of appeals.

We are not proposing any changes to the required timeframes for expedited decisions at 42 CFR 438.210(d)(1) nor the authority for a 14-day extension provided at 42 CFR 438.210(d)(1) and (2)(ii). This proposed requirement would be applicable to CHIP managed care through the cross reference to 42 CFR 438.210 in current 42 CFR 457.1230(d).

To implement the proposed prior authorization timeframes for CHIP, we propose to revise 42 CFR 457.495, such that beginning January 1, 2023, decisions related to prior authorization of health services would be required to be completed in accordance with the medical needs of the patient, but no later than 7 calendar days after the date of the receipt of the request for a standard determination and 72 hours following the receipt of the request for an expedited determination. We are retaining the authority for an extension of up to 14 days to be granted if the enrollee requests or the physician or health plan determines that additional information is needed. We propose to remove the option for states to follow existing state law regarding prior authorization of health services, requiring states to instead follow these updated timeframes. However, if state laws are more stringent, states are not prohibited from complying with enhanced decision timelines. We believe timely prior authorization decisions are an important beneficiary protection, and CHIP beneficiaries should be afforded the same decision timeframes as Medicaid beneficiaries. We seek comment on this proposal, and most specifically from states.

Existing CHIP regulations at 42 CFR 457.1130(b) require a state to ensure that an enrollee has an opportunity for external review of health services matters, including a delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of service. Under this regulation, CHIP enrollees must have an opportunity for external review of prior authorization decisions. We are not proposing any changes to this requirement, as it already applies to decisions related to the prior authorization of services.

In the case of QHP issuers on the FFEs, regulations at 45 CFR 147.136 establish internal claims and appeals processes, external review processes, and pre-service claims requirements for all non-grandfathered group and individual market plans or coverage. Specifically, at 45 CFR 147.136(b)(3), individual health insurance issuers are required to meet minimum internal claims and appeals standards. To avoid adding to the burden that this proposal might impose by applying multiple, potentially inconsistent regulatory standards for individual and group market plans, we are considering, and solicit comments on, whether to extend the timeframes for processing of prior authorizations applicable to other payers, as discussed in this section, to QHP issuers on the FFEs. Specifically, we seek comment on whether having different processing timelines for prior authorizations for QHP issuers on the FFEs would be operationally feasible for issuers, or if such a requirement would have the unintended effect of increasing burden for issuers that are already subject to different requirements.[52] Finally, we note that the alternative of making changes to regulations applicable to all non-grandfathered group and individual market plans or coverage for consistency with our proposed approach here would be outside the scope of this regulation.

Overall, we believe that the decision timeframes proposed for the impacted payers in this rule would help ensure that prior authorization processes do not inappropriately delay patient access to necessary services. The introduction of decision timeframes that are the same across all impacted payers for items and services that require prior authorization would also help providers better organize and manage administrative resources and allow more time for providers to render patient-centered care. We believe these proposals would make substantive progress in improving the care experience for patients and lead to better health outcomes. In turn, better health outcomes would contribute to more efficient use of program resources.

We request comment on these proposals, specifically those that include feedback on any unintended consequences of these proposed policies to reduce payer decision timeframes.

In addition to comments on the proposals regarding timelines and notifications, we seek comment on several related topics. For example, are alternative timeframes feasible or appropriate for prior authorization for items and services?

- Under what circumstances could payers approve an expedited prior authorization in less than the proposed 72 hours? Are there circumstances in which a payer should be required to approve an expedited prior authorization in 24 hours for items and services other than prescription or outpatient drugs? What are the operational and system requirements for a more streamlined scenario for prior authorization approvals?
- Under what circumstances could an approval be provided in less than 7 calendar days for a complex case?
- We also seek comment on process challenges with prior authorization. For example, are there scenarios that could be appropriate to support temporary coverage of services, such as, temporary access to DME, while the patient waits for an authorization during the 14-day review timeframe? What policy conditions might be necessary to include in such authorization determinations? Commenters are encouraged to provide examples of best-case and worst-case scenarios, and explain what changes in process, policy, or technology would be necessary.

7. Proposed Extensions, Exemptions and Exceptions for Medicaid and CHIP and QHP Issuers

a. Extensions and Exemptions for Medicaid and CHIP FFS Programs

If our proposals regarding the DRLS and PAS APIs are finalized, we would strongly encourage state Medicaid and CHIP FFS programs to implement these APIs as soon as possible, in light of the many benefits of these APIs as discussed previously in this section. However, we also recognize that state Medicaid or CHIP FFS agencies could face certain unique circumstances that would not apply to other impacted payers, as discussed in more detail later in this section. As a result, a few states might need to seek an extension of the compliance deadline or an exemption from these requirements. To address this concern, we are proposing a process through which states may seek an extension of and, in specific circumstances, an exemption from, the DRLS and PAS API requirements if they are unable to implement these API requirements, consistent with the extension and exemption proposals for the Provider Access API in section II.B., and the Payer-to-Payer API in section II.D. of this proposed rule. Providing these flexibilities might allow these states to continue building technical

[52] We are not proposing in this proposed rule to impose on individual and group market plans generally timelines for processing of prior authorizations consistent with those we propose for other payers, as such requirements would require rulemaking by the Departments of Labor, the Treasury, and Health and Human Services.

capacity in support of overall interoperability goals consistent with their needs. We therefore propose the following.

Extension. At 42 CFR 431.80(b)(1) and 42 CFR 457.732(b)(1) respectively, we propose to provide states—for Medicaid FFS and CHIP FFS—the opportunity to request a one-time extension of up to one (1) year for the implementation of the PAS API specified at 42 CFR 431.80(a)(1) and 42 CFR 457.732(a)(2) and DRLS API specified at 42 CFR 431.80(a)(1) and 42 CFR 457.732(a)(1). Unique circumstances that might present a challenge to specific states to meet the proposed compliance date could include resource challenges, such as funding. Depending on when the final rule is published in relation to a state's budget process and timeline, some states may not be able to secure the needed funds in time to both develop and execute implementation of the API requirements by the proposed compliance data. A one-year extension could help mitigate this issue. And, some states may need to initiate a public procurement process to secure contractors with the necessary skills to support a state's implementation of these proposed API policies. The timeline for an open, competed procurement process, together with the time needed to onboard the contractor and develop the API, could require additional time as well. Finally, a state might need to hire new staff with the necessary skillset to implement this policy. Again, the time needed to initiate the public employee hiring process, vet, hire, and onboard the new staff may make meeting the proposed compliance timeline difficult, because, generally speaking, public employee hiring processes include stricter guidelines and longer time-to-hire periods than other sectors.[53] In all such situations, a state might need more time than other impacted payers to implement the requirements.

If a state believes it can demonstrate the need for an extension, its request must be submitted and approved as a part of its annual Advance Planning Document (APD) for MMIS operations costs and must include the following: (1) A narrative justification describing the specific reasons why the state cannot reasonably satisfy the requirement(s) by the compliance date, and why those reasons result from circumstances that are unique to states operating Medicaid or CHIP FFS programs; (2) a report on completed and ongoing implementation activities to evidence a good faith effort toward compliance; and (3) a comprehensive plan to meet implementation requirements no later than one year after the initial compliance date.

An extension would be granted if CMS determines based on the information provided in the APD that the request adequately establishes a need to delay implementation, a good faith effort to implement the proposed requirements as soon as possible, and a clear plan to implement no later than one year after the proposed compliance date. We would expect states to explain why the request for an extension results from circumstances that are unique to states operating Medicaid or CHIP FFS programs. We solicit comment on whether our proposal would adequately address the unique circumstances that affect states, and that might make timely compliance with the proposed API requirement sufficiently difficult for states, and thus justify an extension. In particular, we seek comment on whether we should require or use additional information on which to base the determination or whether we should establish different standards in the regulation text for evaluating and granting the request.

Exemption. At 42 CFR 431.80(b)(2) and 42 CFR 457.732(b)(2), respectively, we propose two circumstances that would permit state requests for exemption; namely, (1) when at least 90 percent of all covered items and services are provided to Medicaid or CHIP beneficiaries through Medicaid or CHIP managed care contracts with MCOs, PIHPs, or PAHPs, rather than through a FFS delivery system; or (2) when at least 90 percent of the state's Medicaid or CHIP beneficiaries are enrolled in Medicaid or CHIP managed care organizations as defined in 42 CFR 438.2 for Medicaid and 42 CFR 457.10 for CHIP. In both circumstances, the time and resources that the state would need to expend to implement the API requirements may outweigh the benefits of implementing and maintaining the API. As discussed in section II.B. of this proposed rule, unlike other impacted payers, state Medicaid and CHIP FFS programs do not have a diversity of plans to balance implementation costs for those plans with low enrollment. If there is low enrollment in a state Medicaid or CHIP FFS program, there is no potential for the technology in which they have invested to be leveraged for additional beneficiaries as states, unlike other payers, do not maintain additional lines of business.

We acknowledge that the proposed exemption could mean that a few Medicaid or CHIP FFS systems would not receive the benefits of having these APIs available to facilitate health information exchange. To address this, we propose that states meeting the above thresholds would be expected to employ an alternative plan to enable the electronic exchange and accessibility of health information for those beneficiaries who are served under the FFS program.

A state meeting the above criteria would be permitted to submit a request for an exemption to the requirements for the DRLS and PAS APIs once per calendar year for a one (1) year exemption. The state would be required to submit this annual request as part of a state's annual APD for MMIS operations costs. The state would be required to include in its request document that it meets the criteria for the exemption using data from any one of the three most recent and complete calendar years prior to the date the exemption request is made. We propose that this request be made annually as from year-to-year the nature of the FFS population could change and so it is important that the state provide the most current information for CMS's consideration.

Exemptions would be granted for a one-year period if a state establishes to CMS's satisfaction that it meets the criteria for the exemption and has established a plan to ensure that providers would have efficient electronic access to the same information through alternative means.

We request comment on the proposed extension and exemption.

For Medicaid and CHIP managed care, we are not proposing an extension process at this time because we believe that managed care plans are actively working to develop the necessary IT infrastructure to be able to comply with the existing requirements in 42 CFR part 438 and part 457, and also benefit from efficiencies resulting from their multiple lines of business impacted by these interoperability policies. Many managed care plans are part of parent organizations that maintain multiple lines of business, including plans on the Exchanges. As discussed in the CMS Interoperability and Patient Access final rule (85 FR 25607, 25612, 25620), work done by these organizations can benefit all lines of business and, as such, we do not believe that the proposals in this rule impose undue burden or are unachievable by the compliance date. We are soliciting comment on whether

[53] State hiring processes are comparable with federal hiring processes. According to OMB, the average time-to-hire for federal employees was 98.3 days in 2018, significantly higher than the private sector average of 23.8 days. See: *https://www.opm.gov/news/releases/2020/02/opm-issues-updated-time-to-hire-guidance/.*

our belief concerning the scope of resources and ability of managed care parent organizations to achieve economies of scale is well-founded. Further, we seek comment on whether an extension process is warranted for certain managed care plans to provide additional time for the plan to comply with requirements at proposed 42 CFR 431.80(a)(1) and 431.80(a)(2), which cross references 42 CFR 438.242(b)(5) for Medicaid managed care plans and at proposed 42 CFR 457.732(a)(1) and 457.732(a)(2) which cross reference 42 CFR 457.1223(d)(2) for CHIP managed care entities. While we are not proposing such a process for managed care plans and entities and do not believe one is necessary for the reasons outlined here, we are open to considering one if necessary. If we adopt an extension process for these managed care plans and entities, what criteria would a managed care plan or entity have to meet to qualify for an extension? Should the process consider, for example, enrollment size, plan type, or some unique characteristic of certain plans that could hinder their implementation of the proposed requirements by the proposed compliance date? Also, we seek comment on whether, if we finalize such a process for Medicaid managed care plans or CHIP managed care entities, the state or CMS should manage the process and whether states could successfully adopt and implement the process on the timeline necessary to fulfill the goals and purpose of the process. Consistent with the exception process proposed for QHP issuers on the FFEs at 45 CFR 156.222(d), we would expect any extension request to include, at a minimum, a narrative justification describing the reasons why a plan or entity cannot reasonably satisfy the requirements by the proposed compliance date, the impact of non-compliance upon enrollees, the current or proposed means of providing electronic health information to providers, and a corrective action plan with a timeline to achieve compliance.

We request comment on this proposal.

b. Exceptions for QHP Issuers

For QHP issuers on the FFEs, we propose an exceptions process to the DRLS API requirements proposed at 45 CFR 156.223(a)(1) and the PAS API requirements at proposed at 45 CFR 156.223(a)(2). We propose that if an issuer applying for QHP certification to be offered through an FFE believes it cannot satisfy the requirements to establish one or both of these APIs, the QHP issuer would have to include, as part of its QHP application: (1) A narrative justification describing the reasons why the plan cannot reasonably satisfy the requirements for the applicable plan year; (2) the impact of non-compliance upon enrollees; (3) the current or proposed means of providing health information to providers; and (4) solutions and a timeline to achieve compliance with the requirements of this section. Further, we propose that the FFE may grant an exception if it determines that making a health plan available through the FFE is in the interests of qualified individuals in the state or states in which such FFE operates. This exceptions process is proposed at 45 CFR 156.223(b). As we noted in the Interoperability and Patient Access Final Rule at 45 CFR 156.221(h), we anticipate that the exception would be provided in limited situations. For example, we would consider providing an exception to small issuers, issuers who are only in the individual market, financially vulnerable issuers, or new entrants to the program who demonstrate that deploying standards based API technology would pose a significant barrier to the issuer's ability to provide coverage to consumers, however, not certifying the issuer's QHP or QHPs would result in consumers having few or no plan options in certain areas. We believe that having a QHP issuer offer QHPs through an FFE is in the best interests of consumers. We seek comment on other circumstances in which the FFE should consider granting an exception.

We request comment on these proposed extensions, exemptions and exceptions for Medicaid and CHIP FFS, Medicaid and CHIP managed care, and the QHP issuers on the FFEs.

8. Public Reporting of Prior Authorization Metrics

We are proposing to require impacted payers to publicly report certain prior authorization metrics on their websites at the state-level for Medicaid and CHIP FFS, at the plan-level for Medicaid and CHIP managed care, and at the issuer-level for QHP issuers on the FFEs. As discussed in section II.C.11. of this proposed rule, publicly reporting these metrics would support efficient operations, timely service, and ensure prior authorization processes are executed in such a way as to be in the best interest of patients. Specifically, public reporting of this information would provide patients and providers with important information about Medicaid managed care plans, CHIP managed care entities, and QHP issuers when the patient is making a decision about a plan. When looking for a new plan, patients may compare a variety of factors including, but not limited to, access to care (authorizations), premiums, benefits, and cost sharing or coinsurance. We believe access to care is a critical factor for patients to consider when choosing a plan, and transparency regarding prior authorization processes could be an important consideration.

Similarly, providers may find metrics about prior authorization approvals or appeals useful when selecting payer networks to join, and when considering whether to contract with a payer. Providers should be armed with information about how they will be able to treat their patients, and whether that will be in a manner they believe will support value-based care and services that are appropriate and necessary for each patient's health.

Therefore, we are proposing to require state Medicaid and CHIP FFS programs at 42 CFR 440.230(d)(2) and 457.732(a)(3), respectively; Medicaid managed care plans at 42 CFR 438.210(f); CHIP managed care entities through operation of existing 42 CFR 457.1233(d)(2); and QHP issuers on the FFEs at 45 CFR 156.223(a)(3) to publicly report, at least annually, prior authorization metrics on their websites or via publicly accessible hyperlink(s). We propose that each metric would be reported separately for each item and service, not including prescription drugs and/or covered outpatient drugs, and that the data would be required to be publicly reported for each metric. We propose that these metrics would include, at a minimum, the following:

- A list of all items and services that require prior authorization;
- The percentage of standard prior authorization requests that were approved, reported separately for items and services;
- The percentage of standard prior authorization requests that were denied, reported separately for items and services;
- The percentage of standard prior authorization requests that were approved after appeal, reported separately for items and services;
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported separately for items and services;
- The percentage of expedited prior authorization requests that were approved, reported separately for items and services;
- The average and median time that elapsed between the submission of a request and a decision by the payer, plan or issuer, for standard prior

authorizations, reported separately for items and services.

In this proposal, when we state ''reported separately for items and services,'' we mean each payer would report a percentage for all prior authorization requests in a given year that meet the specified criteria for requests that were for items and a percentage for all prior authorization requests that year for the same criteria that were for services. In this way, a payer's prior authorization requests would be separated into two distinct categories, and these metrics would, if this proposal is finalized, be reported for each of these categories.

By sharing information about prior authorization requirements for items and services, and data about prior authorization decisions, patients and providers would have a better understanding of a payer's prior authorization review and approval processes. Such information may be helpful for making decisions at the time of open enrollment, special enrollment, or plan selection throughout the year. We are proposing that, beginning March 31, 2023, these data be publicly reported annually, by the end of the first calendar quarter each year for the prior year's data. For example, for all impacted payers, all available data for calendar year 2022 would be publicly reported by the end of the first calendar quarter of 2023, or by March 31, 2023.

We acknowledge that the first set of publicly available data would reflect current practices, rather than payer behavior based on compliance with this proposed rule. However, should our proposals be finalized, we anticipate that, over time, data might show improvements. In addition, year-over-year comparisons could demonstrate positive (or negative) trends, which alone could be useful information for patients who are making enrollment decisions. Publicly available data would aid interested providers and patients in understanding payer performance with respect to prior authorization processes for decisions, approvals, denials, and appeals.

We request comments on the proposed reporting of metrics on prior authorization requests, including comments on the proposal to report a separate percentage for all prior authorization requests in a given year that meet the criteria for items and a separate percentage for all prior authorization requests that year for the criteria that were for services, and comments on the proposed reporting dates.

In order to more directly facilitate the incorporation of such data into a consumer-friendly comparison tool, we may consider proposing in future rulemaking to use these data to help develop quality measures to incorporate into quality star ratings across certain payer programs over time, specifically for QHP issuers on the FFEs.

For Medicaid managed care, we propose to remove the text currently at 42 CFR 438.210(f), which addresses the applicability date for the provisions in that section. That text was added in 2016 to clarify that the prior requirements in that section would remain in effect until the new provisions begin starting with rating periods beginning on or after July 1, 2017. As several rating periods have passed since July 1, 2017, we do not believe this clarifying text is needed. We propose to replace the current text at 42 CFR 438.210(f) with the proposed public reporting of prior authorization metrics, as explained above.

9. Request for Comments on ''Gold-Carding'' Programs for Prior Authorization

During the CMS listening sessions, we heard about the potential for additional efficiencies in the prior authorization process, through certain payer policies, including decisions about when to require prior authorization. For example, prior authorization is sometimes required for certain items and services that are almost always approved or for some providers who have demonstrated a history of complying with all payer requirements. Stakeholders stated that it could be more efficient and cost effective if prior authorization requirements were minimized or removed in these cases.

Some payers have implemented what they term ''gold-carding'' or similar programs to relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance. For example, some payers have relieved certain providers from the requirement to request prior authorizations based on data indicating adherence to submission requirements, appropriate utilization of items or services, or other evidence-driven criteria that they deem relevant. CMS uses an approach similar to gold-carding in the Medicare FFS Review Choice Demonstration for Home Health Services, under which home health agencies in demonstration states that select certain review choice options and have a review affirmation rate or claim approval rate of 90 percent or greater over 6 months are given the option to continue in the pre-claim review program or choose a selective post-payment review or spot check review process.[54]

We believe the use of gold-carding programs could help alleviate provider burden related to prior authorization and believe these programs could facilitate more efficient and prompt delivery of health care services to beneficiaries. We encourage payers to adopt gold-carding approaches that would allow prior authorization exemptions or more streamlined reviews for certain providers who have demonstrated compliance with requirements. Gold-carding policies could reduce burden on providers and payers, while improving the patient experience. By taking this step, payers can join CMS in helping to build an infrastructure that would allow clinicians to deliver care in a timely and value-based manner. While we are not including any proposals here, and are not intending to be overly prescriptive in defining requirements in future rulemaking for gold-carding programs, we emphasize the importance of reducing provider burden and seek comment for consideration for future rulemaking on how best to measure whether and how these types of approaches and programs actually reduce provider and payer burden.

To further encourage the adoption and establishment of gold-carding programs, we have considered including gold-carding as a factor in quality star ratings, where applicable, as a way for payers to raise their score in the quality star ratings for QHP issuers. We seek comment for potential future rulemaking on the incorporation of gold-carding into star ratings for QHP issuers on the FFEs. We also considered proposing gold-carding as a requirement in payer's prior authorization policies and seek comment on how such programs could be structured to meet such a potential requirement.

10. Additional Requests for Comment

We seek comment on additional topics pertaining to prior authorization, as feedback may be useful for future rulemaking.

We understand from our listening sessions that there may be opportunities to improve the prior authorization process for individuals with chronic medical conditions. For example, when a patient has a chronic condition that

[54] Centers for Medicare and Medicaid Services. (2019, October 7). Review Choice Demonstration for Home Health Services. Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Choice-Demonstration/Review-Choice-Demonstration-for-Home-Health-Services.html.*

requires ongoing treatment, the provider is often required to resubmit repeated prior authorization requests for the same service, each time treatment is needed. One such condition described in listening sessions was macular degeneration. Patients shared their experience of needing monthly prior authorizations for their monthly injection treatments, despite the fact that those injections are required to avoid loss of vision, and despite the fact that there is no cure for their condition. Repeatedly submitting a prior authorization request for the same item or service, which is always approved, creates a burden on both the patient and the provider and adds costs to the overall health care system. We seek comment on whether there should be certain restrictions regarding requirements for repeat prior authorizations for items and services for chronic conditions, or whether there can be approvals for long term authorizations. What alternative programs are in place or could be considered to provide long-term authorizations for terminal or chronic conditions?

Another topic identified in listening sessions was patient concerns about losing access to approved services after changing health plans. Patients expressed concern about being able to continue a specific course of care where, for example, they might be in the middle of an approved course of care requiring physical therapy, but then change health plans (payer). We seek comments on whether a prior authorization decision should follow a patient when they change from one qualified health plan on the Exchange to another, or to another health plan impacted by this proposed rule, and under what circumstances that prior authorization could follow a patient from payer to payer. We also seek comment for potential future rulemaking on other prior authorization topics, such as whether prior authorizations should be valid and accepted for a specified amount of time. We are interested in comments on who should determine how long an existing approved prior authorization from a previous payer should last and whether prior authorization should be regulated by amount of time and/or by condition.

An additional topic from our listening sessions was the issue of the number of different forms used by payers for prior authorization requests, each with different information requirements (data elements) and methods for submission. The lack of standard forms and requirements from payers is considered burdensome and time consuming for both patients and providers. We request input on solutions to standardizing prior authorization forms, including the possibility of developing an HL7 FHIR based questionnaire for prior authorization requests. Input on requiring the use of a standardized questionnaire could inform future rulemaking.

Finally, we request comments on how to potentially phase out the use of fax technology to request and send information for prior authorization decisions. As we described earlier in this section, we believe the standards-based API process should be the preferred and primary form of exchanging prior authorization communications. However, we acknowledge that providers could vary in their ability to develop and implement API-based prior authorization submission and receipt technology and that there must be a channel for prior authorization for providers whose systems are not API-capable. In particular, we anticipate that providers in rural areas, small providers, and certain types of service providers, such as home and community-based services providers in Medicaid, may be subject to prior authorization processes but may not have the technical expertise, access to high speed internet, infrastructure, or financial resources to implement connectivity with and use the DRLS and PAS APIs. Further, non-API mechanisms like fax, phone, and web portals may be needed in times when other technology is not available or other unexpected emergencies. We request comment on how payers and providers might begin to phase out the use of fax technology, and what barriers must still be overcome to accomplish this goal.

As mentioned previously in this proposed rule, although Medicare FFS is not directly impacted by this rule, we do note that we are evaluating implementation of these provisions, if finalized. In this way, Medicare FFS implementations would conform to the same requirements that apply to the impacted payers under this rulemaking, as applicable, so that participating Medicare providers and beneficiaries would benefit from the APIs and process improvements.

11. Statutory Authorities To Require Prior Authorization Burden Reduction Proposals

a. Medicaid and CHIP

For the reasons discussed below, our proposed requirements in this section for Medicaid managed care plans and Medicaid state agencies fall generally under our authority in section 1902(a)(4) of the Act, which requires that a state Medicaid plan provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the state Medicaid plan. The proposals in this section are also authorized under section 1902(a)(8) of the Act, which requires states to ensure that Medicaid services are furnished with reasonable promptness to all eligible individuals. Additionally, they are authorized by section 1902(a)(19) of the Act, which requires states to ensure that care and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

The proposed requirement for the states and Medicaid managed care plans to implement the DRLS and PAS API (section II.C.3. and II.C.4. of this proposed rule; statutory authority for proposals to require specific IGs is discussed in section II.A.3. of this proposed rule) is expected to improve the efficiency and timeliness of the prior authorization process for Medicaid beneficiaries, providers, and state Medicaid agencies and Medicaid managed care plans by addressing inefficiencies that appear to exist in the process today. These proposals would ensure that all states and Medicaid managed care plans would provide easily accessible information about when a prior authorization is required, and what documentation requirements must be fulfilled to submit the request. The DRLS API would allow a provider to determine if a prior authorization is required, and what the documentation requirements are for that prior authorization request. When using the PAS API, the state or Medicaid managed care plan would send a real time response to a provider's request with the status of the request included. Use of these APIs by states (for FFS programs) and managed care plans could ensure that Medicaid providers are able to submit a request for a prior authorization with the correct and complete documentation, and avoid an incorrect submission which might result in an unnecessary denial. The PAS API would: (i) Enable providers to submit a prior authorization request faster and easier, (ii) support more timely notice to provider and beneficiary of the disposition of the prior authorization request sooner, and (iii) permit faster scheduling of services or filing appeals, depending on the decision. The DRLS API and the PAS API both have the potential to improve the prior

authorization process by making it more efficient, including by limiting the number of denials and appeals, or even by eliminating requests for additional documentation, as noted elsewhere. For the state, these requirements would thus align with section 1902(a)(4) of the Act, which requires that a state Medicaid plan provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the state Medicaid plan. For the Medicaid managed care program, these requirements align with section 1932(c)(1)(A)(i) of the Act, which requires that states using managed care organizations must develop and implement a quality assessment and improvement strategy that includes standards for evaluating access to care so that covered services are available within reasonable timeframes.

The proposal would implement section 1932(b)(4) of the Act, which provides that each Medicaid managed care organization must establish an internal grievance procedure under which an enrollee who is eligible for medical assistance may challenge the denial of coverage of or payment for such assistance. This proposal would enable enrollees to file appeals, when needed, and support them in receiving resolution.

Our proposal to clarify that current notice and fair hearing requirements apply to Medicaid fee-for-service prior authorization decisions is authorized under section 1902(a)(3) of the Act. Section 1902(a)(3) of the Act requires that a Medicaid state plan provide for granting an opportunity for a fair hearing to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness. These proposed clarifications are also supported by the 14th Amendment to the United States Constitution and case law on due process, specifically, *Goldberg* v. *Kelly,* 397 U.S. 254 (1970). States must establish timely notice and fair hearing processes meeting due process standards under *Golberg* v. *Kelly,* as incorporated into existing Medicaid fair hearing regulations at 42 CFR part 431, subpart E; *see* 431.205(d).

The proposed requirement that states and Medicaid managed care plans meet certain timeframes to provide notice of decisions for prior authorizations, including the requirements that expedited decisions be made and communicated in 72 hours and standard decisions be made and communicated in 7 calendar days, may provide an improvement from the current standards for decision timeframes for Medicaid managed care (section II.C.6. of this proposed rule). The proposal is intended to establish more certainty in the prior authorization process for Medicaid providers and enhance beneficiary access to timely and appropriate care, consistent with states' obligations to provide Medicaid services with reasonable promptness and in a manner consistent with beneficiaries' best interests. Improved decision timeframes could improve communication to providers and beneficiaries, as well as increase access to care. The proposal is consistent with, and might help states comply with, section 1902(a)(8) of the Act, which requires the provision of medical assistance with reasonable promptness. A uniform and consistent timeline for Medicaid program prior authorization decisions might improve beneficiaries' prompt access to Medicaid-covered services.

Standardizing Medicaid prior authorization decision timeframes could also support process improvements for the state and Medicaid managed care plans, including the creation of standard operating procedures and internal metric reports for program operations. This is consistent with section 1902(a)(4) of the Act, which requires that a state Medicaid plan provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the state Medicaid plan.

The proposal is also authorized under section 1902(a)(17) of the Act, as implemented under the existing Medicaid regulations at 42 CFR 440.230. This section of the Act requires state Medicaid programs to establish reasonable standards that are consistent with the objectives of title XIX of the Act to determine the extent of covered medical assistance. As set forth at 42 CFR 440.230, these standards could include appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures, so long as each service is sufficient in amount, duration, and scope to reasonably achieve its purpose. Items and services covered under Title XIX benefit authorities are subject to 42 CFR 440.230, unless statute or regulation expressly provides for an exception or waiver. This would include covered items and services described in sections 1905(a), 1915(c), 1915(i), 1915(j), 1915(k), 1915(l), 1937, and 1945 of the Act, and any other authorities as established by Congress.

The proposal is also consistent with section 1902(a)(19) of the Act, which requires that care and services be provided in a manner consistent with simplicity of administration and the best interests of recipients, because it is expected to help make the prior authorization process less burdensome for the state, providers, and beneficiaries. The proposed requirements and standards could result in more prompt prior authorization decisions, improve delivery of covered services, and improve efficiency of operations for the program, thereby serving the best interest of Medicaid beneficiaries.

Our proposal to require states and Medicaid managed care plans to publicly report prior authorization metrics (section II.C.8. of this proposed rule) would support CMS and state Medicaid agency oversight, and evaluation and administration of the state plan, as it would allow for an evaluation of the implementation of the policies proposed in this rule. The data may indicate that payers have implemented the APIs (by showing improvements in prior authorization numbers) or made other improvements in policies and processes that result in improved metrics in the areas that we propose to be reported. Section 1902(a)(6) of the Act authorizes us to request reports from state Medicaid agencies in such form and containing such information as the Secretary may require from time to time. By reporting metrics, states and Medicaid managed care plans could review data to identify areas for improvement. Requiring Medicaid managed care plans to publicly report their prior authorization metrics would hold them accountable and enable them to more easily monitor their own performance and identify process improvement opportunities which could be an integral part of implementing a quality assessment and improvement strategy, consistent with the requirements for quality strategies for managed care programs at section 1932(c)(1)(A)(i) of the Act.

For CHIP, we propose these requirements under the authority in section 2101(a) of the Act, which sets forth that the purpose of title XXI is to provide funds to states to provide child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage. This provision authorizes us to adopt these requirements for CHIP because they would also provide access to program data, which can improve the efficacy of CHIP programs, and allow for more efficient administration of services.

As discussed above, we propose to require implementation of the DRLS API and PAS API (section II.C.3. and II.C.4.

of this proposed rule; statutory authority for proposals to require specific IGs is discussed in section II.A.3. of this proposed rule) to improve the prior authorization process for patients, providers and payers by addressing deficiencies and inefficiencies that exist in the current process. Today, a payer's rules about when a prior authorization is required, and what documentation requirements must be fulfilled to submit the request are not easily accessible for providers, which requires phone calls, access to multiple websites, and use of hard copy manuals, etc. This takes time away from actual patient care. The DRLS API allows a provider to determine if a prior authorization is required, and what the documentation requirements are for that prior authorization request. While we expect providers to be the primary stakeholders that benefit from the DRLS API, making this information available in a standardized way and permitting access through an API also serves the requirements in section 2101(a) of the Act that CHIP ensure access to coverage and coordinate care.

The proposed PAS API would be a mechanism for receiving and responding to requests for coverage determinations before the services are furnished; the PAS APIs would streamline the initial authorization process for the payer, by sharing this information in an easily accessible way; this also allows the provider to know what to do if a prior authorization is required for a certain service, which improves the providers ability to treat the patient timely. The proposed PAS API would enable the payer to send a real time response back to a provider, based on a request for authorization. This too would improve the efficiency of providing services to the patient, because the request and response would be automated, and in real time. Payer use of these APIs could ensure that a provider is able to submit a request for a prior authorization with the correct and complete documentation to avoid an incorrect submission which might result in an unnecessary denial. The PAS API would: (i) Enable providers to submit a prior authorization request faster and easier, (ii) support more timely notice to provider and enrollee of the disposition of the prior authorization request, and (iii) permit faster scheduling of services or filing appeals, depending on the decision. The DRLS API and the PAS API both have the potential to improve the prior authorization process by making it more efficient, including limiting the number of denials and appeals, or even eliminating requests for additional documentation, as noted elsewhere.

The proposed requirement that CHIP FFS and managed care entities meet certain timeframes to provide decisions for prior authorizations, including the requirement that expedited decisions be given in 72 hours and standard decisions be given in 7 calendar days, is an improvement from the current state, when there is uncertainty about expectations for when a prior authorization might be approved (section II.C.6. of this proposed rule). The proposal is intended to establish more certainty in the prior authorization process for providers and enhance patient access to timely and appropriate care. As payers provide notice under a shorter timeframe, patients would have more timely access to care. This is often not the case today, as providers and patients could wait longer for the payer to respond to a request for certain services. This could have an impact on health, particularly for individuals with chronic conditions or who have health risks. Improving certainty around decision timeframes could also reduce administrative time and expense, because providers would not need to make repeat inquiries to payers for a status on the authorization request. The proposal to improve timeliness in responding to providers and patients could support process improvements for the state and managed care programs and is consistent with our authorities under section 2101(a) of the Act in that they improve the efficiency of the CHIP programs.

Our proposal to require CHIP FFS and CHIP managed care entities to report prior authorization metrics also supports the states oversight, evaluation and administration responsibilities, as it would allow us to evaluate the impact of the prior authorization policies in this proposed rule (section II.C.8. of this proposed rule). The data may indicate use of the APIs (improvements in prior authorization numbers) or changes in total numbers, denials and appeals.

b. QHP Issuers on the FFEs

For QHP issuers on the FFEs, we are proposing these new requirements pursuant to the authority of section 1311(e)(1)(B) of the Affordable Care Act, which affords the Exchanges the discretion to certify QHPs if the Exchange determines that making available such health plans through the Exchange is in the interests of qualified individuals in the state in which the Exchange operates.

We believe that the policies included here would improve the efficiency of the issuers who are certified to participate in the QHP program and improve the quality of services they provide to providers and their patients. Qualified individuals in FFEs may receive covered services more quickly, and the information may be more accurate with the use of the APIs. These proposals could improve the quality of the patient experience with their providers by increasing the efficiency in the prior authorization submission and review process. Therefore, we believe generally, that certifying only health plans that implement FHIR based APIs and adhere to the other proposals herein, would be in the interests of qualified individuals in the state or states in which an FFE operates. We encourage SBEs to consider whether a similar requirement should be applicable to QHP issuers participating in their Exchanges.

In sections II.C.3. and II.C.4. of this rule, we propose that QHPs implement two APIs for the prior authorization process (statutory authority for proposals to require specific IGs are discussed in section II.A.3. of this proposed rule). The DRLS API would allow providers to quickly and efficiently know if a prior authorization is needed and locate the documentation requirements easily. This would enable faster, more accurate submission of prior authorization requests and potentially more prompt delivery of services. We also propose that QHPs implement a PAS API, to allow providers to efficiently, and with greater simplicity submit prior authorization requests directly from within their workflow and would allow QHP issuers to respond to the prior authorization request quickly and efficiently, thus enabling more prompt delivery of services.

We also include in our proposal that QHPs provide a denial reason when sending a response to a prior authorization request, to facilitate better communication and understanding between the provider and issuer. This could enable efficient resubmission of the prior authorization request with additional information or an appeal, which could more promptly facilitate the needed patient care.

Finally, proposing to require QHP issuers to publicly report prior authorization metrics would hold issuers accountable to their providers and patients, which could help them improve their program administration (section II.C.8. of this proposed rule.). These data could help QHPs evaluate their processes and determine if there are better ways to leverage the APIs, including the quality and sufficiency of

the coverage and documentation information included in the APIs.

D. Payer-to-Payer Data Exchange on FHIR

1. Background

Research shows that the more complete a patient's record is, and the more data there are at the point of care, the better patient outcomes can be.[55] More data lead to better-coordinated care and more informed decision-making. Data sharing among payers is one powerful way to facilitate this critically valuable flow of information through the health care ecosystem. As a result, in the CMS Interoperability and Patient Access final rule, we finalized a requirement for certain impacted payers to exchange, at a minimum, clinical information as defined in the USCDI version 1 (85 FR 25568 through 25569). We did not specify an API standard for data sharing in that final rule, however, understanding at the time that there may be a variety of transmission solutions that payers could employ to meet this requirement. We did encourage impacted payers to consider the use of a FHIR-based API in line with the larger goal of leveraging FHIR-based APIs to support a number of interoperability use cases for improving patient, provider, and payer access to health care data in order to reduce burden, increase efficiency, and ultimately facilitate better patient care. In addition, we also signaled our intent to consider a future requirement to use FHIR-based APIs for payer-to-payer data sharing, envisioning the increasing implementation of FHIR-based APIs within the industry.

In the time since we proposed the initial payer-to-payer data exchange requirements in the CMS Interoperability and Patient Access rule, we have begun to leverage new tools, most notably the HL7 FHIR Bulk Data Access (Flat FHIR) specification, as discussed in more detail in section II.B. of this proposed rule. We believe the HL7 FHIR Bulk Data Access (Flat FHIR) specification, in particular, provides an opportunity to continue to build upon the requirement for payer-to-payer data sharing in a way that adds valuable efficiencies for payers, further simplifying administration and reducing burden. We believe that the suite of tools that the CMS Interoperability and Patient Access final rule (85 FR 25510) requires and that this proposed rule would require for payers would ultimately lead to payers having more complete information available to share with patients and providers. As a result, we are now proposing an enhanced set of payer-to-payer data-sharing requirements that would build on the policy finalized in the CMS Interoperability and Patient Access final rule (85 FR 25568 through 25569) by leveraging FHIR-based APIs to further support greater interoperability and information flow.

2. Payer-to-Payer Data Exchange on FHIR

There are three primary proposals we are making regarding the payer-to-payer data exchange in this proposed rule. First, we propose to extend the payer-to-payer data exchange to state Medicaid and CHIP FFS programs at 42 CFR 431.61(b) and 457.731(b). We previously finalized in the CMS Interoperability and Patient Access final rule (85 FR 25568 through 25569) that MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs were required, at the patient's request, to share a specified subset of clinical data with another payer of the patient's choice.

Second, we propose to enhance this payer-to-payer data exchange triggered by a patient's request beyond what was previously finalized (for MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs) in the CMS Interoperability and Patient Access final rule. In the final rule, we required impacted payers to exchange, at the patient's request, clinical data as defined in the USCDI, but we did not finalize in what electronic form or how these data would be transmitted. In this rule, we are proposing to require a FHIR-based API for this data exchange. In addition, we propose that this standards-based API must be conformant with specific IGs. We also propose that this Payer-to-Payer API, at the patient's request, must make not just clinical data as defined in the USCDI available, but also claims and encounter data (not including cost information), and information about pending and active prior authorization decisions. We propose these enhancements to the required payer-to-payer exchanges for Medicaid managed care plans (other than NEMT PAHPs) at 42 CFR 438.242(b)(7), CHIP managed care entities at 42 CFR 457.1233(d)(4), and QHP issuers on the FFEs at 45 CFR 156.221(f)(2). We are also proposing to include these enhancements as part of extending the payer-to-payer data exchange requirements to Medicaid and CHIP FFS programs at 42 CFR 431.61(b) and 42 CFR 457.731(b). We believe these proposed enhancements would facilitate more efficient data sharing between payers. In addition, the proposed additions to the data the API must be able to share would be consistent with the proposals discussed in sections II.A. and II.B. of this proposed rule, which would require these payers to share the same types of data with patients and providers via FHIR-based APIs. This would add efficiencies for payers and maximize the value of the work being done to implement APIs, overall reducing burden for all impacted payers.

Third, we propose a second payer-to-payer data exchange policy that would use this Payer-to-Payer API to facilitate data sharing between payers at enrollment. When a patient enrolls with a new payer or when a patient identifies concurrent coverage, we propose that the patient would have an opportunity to opt-in to this data sharing. Unlike the payer-to-payer exchange finalized previously, where the patient must make a request to initiate the data sharing, under this proposal the patient would be presented with data sharing as an option at enrollment. As more than one patient could be moving from one payer to another at enrollment, this new Payer-to-Payer API proposal to share data at enrollment would include a requirement for impacted payers to facilitate data sharing both for individual patients and for more than one patient using the HL7 FHIR Bulk Data Access (Flat FHIR) specification, discussed previously in section II.B. of this proposed rule. We are proposing to codify the requirement for this Payer-to-Payer API, including use of the HL7 FHIR Bulk Data Access (Flat FHIR) specification, at 42 CFR 431.61(c) for Medicaid FFS, at 42 CFR 438.242(b)(7) for Medicaid managed care, at 42 CFR 457.731(c) for CHIP FFS, at 42 CFR 457.1233(d)(4) for CHIP managed care, and at 45 CFR 156.222(b) for QHP issuers on the FFEs.

[55] Office of the National Coordinator. (2019, June 4). Improved Diagnostics & Patient Outcomes. Retrieved from *https://www.healthit.gov/topic/health-it-basics/improved-diagnostics-patient-outcomes.*

[55] See SHO # 20–003, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho20003.pdf.*

[55] HL7 International. (n.d.). Da Vinci Payer Coverage Decision Exchange (PCDE) FHIR IG. Retrieved from *http://www.hl7.org/fhir/us/davinci-pcde/history.cfml.*

[55] State hiring processes are comparable with federal hiring processes. According to OMB, the average time-to-hire for federal employees was 98.3 days in 2018, significantly higher than the private sector average of 23.8 days. See *https://www.opm.gov/news/releases/2020/02/opm-issues-updated-time-to-hire-guidance/.*

3. Payer-to-Payer Data Sharing in Medicaid and CHIP

In the CMS Interoperability and Patient Access final rule, we did not include Medicaid and CHIP FFS programs in the payer-to-payer data exchange policies. In that rule, we also did not specify how these data must be exchanged. As discussed in sections II.B.6.d. and II.C.7., and again later in this section of this proposed rule, Medicaid and CHIP FFS programs can face unique circumstances that might make it more challenging for them to meet new requirements within the same timeframe as other payers. As a result, in our first phase of interoperability policy, we chose to limit the burden on these programs so they could focus their attention and resources on implementing the Patient Access and Provider Directory APIs. Now that we are looking to transition the payer-to-payer data exchange to an API, and understanding the fact that this new API will be leveraging the same data and technical standards, and nearly all the same implementation guides as the Patient Access API, we believe that asking these programs to now implement this payer-to-payer data exchange via a Payer-to-Payer API would not be as burdensome as it would have been had we required these FFS programs to implement a payer-to-payer data exchange that does not require an API in the CMS Interoperability and Patient Access final rule effective January 1, 2022. By the time these programs would need to start preparing to implement this new Payer-to-Payer API, they are expected to have implemented the Patient Access API, and they would thus be able to leverage the work done for that to make implementing this new API more manageable. As a result, we now propose to extend this requirement to Medicaid and CHIP FFS programs at 42 CFR 431.61(b) and 457.731(b), respectively.

In the case of Medicaid and CHIP FFS programs, the state agency is the ''payer'' that can share patient data with other payers. As we discuss in more detail in section II.D.4. of this proposed rule, use of the Payer-to-Payer API could improve operational efficiencies for the state, thereby reducing burden for the state, and leading to better coordinated patient care and improved health outcomes. We thus expect the proposed Payer-to-Payer API requirement to lead to more effective administration of the state plan, and to better enable Medicaid and CHIP programs to ensure care and services are provided in a manner that is consistent with their beneficiaries' best interests. Ensuring that information can follow Medicaid and CHIP beneficiaries as they enter the programs could potentially lead to better care coordination for these patients, and better continuity of care. It could also reduce burden for patients and providers. Payers would have additional information to share via the Patient Access API and the Provider Access API. As a result, patients would have more readily available information to support informed decision making, and providers would have more information about the care their patients are receiving. This could potentially lead to fewer duplicate tests or less time taken collecting and recollecting information about the patient during a visit. Any opportunity a state takes to evaluate the data from a patient's previous payer could allow the state to avoid wasteful or unnecessary action that the previous payer may have already completed, such as an involved process or series of tests to support receipt of certain services. In this way, extending this Payer-to-Payer API to state Medicaid and CHIP programs could benefit them by helping them to operate more efficiently.

Also, as discussed in the CMS Interoperability and Patient Access final rule (85 FR 255664 through 25569), we believe there are numerous benefits for payers to be able to maintain a cumulative record of their current patients' health information. If payers do so, they can make information available to patients and their providers and can help ensure that patient information follows patients as they move from provider to provider and payer to payer. We believe it is important to propose that Medicaid and CHIP FFS agencies facilitate this data access and sharing for their beneficiaries, so that the benefits of both the data sharing required in the final rule and the data sharing proposed in sections II.A. through the Patient Access API and II.B. through the Provider Access API of this proposed rule would extend to Medicaid and CHIP FFS beneficiaries in the same way across other impacted payers. In this way, as a patient moves in and out of Medicaid or CHIP FFS, they will not lose access to their health information—that information would continue to follow them to new payers and providers by virtue of payers being able to send and receive their data and make it available to the patient and providers through these APIs.

States operating Medicaid and CHIP programs may be able to access federal matching funds to support their implementation of this Payer-to-Payer API, because this API is expected to lead to more efficient administration of the Medicaid and CHIP state plans and improved care coordination and health outcomes for Medicaid beneficiaries consistent with sections 1902(a)(4) and 2101(a) of the Act, as discussed in more detail in section II.D.8.a. of this proposed rule.

Consistent with the discussion regarding funding and the Provider Access API proposal discussed in section II.B. of this proposed rule and the DRLS and API APIs in section II.C., we do not consider state expenditures for implementing this Payer-to-Payer API proposal to be attributable to any covered item or service within the definition of ''medical assistance.'' Thus, we would not match these expenditures at the state's regular federal medical assistance percentage. However, federal Medicaid matching funds under section 1903(a)(7) of the Act, at a rate of 50 percent, for the proper and efficient administration of the Medicaid state plan, might be available for state expenditures related to implementing this proposal for their Medicaid programs, because use of the Payer-to-Payer API would help ensure that payers can access data that could improve their ability to render Medicaid services effectively, efficiently, and appropriately, and in the best interest of the patient.

States' expenditures to implement these proposed requirements might also be eligible for enhanced 90 percent federal Medicaid matching funds under section 1903(a)(3)(A)(i) of the Act if the expenditures can be attributed to the design, development, or installation of mechanized claims processing and information retrieval systems. Additionally, 75 percent federal matching funds under section 1903(a)(3)(B) of the Act may be available for state expenditures to operate Medicaid mechanized claims processing and information retrieval systems to comply with this proposed requirement.

States request Medicaid matching funds under section 1903(a)(3)(A)(i) or (B) of the Act through the Advance Planning Document (APD) process described in 45 CFR part 95, subpart F. States are reminded that 42 CFR 433.112(b)(12) and 433.116(c) require them to ensure that any system for which they are receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act aligns with and incorporates the ONC Health Information Technology standards adopted in accordance with 45 CFR part 170, subpart B. The Payer-to-Payer API, and all APIs proposed in this rule, complement this requirement

because these APIs further interoperability through the use of HL7 FHIR standards proposed for adoption by ONC for HHS use at 45 CFR 170.215.[56] And, states are reminded that 42 CFR 433.112(b)(10) explicitly supports exposed APIs as a condition of receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act.

Similarly, 42 CFR 433.112(b)(13) requires the sharing and re-use of Medicaid technologies and systems as a condition of receiving enhanced federal financial participation under section 1903(a)(3)(A)(i) or (B) of the Act. As noted in section II.B. of this proposed rule, CMS would interpret that sharing and re-use requirement also to apply to technical documentation associated with a technology or system, such as technical documentation for connecting to a state's APIs. Making the needed technical documentation publicly available so that systems that need to connect to the APIs proposed in this rule can do so would be required as part of the technical requirements at 42 CFR 431.60(d) for all proposed APIs in this rule, including the Payer-to-Payer API.

Separately, for CHIP agencies, section 2105(c)(2)(A) of the Act, limiting administrative costs to no more than 10 percent of CHIP payments to the state, would apply in developing the APIs proposed in this rule.

Again, we note that the temporary federal medical assistance percentage (FMAP) increase available under section 6008 of the Families First Coronavirus Response Act (Pub. L. 116–127) does not apply to administrative expenditures.

In the CMS Interoperability and Patient Access final rule, the payer-to-payer data exchange is required for Medicaid managed care plans with an applicability date of January 1, 2022 and codified at 42 CFR 438.62(b)(1)(vi) and (vii). Because this rule proposes to require implementation and use of a Payer-to-Payer API for Medicaid FFS programs, and to be consistent with the other provisions of this rule, we propose to codify the requirement for states in connection with Medicaid FFS programs at 42 CFR 431.61(b), amend the requirement specific to Medicaid managed care plans at 42 CFR 438.62(b)(1)(vii) to sunset the requirements at 438.61(b)(1)(vi) when the new requirements take effect with the rating period beginning on or after January 1, 2023, and revise 42 CFR 438.242(b)(7) to add a requirement for Medicaid managed care plans to comply with the requirement imposed on Medicaid FFS program using a cross reference to 42 CFR 431.61. Codifying the requirement for Medicaid managed care plans this way would ensure that the same standards for payer-to-payer data exchange apply across the Medicaid program, regardless of it is through the FFS or managed care delivery system. Similarly, we are proposing revisions to the CHIP managed care regulations to require CHIP managed care entities to comply with the requirement for an API for payer-to-payer data exchanges that applies to CHIP FFS programs; the CHIP managed care entities would also have to comply by the rating period beginning on or after January 1, 2023. We propose to codify this policy for CHIP managed care entities at 42 CFR 457.1233(d)(4). Because CHIP managed care entities are required by current 42 CFR 457.1216 to comply with 42 CFR 438.62, our proposed revisions to 42 CFR 438.62 (for Medicaid managed care plans) would also apply to CHIP managed care entities.

We request comment on these proposals.

4. Enhancing the Payer-to-Payer Data Exchange—Payer-to-Payer API

In the Interoperability and Patient Access final rule, we established a payer-to-payer data exchange that required certain impacted payers to share clinical data as defined in the USCDI version 1 data set with the approval and at the direction of a current or former enrollee. We did not require that this data exchange take place using an API, though we encouraged payers to look at an API solution. We are now proposing to enhance this payer-to-payer data exchange in two ways. First, we are proposing to require that this payer-to-payer data exchange take place via an API. Second, we propose to require impacted payers to make available, at a minimum, not only the USCDI version 1 data, but also claims and encounter data (not including cost information) that the payer maintains with a date of service on or after January 1, 2016, conformant with the same IGs proposed for these data types in sections II.A. and II.B. of this rule, as well as information about pending and active prior authorization decisions, beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023) via this standards-based Payer-to-Payer API. This Payer-to-Payer API is proposed to use the technical standards and the same base content and vocabulary standards used for the Patient Access API. These proposed requirements would be codified for Medicaid and CHIP FFS programs at 42 CFR 431.61(b) and 42 CFR 457.731(b), Medicaid managed care plans other than NEMT PAHPs at 42 CFR 438.242(b)(7), CHIP managed care entities at 42 CFR 457.1233(d)(4), and QHP issuers on the FFEs at 45 CFR 156.221(f)(2). Ultimately, we believe sharing this information across payers can improve operational efficiencies, reduce unnecessary care, reduce care costs, and improve patient outcomes.

Consistent with what was finalized in the CMS Interoperability and Patient Access final rule, impacted payers who receive these data would be required to incorporate the data into the payer's records about the enrollee, making these data part of the data maintained by the receiving payer. We note that unless expressly stated as part of a specific proposal, CMS is not proposing to require the receiving payer to specifically review or act on the data received from other payers. As explained in the CMS Interoperability and Patient Access final rule for the Payer-to-Payer Data Exchange, payers could choose to indicate the part of a data exchange that was received from a previous payer so a future receiving payer, provider, or even patient, would know where to direct questions (such as how to address contradictory or inaccurate information); and we propose that the same principle would apply to this enhancement. As noted in the CMS Interoperability and Patient Access final rule (85 FR 25566), impacted payers would be under no obligation under this proposal to review, utilize, update, validate, or correct data received from another payer. However, if a payer should choose to review or otherwise use received data, the payer would not be prohibited from doing so under any of the policies in this proposed rule.

We believe a patient's current payer is in an optimal position to maintain a cumulative record for the patient and facilitate that record following the patient through their health care journey. Whereas patients may see many providers, patients' payers have a more holistic view of a patient's care across providers over time. It is important to note that, under these proposals, impacted payers would not be required to exchange any cost information, such as enrollee cost-sharing and provider remittances. While there could be some value to patients accessing this cost information via the Patient Access API, sharing this cost information between payers would have only limited beneficial impact on care

[56] See SHO # 20–003, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho20003.pdf.*

coordination. We believe that sharing claims and encounter information without the cost details, however, could complement the clinical data as defined in the USCDI by providing more information to support care coordination and efficient operation, including, for example, information about the patient's care history. As we discussed in the CMS Interoperability and Patient Access final rule, and in section II.B. of this proposed rule, claims and encounter data, used in conjunction with clinical data, can offer a broader and more holistic understanding of an individual's interactions with the health care system (85 FR 25523).

In addition, we believe it would be highly valuable for payers to share pending and active prior authorization decisions generally, and particularly when a patient enrolls with a new payer. Currently, when a patient enrolls with a new payer, little to no information is sent from the previous payer to the new payer about the prior authorization decisions the previous payer made or was in the process of making relevant to the patient's ongoing care. While some previous payers will make this information available to the new payer upon request, most new payers do not request such information. Instead, most payers with a newly enrolling patient require the treating provider to request a new prior authorization, even for items or services for which a patient has a valid and current prior authorization approval. The burden of repeating the prior authorization process with the new payer falls on the provider and patient, which often impedes continuity of care, impacting patient outcomes and complicating care coordination. In addition, it adds burden to payers who must expend time and effort to review a potentially unnecessary and duplicative prior authorization request. While we do not propose to require the new payer that would receive the prior authorization information and documentation under this proposal to specifically consult this information, at the very least this information would now form part of the patient's cumulative record and thus be available to be shared by the payer with the patient and the patient's care team. Should a payer choose to consult this information, it could reduce payer, provider, and patient burden, and possibly cost, over time. If a new payer consulted this information, it could mean fewer prior authorization requests the provider needs to send and the payer needs to process. Patients would not have to wait for a new prior authorization for an item or service they have already demonstrated they need and would benefit from. This is especially true of patients with chronic conditions who are changing payers. As a result, sharing this information between payers could have a significant impact on payers, providers, and patients. Payers and providers could see reduced burden, and patients could experience better, continuous care.

We discuss prior authorization and our proposals regarding prior authorization processes in more depth in section II.C. of this proposed rule. As part of this Payer-to-Payer API proposal, we propose at 42 CFR 431.61(b) for Medicaid FFS, at 42 CFR 438.242(b)(7) for Medicaid managed care, at 42 CFR 457.731(b) for CHIP FFS, at 42 CFR 457.1233(d)(4) for CHIP managed care, and at 45 CFR 156.221(f)(2) for QHP issuers on the FFEs to require all impacted payers make available pending and active prior authorization decisions (and related clinical documentation and forms) via the Payer-to-Payer API using the HL7 FHIR Da Vinci Payer Coverage Decision Exchange (PCDE) [57] IG proposed at 45 CFR 170.215(c)(4) and integrate this information into the patient's record for review and consideration. For purposes of this proposal, ''active prior authorization decisions'' means prior authorizations that are currently open, and being used to facilitate current care, and are not expired or no longer valid. By ''pending prior authorization decision,'' we mean prior authorizations that are under review, either pending submission of documentation from the provider, or being evaluated by the payer's medical review staff, or for another reason have not yet had a determination made. As discussed in section II.A.2. of this proposed rule, when we say ''items and services,'' for purposes of this rule, we are talking about items and services excluding prescription drugs and/or covered outpatient drugs. ''Status'' of the prior authorization means information about whether the prior authorization is approved, denied, or if more information is needed to complete the request. We are proposing that impacted payers, consistent with the proposals for the Patient Access API in section II.A. and the Provider Access API in section II.B. of this proposed rule, limit sharing to pending and active authorizations to reduce the volume of outdated or irrelevant information shared between payers. We propose that this documentation would include the date the prior authorization was approved, the date the authorization ends, as well as the units and services approved and those used to date.

We request comment on this proposal.

In addition to these proposals, we also seek comment for possible future rulemaking on the extent to which we should consider explicitly requiring payers to demonstrate that they have reviewed and considered these previous prior authorization decisions and associated clinical documentation from a patient's previous payer before requiring patients to undergo a new prior authorization process. Such a requirement could minimize the possibility of duplicate testing for the purposes of reaffirming coverage or renewing a prior authorization for a covered benefit that is part of the patient's current care plan. As discussed in section II.C., providers experience burden when navigating through each payer's set of prior authorization policies or rules. It is a burden to payers to administer a prior authorization process. In addition, requiring a new prior authorization can also delay patient care. We also seek comment for possible future rulemaking on whether to, in the alternative, require payers to honor a previous payer's active prior authorization decisions at the time the enrollee moves from one payer to a new payer for some length of time, such as 30, 45, or 60 days, or if there are situations where this may not be possible or appropriate and why.

This Patient Access API requirement was finalized at 42 CFR 422.119(a) through (e) for MA organizations, 42 CFR 431.60(a) through (e) for Medicaid FFS, 42 CFR 438.242(b)(5) for Medicaid managed care, 42 CFR 457.730(a) through (e) for CHIP FFS, 42 CFR 457.1233(d) for CHIP managed care, and at 45 CFR 156.221(a) through (e) for QHP issuers on the FFEs (85 FR 25558 through 25559). Further, we are proposing the same content and compliance with the same technical standards, the same documentation requirements, and the same discontinuation and denial of access requirements for the Patient Access API (discussed in section II.A. of this proposed rule) and the Provider Access API (discussed in section II.B. of this proposed rule) as we are proposing for this proposed Payer-to-Payer API. This degree of overlap and use of the same requirements should ease the burden for payers in developing and implementing these various APIs.

[57] HL7 International. (n.d.). Da Vinci Payer Coverage Decision Exchange (PCDE) FHIR IG. Retrieved from *http://www.hl7.org/fhir/us/davinci-pcde/history.cfml.*

In addition, all of these APIs would need to be conformant with the same IGs proposed for claims and encounter data as well as the USCDI version 1 data as discussed in section II.A. for the Patient Access API and section II.B. of this proposed rule for the Provider Access API. The Patient Access API, in particular, provides the foundation necessary to share claims, encounter, and clinical data. Because the same data elements would be exchanged through all three APIs, payers would have already formatted these data elements and prepared their systems to share these standardized data via a FHIR-based API, doing much of the work needed to implement this Payer-to-Payer API. As a result, we believe payers would have devoted the development resources needed to stand up a FHIR-based API infrastructure that could be adapted for expanded interoperability use cases after 2021, when they have implemented the Patient Access API.

However, we are proposing that the Payer-to-Payer API and the Patient Access and Provider Access APIs be conformant with different IGs for sharing prior authorization decisions. In sections II.A. and II.B. of this proposed rule, we propose that the Patient Access and Provider Access APIs would need to be conformant with the PDex IG when sharing prior authorization decisions with patients and providers, respectively. We propose to require the Payer-to-Payer API be conformant with the PCDE IG instead, when sharing this information, as this IG addresses data sharing between payers more specifically. PDex would be better suited for an exchange from a payer to patients and providers. Given the shared FHIR resources across the two IGs, we do not believe requiring the use of both IGs—one for each appropriate recipient of the data—adds significant burden to payers.

5. Payer-to-Payer API—Sharing Data at Enrollment

As finalized in the CMS Interoperability and Patient Access final rule, the payer-to-payer data exchange is initiated at the direction of the patient. We discussed proposed enhancements to this patient-directed data sharing in the previous section where we noted this data exchange would now require the use of an API and include additional data to be shared. In addition to this case-by-case, patient-directed data sharing, however, we also propose a second, new Payer-to-Payer API data sharing opportunity that would be offered to all patients receiving coverage from a payer impacted by this proposed rule as an option at the time of enrollment with a new payer, if both the current payer and new payer would be subject to the requirements in this proposal. We propose to codify this new Payer-to-Payer API requirement at 42 CFR 431.61(c) for Medicaid FFS, at 42 CFR 438.242(b)(7) for Medicaid managed care, at 42 CFR 457.731(c) for CHIP FFS, at 42 CFR 457.1233(d)(4) for CHIP managed care, and at 45 CFR 156.222(b) for QHP issuers on the FFEs. We are proposing that this exchange be offered to patients receiving coverage from payers impacted by this proposed rule as an option when they enroll with a new payer. The new payer, if an impacted payer under this proposed rule, could then request the data from the previous payer for patients who opt-in to this data sharing via the Payer-to-Payer API.

We are proposing the following if a patient enrolls during a specified annual open enrollment period, or, for a payer that does not have such an enrollment period, during the first calendar quarter of each year. If such a patient opts-in to having their new payer obtain the applicable data from their previous payer at this specified time, we are proposing to require that impacted new payers request such data from the previous payers via the Payer-to-Payer API using the HL7 FHIR Bulk Data Access (Flat FHIR) specification within one week of the end of the enrollment period or the first calendar quarter of each year. The previous payer, if an impacted payer, would be required to respond to this request within one business day of receiving the request.

We do recognize that not every impacted payer has a dedicated annual open enrollment period. For those payers, we are proposing that the opt-in Bulk data sharing occur at the end of the first calendar quarter of each year. We seek comment on whether this is the best time to require the data sharing for such payers. Based on our experience with Bulk data sharing discussed in section II.B.4. of this proposed rule, and based on discussions with payers and technology developers, we believe the efficiencies afforded by having at least one time per year where payers could facilitate this data sharing and employ the Bulk specification to leverage the opportunity to make data available for as many patients as possible at one time could be potentially significant because such an asynchronous data sharing option could limit drain on system resources and promote a dedicated and efficient opportunity each year to ensure patients have their health information follow them as they move from payer to payer, permitting better care coordination and potentially better health outcomes. Therefore, we seek comment on how best to operationalize this across impacted payers. We also see comment on whether the timeframes for the new payer requesting these data—within one week of this enrollment or other defined period ending—and the old payer sending these data—within one business day of receiving the request—are the optimal timeframes and what other timeframes payers may want us to consider. Would payers be able to accommodate a shorter request timeframe—such as one to three business days after the end of the defined enrollment period? Or, do payers need more than one business day to respond to a request? If so, would payers want to have a one week turnaround for data requests? We do think it is important for patient data to move to the new payer as soon as possible to facilitate care coordination, and to ensure the patient's data is available to their providers and to them, hence our current proposal. We also seek comment on whether we should consider any other factors regarding the process and timeline for this Payer-to-Payer API data sharing at enrollment.

Efficient data sharing between payers would ensure that information that could support payer operations and benefit patient care is available to a new payer at the very start of the patient's care covered by a new payer. This could facilitate care coordination and continuity of care. This proposal would require the new payer to adopt a process to obtain the name of an enrollee's previous payer, or concurrent payer if the enrollee has coverage through more than one payer, as part of the enrollment process. Subsequently, the new payer would be required to receive the enrollee's clinical data as defined in the USCDI version 1 and adjudicated claims and encounter data, as well as pending and active prior authorization decisions, from the previous or concurrent payer, if that payer maintains such data for the relevant enrollee.

Under this proposal, impacted payers would be required to maintain a process for capturing data about each patient's previous payer and concurrent payer (if there is one) at enrollment to facilitate this payer-to-payer data sharing. While we wish to leave it to each impacted payer how they choose to implement capturing this information, we seek comment on potential solutions to support payers in obtaining this previous and concurrent payer information in an effort to provide all impacted payers with options to consider. As to concurrent payers, we anticipate that many payers already

have a process in place to request and update information of this sort for coordination of benefits or to implement Medicare Secondary Payer requirements (if applicable), and we wish to allow payers to maintain their current processes if that is beneficial and feasible when incorporating the use of the Payer-to-Payer API into this process.

We are proposing at 42 CFR 431.61(c)(5) for Medicaid FFS, at 42 CFR 438.242(b)(7) for Medicaid managed care, at 42 CFR 457.731(c)(5) for CHIP FFS, at 42 CFR 457.1233(d)(4) for CHIP managed care, and at 45 CFR 156.222(b)(5) for QHP issuers on the FFEs, that payers put a process in place to allow enrollees to opt-in to this payer-to-payer data sharing at enrollment, similar to the opt-in proposal under the Provider Access APIs detailed in section II.B. of this proposed rule. If enrollees do not actively opt-in, impacted payers would not be required to share their data through the Payer-to-Payer API as described under this proposal. This means that only at the defined enrollment period, or at the end of the first calendar quarter for payers that do not have a defined enrollment period, are impacted payers required under this proposal to have a process in place to capture a patient's preference to opt-in to this data sharing under this proposal. If a patient would like their data shared with another payer at another time throughout a given year, the patient could request that data exchange under the enhanced payer-to-payer data exchange proposal discussed in section II.D.4. of this proposed rule.

We seek comment on these proposals.

Some individuals may have concurrent coverage with two or more of the payers impacted by this proposal. We also propose at 42 CFR 431.61(c)(4) for Medicaid FFS, at 42 CFR 438.242(b)(7) for Medicaid managed care, at 42 CFR 457.731(c)(4) for CHIP FFS, at 42 CFR 457.1233(d)(4) for CHIP managed care, and at 45 CFR 156.222(b)(4) for QHP issuers on the FFEs that when an enrollee has concurrent coverage with two or more impacted payers, the impacted payers must make the patient's data available to the concurrent payer quarterly, in addition to when the enrollee obtains new coverage from a payer subject to these proposed requirements. We propose to require payers to provide enrollees the opportunity to opt-in to initiate this quarterly data sharing. This data exchange among concurrent payers is expected to support better care coordination and more efficient operations. We also considered whether to propose more frequent exchange (weekly or monthly), and less frequent exchange (semi-annually or annually); however, we believe a quarterly data exchange would strike the right balance in providing accurate, timely data with minimal payer burden.

We request comment on this proposal, including the appropriate frequency for this payer-to-payer exchange for enrollees with concurrent coverage. We also seek comment on whether payers prefer the flexibility to define their own process for facilitating how patients opt-in to this quarterly data sharing and if there are additional considerations that we should take into account to facilitate data sharing using the Payer-to-Payer API between concurrent payers.

We appreciate that a patient may be moving to or from a payer, or have concurrent coverage with a payer not subject to the requirements in this proposed rule, such as when a patient moves from a QHP on the FFE to an employer-based plan, as an employer-based plan is not impacted by this rulemaking. We encourage all payers to consider the value of implementing a Payer-to-Payer API so that all patients, providers, and payers in the U.S. health care system may ultimately experience the benefits of such data sharing. For instance, we are exploring best next steps for the Medicare FFS program to participate in a Payer-to-Payer API data exchange with all interested payers. That said, if an impacted payer learns that a previous or concurrent payer is not subject to this proposal, we encourage the new payer to evaluate if the other payer can accommodate an API data exchange and seek such exchange in accordance with applicable law. However, an impacted payer would not be required to try to send data to or receive data from a payer that is not required to exchange data through the Payer-to-Payer API under this proposal.

As discussed in section II.B. of this proposed rule, and as further illustrated in the discussion in this section of this proposed rule, it may be valuable for a payer to share data with another payer for more than one patient at a time. It is likely that if payers are sharing data at enrollment, impacted payers would have many patients' data to share at one time. In such a situation, it can be burdensome to make an API call for each patient. This could require significant technological resources and time. To introduce additional efficiencies, we are proposing that this required Payer-to-Payer API must be able to share the specified data conformant with the HL7 FHIR Bulk Data Access (Flat FHIR) specification at 45 CFR 170.215(a)(4) to facilitate sharing information relevant to one or more patients at one time. We are proposing to codify this specific requirement at 42 CFR 431.61(c)(1) for Medicaid FFS, at 42 CFR 438.242(b)(7) for Medicaid managed care, at 42 CFR 457.731(c)(1) for CHIP FFS, at 42 CFR 457.1233(d)(4) for CHIP managed care, and at 45 CFR 156.222(b)(1) for QHP issuers on the FFEs.

We request comment on this proposal.

As with the proposal for the Provider Access API, discussed in section II.B. of this proposed rule, we invite comment on the tradeoffs and benefits of having the Payer-to-Payer API available with and without the use of the HL7 FHIR Bulk Data Access (Flat FHIR) specification. We believe both approaches would offer benefits to payers depending on the specifics of the situation in which they would need to share patient data. As we look to balance providing this flexibility with the burden of implementing and maintaining APIs, we invite public comment on the benefits of having the Payer-to-Payer API available with and without the use of the HL7 FHIR Bulk Data Access (Flat FHIR) specification, which can be leveraged to request the data for a single patient or multiple patients.

6. Extensions and Exemptions for Medicaid and CHIP

If our proposals regarding the Payer-to-Payer API are finalized, we would encourage state Medicaid and CHIP FFS programs to implement the Payer-to-Payer API as soon as possible understanding the many benefits of the API as discussed previously in this section.

However, we also recognize that state Medicaid or CHIP FFS agencies could face certain unique circumstances that would not apply to other impacted payers, as discussed in more detail later in this section. As a result, a few states might need to seek an extension of the compliance deadline or an exemption from these requirements. To address this concern, we are proposing a process through which states may seek an extension of and, in specific circumstances, an exemption from, the Payer-to-Payer API requirements if they are unable to implement these API requirements, consistent with the extension and exemption proposals for the Provider Access API in section II.B., and the DRLS and PAS APIs in section II.C. of this proposed rule. Providing these flexibilities might allow these states to continue building technical capacity in support of overall interoperability goals consistent with their needs. Therefore, we propose the following.

Extension. At 42 CFR 431.61(e)(1) and 42 CFR 457.731(e)(1), respectively, we propose to provide states—for Medicaid FFS and CHIP FFS—the opportunity to request a one-time extension of up to one (1) year for the implementation of the Payer-to-Payer API specified at 42 CFR 431.61(b) and (c) and 42 CFR 457.731(b) and (c). Unique circumstances that might present a challenge to specific states to meet the proposed compliance date could include resource challenges, such as funding. Depending on when the final rule is published in relation to a state's budget process and timeline, some states may not be able to secure the needed funds in time to both develop and execute implementation of the API requirements by the proposed compliance date. A one-year extension could help mitigate this issue. And, some states may need to initiate a public procurement process to secure contractors with the necessary skills to support a state's implementation of these proposed API policies. The timeline for an open, competed procurement process, together with the time needed to onboard the contractor and develop the API, could require additional time as well. Finally, a state might need to hire new staff with the necessary skillset to implement this policy. Again, the time needed to initiate the public employee hiring process, vet, hire, and onboard the new staff may make meeting the proposed compliance timeline difficult, because, generally speaking, public employee hiring processes include stricter guidelines and longer time-to-hire periods than other sectors.[58] In all such situations, a state might need more time than other impacted payers to implement the requirements.

If a state believes it can demonstrate the need for an extension, its request must be submitted and approved as a part of its annual Advance Planning Document (APD) for MMIS operations costs and must include the following: (1) A narrative justification describing the specific reasons why the state cannot reasonably satisfy the requirement(s) by the compliance date, and why those reasons result from circumstances that are unique to states operating Medicaid or CHIP FFS programs, (2) a report on completed and ongoing implementation activities to evidence a good faith effort toward compliance, and (3) a comprehensive plan to meet implementation requirements no later than one year after the initial compliance date.

An extension would be granted if CMS determines based on the information provided in the APD that the request adequately establishes a need to delay implementation, a good faith effort to implement the proposed requirements as soon as possible, and a clear plan to implement no later than one year after the proposed compliance date. We would expect states to explain why the request for an extension results from circumstances that are unique to states operating Medicaid or CHIP FFS programs. We also solicit comment on whether our proposal would adequately address the unique circumstances that affect states, and that might make timely compliance with the proposed API requirement sufficiently difficult for states and thus justify an extension. In particular, we seek comment on whether we should require or use additional information on which to base the determination or whether we should establish different standards in the regulation text for evaluating and granting the request.

Exemption. At 42 CFR 431.61(e)(2) and 42 CFR 457. 731(e)(2), respectively, we propose two circumstances that would permit state requests for exemption; namely, (1) when at least 90 percent of all covered items and services are provided to Medicaid or CHIP beneficiaries through Medicaid or CHIP managed care contracts with MCOs, PIHPs, or PAHPs, rather than through a FFS delivery system; or (2) when at least 90 percent of the state's Medicaid or CHIP beneficiaries are enrolled in Medicaid or CHIP managed care organizations as defined in 42 CFR 438.2 for Medicaid and 42 CFR 457.10 for CHIP. In both circumstances, the time and resources that the state would need to expend to implement the API requirements may outweigh the benefits of implementing and maintaining the API. As discussed in section II.B. of this proposed rule, unlike other impacted payers, state Medicaid and CHIP FFS programs do not have a diversity of plans to balance implementation costs for those plans with low enrollment. If there is low enrollment in a state Medicaid or CHIP FFS program, there is no potential for the technology to be leveraged for additional beneficiaries as states, unlike other payers, do not maintain additional lines of business.

We acknowledge that the proposed exemption could mean that a few Medicaid or CHIP FFS systems would not receive the benefits of having this API available to facilitate health information exchange. To address this, we propose that states meeting the above thresholds would be expected to employ an alternative plan to enable the electronic exchange and accessibility of health information for those beneficiaries who are served under the FFS program.

A state meeting the above criteria would be permitted to submit a request for an exemption to the requirements for the Payer-to-Payer API once per calendar year for a one-year exemption. The state would be required to submit this annual request as part of a state's annual APD for MMIS operations costs. The state would be required to include in its request documentation that it meets the criteria for the exemption using data from any one of the three most recent and complete calendar years prior to the date the exemption request is made. We note we propose that this request be made annually as from year-to-year the nature of the FFS population could change and so it is important that the state provide the most current information for CMS's consideration.

Exemptions would be granted for a one-year period if a state establishes to CMS's satisfaction that it meets the criteria for the exemption and has established a plan to ensure that all impacted payers would have efficient electronic access to the same information through alternative means.

We request comment on the proposed extension and exemption.

For Medicaid and CHIP managed care, we are not proposing an extension process at this time because we believe that managed care plans are actively working to develop the necessary IT infrastructure to be able to comply with the existing requirements in 42 CFR part 438 and part 457 and also benefit from efficiencies resulting from their multiple lines of business impacted by these interoperability policies. Many managed care plans are part of parent organizations that maintain multiple lines of business, including Medicaid managed care plans and plans sold on the Exchanges. As discussed in the CMS Interoperability and Patient Access final rule (85 FR 25607, 25612, 25620), work done by these organizations can benefit all lines of business and, as such, we do not believe that the proposals in this rule impose undue burden or are unachievable by the compliance date. We are soliciting comment on whether our belief concerning the scope of resources and ability of managed care parent organizations to achieve economies of scale is well-founded. Further, we seek comment on whether an extension process is warranted for

[58] State hiring processes are comparable with federal hiring processes. According to OMB, the average time-to-hire for federal employees was 98.3 days in 2018, significantly higher than the private sector average of 23.8 days. See: *https://www.opm.gov/news/releases/2020/02/opm-issues-updated-time-to-hire-guidance/.*

certain managed care plans to provide additional time for the plan to comply with the requirement at proposed 42 CFR 438.242(b)(7) (which cross references 42 CFR 438.61(b) and (c)) for Medicaid managed care plans and at proposed 42 CFR 457.1233(d)(4) (which cross references 42 CFR 457.731(b) and (c)) for CHIP managed care entities. While we are not proposing such a process for managed care plans and entities and do not believe one is necessary for the reasons outlined here, we are open to considering one if necessary. If we adopt an extension process for these managed care plans and entities, what criteria would a managed care plan or entity have to meet to qualify for an extension? Should the process consider, for example, enrollment size, plan type, or some unique characteristic of certain plans that could hinder their achievement of the proposed requirements by the proposed compliance date? Also, we seek comment on whether, if we finalize such a process for Medicaid managed care plans or CHIP managed care entities, the state or CMS should manage the process and whether states could successfully adopt and implement the process on the timeline necessary to fulfill the goals and purposes of the process. Consistent with the exception process proposed for QHP issuers on the FFEs at 45 CFR 156.222(d), we would expect any extension request to include, at a minimum, a narrative justification describing the reasons why a plan or entity cannot reasonably satisfy the requirements by the proposed compliance date, the impact of non-compliance upon enrollees, the current or proposed means of providing electronic health information to providers, and a corrective action plan with a timeline to achieve compliance.

We do propose, however, to exclude non-emergency transportation (NEMT) PAHPs from the Payer-to-Payer API proposals. In this rule, we propose to require MCOs, PIHPs, and PAHPs other than NEMT PAHPs (as defined at 42 CFR 438.9(a)) to implement and maintain the Payer-to-Payer API. We believe that the unique nature and limited scope of the services provided by NEMT PAHPs is not consistent with the proposed purposes of the Payer-to-Payer API proposed at 42 CFR 431.61(b) and (c). Specifically, we do not believe that having all other Medicaid managed care plans, such as acute care or dental managed care plans, be required to request, receive, and incorporate into the plan's records NEMT data from an enrollee's prior or concurrent payer would help achieve the goals of the Payer-to-Payer API, namely to help avoid unnecessary care, ensure that providers are able to spend time with patients focusing on care versus collecting redundant information, or improve patient care through enhanced care coordination. Conversely, we do not believe having NEMT PAHPs be required to request, receive, and incorporate into its records enrollee data from other managed care plans contributes to achieving the goals of the Payer-to-Payer API given the unique nature and limited scope of the services they provide.

We note that the HIPAA Privacy Rule, at 45 CFR 164.502, permits a covered entity to use or disclose PHI for certain treatment, payment, or health care operations without individual authorization. As such, we believe a health plan that needs NEMT PAHP utilization for treatment, payment, or the applicable health care operations for a current enrollee, would generally be permitted to under the applicable HIPAA provisions.

As mentioned previously in this proposed rule, although Medicare FFS is not directly impacted by this rule, we do note that we are targeting to implement a Payer-to-Payer API for the Medicare FFS program, if finalized. In this way, the Medicare FFS Payer-to-Payer API would conform to the same requirements that apply to the impacted payers under this rulemaking, as applicable, so that Medicare FFS beneficiaries would also benefit from this data sharing.

7. Exception for QHP Issuers

With regard to QHP issuers on the FFEs, similar to our exceptions process noted in the CMS Interoperability and Patient Access final rule for the Patient Access API (85 FR 25552 through 25553) and in section II.B.6.e. of this proposed rule for the Provider Access API, we are also proposing an exception for the Payer-to-Payer API at 45 CFR part 156.222(d). As such, if a plan applying for QHP certification to be offered through a FFE believes it cannot satisfy the Payer-to-Payer API requirements, the issuer must include as part of its QHP application a narrative justification describing the reasons why the plan cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance upon enrollees, the current or proposed means of providing health information to payers, and solutions and a timeline to achieve compliance with the requirements of this section. Further, we propose that the FFE may grant an exception to these requirements if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals and qualified employers in the state or states in which such Exchange operates.

We request comment on this proposal.

8. Statutory Authorities for Payer Exchange Proposals

a. Medicaid and CHIP

For Medicaid managed care plans and Medicaid state agencies, we are proposing to require the implementation of a Payer-to-Payer API to exchange claims, encounter, clinical, and pending and active prior authorizations data between payers at a patient's request or any time a patient changes payers using a FHIR-based API. Our proposals in this section fall generally under our authority in the following provisions of the statute:

- Section 1902(a)(4) of the Act, which requires that a state Medicaid plan provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the state Medicaid plan.
- Section 1902(a)(8) of the Act, which requires states to ensure that Medicaid services are furnished with reasonable promptness to all eligible individuals.
- Section 1902(a)(19) of the Act, which requires states to ensure that care and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

We note statutory authority for proposals to require specific IGs for this and all APIs proposed in this rule is discussed in section II.A.3. of this proposed rule.

We believe these proposals related to the Payer-to-Payer API are authorized by these provisions of the Act for the following reasons. First, because the Payer-to-Payer API is designed to enable efficient exchange of data between payers, it is anticipated to help state Medicaid programs improve the efficiencies and simplicity of their own operations, consistent with sections 1902(a)(4) and (a)(19) of the Act. Use of the Payer-to-Payer API could introduce efficiencies in providing Medicaid services, by reducing duplicate prior authorization requests, referrals, or tests. In addition, as is discussed in section II.B. of this proposed rule, with respect to the Provider Access API and the Bulk specification, this Payer-to-Payer API, by allowing payers to share health information for one or more patients at once, could increase efficiency and simplicity of administration. It could give payers access to all of their enrollees' information with limited

effort and enable the state to then make that information available to providers and to patients through the Provider Access and Patient Access APIs. And, it could reduce the amount of time needed to evaluate a patient's current care plan and possible implications for care continuity, which could introduce efficiencies and improve care. Use of the proposed Bulk specification allows state Medicaid programs to receive information on a full panel of patients at once, thus expediting the data collection process. Sharing patient information for a full panel of patients at a specified time annually, such as at the end of the first calendar quarter, would help to ensure payers receive patient information in a timely manner when a beneficiary moves to a new payer, and therefore, could lead to more appropriate service utilization and higher beneficiary satisfaction by supporting efficient care coordination and continuity of care as beneficiaries move from payer to payer, which could lead to better health outcomes.

Second, the proposals are expected to help states and managed care plans furnish Medicaid services with reasonable promptness and in a manner consistent with beneficiaries' best interests, consistent with section 1902(a)(8) and (a)(19) of the Act, for the following reasons. If states were to share information about Medicaid beneficiaries or former beneficiaries with other payers with whom these beneficiaries are enrolled, they could support opportunities for improved care coordination for Medicaid beneficiaries and former beneficiaries. Exchanging information about Medicaid beneficiaries and former beneficiaries between payers might also reduce the amount of time needed to evaluate a Medicaid beneficiary's current care plan, their health risks, and their health conditions at the time that beneficiary enrolls with the Medicaid program. Exchanging this information between payers could also better support care continuity for Medicaid beneficiaries. As discussed in section II.D.4. of this proposed rule, if a state Medicaid program has access to a previous payer's pending and active prior authorization decisions, the Medicaid program could choose to accept the existing decision and support continued patient care without requiring a new prior authorization or duplicate tests. This information exchange might be of particular value in improving care continuity for beneficiaries who might churn into and out of Medicaid coverage, or have concurrent coverage in addition to Medicaid. The proposal could also improve the provision of Medicaid services, by potentially helping to ensure that Medicaid beneficiaries who may require coordinated services with concurrent payers could be identified and provided case management services, as appropriate.

For Medicaid managed care plans, the proposed exchange of claims, encounter, USCDI, and some prior authorization data would greatly enhance an MCO's, PIHP's, or PAHP's ability to fulfill its obligations under 42 CFR 438.208(b) which require them to: Implement procedures to deliver care to and coordinate services including ensuring that each enrollee has an ongoing source of appropriate care; coordinate services between settings of care, among Medicaid programs, and with community and social support providers; make a best effort to conduct an initial screening of each enrollee's needs; and share with the state or other MCOs, PIHPs, and PAHPs serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities. The data provided via the Payer-to-Payer API proposed in this rule would give managed care plans the information needed to much more easily perform these required functions, thus enhancing the effectiveness of the care coordination and helping enrollees receive the most appropriate care in an effective and timely manner.

For CHIP, we are proposing these requirements under our authority in section 2101(a) of the Act, which states that the purpose of title XXI is to provide funds to states to provide child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage. We believe the provisions in this proposed rule could strengthen our ability to fulfill these statutory obligations in a way that recognizes and accommodates the use of electronic information exchange in the health care industry today and would facilitate a significant improvement in the delivery of quality health care to our beneficiaries.

As with the Medicaid FFS and Medicaid managed care programs, the proposals in this section of the proposed rule for CHIP FFS and CHIP managed care require the use of a Payer-to-Payer API to exchange claims, encounter, clinical and pending and active prior authorization data at a beneficiary's request, or any time a beneficiary changes payers, using a FHIR-based API. The current payer could use data from the prior payer to more effectively or accurately respond to a request for a prior authorization, because under this proposal, a new payer would have historical claims or clinical data upon which they may review a request with more background data. Access to information about new patients could enable appropriate staff within the CHIP program to more effectively coordinate care and conduct the care management because they would have better data available to make decisions for planning. In many cases, patients do not remember what services they have had, what vaccines they have had, or other possibly relevant encounters that could help payers manage their care. This proposal is consistent with the goal of providing more informed and effective care coordination, which could help to ensure that CHIP services are provided in a way that supports quality care, which aligns with section 2101(a).

b. QHP Issuers on the FFEs

For QHP issuers on the FFEs, we are proposing these new requirements under our authority in section 1311(e)(1)(B) of the Affordable Care Act, which affords the Exchanges the discretion to certify QHPs if the Exchange determines that making available such health plans through the Exchange is in the interests of qualified individuals in the state in which the Exchange operates. Existing and emerging technologies provide a path to make information and resources for health and health care management universal, integrated, equitable, accessible to all, and personally relevant.

Requiring QHP issuers on the FFEs to build and maintain a Payer-to-Payer API would allow the seamless flow of claims and encounter data, the clinical data the payer maintains for a patient as defined in the USCDI version 1, as well as their pending and active prior authorization decisions, from payer to payer. We believe that ensuring a means for an enrollee's new issuer to electronically obtain the enrollee's claims, encounter, and clinical data, as well as prior authorization information with corresponding medical records, from the previous issuer will reduce administrative burden and result in more timely and efficient care coordination and responses to prior authorization requests.

We believe it is necessary that QHP issuers on FFEs have systems in place to send information important to care coordination with departing enrollees, and that QHP issuers also have systems in place to receive such information from payer to payer on behalf of new and concurrent enrollees, as appropriate

and consistent with the proposals in this section. Therefore, we believe certifying only health plans that make enrollees' health information available to them and their providers, and as discussed in this section, other payers, in a convenient, timely, and portable way is in the interests of qualified individuals and qualified employers in the state in which an FFE operates. We encourage SBEs to consider whether a similar requirement should be applicable to QHP issuers participating in their Exchange.

We previously finalized the Payer-to-Payer Data Exchange in the CMS Interoperability and Patient Access final rule, where, with the approval and at the direction of an enrollee, one payer would have to send clinical data as defined in the USCDI version 1 to another payer named by the enrollee. We are now requiring this to be done via an API and adding claims and encounter data, as well as pending and active prior authorization decisions.

We also believe that requiring QHP issuers on the FFEs to use the Bulk Specification for the Payer-to-Payer API would improve the efficiency and simplicity of data transfers between issuers, by enabling the exchange of all data for all patients at once. We believe the opportunity to support an exchange of large volumes of patient data, rather than data for one patient at a time, may be cost effective for the issuers, and having patient care at the beginning of a new plan, could assist the new payer in identifying patients who need care management services, which could reduce the cost of care. Taking in volumes of data would also enable the QHPs to perform analysis on the types of new patients in their plan, if they choose to analyze data for existing patients as well.

E. Adoption of Health IT Standards and Implementation Specifications

As first mentioned in section II.A. of this proposed rule, at 45 CFR 170.215, ONC is proposing the specific IGs discussed in sections II.A., II.B., II.C., and II.D. of this proposed rule for HHS adoption in support of the API provisions included in this proposed rule. This section outlines ONC's authority to do so, and how this will support HHS generally, and CMS specifically, in continuing to advance standards and the use of FHIR to reduce burden, improve the prior authorization process, and support patient electronic access to health information.

1. Statutory Authority

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created ''Title XXX—Health Information Technology and Quality'' (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health IT and exchange of electronic health information (EHI). Subsequently, Title IV of the 21st Century Cures Act (Pub. L. 114–255) (''Cures Act'') amended portions of the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

a. Adoption of Standards and Implementation Specifications

Section 3001 of the PHSA directs the National Coordinator for Health Information Technology (National Coordinator) to perform duties in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information. Section 3001(b) of the PHSA establishes a series of core goals for development of a nationwide health information technology infrastructure that:

- Ensures that each patient's health information is secure and protected, in accordance with applicable law;
- Improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;
- Reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;
- Provides appropriate information to help guide medical decisions at the time and place of care;
- Ensures the inclusion of meaningful public input in such development of such infrastructure;
- Improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;
- Improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;
- Facilitates health and clinical research and health care quality;
- Promotes early detection, prevention, and management of chronic diseases;
- Promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and
- Improves efforts to reduce health disparities.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria, and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1) of the PHSA, the Secretary is required, in consultation with representatives of other relevant federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) of the PHSA and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, which is titled ''Subsequent Standards Activity,'' provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the Health IT Advisory Committee (HITAC). As noted in the final rule, ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' (''ONC 2015 Edition Final Rule''), published on October 16, 2015, we consider this provision in the broader context of the HITECH Act and the Cures Act to continue to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria (80 FR 62606).

Under the authority outlined in section 3004(b)(3) of the PHSA, the Secretary may adopt standards, implementation specifications, and certification criteria as necessary even if those standards have not been recommended and endorsed through the process established for the HITAC under section 3002(b)(2) and (3) of the PHSA. Moreover, while HHS has traditionally adopted standards and implementation

specifications at the same time as adopting certification criteria that reference those standards, the Secretary also has the authority to adopt standards or implementation specifications apart from the certification criteria adopted specifically for the voluntary certification of health IT under the ONC Health IT Certification Program.

Finally, the Cures Act amended the PHSA to add section 3004(c) of the PHSA to specify that in adopting and implementing standards under this section, the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.

b. Coordination of Federal Activities With Adopted Standards and Implementation Specifications, and Application to Private Entities

Section 13111 of the HITECH Act requires that when a federal agency implements, acquires, or upgrades health information technology systems used for the direct exchange of individually identifiable health information between agencies and with non-federal entities, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the PHSA, as added by section 13101 of the HITECH Act. Similarly, section 13112 of the HITECH Act states that federal agencies shall require in its contracts and agreements with providers, plans, or issuers that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the PHSA.

2. Background

Consistent with section 3004(b)(3) of the PHSA, we believe the standards and implementation specifications proposed at 45 CFR 170.215 by ONC for HHS adoption are appropriate and necessary and would, if adopted, contribute to key health care priorities of a nationwide health IT infrastructure as described in section 3001(b) of the PHSA. The use of the identified implementation specifications across health IT systems would support more effective prior authorization transactions between providers and payers, and would help to reduce administrative burden and support medical decision-making. Use of the proposed payer data implementation specifications would help to bring together administrative and clinical data, and make such data accessible, which is an essential step to connecting cost and quality data to promote a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services. Finally, use of the additional implementation specifications for a Provider Directory API would support more robust care coordination and increased patient choice through improved availability of health care provider contact and exchange information. In support of these likely outcomes, we note that the CMS proposals in sections II.A., II.B., II.C., and II.D. of this rule detail further benefits that would result from the use of these implementation specifications for each of the relevant CMS payer API requirement proposals.

In the following section, consistent with section 3004(b)(3) of the PHSA and on behalf of the Secretary, ONC proposes to adopt at 45 CFR 170.215(c) implementation specifications for APIs based upon the HL7® FHIR® Release 4 base standard adopted by ONC on behalf of HHS at 45 CFR 170.215(a). The proposed implementation specifications were developed through a voluntary consensus-based standard organization, HL7®, a non-profit standard development organization. In concert with CMS, ONC has led or participated in a variety of activities related to monitoring and evaluating the standards and implementation specifications identified in this proposed rule, utilizing available mechanisms for gathering input on these standards from stakeholders and experts. Based on these activities and input, it is appropriate to propose these specifications for adoption.

a. Standards Development Organization Activities

Consistent with section 3004(c) of the PHSA, the implementation specifications proposed for adoption have been developed through an industry-led, consensus-based public process by a nationwide voluntary consensus-based standards body. HL7® is an American National Standards Institute (ANSI) accredited standards development organization. HL7® FHIR® standards are unique in their ability to allow disparate systems that otherwise represent data differently to exchange such data in a standardized way that all systems can share and consume via standards-based APIs. HL7® FHIR® IGs are also openly accessible, so any interested party can go to the HL7® website and access the IG. Once accessed, all public comments made during the balloting process as well as the IG version history are available for review.

A number of the FHIR® IGs proposed for adoption have been developed by the Da Vinci project, an initiative established in 2018 to help payers and providers positively impact clinical, quality, cost, and care management outcomes.[59] The Da Vinci project is part of the HL7® FHIR® Accelerator Program.[60] Under the Da Vinci project, industry stakeholders have facilitated the definition, design, and creation of use-case-specific reference implementations of solutions based upon the HL7® FHIR® platform to address value-based care initiatives. Because the Da Vinci project is aligned with HL7®, new and revised requirements can become open industry standards.

b. Interoperability Standards Advisory

ONC's Interoperability Standards Advisory (ISA) supports the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the United States health care industry to address specific interoperability needs (see *https://www.healthit.gov/isa*). The ISA is updated on an annual basis based on recommendations received from public comments and subject matter expert feedback. This public comment process reflects ongoing dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be used to address a specific interoperability need.

ONC currently identifies the IGs referenced throughout this proposed rule within the ISA as available standards for a variety of potential use cases. For instance, the HL7® FHIR® Da Vinci PDex IG proposed for adoption at 45 CFR 170.215(c)(6) is currently identified under the ''Query for Documents Outside a Specific Health Information Exchange Domain'' within the ISA.[61] We encourage stakeholders to review the ISA to better understand key applications for the IGs proposed for adoption in this proposed rule.

c. Alignment With Federal Advisory Committee Activities

The HITECH Act established two federal advisory committees, the HIT

[59] See *https://www.hl7.org/about/davinci/.*

[60] See *http://www.hl7.org/documentcenter/public/pressreleases/HL7_PRESS_20190211.pdf.*

[61] See *https://www.healthit.gov/isa/query-documents-outside-a-specific-health-information-exchange-domain.*

Policy Committee (HITPC) and the HIT Standards Committee (HITSC). Each was responsible for advising the National Coordinator on different aspects of health IT policy, standards, implementation specifications, and certification criteria.

Section 3002 of the PHSA, as amended by section 4003(e) of the Cures Act, replaced the HITPC and HITSC with one committee, the Health Information Technology Advisory Committee (HIT Advisory Committee or HITAC). After that change, section 3002(a) of the PHSA established that the HITAC would advise and recommend to the National Coordinator on different aspects of standards, implementation specifications, and certification criteria, relating to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. The Cures Act specifically directed the HITAC to advise on two areas: (1) A policy framework to advance an interoperable health information technology infrastructure (section 3002(b)(1) of the PHSA); and (2) priority target areas for standards, implementation specifications, and certification criteria (section 3002(b)(2) and (3) of the PHSA).

For the policy framework, as described in section 3002(b)(1)(A) of the PHSA, the Cures Act tasks the HITAC with providing recommendations to the National Coordinator on a policy framework for adoption by the Secretary consistent with the Federal Health IT Strategic Plan under section 3001(c)(3) of the PHSA. In February of 2018, the HITAC made recommendations to the National Coordinator for the initial policy framework [62] and has subsequently published a schedule in the **Federal Register**, and an annual report on the work of the HITAC and ONC to implement and evolve that framework.[63] For the priority target areas for standards, implementation specifications, and certification criteria, section 3002(b)(2)(A) of the PHSA identified that in general, the HITAC would recommend to the National Coordinator, for purposes of adoption under section 3004 of the PHSA, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. In October of 2019, the HITAC finalized recommendations on priority target areas for standards, implementation specifications, and certification criteria.[64]

As described above and in the ONC 2015 Edition final rule (80 FR 62606), section 3004(b)(3) of the PHSA provides broad authority for the Secretary to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria. Under this authority, the Secretary may adopt standards, implementation specifications, and certification criteria as necessary even if those standards have not been recommended and endorsed through the process established for the HITAC under section 3002(b)(2) and (3) of the PHSA. While the implementation specifications we are proposing to adopt have not been specifically recommended and endorsed through the HITAC process, the HITAC has recommended the adoption of interoperability standards for specific data flows addressed by the standards we propose to adopt in this proposed rule. In other instances, the HITAC has addressed issues related to interoperability standards for health care operations relevant to these proposed standards. In addition, our proposal to adopt the identified implementation specifications for health care operations under section 3004(b)(3) of the PHSA is consistent with the HITAC policy framework schedule as well as with the priority target areas for standards and implementation specifications.

In the October 16, 2019 recommendations from the HITAC establishing the Interoperability Standards Priority Target Areas, the HITAC recommendations identified a ''need for standards to support the integration of prior authorization (PA).'' The 2019 HITAC annual report (published March 2020) describes a hearing held by the HITAC related to prior authorization and administrative simplification. The report identifies continuing work in this area including highlighting the HL7 standards development organization efforts to improve automation and interoperability of administrative and clinical data, and the Da Vinci Project use case supporting payers sending administrative data to providers using the HL7 FHIR standard.[65]

In CY 2020, ONC charged the HITAC to establish the Intersection of Clinical and Administrative Data (ICAD) Task Force to produce information and considerations related to the merging of clinical and administrative data. The ICAD Task Force explored a wide range of considerations including transport and exchange structures, areas for clinical and operations data alignment, and privacy and security rules and protections. The ICAD Task Force, which included members of the HITAC, NCVHS, industry, and the public, received input from a variety of experts and stakeholders in the field. In November 2020, the ICAD Task Force presented final recommendations [66] to the HITAC, which were then approved by the full Committee. These included a recommendation to ''Establish Standards for Prior Authorization Workflows.'' Specifically, the final report recommends that ONC work with CMS, other federal actors, and standards development organizations to ''develop programmatic (API) specifications to create an authorization (digital prior authorization or related determinations such as Medical Necessity) such that the authorization and related documentation can be triggered in workflow in the relevant workflow system where the triggering event for the authorization is created.'' In addition, the final report identifies for consideration the potential use of HL7® FHIR® standards as part of this recommendation including discussion of: The HL7® FHIR® Da Vinci CRD and DTR IGs, and the HL7® FHIR® Da Vinci PAS IG. These implementation specifications, which ONC proposes to adopt on behalf of HHS in this proposed rule, are discussed extensively as part of the final report as examples of FHIR® specifications that can support prior authorization. ONC has considered these recommendations and considerations in our decision to propose to adopt these prior authorization implementation specifications for health care operations at 45 CFR 170.215(c)(1) through (3) as

[62] HITAC Policy Framework Recommendations, February 21, 2018: *https://www.healthit.gov/sites/default/files/page/2019-07/2018-02-21_HITAC_Policy-Framework_FINAL_508-signed.pdf.*

[63] HITAC Annual Report CY 2019 published March 2, 2020: *https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf.*

[64] HITAC recommendations on priority target areas, October 16, 2019: *https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf.*

[65] HITAC Annual Report CY 2019 published March 2, 2020: *https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf.*

[66] Final Recommendations of the ICAD Task Force, November 2020: *https://www.healthit.gov/sites/default/files/facas/ICAD_TF_FINAL_Report_HITAC_2020-11-06_0.pdf.*

described below in section II.E.3. of this proposed rule.

In addition to the recommendation regarding standards, the final report includes several additional recommendations to support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden, and improve efficiency. We believe our proposal to adopt implementation specifications for health care operations relating to payer data exchange and provider directories at 45 CFR 170.215(c)(4) through (8) will help to advance these aims (see section II.E.3. of this proposed rule for further detail). These include recommendations relating to prioritizing administrative efficiency in relevant federal programs, focusing on convergence of health care standards, and developing patient-centered workflows and standards. We agree with the findings in the final report which state that these recommendations will help to form a solid basis on which to develop the future policies, standards, and enabling technologies that will truly put the patient at the center of an efficient health care information ecosystem.

d. Coordination of Federal Activities With Adopted Standards and Implementation Specifications

Consistent with sections 13111 and 13112 of the HITECH Act, ONC has worked with CMS, HHS agencies, and other federal partners to ensure that federal activities involving the implementation, acquisition, and upgrade of systems that collect and process health information are consistent with the standards and implementation specifications adopted under section 3004 of the PHSA. Aligning the use of such standards and implementation specifications would ensure that the same health IT standards are utilized by federal government programs and federal partners in the health care industry and reduce the risk of competing or inconsistent regulatory requirements increasing stakeholder burden. In addition, alignment of standards and implementation guidance would be expected to reduce fragmentation between and among systems supporting interoperability across the health care continuum for a wide range of use cases.

This includes specific efforts to align federal activities with the standards for APIs adopted in the ONC 21st Century Cures Act final rule as proposed in 2019 and finalized in 2020 (85 FR 25642). The ONC 21st Century Cures Act final rule implements provisions of the Cures Act, which prioritize the adoption of APIs across the health care industry. In the API requirements for payers finalized in the CMS Interoperability and Patient Access final rule (85 FR 25510), which serve as the basis for several additional proposals in this proposed rule, CMS specified alignment of their final policies with technical standards for APIs adopted in the ONC 21st Century Cures Act final rule at 45 CFR 170.215, as well as the USCDI version 1 standard vocabulary standard adopted at 45 CFR 170.213.

In addition to the efforts described in this proposed rule, HHS agencies are exploring areas for alignment to these adopted standards to improve health information exchange for a wide range of use cases. Some examples include:

- In fall 2019, NIH published a request for information on the use of FHIR-based APIs to support research use cases (*https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-150.html*).
- In partnership with the CDC, ONC has worked with HL7 and other standards development process participants to develop an IG to provide developers and IT staff details on how to access prescription drug monitoring program (PDMP) data from clinical systems. This ongoing work includes aligning the IG with updates to existing standards and specifically FHIR Release 4 (*http://hl7.org/fhir/us/meds/2018May/pdmp.html*).
- CMS is leading the PACIO Project for the development of post-acute care FHIR implementation specifications and reference implementations that will facilitate health data exchange through standards-based APIs (*https://confluence.hl7.org/display/PC/PACIO+Project*).

As these efforts continue, ONC will continue to work with federal partners and monitor and analyze interoperability standards and implementation specifications for potential adoption on behalf of the Secretary and HHS. This ongoing process aims to support coordination and alignment of federal activities involving the broad collection and submission of health information, as well as the applicability to private entities engaged in health information exchange with federal partners. The overarching goal is to continue to support the advancement of a nationwide health information technology infrastructure that reduces burden and health care costs, and, most importantly, improves patient care.

3. Proposal To Adopt the Standards for Use by HHS

Consistent with section 3004(b)(3) of the PHSA and the efforts described above to evaluate and identify standards for adoption, on behalf of the Secretary, we propose to adopt the implementation specifications for health care operations at 45 CFR 170.215 to support the continued development of a nationwide health information technology infrastructure as described under section 3001(b) of the PHSA and to support federal alignment of standards for interoperability and health information exchange. Specifically, we propose to adopt the latest versions of the following standards at 45 CFR 170.215 under a new paragraph (c), ''Standards and Implementation Specifications for Health Care Operations.'' We note that each IG is discussed in detail in relation to the specific API it will support in sections II.A., II.B., II.C., and II.D. of this proposed rule, as well as in section IV. of this proposed rule. The latest version of each standard may be accessed at the links provided:

- HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide: Version STU 1.0.0. URL: *http://hl7.org/fhir/us/davinci-crd/history.html.*
- HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide: Version STU 1.0.0. URL: *http://hl7.org/fhir/us/davinci-dtr/history.html.*
- HL7 FHIR Da Vinci—Prior Authorization Support (PAS) Implementation Guide: Version STU 1.0.0. URL: *http://hl7.org/fhir/us/davinci-pas/history.html.*
- HL7 FHIR Da Vinci—Payer Coverage Decision Exchange (PCDE) Implementation Guide: Version STU 1.0.0. URL: *http://www.hl7.org/fhir/us/davinci-pcde/history.cfml.*
- HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide: Version STU 1.0.0. URL: *http://hl7.org/fhir/us/carin-bb/history.html.*
- HL7 FHIR Da Vinci Payer Data Exchange (PDex) Implementation Guide: Version STU 1.0.0. URL: *http://hl7.org/fhir/us/davinci-pdex/history.html.*
- HL7 FHIR Da Vinci—Payer Data Exchange (PDex) US Drug Formulary Implementation Guide: Version STU 1.0.1. URL: *http://hl7.org/fhir/us/Davinci-drug-formulary/history.html.*
- HL7 FHIR Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide: Version STU 1.0.0. URL: *http://www.hl7.org/fhir/us/davinci-pdex-plan-net/history.cfml.*

The implementation specifications proposed for adoption in this rule would be important additions to the group of interoperability specifications adopted by HHS. We believe that by adopting these standards, as proposed at 45 CFR 170.215(c), we would support future alignment across health care system stakeholders and the development of a robust nationwide health IT infrastructure.

Unlike other rulemakings in which ONC has engaged, we are *not* proposing new or revised certification criteria based on the proposed adoption of these standards, nor are we proposing to require testing and certification to these implementation specifications for any existing certification criteria in the ONC Health IT Certification Program. These proposals focus on the adoption of standards and implementation specifications for health information technology to support interoperability and health information exchange across a wide range of potential use cases. We expect that, as new models of care delivery continue to connect clinical and payment data in innovative ways to reduce burden and increase efficiency, the implementation specifications we are proposing to adopt at 45 CFR 170.215(c) will contribute to advancing the interoperability of data across clinical and administrative systems. We further believe this approach will support federal alignment and coordination of federal activities with adopted standards and implementation specifications for a wide range of systems, use cases, and data types within the broad scope of health information exchange. As noted above under section II.E.1.b. of this proposed rule, historically, state, federal, and local partners have leveraged the standards adopted by ONC on behalf of HHS (as well as those identified in the ISA) to inform program requirements, technical requirements for grants and funding opportunities, and systems implementation for health information exchange. We believe the adoption of these standards will support these HHS partners in setting technical requirements and exploring the use of innovative health IT solutions for health information exchange for health care operations.

We additionally propose to make minor revisions to the regulation text at 45 CFR 170.215 to support clarity in the short descriptions of the standards and implementation specifications previously adopted at 45 CFR 170.215(a) and (b). However, we are *not* proposing any changes to the standards and implementation specifications, or versions thereof, previously adopted in 45 CFR 170.215(a) or (b). For the implementation specifications proposed for adoption at 45 CFR 170.215(c) *Standards and Implementation Specifications for Health Care Operations,* we propose to incorporate by reference the specified version of each implementation specification at 45 CFR 170.299.

III. Requests for Information

A. Methods for Enabling Patients and Providers To Control Sharing of Health Information

The CMS Interoperability and Patient Access final rule (85 FR 25510) and this proposed rule are focused on unleashing data in order to empower patients to make informed decisions and empowering providers with the data they need at the moment they are caring for their patients. Stakeholders have shared that they believe part of empowering patients and providers is being sure both have a say in what specific data are shared, when, and with whom. We have started to address this issue within these two regulations. However, we received several comments on the CMS Interoperability and Patient Access proposed rule (84 FR 7610) indicating that patients and providers want more options for controlled sharing of health information beyond what is currently in place under current federal and state laws and regulations. Commenters indicated a preference for a framework that honors an individual's privacy rights, without constricting permissible uses of health information to improve the health and wellness of individuals and populations.

Commenters indicated that some patients want the right to choose which data elements from their health record are shared with specified providers, payers, and third parties. Other patients want the ability to opt out of information exchanges between payers and other stakeholders, such as health care providers and health information exchanges. Some patients indicated that they want their preferences considered in the determination of what data should be shared, and they desire the ability to deem certain aspects of their health information as sensitive and not to be shared under pre-defined circumstances. These patient preferences could provide the opportunity to continue support for patient autonomy and encourage greater patient participation, as patients should have an understanding of how their health information is being shared and used, given this could have an impact on their care.

We received comments indicating that providers want the right to choose if all or some of a patient's data should be shared with other providers and/or the patient themselves, especially if they believe sharing specific information could lead to negative outcomes. One example mentioned is where a provider may want to edit or remove a section of a patient's clinical notes before sharing the record with the patient and/or another provider if the notes indicate a possible diagnosis that may be misunderstood by the patient or lead to stigmatization by another provider who does not possess sufficient context prior to reading the notes.

In regards to providers having the ability to choose which data are shared, we noted that the HIPAA Privacy Rule allows for certain limited circumstances for which a provider may deny a patient access to all or a portion of a patient's data under 45 CFR 164.524(a)(2) and 45 CFR 164.524(a)(3). While there may also be relevant state laws, those that applied additional restrictions on individual access would be preempted by HIPAA, and we note that providing patients with easy access to their health information empowers them to be more in control of decisions regarding their health and well-being.

We also note that in ONC's 21st Century Cures Act final rule (85 FR 25642), ONC finalized certain exceptions to the practice of information blocking, which would allow health care providers, health IT developers, exchanges, and networks to withhold data from other health care providers, health IT developers, exchanges, and networks under certain circumstances. This allows organizations to respect an individual's request not to share information, where not required or prohibited by law.

Additionally, we received comments about the maturity of existing processes that impact access controls of heath IT systems, such as data segmentation, or processes that enable more granular consent capabilities. Commenters indicated concerns that the current standards available are not well adopted or appropriately conformant with the FHIR version 4 (85 FR 25546).

Taking into consideration applicable federal, state, local, and tribal law, we are interested in stakeholder feedback on different methods that enable patients and providers to have more granular control over the sharing of patient health information. Specifically, we are seeking stakeholder feedback on the following questions:

- *Patient Engagement and Provider Discretion.* What role should patients and providers play in data segmentation

decisions? Should patients assume this responsibility and are there mechanisms currently in place or available that could support the documenting of these preferences? Would providing opportunities to express these preferences negatively impact patients who are unable or choose not to state their preferences? For instance, would a patient who did *not* fully understand how, or, or the pros and cons of, sharing some data but not other data be at a disadvantage in some way? How can patients be engaged in these decisions and acquire adequate understanding of how their data are being shared without burdening them? Are there specific situations, use cases, or considerations that should limit how the impacted entity responds to a data segmentation request to either restrict uses and disclosures of some of the data, or to obtain access to some of the data from a patient or provider? Are there unintended consequences of such data segmentation requests or options? If so, how can they be addressed?

- *Methods and Readiness.* What are examples of effective tools and methods for patients and providers to control access to portions of patients' health data? What is the readiness and feasibility of implementing successful access control methods?
- *Resource Burden.* Commenters raised concerns about the potential cost and burden of data segmentation at the data element level. Specifically, would requiring the ability to segment the data by, for instance, conducting data tagging, place additional burden on clinical providers? Please describe the nature of any additional burden. What are possible solutions to consider to address these concerns?
- *Current Patient Consent Practices.* How do current consent practices inform patients of opportunities for patient engagement and provider discretion in responding to patient requests? What technology and policy gaps exist for achieving widespread successful segmentation practices?
- *FHIR Utility.* What recommendations do stakeholders have to improve the data segmentation capabilities of existing FHIR standards? How would you describe the state of development projects or standards efforts planned or ongoing to address data segmentation (or segmentation of sensitive information) on FHIR or other standards? What are the key gaps or constraints that exist within ongoing and emerging efforts?
- *Technical Considerations.* What general data segmentation strategies can we leverage for the programs described in this proposed rule from standards like the Substance Abuse and Mental Health Services Administration's (SAMSHA) Consent2Share [67] and HL7 Data Segmentation for Privacy (DS4P)? [68] What lessons can we learn from use of these existing standards?
- How can existing tools, resources, and approaches with data segmentation be used to help inform any approaches or strategies that CMS might consider proposing for impacted entities? [69]
- *Patient Options.* Should preferences be something that data senders should try to honor but retain flexibility to deny in certain situations, when consistent with applicable regulations? For example, the HIPAA Privacy Rule requires a covered entity to permit an individual to request restrictions on the entity's uses and disclosures of PHI, but only requires the entity to agree to the request in limited circumstances (see 45 CFR 164.522(a)(1)(vi)).
- *Current Segmentation Efforts.* Varied segmentation practices exist, and we are seeking stakeholder input from those who have implemented or piloted patient-controlled segmentation models, individual provider-controlled models, or other related models or tools. What prevents patients and/or providers from recording, maintaining, or using a patient's privacy preferences when exchanging health information? How can data segmentation decisions be automated? Are there particular processes or workflows related to patient privacy preferences, consent, or data segmentation that could be improved by automation and/or standardization?

B. Electronic Exchange of Behavioral Health Information

Several factors have led to an EHR adoption rate that is significantly lower among behavioral health providers compared to other types of health care providers. One possible contributing factor was that the Health Information Technology for Economic and Clinical Health Act (Pub. L. 111–5, enacted February 17, 2009) (HITECH Act) made Medicare fee-for-service and Medicaid incentive payments for the adoption and meaningful use of certified EHR technology available only to eligible professionals, eligible hospitals, and critical access hospitals (CAH). Behavioral health providers that did not meet the criteria to be considered an eligible professional, eligible hospital, or CAH were not eligible for these incentive payments. For example, behavioral health providers who were physicians (eligible professionals) could receive the incentive payments, but other types of non-physician behavioral health providers may not have been eligible.

Today, behavioral health providers lag behind their peers in the ability to electronically share health information across providers and with patients. ONC noted that, in 2017, only 12 percent of office-based physicians reported sending data to behavioral health providers, while 14 percent of office-based physicians reported receiving data from behavioral health providers.[70] Other technical and regulatory restrictions, such as 42 CFR part 2, which governs the confidentiality of substance use disorder patient records maintained by a covered substance use disorder treatment program can also inhibit the exchange of behavioral health information.

Understanding the time and cost of implementing an EHR system, we are interested in evaluating whether using other applications that exchange data using FHIR-based APIs and do not require implementation of a full EHR system might be a way to help behavioral health providers leverage technology to exchange health data to improve care quality and coordination in a more agile fashion. Specifically, would small practices, community-based providers, and other non-traditional providers be able to more quickly adopt applications using API technology to exchange health information when the technology is not tied to an EHR? Would these providers be able to achieve the same care coordination goals using such applications as with a more extensive EHR implementation, or would the value be lower but still sufficient to improve care quality and care coordination?

[67] HL7 International Community-Based Care and Privacy. (n.d.). Consent2Share Implementation Guide. Retrieved from *https://gforge.hl7.org/gf/project/cbcc/frs/?action=FrsReleaseBrowse&frs_package_id=303.*

[68] Office of the National Coordinator for Health Information Technology. (2020). Data Segmentation of Sensitive Information. Retrieved from *https://www.healthit.gov/isa/data-segmentation-sensitive-information.*

[69] For selected resources on practices for privacy and data segmentation, see p. 61 of the Health IT Advisory Committee Notice of Proposed Rulemaking Task Force. (2019, June 3). Information Blocking Task Force Recommendations. Retrieved from *https://www.healthit.gov/sites/default/files/page/2019-07/2019-06-03_All%20FINAL%20HITAC%20NPRM%20Recs_508-signed.pdf.*

[70] Office of the National Coordinator. ''Interoperability among Office-Based Physicians in 2015 and 2017.'' ONC Data Brief No. 47 (May 2019). Retrieved from *https://www.healthit.gov/sites/default/files/page/2019-05/2015to2017PhysicianInteroperabilityDataBrief_0.pdf.*

Over the past few years, HHS continued to highlight the importance of coordinated care and removing any unnecessary obstacles. In 2018, HHS launched the ''Regulatory Sprint to Coordinated Care'' prompting agencies within the Department to assess a variety of long-standing regulatory requirements to see whether they hinder innovative progress and how they can better incentivize coordination. We have also seen the Substance Abuse and Mental Health Services Administration (SAMHSA) publish regulations related to improved care coordination among providers that treat substance use disorders as well as protecting those patients' records (42 CFR part 2), and the enactment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Pub. L. 115–271, October 24, 2018), which encouraged us to consider ways to facilitate information sharing among behavioral health providers. In the spirit of the ''Regulatory Sprint to Coordinated Care'' and these policies, we are looking for innovative approaches to addressing the need to facilitate the electronic exchange of behavioral health information, as well as approaches to support the exchange of health information to behavioral health providers to inform care and provision of behavioral health services.

Many behavioral health providers are in the community. As a result, when thinking about behavioral health specifically, it is valuable to think about community-based providers more broadly.

We are interested in public comments on how we might best support electronic data exchange of behavioral health information between and among behavioral health providers, other health care providers, and patients, as well as how we might best inform and support the movement of health data (and its consistency) to behavioral health providers for their use to inform care and treatment of behavioral health services. Specifically, we are seeking public comments on the following questions:

- Can applications using FHIR-based APIs facilitate electronic data exchange between behavioral health providers and with other health care providers, as well as their patients, without greater EHR adoption? Is EHR adoption needed first? What opportunities do FHIR-based APIs provide to bridge the gap? What needs might not be addressed by the use of applications with more limited functionality than traditional EHRs?
- What levers could CMS consider using to facilitate greater electronic health data exchange from and to behavioral health providers? What costs, resources, and/or burdens are associated with these options?
- Are there particular considerations for electronic data exchange for behavioral health providers who practice independently, are community-based, or are non-traditional providers? What about rural-based behavioral health providers? How could an API-based solution help address these considerations?
- Are there state or federal regulations or payment rules that are perceived as creating barriers to technical integration of systems within these practices? What additional policy issues, technical considerations, and operational realities should we consider when looking at ways to best facilitate the secure electronic exchange of health information that is maintained by behavioral health providers including sensitive health information?
- What levers and approaches could CMS consider using and advancing to facilitate greater electronic health data exchange from and to community-based health providers including use of relevant health IT standards as feasible? What costs, resources, and/or burdens are associated with these options?

We seek comments on these questions and issues for future consideration.

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We seek comments on these questions and issues for future consideration.

D. Reducing Burden and Improving Electronic Information Exchange of Prior Authorizations

As discussed in section II.C. of this proposed rule, we believe there are many benefits to using electronic prior authorization solutions. Specifically, we propose to require impacted payers to implement, maintain, and use a Prior Authorization Support API. However, as we discuss in section VII. of this proposed rule, the health care system would gain maximum benefits if providers adopted use of the Prior Authorization Support API as well. As a result, we are requesting information for consideration in future rulemaking regarding how CMS can best incentivize providers to use electronic prior authorization solutions.

1. Electronic Prior Authorization for Medicare- and Medicaid-Participating Providers and Suppliers

We have been working with the provider community to ensure that the Conditions of Participation, Conditions for Certification, and Conditions for Coverage (CoPs and CfCs) reflect the latest advances in health information technology and interoperability to the greatest extent possible. For instance, the CMS Interoperability and Patient Access final rule (85 FR 25510, finalized on May 1, 2020) revised the CoPs for hospitals, psychiatric hospitals, and critical access hospitals (CAHs) by adding new standards that require a hospital, including a psychiatric hospital, or a CAH, which utilizes an electronic medical records system or other electronic administrative system that meets certain technical specifications, to demonstrate that it sends electronic patient event notifications to the patient's primary care practitioner, practice group, or other practitioner or practice group identified by the patient as being responsible for his or her primary care, when a patient is admitted to, and discharged (and/or transferred) from, the hospital or the CAH.

The notifications must include, at a minimum, the patient's name, the name of the treating practitioner, and the name of the sending institution. These provisions were finalized at § 482.24(d), ''Electronic notifications,'' for hospitals; at § 482.61(f), ''Electronic notifications,'' for psychiatric hospitals; and at § 485.638(d), ''Electronic notifications,'' for CAHs. The CMS Interoperability and Patient Access final rule (85 FR 25510) requires hospitals, including psychiatric hospitals, and CAHs to implement the patient event notification provisions by April 30, 2021. As we explained in that final rule, there is growing evidence that health information exchange can lower cost and improve outcomes, particularly when the exchange of information, such as a patient event notification, is between providers. These exchanges are associated with better care coordination, a reduction in 30-day readmissions, and improved medication reconciliation, for instance (85 FR 25585).

In reviewing other areas where the electronic exchange of patient information through interoperable systems offers significant opportunities for improvements for direct patient care, and also to overall health care system efficiency, we have identified electronic prior authorization as an area that might benefit from these technological advances. As we have discussed elsewhere in this proposed rule, we believe that the electronic prior authorization process is an opportunity to reduce burden and improve care. Prior authorization is the request and approval for payment of items and services (including prescription drugs) provided by Medicare- and Medicaid-participating providers and suppliers (including, but not limited to, hospitals, psychiatric hospitals, and CAHs) to beneficiaries. We recognize that there are gaps in the current prior authorization process, including:

- Prior authorization requirements not residing within a provider's EHR or not being visible to the provider or staff members as part of the workflow;
- Inability to rely on a consistent submission method for prior authorization requests. In many cases, only some of the process is automated, or electronic, making for a hybrid process that is partially computer-based through an EHR or practice management system, and partially manual, requiring phone calls, faxes, or emails, resulting in various workarounds that may or may not meld together;
- Paper forms and portals require manual data reentry that may already reside electronically within an EHR; and
- There are multiple routes to obtain a prior authorization depending on the

payer, item or service, and provider (such as a hospital).

We are interested in learning what barriers exist for hospitals (and other providers and suppliers) to electronically transmit prior authorization requests and receive prior authorization decisions for patients receiving care and services by the applicable provider. We believe answers to the following questions would be beneficial in obtaining additional information on the overall electronic prior authorization process, the impact of this process on patient health and safety issues, and whether the hospital (and other providers and suppliers)CoP requirements are a good vehicle to achieve nearly universal adoption and use of electronic prior authorization requests and receipts:

- What are the current barriers to transmitting prior authorization requests and receipts electronically? What actions could CMS and/or industry take to remove barriers?
- Do the current methods for electronic transmission of prior authorization requests and receipts, including the adopted standard, and any that have been established and maintained by third-party health care insurers (including Medicare) provide the efficient and timely request and receipt of prior authorization decisions? Please provide relevant detail in your response.
- Would the CMS CoP/CfC requirements for hospitals and other providers and suppliers be the appropriate lever by which CMS should propose new or additional provisions that would require the electronic request and receipt of prior authorization decisions? If so, under which provisions would this best be accomplished?

We intend to utilize this information as we evaluate opportunities to revise the hospital and CAH CoP requirements related to electronic prior authorization request and receipt.

2. Request for Information: Future Electronic Prior Authorization Use in the Merit-Based Incentive Payment System (MIPS)

As discussed in section II.C. of this proposed rule, we believe the tools to support more efficient electronic prior authorization processes have the potential to greatly reduce the amount of time needed for submitting, reviewing, and making prior authorization decisions. We are considering ways to encourage clinicians to use electronic prior authorization solutions and are seeking input on the addition of an improvement activity for the Merit-Based Incentive Payment System (MIPS). The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) established MIPS for certain Medicare-participating eligible clinicians, a system that will make payment adjustments based upon scores from four performance categories. We first established policies for MIPS in the CY 2017 Quality Payment Program final rule (81 FR 77008 through 77831) and annually thereafter.

Section 1848(q)(2)(C)(v)(III) of the Act defines an improvement activity as an activity that relevant eligible clinician organizations and other relevant stakeholders identify as improving clinical practice or care delivery, and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. For previous discussions on the background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 59776 through 59777), and the CY 2020 PFS final rule (84 FR 62980 through 62990). We also refer readers to 42 CFR 414.1305 for the definition of improvement activities and attestation, § 414.1320 for the performance period, § 414.1325 for data submission requirements, § 414.1355 for the improvement activity performance category generally, § 414.1360 for data submission criteria, and § 414.1380(b)(3) for improvement activities performance category scoring.

In section II.C of this proposed rule, we note that prior authorization is the process through which a provider must obtain approval from a payer before providing care, and prior to receiving payment for delivering items or services. In that section, we propose that state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs implement and maintain a Prior Authorization Support (PAS) Application Programing Interface (API) conformant with the HL7 Fast Healthcare Interoperability Resources (FHIR) (PAS) IG beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023). We believe the PAS API would provide an opportunity to leverage the convenience and efficiency of API technology, while maintaining compliance with the mandated HIPAA transaction standard, to accelerate electronic prior authorization adoption and use by enabling the prior authorization process to be integrated into a provider's EHR or practice management system. Providers could leverage the PAS API to improve care coordination and patient and clinician shared decision making through improvements to the prior authorization process, particularly if the API is integrated into the provider workflow.

We believe that MIPS eligible clinicians would also benefit from the PAS API, and we are seeking comment on whether we should add a MIPS improvement activity to our Inventory that would utilize this PAS API to facilitate submitting and receiving electronic prior authorization requests and decisions to reduce burden, improve efficiency, and ultimately ensure patients receive the items and services they need in a timely fashion. We believe this could fall under the care coordination subcategory (81 FR 77188) and section 1848(q)(2)(B)(iii) of the Act. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables X and G in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303), and Tables A, B, and C in the Appendix 2 of the CY 2020 PFS final rule (84 FR 63514 through 63538) for our previously finalized improvement activities Inventory. We also refer readers to the Quality Payment Program website at *https://qpp.cms.gov/* for a complete list of the most current improvement activities.

We are interested in comments regarding the addition of a MIPS improvement activity, and if this area will be appropriate to encourage clinicians to make certain improvements.

- Is this an activity that stakeholders identify as improving clinical practice or care delivery?
- When effectively executed, is implementation of such technology and use of these standards likely to result in improved outcomes?
- If yes, should this activity be assigned a medium-weight or high-weight?

We refer readers to section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59776 through 59777) where we discussed that high-weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. If the

addition of a MIPS improvement activity incorporating the use of a FHIR-based Prior Authorization Support API is not an incentive to encourage clinicians to use electronic prior authorization solutions, are there other ways that we could do so?

In addition to the above questions, we are also seeking comment on the following questions regarding how best to encourage the use of electronic prior authorization:

- Should CMS consider adding a measure to the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals and the MIPS Promoting Interoperability performance category for clinicians and groups to encourage the use of electronic prior authorization through a payer's Prior Authorization Support API?
- What are the primary considerations for developing such a measure?
- How would the measure require the use of certified electronic health record technology?
- Should the Prior Authorization Support IG be incorporated into potential future certification requirements for health IT under the ONC Health IT Certification Program?
- Should CMS consider additional measures and activities under MIPS Quality, Cost, or Improvement Activities performance categories involving FHIR-based electronic prior authorization solutions?
- If so, what are the primary considerations for developing such measures and activities?
- What other approaches should CMS consider to help support clinician use of electronic prior authorization solutions such as the Prior Authorization Support API?

E. Reducing the Use of Fax Machines

CMS is continually looking for ways to facilitate efficient, effective, and secure electronic data exchange to help ensure more timely, better quality, and highly coordinated care. Historically, we have relied on fax technology as a primary method for sharing information across the health care system, which can allow for easy sending and receiving of documents. However, the data in those documents are not easily integrated electronically into a patient's medical record or shared in an interoperable way with other payers and providers. Therefore, using fax technology limits our ability to reach true interoperability.

Fax technology creates inefficiencies. It requires time spent manually pulling together clinical and administrative data from EHRs and practice management systems, transmitting data back and forth between health care providers and payers using a mechanism slower than the internet, and making frequent follow-up phone calls between health care providers and other providers and payers to clarify unclear transaction statuses in real-time. We discuss examples of these inefficiencies further in sections II.C. and V.C. of this proposed rule, to which we refer readers.

To work toward true interoperability, we believe we must reduce or completely eliminate the use of fax technology in health care. To this end, we seek comment on how CMS can reduce or completely eliminate the use of fax technology across programs, including both hospitals and post-acute care facilities, so that information can be shared electronically in real time without extensive follow-up to determine if the information was received. At CMS, we are working to identify all programs and processes that currently require and/or encourage the use of fax technology for data exchange to determine whether the use of fax can be removed or significantly reduced in those programs. We acknowledge that there are instances where the use of fax may be necessary to send data, for example, where rural providers do not have sufficient internet access to exchange certain data electronically and must rely on fax technology, and also the impact of reduced fax use on preparedness and response to disasters. We note section 202(c) of the E-Government Act of 2002 (Pub. L. 107–347, December 17, 2002), requires CMS to avoid diminished access for those lacking internet access or computer access. We seek a balance and want to ensure that elimination of fax technology in CMS programs does not eliminate options for those without internet access.

In an effort to reduce burden and increase efficiency, we are requesting feedback from the public on how electronic data exchange could replace fax technology. Specifically, we are seeking stakeholder feedback on the following questions:

- What specific programs, processes, workflows, or cases are you currently using a fax machine to accomplish? In what ways would replacing this with an electronic data exchange, such as via a FHIR-based API, add value, efficiencies, and/or improve patient care? Are there specific processes (such as prior authorization) that you would prioritize first to reduce the reliance on fax technology? Has your organization implemented an electronic data exchange in an effort to reduce the reliance on the fax machine?
- What challenges might payers and providers face if use of the fax technology for health care data exchange is completely eliminated? Are there particular types of providers or health care settings that would be more negatively impacted than others? What solutions might mitigate these challenges?
- What recommendations are there for balancing the goal of improving efficiencies in health care data exchange through reducing the use of fax while ensuring that health care providers without ready access to internet can still share information?
- To what extent can electronic and cloud-based fax technology bridge the gap between electronic transmission and traditional fax technology?
- What impact will the reduction of use of fax technology have on preparedness and response to disasters? How might organizations begin to reduce reliance on this technology, and mitigate these impacts?

F. Request for Information: Accelerating the Adoption of Standards Related to Social Risk Data

CMS recognizes that social risk factors (for example, housing instability, food insecurity) impact beneficiary health and utilization outcomes. Providers in value-based payment arrangements rely on comprehensive, high-quality data to identify opportunities to improve patient care and drive value. When implemented effectively, value-based payment encourages clinicians to care for the whole person and address the social risk factors that are critical for beneficiaries' quality of life.

As value-based payment has grown, so has provider interest in data on social risk factors. For example, a recent study [72] found that 24 percent of hospitals and 16 percent of physician practices were screening patients for all five health-related social needs (housing, food, transportation, utilities, and safety needs) included in the Accountable Health Communities model. Providers use these data to inform care and connect patients with the right community resources and supports.

Unfortunately, social risk data are often fragmented and duplicative due to a lack of clear standards for recording and exchanging these data. For example, multiple providers who cannot exchange these data with each other may ask the same beneficiary similar

[72] See *https://www.ncbi.nlm.nih.gov/pubmed/31532515.*

questions, or hospitals within a single system may all collect varying food insecurity data in different formats. Additionally, relevant data collected by community-based organizations outside the health sector can be difficult to integrate and utilize. Siloed data increase the burden on beneficiaries, create inefficiencies in managing referrals for social services, create duplicative workflows in an already strained system, and impede opportunities to provide higher quality care.

As providers assume greater accountability for costs and outcomes through value-based payment, they need tools to successfully identify and address social risk factors to improve care and health outcomes. Over the last several years, a variety of community led efforts are developing industry-wide standards [73] to collect social risk data, electronically represent these data, and enable exchange of person-centered data between medical providers and community-based organizations through health information technology platforms. CMS seeks input on barriers the health care industry faces to using industry standards and opportunities to accelerate adoption of standards related to social risk data. Specifically:

- What are the challenges in representing and exchanging social risk and social needs data from different commonly used screening tools? How do these challenges vary across screening tools or social needs (for example, housing, food)?
- What are the barriers to the exchange of social risk and social needs data across providers? What are key challenges related to exchange of social risk and social needs data between providers and community-based organizations?
- What mechanisms are currently used to exchange social risk and social needs data (EHRs, HIEs, software, cloud-based data platforms, etc.)? What challenges, if any, occur in translating social risk data collected in these platforms to Z-codes on claims?
- How can health care payers promote exchange of social risk and social needs data? Are there promising practices used by public or private payers that can potentially be further leveraged in other settings?

[73] See *https://www.healthit.gov/buzz-blog/interoperability/advancing-interoperable-social-determinants-of-health-data.*

IV. Incorporation by Reference

A. Standards, Implementation Guides, and Specifications

1. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A–119 [74] require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to electing only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. In these cases, agencies have the discretion to decline the use of existing voluntary consensus standards, and instead can use a government-unique standard or other standard. In addition to the consideration of voluntary consensus standards, the OMB Circular A–119 recognizes the contributions of standardization activities that take place outside of the voluntary consensus standards process. Therefore, as stated in OMB Circular A–119, in instances where use of voluntary consensus standards would be inconsistent with applicable law or otherwise impracticable, other standards should be considered that meet the agency's regulatory, procurement, or program needs; deliver favorable technical and economic outcomes; and, are widely utilized in the marketplace. In this proposed rule, we propose use of voluntary consensus standards, including implementation guides (IGs) and specifications.

2. Compliance With Adopted Standards, Implementation Guides, and Specifications

In accordance with the Office of the Federal Register (OFR) regulations related to ''incorporation by reference,'' 1 CFR part 51, which we follow when we adopt proposed standards, implementation guides, or specifications in any subsequent final rule, the entire standard, implementation guide, or specification document is deemed published in the **Federal Register** when incorporated by reference therein with the approval of the Director of the Federal Register. Once published, compliance with the standard, implementation guide, or specification includes the entire document unless specified otherwise in regulation. For example, if the Health Level 7® (HL7) Fast Healthcare Interoperability Resources® (FHIR) Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide: Version STU 1.0.0 proposed in this rule is adopted (see section II.E. of this proposed rule), and API requirements for payers based on this IG are finalized (see section II.D. of this proposed rule, payers developing and implementing a Documentation Requirements Lookup Service (DRLS) application programming interface (API) would need to demonstrate compliance with all mandatory elements and requirements of the IG. If an element of the IG is optional or permissive in any way, it would remain that way for compliance unless we specified otherwise in regulation. In such cases, the regulatory text would preempt the permissiveness of the implementation guide. This also applies to standards and specifications.

[74] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A119/revised_circular_a-119_as_of_1_22.pdf.*

3. ''Reasonably Available'' to Interested Parties

The OFR has established requirements for materials (for example, standards, implementation guides, and specifications) that agencies propose to incorporate by reference in Federal Regulations (79 FR 66267; 1 CFR 51.5(a)). To comply with these requirements, in this section we provide summaries of, and uniform resource locators (URLs) to the standards, implementation guides, and specifications we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations (CFR). To note, we also provide relevant information about these standards, implementation guides, and specifications throughout the relevant sections of the proposed rule.

B. Incorporation by Reference

OFR has established requirements for materials (for example, standards, IGs, or specifications) that agencies propose to incorporate by reference in the CFR (79 FR 66267; 1 CFR 51.5(a)). Section 51.5(a) requires agencies to discuss, in the preamble of a proposed rule, the ways that the materials it proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties, and summarize in the preamble of the proposed rule, the material it proposes to incorporate by reference.

To make the materials we intend to incorporate by reference reasonably

available, we provide a URL for the IGs and specifications. In all cases, these IGs and specifications are accessible through the URLs provided by selecting the specific version number from the version history page the URL directly links to. In all instances, access to the IGs or specification can be gained at no-cost (monetary). There is also no requirement for participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization to obtain these materials.

As noted above, the NTTAA and OMB Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. As discussed, HHS has followed the NTTAA and OMB Circular A–119 in proposing standards, IGs, and specifications for adoption. HHS has worked with HL7 to make the IGs and specifications being proposed for adoption and subsequently incorporated by reference in the **Federal Register**, available to interested stakeholders. As discussed in section II.B. of this proposed rule, all HL7 FHIR IGs are developed through an industry-led, consensus-based public process. HL7 is an American National Standards Institute (ANSI) accredited standards development organization. HL7 FHIR standards are unique in their ability to allow disparate systems that otherwise represent data differently to exchange such data in a standardized way that all systems can share and consume via standards-based APIs. HL7 FHIR IGs are also openly accessible, so any interested party can go to the HL7 website and access the IG. Once accessed, all public comments made during the balloting process as well as the version history of the IGs are available for review. In this way all stakeholders can fully understand the lifecycle of a given IG. Use of such guidance facilitates interoperability in a transparent and cost-effective way that ensures the IGs are informed by, and approved by, industry leaders looking to use technology to improve patient care. As such, all of the standards we propose for HHS adoption and subsequent incorporation by reference are developed and/or adopted by voluntary consensus standards bodies.

As required by § 51.5(a), we provide summaries of the standards we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations. We also provide relevant information about these standards, implementation guides, and specifications throughout the relevant sections of the proposed rule.

Standards Including Implementation Guides and Specifications for Health Care Interoperability—45 CFR Part 170

• HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide: Version STU 1.0.0.

URL: *http://hl7.org/fhir/us/davinci-crd/history.html.*

This is a link to the version history. Select the specified version from the list on this page to access the IG and all related documentation.

Summary: The purpose of this IG is to define a workflow whereby payers can share coverage requirements with clinical systems at the time treatment decisions are being made. This ensures that clinicians and administrative staff have the capability to make informed decisions and can meet the requirements of the patient's insurance coverage. We are specifically proposing this IG to support the DRLS API discussed by CMS in section II.C. of this proposed rule. The various CMS-regulated insurance and coverage products accepted by a given provider may have very different requirements for prior authorization documentation. Providers who fail to adhere to payer requirements may find that costs for a given service are not covered or not completely covered. The outcome of this failure to conform to payer requirements can be increased out of pocket costs for patients, additional visits and changes in the preferred care plan, and increased burden.

The information that may be shared using this IG includes:

—Updated coverage information.
—Alternative preferred/first-line/lower-cost services/products.
—Documents and rules related to coverage.
—Forms and templates.
—Indications of whether prior authorization is required.

• HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide: Version STU 1.0.0.

URL: *http://hl7.org/fhir/us/davinci-dtr/history.html.*

This is a link to the version history. Select the specified version from the list on this page to access the IG and all related documentation.

Summary: This IG specifies how payer rules can be executed in a provider context to ensure that documentation requirements are met. The DTR IG is a companion to the CRD IG, which uses Clinical Decision Support (CDS) Hooks [75] to query payers to determine if there are documentation requirements for a proposed medication, procedure, or other service. When those requirements exist, CDS Hooks Cards will be returned with information about the requirements. This IG leverages the ability of CDS Hooks to link to a Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR [76] app to launch and execute payer rules. The IG describes the interactions between the SMART on FHIR app and the payer's IT system to retrieve the payer's documentation requirements, in the form of Clinical Quality Language (CQL) [77] and a FHIR Questionnaire resource, for use by the provider.

The goal of DTR is to collect clinical documentation and/or to encourage the completion of documentation that demonstrates medical necessity for a proposed medication, procedure, or other service. To accomplish this, the IG details the use of a payer provided Questionnaire resource and results from CQL execution to generate a Questionnaire Response resource containing the necessary information. Essentially, the provider's EHR communicates to the payer's system, which informs the EHR of the documentation that needs to be completed—this is the Questionnaire resource. To populate the Questionnaire response, this IG supports the provider's EHR in populating the response form with the relevant patient information from the patient's electronic record. As much as can be auto-populated by the system is completed. The IG then instructs the system to alert a provider to any gaps in information that may need to be manually filled before the Questionnaire response resource is sent back to the payer through the EHR via the SMART on FHIR app. This IG will also support the DRLS API discussed by CMS in section II.C. of this proposed rule.

• HL7 FHIR Da Vinci—Prior Authorization Support (PAS) Implementation Guide: Version STU 1.0.0.

URL: *http://hl7.org/fhir/us/davinci-pas/history.html.*

This is a link to the version history. Select the specified version from the list on this page to access the IG and all related documentation.

Summary: The PAS IG uses the FHIR standard as the basis for assembling the information necessary to substantiate the need for a particular treatment and submitting that information and the

[75] *https://cds-hooks.org/.*
[76] *https://docs.smarthealthit.org/.*
[77] *https://cql.hl7.org/.*

request for prior authorization to an intermediary end point. That endpoint is responsible for ensuring that any HIPAA requirements are met. The response from the payer is intended to come back to that intermediary endpoint and be available to the provider's EHR solution using the FHIR standard. The goal is to provide real time prior authorization, where possible, in the provider's clinical workflow.

This IG, in this way, strives to enable direct submission of prior authorization requests initiating from a provider's EHR system or practice management system. To meet regulatory requirements, these FHIR interfaces will communicate with an intermediary that converts the FHIR requests to the corresponding X12 instances prior to passing the requests to the payer. Responses are handled by a reverse mechanism (payer to intermediary as X12, then converted to FHIR and passed to the provider's EHR). Direct submission of prior authorization requests from the provider's EHR will reduce costs for both providers and payers and result in faster prior authorization decisions resulting in improved patient care and experience.

When combined with the Da Vinci CRD and DTR IGs, direct submission of prior authorization requests will further increase efficiency by ensuring that authorizations are always sent when (and only when) necessary, and that such requests will almost always contain all relevant information needed to make the authorization decision on initial submission.

This IG also defines capabilities around the management of prior authorization requests, including checking the status of a previously submitted request, revising a previously submitted request, and cancelling a request. This IG will support the Prior Authorization Support API discussed by CMS in section II.C. of this proposed rule.

- HL7 FHIR Da Vinci—Payer Coverage Decision Exchange (PCDE) Implementation Guide: Version STU 1.0.0.

URL: *http://www.hl7.org/fhir/us/davinci-pcde/history.cfml.*

This is a link to the version history. Select the specified version from the list on this page to access the IG and all related documentation.

Summary: The IG defines standardized mechanisms for a patient or payer to enable a transfer of ''current active treatments'' with other relevant metadata and coverage-related information from a prior payer to a new payer. It also defines a standardized structure for organizing and encoding that information to ease its consumption by the new payer organization.

This IG addresses the need for continuity of treatment when patients move from one payer's health insurance or benefit plan to another. In the current situation, the patient and new payers often do not have the information needed to continue treatment in progress or to determine that the therapies are necessary or medically appropriate. As a result, patients can face a break in continuity of care, challenges to share additional information, and increased costs as tests are re-run or prior therapies need to be re-tested in order to comply with the rules of the new payer. By enabling an authorized transfer of information from the original payer to the new payer, the new payer can have access to information about what therapies are currently in place and the rationale for them, as well as what precursor steps have been taken to demonstrate the medical necessity and appropriateness of the current therapy. By automating this exchange and maximizing the computability of the information shared, a process that frequently takes weeks or months can be reduced to a few days or even minutes reducing costs and improving patient safety, quality, and experience. This IG will support the Payer-to-Payer API discussed by CMS in section II.D. of this proposed rule.

- HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide: Version STU 1.0.0.

URL: *http://hl7.org/fhir/us/carin-bb/history.html.*

This is a link to the version history. Select the specified version from the list on this page to access the IG and all related documentation.

Summary: This IG describes the CARIN for Blue Button Framework, providing a set of resources that payers can exchange with third-parties to display to consumers via a FHIR-based API. This IG will help impacted payers share adjudicated claims and encounter data via the Patient Access API discussed by CMS in section II.A. of this proposed rule. It includes data elements and coding instructions each impacted payer can use to prepare and share the specified data.

- HL7 FHIR Da Vinci Payer Data Exchange (PDex) Implementation Guide: Version STU 1.0.0.

URL: *http://hl7.org/fhir/us/davinci-pdex/history.html.*

This is a link to the version history. Select the specified version from the list on this page to access the IG and all related documentation.

Summary: This IG enables payers to create a member's health history from clinical Resources based on FHIR Release 4 that can be exchanged with other payers, providers, and thirty-party applications. It supports patient-authorized exchange to a third-party application, such as the patient-requested prior authorization information via the Patient Access API as discussed in section II.A. of this proposed rule. It will also support exchanging active prior authorization decisions between payers and providers via the Provider Access API discussed by CMS in section II.B. of this proposed rule.

- HL7 FHIR Da Vinci—Payer Data Exchange (PDex) US Drug Formulary Implementation Guide: Version STU 1.0.1.

URL: *http://hl7.org/fhir/us/Davinci-drug-formulary/history.html.*

This is a link to the version history. Select the specified version from the list on this page to access the IG and all related documentation.

Summary: This IG defines a FHIR interface to a health insurer's current drug formulary information for patient access. A drug formulary is a list of brand-name and generic prescription drugs a payer agrees to pay for, at least partially, as part of health insurance or benefit coverage. Drug formularies are developed based on the efficacy, safety, and cost of drugs. The primary use cases for this FHIR interface is to enable patients' ability to understand the costs and alternatives for drugs that have been or can be prescribed, and to enable the comparison of their drug costs across different insurance plans. This IG would support the inclusion of current formulary and preferred drug list information via the Patient Access API as discussed by CMS in section II.A. of this proposed rule.

- HL7 FHIR Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide: Version STU 1.0.0.

URL: *http://www.hl7.org/fhir/us/davinci-pdex-plan-net/history.cfml.*

This is a link to the version history. Select the specified version from the list on this page to access the IG and all related documentation.

Summary: This IG is modeled off of the Validated Healthcare Directory Implementation Guide (VHDir), an international standard developed to support a conceptual, centralized, national source of health care data that would be accessible to local directories and used across multiple use cases. VHDir, as a basis for a centralized health care directory, is in development. This PlanNet IG leverages the lessons learned

and input provided throughout the extended VHDir development process, which has been informed by a large cross-section of stakeholders, and to address a more narrow scope of health care directory needs. This IG specifically allows payers to share basic information about their own, local networks via a publicly-accessible API. At a minimum, this IG will support impacted payers sharing their providers' names, addresses, phone numbers, and specialties, which is the information required to be shared via the Provider Directory API discussed by CMS in section II.A. of this proposed rule. Where the VHDir IG looks to create a central resource that a payer, for instance, could use to populate their local directory; the PlanNet IG allows the payer to make their local directory accessible to the public via an API.

V. Collection of Information Requirements

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

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. Background

Payers are in a unique position to offer patients and providers a holistic view of a patient's health care data that might otherwise be distributed across disparate IT systems. Payers should have the capability to exchange data with patients and providers for care and payment coordination or transitions, and to facilitate more efficient care.

To advance our commitment to interoperability, we are proposing new requirements for various impacted CMS-regulated payers to implement a series of standards-based APIs. These standards-based APIs would permit patients and providers to have access to a defined set of standardized data. We believe that these proposals would help facilitate coordinated care by helping to ensure that patients can access their own health information, and that providers can access the health care data of their patients through the use of common technologies, without special effort and in an easily usable digital format.

We additionally propose to reduce prior authorization burden on payers, providers, and patients, especially in terms of delays in patient care, through a number of proposals that would require impacted payers to implement standards-based APIs for prior authorization processes, reduce the amount of time to process prior authorization requests, and publicly report certain metrics about prior authorization processes for transparency, among other proposals.

B. Wage Estimates

To derive average costs, we use data from the U.S. Bureau of Labor (BLS) Statistics' National Occupational Employment and Wage Estimates for Direct Health and Medical Insurance Carriers (NAICS Code 524114) (*https://www.bls.gov/oes/current/oes_nat.htm*). Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1: Hourly Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($ / Hour)	Fringe Benefit ($ / Hour)	Adjusted Hourly Wage ($ / Hour)
Business Operations Specialists	13-1000	$36.31	$36.31	$72.62
Clerical	43-3000	$19.60	$19.60	$39.20
Computer and Information Analysts	15-1210	$46.91	$46.91	$93.82
Computer and Information Systems Managers	11-3021	$75.19	$75.19	$150.38
Computer Systems Analysts	15-1211	$46.21	$46.21	$92.42
Database Administrators and Architects	15-1245	$46.21	$46.21	$92.42
Designers, All Other	27-1029	$35.34	$35.34	$70.68
Engineers, All Other	17-2199	$49.26	$49.26	$98.52
General and Operations Managers	11-1021	$59.15	$59.15	$118.30
Medical Records Specialists	29-2098	$22.40	$22.40	$44.80
Registered Nurses	29-1141	$37.24	$37.24	$74.48
Operations Research Analysts	15-2031	$43.56	$43.56	$87.12
Physicians	29-1228	$97.81	$97.81	$195.62
Software and Web Developers	15-1250	$51.44	$51.44	$102.88
Technical Writers	27-3042	$36.95	$36.95	$73.90

As indicated, we are adjusting the employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate

total cost is a reasonably accurate estimation method.

C. Information Collection Requirements (ICRs)

Consistent with our approach in the CMS Interoperability and Patient Access final rule (85 FR 25622–25623), we determine ICRs by evaluating cost and burden at the parent organization level, as defined and discussed in detail in that rule. In that final rule, we provided a detailed rationale for how we determined the number of parent organizations (85 FR 25622). For this proposed rule, we used a similar approach to determine the number of parent organizations. We started by reviewing the parent organizations of health plans across Medicaid and CHIP managed care and QHP issuers on the FFEs to remove organizations that would not be subject to our proposed policies. We then de-duplicated the list to accurately represent those parent organizations that have multiple lines of business across programs only once. Ultimately, we determined that there are 209 parent organizations across Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs. In addition, we again identified 56 states, territories, and U.S. commonwealths which operate FFS programs, as well as one state that operates its CHIP and Medicaid FFS programs separately, for a total of 266 parent organizations that together represent the possible plans, entities, issuers, and state programs impacted by these proposals. We are interested to hear from the public regarding this methodology and whether parent organizations can implement the following information collection requirements across their lines of business.

1. ICRs Regarding Patient Access API Proposal (42 CFR 431.60, 438.242, 457.730, 457.1233, and 45 CFR 156.221)

To improve patient access to their health information, as discussed in section II.A. of this proposed rule, we are proposing to expand the Patient Access API finalized in the CMS Interoperability and Patient Access final rule (85 FR 25510). Specifically, we are proposing that impacted payers implement the API conformant with a specific set of IGs at 45 CFR 170.215 to improve interoperability. We are also proposing to enhance the API by proposing to require information about pending and active prior authorization decisions be made available by all impacted payers.

The cost of upgrading the Patient Access API to be conformant with the specified IGs is accounted for in the maintenance costs estimated in the CMS Interoperability and Patient Access final rule (85 FR 25607). We note that those maintenance costs also include costs for MA organizations, which are still relevant to the CMS Interoperability and Patient Access final rule policies, and would not be directly regulated by these proposed policies. As discussed therein, the maintenance we estimated accounts for additional capability testing and long-term support of the APIs, increased data storage needs, such as additional servers, or cloud storage to store any additional patient health information, and allocation of resources to maintain the FHIR server. In the CMS Interoperability and Patient Access final rule (85 FR 25510), we provided a link to additional information about the set of IGs that we are now proposing to require, and we encouraged, but did not require, the use of the these IGs. We understand that most payers are currently using these IGs to implement the API. We seek comment on our assumptions that use of these IGs is adequately accounted for in the maintenance costs of the Patient Access API in the CMS Interoperability and Patient Access final rule.

We are also proposing to require the Privacy Policy Attestation provision that we had presented as an option in the CMS Interoperability and Patient Access final rule (85 FR 25549 through 25550). Facilitating this attestation process is part of the regular work of keeping the API up to date and functioning.

2. ICRs Regarding Reporting Patient Access API Metrics to CMS Proposal (42 CFR 431.60, 438.242, 457.730, 457.1233, and 45 CFR 156.221)

In order to assess whether our policy requirements concerning the Patient Access API finalized in the CMS Interoperability and Patient Access final rule (85 FR 25558) are providing patients information in a transparent and timely way, we are proposing at 42 CFR 431.60(h), 438.242(b)(5), 457.730(h), 457.1233(d)(2), and 45 CFR 156.221(i) to require impacted payers to report quarterly to CMS certain metrics on use of the Patient Access API. We estimate that impacted payers would conduct two major work phases: 1) implementation, which includes defining requirements and system design (and updates) to generate and compile reports; and 2) maintenance, compiling and transmitting quarterly reporting to CMS. In the first phase (implementation), we believe impacted payers would need to define requirements concerning the types and sources of data that would need to be collected on the use of the Patient Access API and build the capability for a system to generate data that can be sent to CMS. In the second phase (maintenance), we believe impacted payers would need to prepare the quarterly data to be transmitted to CMS.

The burden estimate related to the new proposed requirements reflects the time and effort needed to collect the information described above and to disclose the information. We estimate an initial set of one-time costs associated with implementing the reporting infrastructure, and an ongoing annual maintenance cost to report after the reporting infrastructure is set up.

Table 2 presents our estimates for first year implementation and ongoing maintenance costs. For example, in the second row of Table 2, we estimate for first-year implementation that Business Operations Specialists would spend 60 hours at a wage of $72.62 an hour for a total cost of $4,357.20.

As captured in the bottom two rows of Table 2:

- First-year implementation would require, on average, a total of 160 hours per organization at an average cost of $14,645.20 per organization.
- Therefore, the aggregate burden of the first-year implementation across 266 parent organizations would be 42,560 hours (160 hours * 266 parent organizations) at a cost of $3,895,623 ($14,645.20 * 266 parent organizations).
- Similarly, ongoing maintenance after the first year would require a total of 40 hours per organization per year at an average cost of $2,904.80 per organization.
- Therefore, the aggregate burden of ongoing maintenance across 266 parent organizations would be 10,640 hours (40 hours * 266 parent organizations) at a cost of $772,677 ($2,904.80 * 266 parent organizations).

TABLE 2: Aggregate Burden for Complying with the Proposed Patient Access API Reporting Requirements

Occupation Title	Occupation Code	Labor Cost ($ / Hour)	Development Hours First Year Only (Hours)	Maintenance Hours Per Year (Hours)	1st Year Development Cost ($)	Annual Maintenance Cost ($)
Software and Web Developers	15-1250	$102.88	100	0	$10,288.00	0
Business Operations Specialists	13-1000	$72.62	60	40	$4,357.20	$2,904.80
Totals per Parent Organization			160	40	$14645.2	$2904.8
Totals for 266 Parent Organizations			42,560	10,640	$3,895,623	$772,677

We solicit comment on our assumptions and approach.

3. ICRs Regarding Provider Directory API Proposal (42 CFR 431.70, 438.242, 457.760, and 457.1233)

As discussed in section II.A. of this proposed rule, we are proposing to require impacted payers implement and maintain the Provider Directory API conformant with the HL7 FHIR Da Vinci Payer Data Exchange Plan Net IG. The Provider Directory API was finalized in the CMS Interoperability and Patient Access final rule (85 FR 25564). We note that those maintenance costs also include costs to MA organizations, which are still relevant to the CMS Interoperability and Patient Access final rule policies, and would not be directly regulated by these proposed policies. In the CMS Interoperability and Patient Access final rule (85 FR 25562), we encouraged, but did not require the use of this IG. We seek comment on this assumption that use of the IG is fully accounted for in the maintenance costs from the CMS Interoperability and Patient Access final rule.

4. ICRs Regarding Provider Access API Proposal (42 CFR 431.61, 438.242, 457.731, 457.1233, and 45 CFR 156.222)

To promote our commitment to interoperability, we propose new requirements for APIs at 42 CFR 431.61(a), 438.242(b)(5), 457.731(a), 457.1233(d)(2), and 45 CFR 156.222(a). This standards-based Provider Access API would permit providers to retrieve standardized patient data to facilitate coordinated care. To estimate costs to implement the new requirements for all new APIs proposed in this rule, we are using the same methodology that we used in the CMS Interoperability and Patient Access final rule (85 FR 25510).

In the CMS Interoperability and Patient Access final rule (85 FR 25510), we estimated that impacted payers would conduct three major work phases: Initial design; development and testing; and long-term support and maintenance. In this proposed rule, we assume the same major phases of work would be required, with a different level of effort during each work phase for each of the new proposed APIs. Consistent across all new proposed API provisions, we describe below the tasks associated with the first two phases. Where we believe additional effort associated with these tasks is necessary, we describe those as relevant in subsequent ICRs depending on how we believe they impact cost estimates. We discuss the costs for the third phase, long-term support and maintenance, and our methodology for the development of those costs in aggregate for all proposed APIs below in this section.

In the initial design phase, we believe tasks would include: Determining available resources (personnel, hardware, cloud storage space, etc.); assessing whether to use in-house resources to facilitate an API connection or contract the work to a third party; convening a team to scope, build, test, and maintain the API; performing a data availability scan to determine any gaps between internal data models and the data required for the necessary FHIR resources; and, mitigating any gaps discovered in the available data.

During the development and testing phase, we believe impacted payers would need to conduct the following: Map existing data to the HL7 FHIR standards, which would constitute the bulk of the work required for implementation; allocate hardware for the necessary environments (development, testing, production); build a new FHIR-based server or leverage existing FHIR-based servers; determine the frequency and method by which internal data is populated on the FHIR-based server; build connections between the databases and the FHIR-based server; perform capability and security testing; and vet provider requests.

The payers impacted by the proposed Provider Access API provision are required by the CMS Interoperability and Patient Access final rule by January 1, 2021 (beginning with plan years beginning on or after January 1, 2021 for QHP issuers on the FFEs) [78] (85 FR 25510) to implement a FHIR-based Patient Access API using the same baseline standards. These include HL7 FHIR Release 4.0.1, and complementary security and app registration protocols, specifically the SMART Application Launch Implementation Guide (SMART IG) 1.0.0 (including mandatory support for the ''SMART on FHIR Core Capabilities''), which is a profile of the OAuth 2.0 specification. Therefore, we believe payers will be able to gain efficiencies and leverage efforts and knowledge of the staff required to build, implement, and maintain the Provider Access API (as well as the other APIs in this proposed rule) because part of the cost of training and staff necessary is built into the development of the APIs required in the CMS Interoperability and Patient Access final rule (85 FR 25510).

One additional requirement new for both the Provider Access API and the Payer-to-Payer API is conformance with the HL7 FHIR Bulk Data Access (Flat FHIR) specification. We believe this is an additional package layer on top of the baseline standards that supports the exchange of health information for one or more patients at a time in a secure manner. We believe this would require additional development. We are also proposing that the Provider Access API include active and pending prior authorization decisions and related clinical documentation and forms, including the date the prior authorization was approved, the date the authorization ends, as well as the units and services approved and those used to-date. We factor in these proposed requirements in the estimated

[78] In the CMS Interoperability and Patient Access final rule, we finalized that these provisions would be applicable to data with a date of service on or after January 1, 2016, beginning January 1, 2021, and enforced beginning July 1, 2021 taking into account the 6 months of enforcement discretion we are exercising as a result of the current public health emergency (PHE).

costs for the Provider Access API in Table 3. We assume this cost accounted for here will absorb costs to include the same data in other proposed APIs. As a result, we account for these new costs once appreciating the efficiencies of using the same mapped data across more than one API. We seek comment on this assumption that the underlying content and exchange standards can be shared across the multiple APIs discussed in this proposed rule.

Our estimates as summarized in Table 3 are based on feedback from industry experts on the anticipated burden to implement the HL7 FHIR Bulk Data Access (Flat FHIR) specification—including input based on CMS' experience with the DPC pilot discussed in section II.B. of this proposed rule. Therefore, we believe this to be a reasonable estimate of the implementation burden.

The burden estimate related to the new requirements for APIs reflects the time and effort needed to collect the information described above and to disclose this information. We estimate an initial set of one-time costs associated with implementing the proposed Provider Access API requirements. Below we describe the burden estimates for the development and implementation phases for the Provider Access API.

Table 3 presents the total activities, hours, and dollar burdens for the implementation of the Provider Access API (initial design phase and the development and testing phase). Based on the same assumptions as those included in the CMS Interoperability and Patient Access final rule (85 FR 25510), we have selected the medium estimate as the primary estimate. As can be seen from the bottom rows of Table 3:

- One-time implementation efforts for the first two phases would (for the primary estimate) require on average a total of 2,800 hours per organization at an average cost of $275,743 per organization.
- The aggregate burden of the first-year implementation across 266 parent organizations would be 744,800 hours (2,800 hours * 266) at a cost of $73.3 million ($275,743 * 266). This corresponds to the primary estimate; the primary and high estimates are obtained by multiplying the low estimate by a factor of two and three, respectively.

TABLE 3: Burden Estimates for the Provider Access API*

Occupation Title	Labor Cost ($ / Hour)	Hours (Low)	Hours (*Primary*)	Hours (*High*)	Total Cost (Wages * Hours) (*Low*)	Total Cost (Wages * Hours) (*Primary*)	Total Cost (Wages * Hours) (*High*)
Database Administrators and Architects	$92.42	240	480	720	$22,181	$44,362	$66,542
Engineers, All Other	$98.52	160	320	480	$15,763	$31,526	$47,290
Computer Systems Analysts	$92.42	80	160	240	$7,394	$14,787	$22,181
General and Operations Managers	$118.30	160	320	480	$18,928	$37,856	$56,784
Operations Research Analysts	$87.12	160	320	480	$13,939	$27,878	$41,818
Software and Web Developers	$102.88	120	240	360	$12,346	$24,691	$37,037
Computer and Information Systems Managers	$150.38	120	240	360	$18,046	$36,091	$54,137
Designers, All Other	$70.68	160	320	480	$11,309	$22,618	$33,926
Technical Writers	$73.90	40	80	120	$2,956	$5,912	$8,868
Computer and Information Analysts	$93.82	160	320	480	$15,011	$30,022	$45,034
Totals per Parent Organization		1,400	2,800	4,200	$137,873	$275,743	$413,617
Totals for 266 Parent Organizations		372,400	744,800	1,117,200	$36,674,218	$73,347,638	$110,022,122

*Estimated burden is total burden of implementation; this burden is apportioned over 24 months in the COI summary table. Annual maintenance costs are 25 percent of total implementation costs as reflected in subsequent year costs in Table 10.

*Note: Table 3 (as other Tables in this Collection of Information Requirements section) reflects a spreadsheet accuracy and calculation; therefore, minor errors that seem to be in the Table are due to rounding.

Although this provision would be first applicable January 1, 2023, we believe it is reasonable that the APIs will be under development prior to this date. Acknowledging that impacted payers will have varying technological and staffing capabilities, we estimate that development of the APIs will require six to 12 months of work. Expecting that this rule will be finalized in early 2021, we have distributed the cost estimates over approximately 2 calendar years of time to reflect payers being given flexibility regarding when they complete the work (see Table 10, summary table).

We solicit comment on our approach and assumptions for the cost of the Provider Access API, including whether our estimates and ranges are reasonable or should be modified.

a. API Maintenance Costs

We discuss the costs for the third phase, long-term support and maintenance, and our methodology for the development of those costs in aggregate for all four proposed APIs below.

As relevant to the APIs discussed in sections V.C.4., 5., 6., and 10., we estimate ongoing maintenance costs for the Provider Access API, DRLS API, PAS API, and Payer-to-Payer API in aggregate. This approach aligns with the approach taken in the CMS Interoperability and Patient Access final rule (85 FR 25606–25607) whereby the costs of API development are split into three phases: Initial design, development and testing, and long-term support and maintenance. However, unlike the CMS Interoperability and Patient Access final rule, this rule assumes that maintenance costs only account for cost associated with the technical requirements as outlined in this rule. Any changes to requirements would require additional burden which would be discussed in future rulemaking. Throughout this Collection of Information section, we discuss initial design and development, and testing costs per API. We now discuss a total maintenance cost for all four APIs.

As discussed in the CMS Interoperability and Patient Access final rule (85 FR 25606), once the API is established, we believe that there would be an annual cost to maintain the FHIR server, which includes the cost of maintaining the necessary patient data, supporting the privacy policy attestation, and performing capability and security testing. We do believe there are efficiencies gained in implementation and maintenance due to the fact that these proposed APIs rely on several of the same underlying foundational technical and content. For example, the same baseline standards including the HL7 FHIR Release 4.0.1, and complementary security and app registration protocols—specifically the SMART Application Launch Implementation Guide (SMART IG) 1.0.0 (including mandatory support for the ''SMART on FHIR Core Capabilities''), which is a profile of the OAuth 2.0 specification, as noted above. However, we do believe that maintenance costs will be higher than what we estimated for the CMS Interoperability and Patient Access final rule (85 FR 25510) for the new APIs proposed in this rule as our estimates also account for new data mapping needs, standards upgrades, additional data storage, system testing, initial bug fixes, fixed-cost license renewals, contracting costs, and ongoing staff education and training.

In order to account for these maintenance costs, we based our estimates on input from industry experience piloting and demoing APIs for provider access, prior authorization, and payer-to-payer data exchange. We estimate an annual cost averaging approximately 25 percent of the primary estimate for one-time API costs, or $575,285 per parent organization ($275,743 (Provider Access API) + $984,181 (DRLS API) + $936,400 (PAS API) + $104,816 (Payer-to-Payer API) * 25 percent) (see V.C.4., 5., 6., and 10. for calculation of these estimates). Therefore, the aggregate maintenance burden across 266 parent organizations would be approximately $153,025,810 ($575,284 * 266). In Table 10 (summary table) we account for this maintenance cost separately for each API (at 25 percent of the one-time API cost) but, as discussed previously, the overlap in IGs across the proposed APIs, for example, is a shared efficiency that we believe supports the assumption that maintenance should be accounted for in aggregate and is presented in this section as such.

We solicit public comment on our approach and assumptions for the aggregate maintenance cost of the APIs, including whether our estimate is reasonable or should be modified.

5. ICRs Regarding Documentation Requirement Lookup Service (DRLS) API Proposal (42 CFR 431.80, 438.242, 457.732, 457.1233, and 45 CFR 156.223)

To promote our commitment to interoperability, we propose requirements for DRLS API at 42 CFR 431.80(a)(1), 438.242(b)(5), 457.732(a)(1), 457.1233(d)(2), and 45 CFR 156.223(a)(1). This DRLS API, would permit providers to access data showing whether prior authorization is required by the payer for the requested item or service, and if so, the documentation requirements for submitting the prior authorization request. This API is proposed to be conformant with the CRD and DTR IGs, and would begin January 1, 2023 (for Medicaid and CHIP managed care plans, by the rating period beginning on or after January 1, 2023).

As discussed above regarding the Provider Access API, to implement the new requirements for the DRLS API, we estimate that impacted payers would conduct three major work phases: Initial design, development and testing, and long-term support and maintenance. Additionally, for this proposed API, we believe additional tasks are necessary to accomplish the proposed requirements, which we describe below as they impact the cost estimates. As discussed previously, the costs for the third phase, long-term support and maintenance, and our methodology for the development of those costs in aggregate for all proposed APIs is presented in section V.C.4. of this proposed rule.

We base our estimates on feedback from industry experts on the anticipated burden to implement the DRLS API, including input from our own experience working on the prototype as further discussed in section II.C. of this proposed rule. We base our estimates on our own experience because we believe many impacted payers will find the experience similar to that used to estimate the cost. Additionally, the necessary IGs are openly available as HL7 provides access to all IGs as open source materials. Thus, HL7 IGs and many reference implementations and test scripts are also available free of charge to the health care community. These shared resources help support our belief that other payers will incur similar costs. Lessons learned from this DRLS prototype experience to-date indicate the efforts may require clinical expertise and software and web developers. As such, we have accounted for the necessary engineers, subject matter experts, and health informaticists. These personnel resources would, for example, need to convert payer prior authorization documentation rules into computable formats, create provider questionnaires regarding whether a patient had a medical necessity for a medical item or service, create formats that could interface with the provider's EHR or practice management system, and integrate the DRLS API with the payer's system.

Table 4 presents the total activities, hours, and dollar burdens for the implementation of the DRLS API (initial design phase and the development and testing phase). Based on the same assumptions as those included in the CMS Interoperability and Patient Access final rule (85 FR 25510), we have selected the mid-range estimate as the primary estimate. As can be seen from the bottom rows of Table 4:

- One-time implementation efforts for the first two phases would (for the primary estimate) require on average a total of 9,630 hours per organization at an average cost of $984,181 per organization.
- Aggregate burden of the one-time implementation costs across 266 parent organizations would be 2,561,580 hours (9,630 hours * 266) at a cost of $261.8 million ($984,181 * 266). This

corresponds to the primary estimate; the primary and high are obtained by multiplying the low estimate by a factor of two and three, respectively.

TABLE 4: Burden Estimates for the Documentation Requirement Lookup Service (DRLS) API *

Occupation Title	Labor Cost ($ / Hour)	Hours (*Low*)	Hours (*Primary*)	Hours (*High*)	Cost (Labor Cost * Hours) (*Low*)	Cost (Labor Cost * Hours) (*Primary*)	Cost (Labor Cost Wages * Hours) (*High*)
Software and Web Developers	$102.88	3070	6140	9210	$315,842	$631,683	$947,525
Engineers, All Other	$98.52	320	640	960	$31,526	$63,053	$94,579
Computer and Information Systems Managers	$150.38	150	300	450	$22,557	$45,114	$67,671
Database Administrators and Architects	$92.42	485	970	1455	$44,824	$89,647	$134,471
General and Operations Managers	$118.30	150	300	450	$17,745	$35,490	$53,235
Computer Systems Analysts	$92.42	320	640	960	$29,574	$59,149	$88,723
Computer and Information Analysts	$93.82	320	640	960	$30,022	$60,045	$90,067
Totals per Parent Organization		4,815	9,630	14,445	$492,091	$984,181	$1,476,272
Totals for 266 Parent Organizations		1,280,790	2,561,580	3,842,370	$130,896,206	$261,792,146	$392,688,352

*Estimated burden is total burden of implementation; this burden is apportioned over 24 months in the COI summary table. Annual maintenance costs are 25 percent of total implementation costs.

As noted previously, although this provision would be first applicable January 1, 2023, we believe it is reasonable that the APIs will be under development prior to that date. Acknowledging that impacted payers will have varying technological and staffing capabilities, we estimate that development of the APIs will require six to 12 months of work. Expecting that this rule will be finalized in early 2021, we have distributed the cost over approximately two calendar years of time to give payers the flexibility to complete the work necessary (see Table 10, summary table).

We solicit public comment on our approach and assumptions for the cost of the DRLS API, including whether our estimates and ranges are reasonable or should be modified.

6. ICRs Regarding Prior Authorization Support (PAS) API Proposal (42 CFR 431.80, 438.242, 457.732, 457.1233, and 45 CFR 156.223)

We are also proposing new requirements for a PAS API at 42 CFR 431.80(a)(2), 438.242(b)(5), 457.732(a)(2), 457.1233(d)(2), and 45 CFR 156.223(a)(2). Impacted payers would be required to implement the PAS API, and, when sending the response, include information regarding whether the organization approves (and for how long), denies, or requests more information for the prior authorization request. This API must be conformant with the HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG beginning January 1, 2023 (for Medicaid and CHIP managed care plans, by the rating period beginning on or after January 1, 2023).

As discussed previously, to implement the new requirements for the PAS API, we estimate that impacted payers would conduct three major work phases: Initial design, development and testing, and long-term support and maintenance. Additionally, for this proposed PAS API, we believe additional tasks are necessary to accomplish the proposed requirements, which we describe below as they impact the cost estimates. As discussed previously, the costs for the third phase, long-term support and maintenance, and our methodology for the development of those costs in aggregate for all proposed APIs is presented in section V.C.4. of this proposed rule.

Our estimates are based on feedback from industry experts on the anticipated burden to implement the PAS API. We believe this to be a reasonable estimate of the implementation burden. Payers would need to develop APIs that could receive providers' prior authorization requests, and associated documentation and send the payer's decision. In addition to implementing the PAS API, these payers would also be required to send a reason for denial for any prior authorization decisions that are denied. We note, as discussed in section II.C. of this proposed rule, while the PAS API will leverage the HL7 FHIR standard, the prior authorization transactions would remain conformant with the X12 278 standard and thus remain HIPAA-compliant. As such, given the added complexity of accounting for the HIPAA standards, we have accounted for the multiple skill sets required in developing the burden estimates.

Table 5 presents the total activities, hours, and dollar burdens for the implementation of the PAS API (initial design phase and the development and testing phase). Based on the same assumptions as those included in the CMS Interoperability and Patient Access

final rule (85 FR 25510), we have selected the medium estimate as the primary estimate. As can be seen from the bottom rows of Table 5:

- One-time implementation efforts for the first two phases would (for the primary estimate) require on average a total of 9,200 hours per organization at an average cost of $936,400 per organization.
- The aggregate burden of the one-time implementation costs across 266 parent organizations would be 2,447,200 hours (9,200 hours * 266) at a cost of $249.1 million ($936,400 * 266). This corresponds to the primary estimate; the primary and high are obtained by multiplying the low estimate by a factor of two and three, respectively.

TABLE 5: Burden Estimates for the Prior Authorization Support (PAS) API *

Occupation Title	Labor Cost ($ / Hour)	Hours (Low)	Hours *(Primary)*	Hours (*High*)	Total Cost (Wages * Hours) (*Low*)	Total Cost (Wages * Hours) (*Primary*)	Total Cost (Wages * Hours) (*High*)
Software and Web Developers	$102.88	3530	7060	10590	$363,166	$726,333	$1,089,499
Engineers, All Other	$98.52	320	640	960	$31,526	$63,053	$94,579
Computer and Information Systems Managers	$150.38	50	100	150	$7,519	$15,038	$22,557
Database Administrators and Network Architects	$92.42	650	1300	1950	$60,073	$120,146	$180,219
General and Operations Managers	$118.30	50	100	150	$5,915	$11,830	$17,745
Totals per Parent Organization		4,600	9,200	13,800	$468,200	$936,400	$1,404,599
Totals for 266 Parent Organizations		1,223,600	2,447,200	3,670,800	$124,541,147	$249,082,294	$373,623,440

*Estimated burden is total burden of implementation; this burden is apportioned over 24 months in the COI summary table. Annual maintenance costs are 25 percent of total implementation costs as reflected in subsequent year costs in Table 10.

As noted previously, although compliance with this provision is required to begin January 1, 2023, the APIs will be under development prior to this date in order to be implemented and operational on January 1, 2023 (or the rating period that begins on or after January 1, 2023 for Medicaid managed care plans and CHIP managed care entities). Acknowledging that impacted payers will have varying technological and staffing capabilities, we estimate that development of the APIs will require six to 12 months of work. Expecting that this rule will be finalized in early 2021, we have distributed the cost over approximately two calendar years of time to give payers the flexibility to complete the work necessary (see Table 10, summary table).

We solicit public comment on our approach and assumptions for the one-time implementation cost of the PAS API, including whether our estimates and ranges are reasonable or should be modified. The burden of this provision will be included in OMB Control #0938–NEW.

7. ICRs Regarding Requirement To Send Prior Authorization Decisions Within Certain Timeframes Proposals (42 CFR 438.210, 440.230, 457.495, and 457.1230)

To increase transparency and reduce burden, we are proposing to require that impacted payers, not including QHP issuers on the FFEs, send prior authorization decisions within 72 hours for urgent requests and 7 calendar days for non-urgent requests at 42 CFR 438.210(d)(1), 440.230(d)(1), and 457.495(d)(1). We are proposing that the payers would have to comply with these provisions beginning January 1, 2023 (for Medicaid and CHIP managed care plans, by the rating period beginning on or after January 1, 2023).

Since this provision is only applicable to Medicaid and CHIP, only 235 of the 266 Parent Organizations, those parent organizations that offer Medicaid or CHIP plans, would have to implement this provision.

In order to implement this policy, there would be up-front costs for impacted payers to update their policies and procedures, the burden for which we now estimate. We anticipate this burden per payer is 8 hours to update policies and procedures reflecting two half-days of work. We estimate a per entity cost of $946.40 (8 hours to develop * $118.30/hour, the hourly wage for General and Operations Managers). The total burden for all 235 payers is 1,880 hours (8 hours * 235), at an aggregate first year cost of $222,404 ($946.40 * 235).

These calculations are summarized in Table 6.

TABLE 6: First Year Cost to Update Policies and Procedures Regarding Requirement to Send Prior Authorization Decisions within Certain Timeframes

Item	Hours	Labor Cost ($ / Hour)	Cost (Hours * Labor)
Impact per Parent Organization	8	$118.30	$946.40
Totals for 235 Parent Organizations	1880		$ 222,404

We solicit public comments on our assumptions and approach.

8. ICRs Regarding Public Reporting of Prior Authorization Metrics Proposal (42 CFR 438.210, 440.230, 457.732, 457.1233, and 45 CFR 156.223)

In order to support transparency for patients in choosing health coverage, and for providers when selecting payer networks to join, we are proposing to require at 42 CFR 438.210(g), 440.230(d)(2), 457.732(a)(3), 457.1233(d)(2), and 45 CFR 156.223(a)(3) the applicable payers to publicly report, annually, certain plan-level prior authorization metrics on their websites or via publicly accessible hyperlink(s). Impacted payers would be required to report once, annually, by the end of the first calendar quarter each year for the prior year's data beginning March 31, 2023.

We estimate that impacted payers would conduct two major work phases: (1) Implementation, which includes defining requirements and system design (and updates) to generate and compile reports; and (2) maintenance, including annual compilation of reports and public reporting of metrics on a website or through a publicly accessible hyperlink(s). In the first phase, we believe impacted payers would need to define requirements concerning the types and sources of data that would need to be compiled regarding prior authorization activities, build the capability for a system to generate reports, and update or create a public web page to post the data. In the second phase, we believe impacted payers would need to create the quarterly reports and post to a public web page on an annual basis.

- First-year implementation would require on average a total of 320 hours per organization at an average cost of $28,685.20 per organization.
- Therefore, the aggregate burden of the first-year implementation across 266 parent organizations would be 85,120 hours (320 hours * 266) at a cost of $7,630,263 ($28,685.20/organization * 266).
- Similarly, ongoing maintenance after the first year will require a total of 120 hours per organization at an average cost of $8,714.40 per organization.
- Therefore, the aggregate burden of ongoing maintenance across 266 parent organizations would be 31,920 hours (120 hours * 266 parent organizations) at a cost of $2,318,030 ($8,714.40 * 266).

TABLE 7: Aggregate Burden for Complying with Public Reporting of Prior Authorization Metrics

Occupation Title	Labor Cost ($ / Hour)	Development Hours (1st Year Only) (Hours)	Maintenance Hours Per Year (Hours)	1st Year Development Cost ($)	Annual Maintenance Cost ($)
Software and Web Developers	$102.88	180	0	$18,518.40	0 -
Business Operations Specialists	$72.62	140	120	$10,166.80	$8,714.40
Totals per Parent Organization		320	120	$28,685	$8,714
Totals for 266 Parent Organizations		85,120	31,920	$7,630,263	$2,318,030

We solicit comment on this approach and our assumptions.

9. ICRs for Implementing Third Party Application Attestation for Privacy Provisions (42 CFR 431.60(g), 438.242(b)(5), 457.70(g), 457.1233(d)(2), and 45 CFR 156.221(h))

We are proposing at 42 CFR 431.60(g) for state Medicaid FFS programs, at 42 CFR 438.242(b)(5) for Medicaid managed care plans, at 42 CFR 457.730(g) for state CHIP FFS programs, at 42 CFR 457.1233(d)(2) for CHIP managed care entities, and at 45 CFR 156.221(h) for QHP issuers on the FFEs that beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023), that impacted payers must establish, implement, and maintain a process for requesting an attestation from a third-party app developer requesting to retrieve data via the Patient Access API that indicates the app adheres to certain privacy provisions.

Since the two tasks of establishing, implementing, and maintaining a process for requesting an attestation from a third-party app developer and the task of informing patients of the privacy policy evaluation of the third-party app developer are connected, we estimate the cost together.

We estimate the system work required is similar to the system work required for the public reporting requirements (Table 7) which involves both data lookup and data display. We therefore assume that first year development costs would involve 180 hours by a software developer working in collaboration with a business operations specialist for 140 hours to develop these systems. After the first year, the business operations specialist would require 120 hours to maintain the system.

TABLE 8: Aggregate Burden for Complying with Privacy Policy Attestation

Occupation Title	Labor Cost ($ / Hour)	Development Hours (1st Year Only) (Hours)	Maintenance Hours Per Year (Hours)	1st Year Development Cost ($)	Annual Maintenance Cost ($)
Software and Web Developers	$102.88	180	0	$18,518.40	$0
Business Operations Specialists	$72.62	140	120	$10,166.80	$8,714.40
Totals per Parent Organization		320	120	$28,685	$8,714.40
Totals for 266 Parent Organizations		85,120	31,920	$7,630,263	$2,318,030

The aggregate first year burden is therefore 85,120 hours (266 parent organizations *(180 for development plus 140 for input from a business operations specialist)) at a cost of $7.6 million (266 organizations * (180 hr * $102.88/hr for a software and web developer plus 140 hr * $72.62/hr for a business operations specialist). Second and later year burden would be 31,920 hours (266 parent organizations * 120 hr) at a cost of $2.3 million (266 parent organizations * 120 hr * $72.62/hr).

10. ICRs Regarding Payer-to-Payer API Proposal (42 CFR 431.61, 438.242, 457.731, 457.1233, and 45 CFR 156.222)

To reduce payer, and ultimately, provider burden and improve patient access to their health information through care coordination between payers, as discussed in section II.D. of this proposed rule, we are proposing new requirements at 42 CFR 431.61(c), 438.242(b), 457.731(c), 457.1233(d), and 45 CFR 156.222(b). These proposals would improve care coordination between payers by requiring payers to exchange, at a minimum, adjudicated claims and encounter data (not including remittances and enrollee cost-sharing information), clinical information as defined in the USCDI (version 1), and pending and active prior authorization decisions, using a FHIR-based Payer-to-Payer API by January 1, 2023 (for Medicaid and CHIP managed care plans, by the rating period beginning on or after January 1, 2023).

As discussed for the other APIs being proposed in this rule, we estimate that impacted payers would conduct three major work phases: Initial design, development and testing, and long-term support and maintenance. Additionally, for this proposed API, we believe additional tasks are necessary to accomplish the proposed requirements, which we describe below as they impact the cost estimates. The costs for the third phase, long-term support and maintenance, and our methodology for the development of those costs in aggregate for all proposed APIs is presented in section V.C.4. of this proposed rule.

Payers should be able to leverage the API infrastructure already accounted for in other requirements, including the Patient Access API finalized in the CMS Interoperability and Patient Access final rule (85 FR 25510) and the Provider Access API proposal in this rule. As discussed in the CMS Interoperability and Patient Access final rule (85 FR 25510) (as well as the companion ONC 21st Century Cures Act final rule (85 FR 25642)) and this proposed rule, payers would be using the same FHIR standards for content and transport; IGs to support interoperability of data sharing; as well as the same underlying standards for security, authentication, and authorization. In addition, impacted payers would be required to implement the HL7 FHIR Bulk Data Access (Flat FHIR) specification for the Provider Access API, the same specification proposed for this Payer-to-Payer API, to support the exchange of patient health information for one or more patients at a time. Taken together, these standards would also support the proposed Payer-to-Payer API. Thus, we believe there will be some reduced development costs to implement the Payer-to-Payer API because of efficiencies gained in implementing many of the same underlying standards and IGs for the Patient Access API and the other APIs proposed in this rule.

We do believe there will be some costs for impacted payers to implement the proposed Payer-to-Payer API that are unique to this proposal. Even though there will be some efficiencies gained in using the same standards and IGs as other APIs, we believe based on input from industry experience in implementing APIs that there will be costs to test and integrate the Payer-to-Payer API with payer systems, albeit potentially lower costs than estimated for the Provider Access API. We estimate the one-time implementation costs at about one-third the cost of a full de novo Provider Access API implementation based on input from developers who have implemented and piloted prototype APIs using the proposed required standards and IGs. As such, we have accounted for the necessary staff required as we also believe there will be unique costs for implementing the HL7 FHIR Payer Coverage Decision Exchange IG so that payers can exchange active and pending prior authorization decisions and related clinical documentation and forms when an enrollee or beneficiary enrolls with a new impacted payer.

Table 9 presents the total activities, hours, and dollar burdens for the implementation of the Payer-to-Payer API given our assumptions above (initial design phase and the development and testing phase). Based on the same assumptions as those published in the CMS Interoperability and Patient Access final rule (85 FR 25510), we have selected the medium estimate as the primary estimate. As can be seen from the bottom rows of Table 9:

- One-time implementation efforts for the first two phases would (for the primary estimate) require on average a total of 1,012 hours per organization at an average cost of $104,816 per organization.
- Therefore, the aggregate burden of the one-time implementation costs across 266 parent organizations would be 269,192 hours (1,012 hours * 266) at a cost of $27.9 million ($104,816 * 266). This corresponds to the primary estimate; the primary and high are obtained by multiplying the low estimate by a factor of two and three, respectively.

TABLE 9: Burden Estimates for the Payer-to-Payer API *

Occupation Title	Labor Cost ($ / Hour)	Hours (*Low*)	Hours (*Primary*)	Hours (*High*)	Total Cost (Wages * Hours) (*Low*)	Total Cost (Wages * Hours) (*Primary*)	Total Cost (Wages * Hours) (*High*)
General and Operations Managers	$118.30	48	96	144	$5,678	$11,357	$17,035
Computer and Information Analysts	$93.82	43	86	129	$4,034	$8,069	$12,103
Software and Web Developers	$102.88	415	830	1245	$42,695	$85,390	$128,086
Totals per Parent Organization		506	1012	1518	$52,408	$104,816	$157,224
Totals for 266 Parent Organizations		134,596	269,192	403,788	$13,940,491	$27,880,982	$41,821,472

*Estimated burden is total burden of implementation; this burden is apportioned over 24 months in the COI summary table. Annual maintenance costs are 25 percent of total implementation costs as reflected in subsequent year costs in Table 10.

As noted previously, although this provision would first be applicable January 1, 2023, we believe it is reasonable that the APIs will be under development prior to that date. Acknowledging that impacted payers will have varying technological and staffing capabilities, we estimate that development of the APIs will require six to twelve months of work. Expecting that this rule will be finalized in early 2021, we have distributed the cost estimates over approximately two calendar years of time to reflect impacted payers being given flexibility regarding when they complete the work (see Table 10).

We solicit public comments on our approach and assumptions for the cost of the Payer-to-Payer API, including whether our estimates and ranges are reasonable or should be modified.

c. Summary of Information Collection Burdens

The previous sections have detailed costs of individual provisions. Table 10 summarizes costs for the first, second, and subsequent years of these provisions (as described in detail above). Table 10 reflects an assumption of an early 2021 publication date for the final rule; the API provisions would be effective January 1, 2023. Table 10 reflects the primary estimates. Calculations of the high and low estimates for the APIs may be found in the tables and narrative of the relevant sections for each of the provisions as discussed in this Collection of Information section. Labor costs are either BLS wages when a single staff member is involved, or a weighted average representing a team effort obtained by dividing the aggregate cost (calculated in the tables above) by the aggregate hours; for example, in the first row the $91.53 equals the aggregate $3.9 million cost divided by the aggregate 42,560 hours.

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TABLE 10: Summary of Annual Information Collection Burden Estimates for Proposed Requirements

Item	Regulatory Citations	Hours / Respondent	Number of Respondents	Total Hours	Labor Cost ($ / Hour)	1st Year Cost (Millions $)	2nd Year Cost (Millions $)	3rd and Subsequent Year Cost (Millions $)
Patient Access API Metrics Reporting, 1st year	(1)	160	266	42,560	$91.53	$3.9		
Patient Access API Metrics Reporting, subsequent years	(1)	40	266	10,640	$72.62		$0.8	$0.8
Provider Access API	(2)	2,800	266	744,800	$98.48	$36.7	$36.7	$18.3
DRLS API	(3)	9,630	266	2,561,580	$102.20	$130.9	$130.9	$65.4
PAS API	(4)	9,200	266	2,447,200	$101.78	$124.5	$124.5	$62.3
Timeframes for Prior Authorization Decisions	(5)	8	235	1,880	$118.30	$0.2		
Public Reporting of Prior Authorization Metrics, 1st Year	(6)	320	266	85,120	$89.64	$7.6		
Public Reporting of Prior Authorization Metrics, subsequent years	(6)	120	266	31,920	$72.62		$2.3	$2.3
Privacy Policy Attestation, 1st year	(7)	320	266	85,120	$89.64	$7.6		
Privacy Policy Attestation, 2nd year	(7)	120	266	31,920	$72.62		$2.3	$2.3
Payer-to-Payer API	(8)	1,012	266	269,192	$103.57	$13.9	$13.9	$7.0
Totals		23,730	2,742,964	6,311,932	*Varies*	$325.4	$311.5	$158.4

NOTES:
(1) 42 CFR 431.60, 438.242, 457.730, 457.1233, and 45 CFR 156.221
(2) 42 CFR 431.61, 438.242, 457.731, 457.1233, and 45 CFR 156.222
(3) 42 CFR 431.80, 438.242, 457.732, 457.1233, and 45 CFR 156.223
(4) 42 CFR 431.80, 438.242, 457.732, 457.1233, and 45 CFR 156.223
(5) 42 CFR 442.631, 440.230, 457.495, and 457.1230
(6) 42 CFR 438.210, 440.230, 457.732, 457.1233, and 45 CFR 156.223
(7) 42 CFR 431.60(g), 438.242(b)(5), 457.730(g), 457.1233(d)(2), and 45 CFR 156.221(h)
(8) 42 CFR 431.61, 457.731, 438.242, 457.1233(d), and 45 CFR 156.222

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D. Conclusion

The provisions of this proposed rule could greatly improve data sharing across stakeholders by facilitating access, receipt, and exchange of patient data. This could both increase access to patient data and decrease burden associated with gaining access to patient data. We are committed to providing patients, providers, and payers with timely access to patient health information. We welcome comments on our approaches for estimating cost burden and cost savings.

The requirements of this proposed rule are extensions of the requirements of the CMS Interoperability and Patient Access final rule (85 FR 25510). Therefore, the information collection requirements will be submitted to OMB for review and approval.

If you would like to provide feedback on these information collections, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by January 4, 2021.

VI. Response to Comments

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

VII. Regulatory Impact Analysis

A. Statement of Need

As described in prior sections of this proposed rule, the proposed changes to 42 CFR parts 431, 435, 438, 440, and 457, and 45 CFR parts 156 and 170 further support the agency's efforts to reduce burden on patients, providers, and payers, and to empower patients and providers by increasing electronic access to health care data, while keeping that information safe and secure. The proposals in this rule would largely build on the foundation we laid in the CMS Interoperability and Patient Access final rule (85 FR 25510). This proposed rule continues the efforts started with that final rule to move the health care system toward greater interoperability and reduce burden by proposing to increase the data sharing capabilities of impacted payers, encourage health care providers' use of new capabilities, and

make patient data more easily available to them through standards-based technology.

The provisions in this proposed rule would allow providers and payers new means to receive their patient population's data from impacted payers through the Provider Access and Payer-to-Payer APIs. This would allow providers to improve their ability to deliver quality care and improve care coordination by ensuring that providers have access to patient data at the point of care. These proposals would also assist impacted payers by improving their ability to exchange claims and clinical data on enrollees who switch payers or have concurrent payers, which would reduce burden and improve continuity of care for patients, as well as ensure more efficient payer operations. Further, patients would have more timely access to their claims and other health care information from impacted payers, empowering them to more directly understand and manage their own care through enhancements to the Patient Access API.

Additionally, we believe these proposals would reduce burden on patients, providers, and payers, as well as reduce interruptions or delays in patient care by improving some aspects of the prior authorization process. To accomplish this, we are proposing a number of requirements, including proposing to require impacted payers implement and maintain a FHIR-based API to support a documentation requirement lookup service (DRLS). The DRLS API would be able to integrate with a provider's EHR or practice management system to allow providers to discover the items and services that require prior authorization, as well as the documentation required to submit a prior authorization. Impacted payers would also be required to implement and maintain a Prior Authorization Support (PAS) API that would have the capability to accept and send prior authorization requests and decisions, and could be integrated directly in a provider's workflow, while maintaining alignment with, and facilitating the use of, the required HIPAA transaction standards.

As noted below, we believe that the policies in this proposed rule, if finalized, would result in some financial burdens for impacted payers. We have weighed these potential burdens against the potential benefits, and believe the potential benefits justify potential costs.

B. Overall Impact

We have examined the impacts of this proposed 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 Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), 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 must be prepared for major rules with economically significant effects ($100 million or more in any one year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of this rulemaking.

C. Regulatory Flexibility Act

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the Regulatory Flexibility Act (RFA)). If a proposed rule may have a significant economic impact on a substantial number of small entities, then the proposed rule must discuss steps taken, including alternatives considered, to minimize burden on small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a ''significant'' impact to be three to five percent or more of the affected entities' costs or revenues.

For purposes of the RFA, we estimate that many impacted payers are small entities as that term is used in the RFA, either by being nonprofit organizations or by meeting the SBA definition of a small business. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The North American Industry Classification System (NAICS) is used in the U.S., Canada, and Mexico to classify businesses by industry. While there is no distinction between small and large businesses among the NAICS categories, the SBA develops size standards for each NAICS category.[79] Note that the most recent update to the NAICS went into effect for the 2017 reference year.

We first review the provisions of this rule at a high level, and then discuss each of the impacted payer types, and through this discussion evaluate the impact on small entities.

1. Overview of Overall Impact

The annual information collection burden estimates for the proposed requirements in this rule are summarized in Table 10 of the Collection of Information (section V. of this proposed rule). The specific information collection requirement (ICR) proposals, which we have calculated burden estimates for, include: (1) Provider Access API (Table 3); (2) DRLS API (Table 4); (3) PAS API (Table 5); (4) Proposed requirement to send prior authorization decisions within certain timeframes (Table 6); (5) Payer-to-Payer API (Table 9); (6) two metrics reporting requirements (specifically, Patient Access API and prior authorization metrics) (Tables 2

[79] Office of Management and Budget. (2017). North American Industry Classification System. Retrieved from: *https://www.census.gov/eos/www/naics/2017NAICS/2017_NAICS_Manual.pdf.*

and 7) and (7) Requirements to comply with privacy policy attestations (Table 8).

Additionally, this Regulatory Impact Analysis section provides an analysis about potential savings from voluntary provider compliance with the DRLS and PAS API proposed provisions (however, this savings is neither included in monetized tables nor in summary tables, as further discussed below). We have identified assumptions for these analyses, and we solicit public comment.

In analyzing the impact of this proposed rule, we note that there would be a quantifiable impact for the proposed Provider Access, DRLS, and PAS APIs. The proposed requirements would apply to 266 parent organizations. Throughout this proposed rule we use the term ''parent organizations'' to refer to impacted payers. These parent organizations include the states that administer state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs.

The NAICS category relevant to these proposed provisions is Direct Health and Medical Insurance Carriers, NAICS 524114, who have a $41.5 million threshold for ''small size.'' Seventy-five percent of insurers in this category have under 500 employees, thereby meeting the definition of small business.

We are certifying that, for impacted payers, this proposed rule does not have a significant economic impact on a substantial number of small entities with regard to the provisions noted above.

2. Health Coverage Groups

If the proposals in this rule are finalized, the 266 parent organizations, including state Medicaid and CHIP agencies, would be responsible for implementing and maintaining four new APIs, updating policies and procedures regarding timeframes for making prior authorization decisions, and reporting certain metrics either to CMS or the public. Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs are classified as NAICS code 524, direct health insurance carriers. We are assuming that a significant number of these entities are not small. And, we note that none of the state Medicaid and CHIP agencies are considered small.

At a high level, state Medicaid managed care plans and CHIP managed care entities have many of their costs covered through capitation payments from the federal government or through state payments. Therefore, there is no significant burden, as detailed below. If finalized as proposed, QHP issuers on the FFEs and certain states operating Medicaid and CHIP FFS programs would be able to apply for an extension, exception or exemption under which they would not be required to meet the new API provisions of the proposed rule on the proposed compliance dates, provided certain conditions are met as discussed in sections II.B., II.C., and II.D. of this proposed rule. We therefore believe there is no significant burden to a significant number of entities from this proposed rule for these provisions as discussed.

a. Medicaid and CHIP

Title XIX of the Act established the Medicaid program as a federal-state partnership for the purpose of providing and financing medical assistance to specified groups of eligible individuals. States claim federal matching funds on a quarterly basis based on their program expenditures. Since states are not small entities under the Small Business Act we need not further discuss in this section the burden imposed on them by this rule.

With regard to Medicaid managed care plans and CHIP managed care entities, since managed care plans receive 100 percent capitation payments from the state, we generally expect that the costs associated with the provisions of this proposed rule would be included in their capitation rates and may be reasonable, appropriate, and attainable costs whether they are a small business or not. Consequently, we can assert that there is no significant impact on a significant number of entities.

As discussed in sections II.B., II.C., and II.D. for the new proposed API provisions, states operating Medicaid FFS and CHIP FFS programs could submit an application for an extension of up to one year to comply with the requirements of this rule. Additionally, we propose that states operating Medicaid and CHIP FFS programs with very low enrollment and high managed care penetration rates (at least 90 percent), can apply for an exemption under which they would not be required to meet certain proposed requirements, provided certain conditions are met.

b. QHP Issuers on the FFEs

Few, if any, QHP issuers on the FFEs are small enough to fall below the size thresholds for a small business established by the SBA. Consistent with previous CMS analyses, we estimate that any issuers that would be considered a small business are likely to be subsidiaries of larger issuers that are not small businesses (78 FR 33238) and thus do not share the same burdens as an independent small business. Therefore, even though QHP issuers do not receive federal reimbursement for the costs of providing care, we do not conclude that there would be a significant small entity burden for these issuers. In addition, we propose an exception process for QHP issuers on the FFEs from certain proposed requirements, which further helps to address burden that could otherwise prohibit a QHP issuer from participating in an FFE.

Based on the above, we conclude that the requirements of the RFA have been met by this proposed rule.

D. UMRA and E.O. 13132 Requirements

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This proposed rule would not impose an unfunded mandate that would result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $156 million in any one year.

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. As previously outlined, while the API provisions would be a requirement for state Medicaid and CHIP agencies under these proposals, the cost per enrollee for implementation is expected to be negligible when compared with the overall cost per enrollee. This analysis does not take into account federal matching funds provided to state Medicaid and CHIP agencies, but the conclusion is the same: There is not expected to be a significant cost impact on state entities.

For Medicaid and CHIP, we do not believe that the proposals in this rule would conflict with state law, and therefore, do not anticipate any preemption of state law. However, we invite states to submit comments on this proposed rule if they believe any proposal in this rule would conflict with state law, so that we can fully evaluate any potential conflicts.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with

regulatory review. We model our estimates of review burden based on similar estimates presented in the CMS Interoperability and Patient Access final rule (85 FR 25510).

The particular staff involved in such a review would vary from one parent organization to another. We believe that a good approximation for a range of staff would be a person such as a medical and health service manager or a lawyer. Using the wage information from the BLS for medical and health services managers (Code 11–9111) and lawyers (Code 23–1011) we estimate that the cost of reviewing this proposed rule is $125.23 per hour, including overhead and fringe.[80] This number was obtained by taking the average wage of a medical manager and lawyer.

In the CMS Interoperability and Patient Access final rule (85 FR 25510), we estimated six hours of reading time. Therefore, we believe 10 hours would be enough time for each parent organization to review relevant portions of this proposed rule.

We believe the review would be done by parent organizations that would be required to implement the proposed provisions. There are 266 parent organizations accounted for in our estimates. Thus, we estimate a one-time aggregated total review cost of $333,112 million ($125.23 * 10 hours * 266 entities). We solicit comments on our estimate.

E. Impact of Individual Proposals

The proposed provisions of this rule would have information collection-related burden. Consequently, the impact analysis may be found in Table 10 of the Collection of Information in section V. of this proposed rule. To facilitate review of the provisions and estimates made in the Collection of Information, we include Table 11, which provides the related ICRs in section V. of this proposed rule, the tables in section V. where impact is presented, as well as a title used for cross-reference in the remainder of this Regulatory Impact Analysis section.

Table 19 of this section, using Table 10 as a basis, provides a 10-year impact estimate. Table 19 includes impact by year, by type (parent organizations, including Medicaid and CHIP state agencies), as well as the cost burden to the federal government, allocations of cost by program, and payments by the federal government to Medicaid and CHIP, as well as the premium tax credits (PTC) paid to certain enrollees in the individual market.

TABLE 11: Cross-References to Impacts in the Collection of Information Requirements (Section V.) of this Proposed Rule

ICR number	Title	Tables with Impact Analysis
2	Patient Access API Metrics Reporting to CMS Proposal	Table 2
4	Provider Access API Proposal	Table 3
5	DRLS API Proposal	Table 4
6	PAS API Proposal	Table 5
7	Timeframes for Prior Authorization Decisions Proposals	Table 6
8	Public Reporting of Prior Authorization Metrics Proposal	Table 7
9	Complying with Privacy Policy Attestation	Table 8
10	Payer-to-Payer API Proposal	Table 9
Summary Table	3-Year Analysis of Cost Impact of Proposed Provisions	Table 10

F. Alternatives Considered

In this proposed rule, we continue to build on the efforts initiated with the CMS Interoperability and Patient Access final rule (85 FR 25510) and the work we have done to reduce burden in the health care system, to advance interoperability, improve care coordination, reduce burden, and empower patients with access to their health care data. This proposed rule covers a range of policies aimed at achieving these goals. We carefully considered alternatives to the policies we are proposing in this rule. We concluded that none of the alternatives would adequately or immediately begin to address the critical issues related to patient access and interoperability or help to address the processes that contribute to payer, provider, and patient burden.

We now discuss the alternatives we considered to our proposed provisions and the reasons why we did not select them as proposed policies.

1. Alternatives Considered for the Proposed Patient Access API Enhancements

We are proposing to require that payers make enhancements to the Patient Access API finalized in the CMS Interoperability and Patient Access final rule (85 FR 25510) including requiring the Patient Access API be conformant with the IGs specified in section II.A.2. of this proposed rule, proposing additional information be made available to patients through the Patient Access API, proposing a privacy attestation policy, and proposing certain metrics about patient use of the Patient Access API be reported directly to CMS quarterly. Before proposing to require these provisions, we considered several policy alternatives.

As we discussed in the CMS Interoperability and Patient Access final rule (85 FR 25627), one alternative to the proposed updates to the Patient Access API we considered is allowing payers and providers to upload patient

[80] U.S. Bureau of Labor Statistics. (2019, April 02). May 2018 National Occupational Employment and Wage Estimates. Retrieved from *https://www.bls.gov/oes/current/oes_nat.htm.*

data directly to a patient portal, operated by a provider. However, despite the availability of patient portals, ONC reported in 2017 that only 52 percent of individuals have been offered online access to their medical records by a health provider or payer. And of the 52 percent that were offered access, only half of those viewed their record.[81] Therefore, we do not believe that patient portals are meeting patients' needs and would not be a suitable policy option to propose. We also believe that there would be additional burden associated with using portals, because providers and patients would need to utilize multiple portals and websites, requiring various log-ins, to access all of a patient's relevant data—one for each provider a patient is associated with—instead of a single app. Portals would require developers to link systems or ensure system-level compatibility to enable patients to see a more comprehensive picture of their care. Alternatively, FHIR-based APIs have the ability to make data available without the need to link multiple systems or portals and would provide a patient a single point of access to their data. APIs that make data available to third-party apps permit the patient to choose how they want to access their data and promote innovation in industry to find solutions to best help patients interact with their data in a way that is most meaningful and valuable to them. The nature of portals does not lend as well to such interoperability or innovation. Because business models and processes pertaining to patient portals are varied across the industry, and any one patient could be associated with a number of different portals, we believe it would be very difficult to evaluate the cost impacts of requiring individual portals versus the estimates for enhancing the Patient Access API.

As explained in the CMS Interoperability and Patient Access final rule (85 FR 25627), another alternative considered was to allow Health Information Exchanges (HIEs) and Health Information Networks (HINs) to serve as a central source for patients to obtain aggregated data from across their providers and payers in a single location. HIEs and HINs could provide patients with information via an HIE portal that is managed by the patient. However, as described above, there are various reasons why patient portal access does not lend itself to interoperability or innovation, and not all patients might have access to an HIE or HIN. For these reasons, we ultimately decided to proceed with our proposed requirements versus this alternative.

We had also considered alternative compliance dates for the proposed policies. For instance, we considered January 1, 2022, as a possible compliance date for the Patient Access API enhancements. However, due to the current public health emergency and the enforcement discretion we are exercising for the API policies finalized in the CMS Interoperability and Patient Access final rule, we believe it is more appropriate, and less burdensome to impacted payers to propose compliance dates for these policies beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023).

2. Alternatives Considered for the Proposed Provider Access API

In this proposed rule, to better facilitate the coordination of care across the care continuum, we are proposing to require impacted payers to implement and maintain a Provider Access API conformant with the specified HL7 FHIR IGs, as well as the HL7 FHIR Bulk Data Access (Flat FHIR) specification to support exchanging data for one or more patients at a time. This proposed API would require payers to make available to providers the same types of data they would make available to patients via the enhanced Patient Access API.

Alternatively, we considered other data types that could be exchanged via the Provider Access API. We considered only requiring the exchange of clinical data, as defined in the USCDI. While this would be less data to exchange and, thus, potentially less burdensome for payers to implement, we believe that claims and encounter information can complement the USCDI data and offer a broader and more holistic understanding of a patient's interactions with the health care system. Furthermore, the data that we propose to be available through the proposed Provider Access API aligns with the data that we propose be available to individual patients through the Patient Access API. Therefore, we do not believe there is significant additional burden to include these data as once the data are mapped and prepared to share via one FHIR-based API, these data are available for all payer APIs to use.

We did also consider only having payer claims and encounter data available to providers, understanding that providers are generally the source of clinical data. Again, this could potentially reduce burden on payers by potentially requiring less data to be made available. However, even if a provider is the source for the clinical data relevant to their patients' care, a provider may not have access to clinical data from other providers a patient is seeing. As a result, and understanding payers were already preparing these data for use in other APIs, we decided a more comprehensive approach would be most beneficial to both providers and patients and thus aligned the proposed Provider Access API data requirements with those proposed for the Patient Access API.

We also considered including additional data elements in this proposal. We considered requiring the patient's complete medical record. However, we believe this would require additional resources and be overly burdensome for impacted payers at this time. The USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.[82] Because this limited set of data has been standardized, and corresponding HL7 FHIR IGs have been developed, payers can map these data and make them more easily available via an API. Industry has not yet fully developed the needed IGs to facilitate sharing a patient's full medical record. Before this alternative would be feasible, more FHIR development work needs to be done, and important questions about data segmentation, and a patient's role in potentially specifying what parts of their medical record could or should be available to which providers, need to be considered.

3. Alternatives Considered for the Proposed DRLS API and PAS API and Other Prior Authorization Proposals

In this rule, we are also proposing several policies that would reduce burden associated with the prior authorization process. First, we are proposing to require all impacted payers implement and maintain a DRLS API conformant with the HL7 FHIR CRD and DTR IGs. We believe this would reduce burden for payers, providers, and patients by streamlining access to information about which items and services require a prior authorization and the associated documentation requirements, potentially reducing the number of incomplete and denied prior authorization requests. This would add efficiencies for both payers and

[81] Patel, V. & Johnson, C. (2018, April). Individuals' Use of Online Medical Records and Technology for Health Needs (ONC Data Brief N. 40). Retrieved from *https://www.healthit.gov/sites/default/files/page/2018-03/HINTS-2017-Consumer-Data-Brief-3.21.18.pdf.*

[82] Interoperability Standards Advisory. (n.d.). U.S. Core Data for Interoperability. Retrieved from *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

providers, and it would improve patient care by avoiding gaps and delays in care.

As proposed, by January 1, 2023, (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023), impacted payers would be required to implement the DRLS API, populate the API with their list of items and services for which prior authorization is required, populate the API with their associated documentation rules, and ensure the DRLS API is functional. Alternatively, we considered proposing a phased approach to the DRLS API where payers would first upload a specified subset of documentation to the DRLS API, as opposed to all of the documentation for all applicable items and services at one time. For instance, we considered requiring that payers only prepare the DRLS for a specific set of services most commonly requiring prior authorization across payers. However, we believe this would be more burdensome in some ways. It would require payers to use different systems to find requirements for different services for a single payer, for instance. If the requirements for different services were in different places—such as some information in payer portals and some through the DRLS API—providers would have to spend additional time searching for the information in multiple locations for one payer. Therefore, we believe it is ultimately less burdensome overall to require impacted payers to populate the prior authorization and documentation requirements for all items and services at the same time.

We also considered whether we should propose to require that payers post, on a public-facing website, their list of items and services for which prior authorization is required, populate the website with their associated documentation rules as in interim step while they implement the DRLS. However, we are aware that payers already have this information publicly available, and determined that this would not provide any reduced burden on payers or providers at this time. We seek comment on whether a payer website to provide additional transparency to prior authorization requirements and documentation would be beneficial in reducing overall burden in this process.

We are also proposing to require impacted payers implement and maintain a FHIR-based PAS API conformant with the HL7 FHIR Da Vinci PAS IG that would have the capability to accept and send prior authorization requests and decisions. This API would be accessible to providers to integrate directly into their workflow, while maintaining alignment with, and facilitating the use of, the required HIPAA transaction standards. This requirement is proposed to be effective at the same time as the DRLS API, January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023). We considered a phased timeline approach to implement both of these APIs. For instance, we considered first requiring implementation of the DRLS API in 2022 and then a year later requiring implementation of the PAS API. However, given the current situation with the public health emergency, and taking into account the enforcement discretion we are exercising as a result for the APIs finalized in the CMS Interoperability and Patient Access final rule (85 FR 25510), we believe it is more appropriate, and less burdensome to impacted payers, to propose compliance dates for both of these policies in 2023, providing payers with more time to potentially implement both policies. We further determined that because the DRLS API and the PAS API are steps in the same prior authorization workflow, the full benefits of both APIs are best realized when used concurrently.

We are proposing other provisions to reduce prior authorization burden including requiring payers to ensure that prior authorization decisions are made within 72 hours of receiving an expedited request and no later than 7 days after receiving a standard requests, and proposing to require impacted payers to publicly report prior authorization metrics on their websites or via publicly accessible hyperlink(s) annually.

We considered several alternative policies before deciding to propose these policies. We considered alternative timeframes such as whether payers could provide a decision in less than 72 hours (for expedited decisions) and 7 days (for standard decisions). For example, we considered requiring payers to provide a decision in 48 hours for expedited requests and 3 days for standard requests. Despite the importance of having providers and patients get decisions as quickly as possible, we believe that the timeframes we propose in this rule would help increase reliability in the prior authorization process and establish clear expectations without being overly burdensome for payers. These timeframes would allow payers to process the prior authorization decisions in a timely fashion and give providers and patients an expectation for when they can anticipate a decision, while at the same time encouraging a timelier decision-making process. We also considered whether more than 7 days would be necessary for complex cases. We did not propose this alternative, however, because we believe it is important for patients and providers to be able to receive a decision in a shorter timeframe. We believe 7 days is sufficient time for a payer to process prior authorization decisions.

Regarding publicly reporting prior authorization metrics, we considered requiring impacted payers to publicly report these metrics more frequently than annually. For instance, we considered a quarterly requirement. While we considered this alternative, we believe that our proposal is sufficient to accomplish our goals without creating additional burden. Because patients typically shop for health coverage on an annual basis, we believe updating this information annually would be sufficient for supplying patients and providers with transparent and valuable information. We also considered reporting these metrics at the parent organization versus at the plan or issuer level for all impacted payers. After further consideration, we decided this may not be truly operational and may be too aggregated a level of reporting for some payer types to provide true transparency or useful information for patients and providers. As a result, we are proposing reporting at the state-level for Medicaid and CHIP FFS, plan-level for Medicaid and CHIP managed care, and at the issuer-level for QHP issuers on the FFEs.

4. Alternatives Considered for the Proposed Payer-to-Payer API

We are proposing to require impacted payers to implement and maintain a Payer-to-Payer API that makes the same data available to other payers via a FHIR-based API as we propose payers make available to patients and providers, conformant with the same IGs as proposed for the Patient Access API discussed in section II.A. and the Provider Access API discussed in section II.B. of this proposed rule. Before proposing these policies, we considered several policy alternatives.

We considered proposing to enhance the Payer-to-Payer Data Exchange finalized in the CMS Interoperability and Patient Access final rule without naming a specific standard. We considered maintaining a payer's ability to share data with another payer without requiring the use of an API, and instead only requiring the additional

types of data be made available to share. But, ultimately, there are numerous benefits to requiring the FHIR-based API conformant with the specified IGs for this data sharing. We have heard from several stakeholders that sharing these data in a standardized way is the only way to introduce valuable efficiencies and achieve true interoperability. Furthermore, for the Payer-to-Payer API, once an organization implements the other proposed APIs, there would be less additional investment necessary to implement the Payer-to-Payer API as payers would be able to leverage the infrastructure already established for the Patient Access API and Provider Access API. Given this available infrastructure, and the efficiencies of sharing standardized data via the API, we determined it was most advantageous for payers to again leverage an API for this enhanced data exchange.

We also considered which data elements would be the most appropriate. Similar to the Provider Access API alternatives, we considered only requiring the exchange of clinical data as defined in the USCDI via an API. As we described above, we believe that claims and encounter information can complement the USCDI data and potentially allow for better care coordination, as well as more efficient payer operations. And, we do not believe there would be significant additional burden once the data are mapped to FHIR for the other proposed APIs.

We also considered requiring payers to exchange all prior authorization decisions, including expired decisions, via the Payer-to-Payer API. However, we recognize that much of this information may be outdated and may not have an effect on the new payer's prior authorization process. Therefore, in an effort to reduce the volume of outdated or irrelevant information shared among payers, we have decided to limit the proposal to only active and pending prior authorization decisions.

G. Analysis of Potential Impact for Savings by Voluntary Participation of Individual Providers in the Proposed Prior Authorization Provisions

To support our commitment to promoting interoperability and reducing burden on payers, providers, and patients, as discussed in section II.C. of this proposed rule, we are proposing new requirements related to prior authorization for states operating Medicaid FFS programs at 42 CFR 431.80 and 440.230; states operating CHIP FFS programs at 42 CFR 457.495 and 457.732; Medicaid managed care plans at 42 CFR 438.210 and 438.242; CHIP managed care entities at 42 CFR 457.495, 457.1230, and 457.1233; and QHP issuers on the FFEs at 45 CFR 156.223. While we discussed the ICRs regarding cost estimates of those proposals with anticipated impact in sections V.C.5. through V.C.8., here, we discuss the anticipated cost savings of these proposals to the health care industry.

We have detailed in this section the cost impact of creating the proposal discussed in section II.C. of this rule, including the DRLS and PAS APIs, as well as a number of other policies focused on reducing burden associated with the prior authorization process. Potentially offsetting some of these costs are the savings that would result from reduced administrative work associated with existing prior authorization protocols.

These savings would be true savings, not transfers, since they reflect savings in reducing the administrative costs required to process prior authorizations. However, these savings would be an indirect consequence of the proposed rule, not direct savings. To be clear, this proposed rule does not reduce the current paperwork required for prior authorization. Rather, a consequence of the efficiencies resulting from the prior authorization proposals would be significantly reduced time spent on the paperwork. In general, it is only appropriate to claim that a regulatory provision's benefits are in excess of its costs after a substantive, and preferably quantitative, assessment of the pre-existing market failure and the provision's suitability for addressing it. As a result of data limitations and other analytic challenges preventing such an assessment in this, the case illustrative savings estimates are neither included in the monetized table, nor the summary table of the Regulatory Impact Analysis in section VII. of this proposed rule, nor in the 2016-dollar calculation. Nevertheless, the savings could be significant and we believe should be a factor in the evaluation of this proposed rule.

In calculating these potential savings, uncertainties arise in five areas, described below. The result of this illustrative analysis is that we find a potential savings impact of a billion dollars over 10 years. In this section, we carefully explain each uncertainty, indicate how we approached estimation, and solicit public comment.

The five areas of uncertainty we had to take into account include:

(1) Assumptions on the number of providers voluntarily engaging with the provisions of this proposed rule: A major obstacle in estimating impact is the fact that these provisions, if finalized, would be mandatory for impacted payers but engagement by providers is voluntary. Before proposing this rule, we conducted conversations with stakeholders who indicated that more efficient prior authorization processes would ultimately reduce burden for all affected parties and would therefore likely be utilized by providers.

To address the voluntary nature of provider utilization of the electronic prior authorization tools, we assume no provider participation in the first year, gradually increasing to 25 percent participation in 10 years. We believe this is a usefully illustrative assumption.[83] We also believe that it is reasonable to assume that additional providers would participate as prior authorization capabilities become more widely available in EHRs, which are not regulated by this rule, and the benefits of having more efficient prior authorization processes become clear through burden reduction and improved patient care.

In going from no providers leveraging the technology in the first year of implementation to 25 percent of providers using the technology in 10 years, we did not believe it appropriate to use a strict linear approach of a 2.5 percent increase of providers per year. We are aware that many providers do not yet have the necessary technical capabilities to facilitate interoperable exchange of data for prior authorization. Specifically, their EHR systems are not yet prepared to leverage the DRLS or PAS APIs. Absent that technology in the EHR, the DRLS and PAS APIs would provide minimal benefit to providers. We assume that providers in hospitals and providers in large health systems who already have such software would use it as soon as technologically feasible. Therefore, we modeled the growth of providers participating with a gradually increasing exponential model, since the exponential model is typically used to indicate slow growth in the beginning but faster growth later on. Our numerical assumptions of the percent of providers using DRLS and PAS APIs are presented in Table 12.

[83] This assumption may be supported by some states already adopting legislation around electronic prior authorization, and federal legislation such as provision 6062 in the SUPPORT Act (H.R. 6) where electronic prior authorization is stipulated for drugs covered under Medicare Part D by January 1, 2021. However, reasons for electronic prior authorization tools to be used are not necessarily reasons why their use is attributable to this proposed rule; they might instead be reasons why use would occur even in the rule's absence. We request comment that would help with identifying impacts attributable to this proposal.

(Note, exponential models cannot start at 0; therefore, we started at 0.01 percent.)

We solicit public comments on all assumptions: The assumption of no providers in the first year; the assumption of 25 percent participation in the tenth year; and the use of an exponential model.

TABLE 12: Assumptions on the Percent of Providers by Year Using Electronic Prior Authorization*

Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Assumed percentage of providers using the prior authorization APIs	0.01%	0.02%	0.06%	0.14%	0.32%	0.77%	1.84%	4.39%	10.48%	25.00%

*As explained in the narrative, it would be unreasonable to assume that immediately 25 percent of providers would voluntarily use the new technologies. We therefore target a 25 percent usage in 10 years, and model the growth, not linearly, but with an exponential growth.

(2) Assumptions on the current workload hours for prior authorization: To estimate the savings impact, we first require estimates of the current amount of paperwork involved in prior authorization, the type and number of staff involved, the type of physician offices involved, and hours per week spent engaged in prior authorization processes. Our assumptions are based on a well-conducted survey presented in Casalino et al. (2009) [84], which gives a detailed analysis based on a validated survey instrument employed in 2006.

This survey excluded certain physician practices, including health maintenance organizations (HMOs), but analyzed workload by staff type (doctor, nurse, clerical, administrator, lawyer, and accountant), office type (solo, three to 10 physicians, 10 or more physicians), and type of medical work involved (prior authorization, formulary, claims billing, quality, etc.). Consistent with our approach, we restricted ourselves to prior authorization activities, though formulary work could possibly add to burden related to prior authorization activities.

Using the methods and data from Casalino et al. (2009), Table 13 presents an estimate of the current average annual paperwork burden per physician office for prior authorization activities. Table 13 estimates an annual burden per physician office of 1,060.8 hours at a cost of $73,750.

TABLE 13: Total Cost of Prior Authorization per Physician Practice per Year

Occupation Title	Hours / Week	Hours / Year	Labor Cost ($ / Hour)	Total Cost per Staff (Hours * Labor)
Physicians	1	52	$195.62	$10,172
Registered Nurses	13.1	681.2	$74.48	$50,736
Clerical	6.3	327.6	$39.20	$12,842
Total	20.4	1,060.8		
Total Cost Per Physician Practice per Year ($)				$73,750

Table 13 estimates are based on Casalino et al. (2009). Several other examples in the literature were reviewed [85 86 87 88 89] which, although reflecting more recent research, either did not show the basis for their calculations, showed a basis based on a very small number of people, or used a non-validated survey. For this reason, we used the Casalino et al. (2009) article for our calculations.

The wages in Table 13 have been updated from those used in the Casalino et al. (2009) work to the latest BLS wages. The hours should also be adjusted for 2021, to account for increased prior authorization requirements. However, we do not have a more recent reliable survey on which to base this. Table 16 in this section presents an alternate estimate assuming a 4 percent growth rate in hours per week spent on prior authorization, the 4 percent coming from the articles cited above. We solicit public comment on these assumptions on the hours per week spent on prior authorization paperwork.

(3) Assumptions on the total number of physician practices: Table 13 presents current hour and dollar burden per physician office. To obtain aggregate annual burden of prior authorization over all physician practices including those exclusively furnishing services to Fee For Service (FFS) enrollees, Casalino et al. (2009) multiplies the Table 13 burdens for physician office by the total number of physician practices. Thus, we need an estimate of total number of physician practices. Additionally, in this section, we need to

[84] Casalino, L.P., Nicholson, S., Gans, D., Hammons, T., Morra, D., Karrison, T., & Levinson, W. (May 2009). What Does It Cost Physician Practices To Interact With Health Insurance Plans? *Health Affairs, 28*(4): w533–w543. doi: 10.1377/hlthaff.28.4.w533.

[85] Morley, C.P., Badolato, D.J., Hickner, J., Epling, J.W. (2013, January). The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies. The Journal of the American Board of Family Medicine, 26(1), 93–95. doi: 10.3122/jabfm.2013.01.120062.

[86] Ward, V. (2018, April). The Shocking Truth About Prior Authorization in Healthcare. Retrieved from *https://getreferralmd.com/2018/04/prior-authorization-problems-healthcare/.*

[87] Center for Health Innovation & Implementation Science. (2018, July 26) The Prior Authorization Burden in Healthcare. Retrieved from *http://www.hii.iu.edu/the-prior-authorization-burden-in-healthcare/.*

[88] Robeznieks, A. (2018, November 16). Inside Cleveland Clinic's $10 million prior authorization price tag. Retrieved from *https://www.ama-assn.org/practice-management/sustainability/inside-cleveland-clinic-s-10-million-prior-authorization-price.*

[89] American Medical Association. (2019, June). Prior Authorization and Utilization Management Reform Principles. Retrieved from *https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf.*

modify the total number of physician practices by a factor accounting for the fact that only a percentage of physician practices accept enrollees in the Medicaid, CHIP, and QHP programs.

We first discuss the total number of physician practices. Casalino et al. (2009) cited that the AMA listed a figure of 560,000 physician offices in 2006. Casalino et al. (2009) criticized this 560,000 (rounded from 560,118 physician offices exactly) based on available sources in 2006 and reduced it to 450,000 physician offices (rounded from 453,696 physician offices exactly). The sources cited in the article have not been updated. Furthermore, the CY 2012 PFS final rule redefined physician group practice to require at least 25 physicians. As of 2016, there are 230,187 physician practices (76 FR 73026). We note that this number is lower than the value used in the 2016 survey, which makes sense given the high rates of consolidation in the medical field. In Table 16 later in this section, we present an alternative analysis of savings with 450,000 practices. We solicit public comment on our assumptions of the number of physician offices.

(4) Percent of providers accepting Medicaid, CHIP, or QHP: The 230,187 physician practices just mentioned include providers who exclusively service Fee For Service enrollees. We must therefore adjust this number by the percent of providers furnishing services to Medicaid, CHIP, and QHP enrollees. According to the Medicaid and CHIP Payment and Access Commission (MACPAC),[90] 71 percent of providers accept Medicaid, but only 36 percent of psychiatrists accept new Medicaid patients, and 62 percent accept private insurance. Therefore we estimate that 50 percent of provider groups treat patients in the Medicaid and QHP. Although we don't account for it, we note that these provisions, which reduce the amount of paperwork, might encourage a greater participation in the coming years of providers accepting Medicaid, CHIP, and QHPs in the FFEs.

(5) Assumptions on the reduction in hours spent on prior authorization as a result of the provisions of this proposed rule: Table 13 provides current hours spent on prior authorization; to calculate potential savings we must make an assumption on how much these hours are being reduced as a result of the provisions of this rule. Therefore, we review the specific provisions of this proposed rule.

We believe two provisions in this proposed rule would reduce prior authorization burden:

- Section II.C. of this proposed rule would require payers to implement a DRLS API. This service, if voluntarily used by providers, would allow them, at the point of care, to discover whether a requested item or service requires prior authorization and, if so, the relevant documentation requirements. All provider office staff types, including doctors, nurses, and clerical staff, would experience reductions in the time needed to locate prior authorization rules and documentation requirements, which are currently either not readily accessible or available in many different payer-specific locations and formats. We believe that our proposal would make it possible for provider staff to use one system (such as their EHR or practice management system) or software application to find the prior authorization rules and documentation requirements for all impacted payers. With these rules and requirements more consistently and easily accessible, we anticipate a reduction in the need for providers to make multiple attempts at submitting the full set of information necessary for the payer to approve or deny a prior authorization. As a consequence, a DRLS API could also reduce appeals and improper payments,[91] but we are not addressing such savings here, as we have no real-world basis on which to make an estimate. (We also note that reduction in improper payments, though experienced as savings by certain entities, would be categorized as transfers from a society-wide perspective.)

Overall, once the APIs are in place and providers integrate with them, we assume providers and nurses could experience a 25 percent reduction in hours spent working to identify prior authorization rules and requirements. (Again, we are uncertain when providers may connect to the APIs.) The level annual 25 percent reduction reflects the belief that these provisions would accomplish savings through reduced administrative burden and therefore in the absence of additional data, the 25 percent reflects a midpoint between 0 percent and 50 percent indicating some savings (more than 0 percent but not more than 50 percent). We solicit public comment on the estimated reduction in hours spent determining prior authorization rules and requirements due to the DRLS API proposal in this proposed rule. We are interested in understanding if there is burden reduction prior to the development of an EHR integration with the API. We also note that Table 16 in this section provides an alternative analysis using a 75 percent reduction for doctors and nurses. The intent in Table 16 is to provide a broad range inclusive of many possibilities (hence 25 percent to 75 percent for providers and nurses).

- Section II.C. of this proposed rule would require that payers implement and maintain a PAS API that would, if voluntarily used by providers, allow them, through an existing EHR or practice management system that is capable of connecting to the API, to submit prior authorization requests along with any associated documentation needed, and receive an approval or denial decision from the payer, including any ongoing communications regarding additional information needed or other status updates. Currently, most prior authorization requests and decisions are conducted through one of several burdensome channels, including telephone, fax, or payer-specific web portals—each of which require taking actions and monitoring status across multiple and varying communication channels. Since submission support is predominantly done by clerical staff, not by doctors or nurses, we would estimate no savings to doctors and nurses, but a 50 percent reduction in hours spent by clerical staff. The 50 percent reduction represents a reasonable estimate of time spent in the absence of any experience or data. We solicit comments on this estimated 50 percent reduction in hours spent by clerical staff and whether our assumptions of the affected staff type are accurate.

Having presented our assumptions on the number of providers voluntarily using the DRLS and PAS APIs for electronic prior authorization, the current hour and dollar burden per week spent on prior authorization, the number of physician practices, and the reduction in hours arising from the proposed provisions of this rule, Tables 14 and 15 present total hours and dollars saved. Table 14 presents the savings per physician practice. Table 15 multiplies these per physician practice savings by 50 percent of the 230,187 provider practices to obtain aggregate savings The following illustrative calculations help explain the entries in Table 14 and 15:

[90] Kayla Holgash and Martha Heberlin, ''Physician Acceptance of New Medicaid Patients,'' January 24, 2019 *https://www.macpac.gov/wp-content/uploads/2019/01/Physician-Acceptance-of-New-Medicaid-Patients.pdf*

[91] Centers for Medicare and Medicaid Services. (2019, November 15). Simplifying Documentation Requirements. Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/SimplifyingRequirements.html.*

• In Table 14, the row on nurses cites Table 13, which shows that currently, annually, per physician practice, nurses spend 681.2 hours per year on prior authorization. Multiplying this number of hours by our assumed savings for nurses of 25 percent, we obtain 170.3 hours per year saved. Multiplying these reduced hours by the hourly wage for nurses of $74.48, we obtain a savings of $12,684 per physician practice for nurses. This calculation is repeated for all staff and then summed to obtain the total hours and dollars saved per physician practice. We save 347.1 hours per physician practice per year and $21,648 per physician practice per year.

• Table 15 now multiplies the 347.1 hours and $21,648 saved per physician practice by 50 percent (percent of providers furnishing enrollees in Medicaid, CHIP, and QHP), times 230,187 (total number of physician practices) times the percent of providers using these technologies by year as outlined in Table 12. For example, for the 1st year, 2023, we multiply, $21,648 * 50 percent * 230,187 * 0.01% to obtain a reduced dollar spending of $0.2 million. The other rows in Table 15 are similarly calculated. As can be seen, the total savings over 10 years is 17.2 million hours and $1.1 billion.

The savings for the first three years, obtained by summing the first three rows, is 36,254 hours and $2.26 million. The method of calculating the hours and dollars in these rows was just illustrated. Because we assume a 10-year gradual increase in voluntary provider participation, we present a 10-year horizon in Table 15 in this section.

TABLE 14: Hour and Dollar Savings from Prior Authorization Provisions, Per Physician Practice

Occupation Title	Hours / Year	Assumed Percent Reduction in Hours	Total Reduced Hours per Year	Labor Cost ($ / Hour)	Total Reduced Dollar Spending Per Year ($)
Physicians	52	25%	13	$195.62	$2,543
Registered Nurses	681.2	25%	170.3	$74.48	$12,684
Clerical	327.6	50%	163.8	$39.20	$6,421
Totals per Physician Practice	1060.8		347.1		21648.0

TABLE 15: Hour and Dollar Savings by Year, Assuming Gradual Voluntary Provider Participation

Year	Hour Savings per Physician Practice (Hours)	Potential Dollar Savings per Physician Practice ($)	Fifty Percent (percent of providers accepting Medicaid/CHIP and QHP enrollees) of 230,187 Total Physician Practices	Assumed Percentage of Providers Participating per Year (Table 12)	Aggregate Hours Saved per Year (Millions of Hours) (Assumed percentage of provider participation* potential hour savings assuming 100% provider participation)	Aggregate Dollars Saved per Year (Millions $) (Assumed percentage of provider participation* potential dollar savings assuming 100% provider participation)
2023	347.1	21,648.0	115,093.5	0.01%	0.004	0.2
2024	347.1	21,648.0	115,093.5	0.02%	0.010	0.6
2025	347.1	21,648.0	115,093.5	0.06%	0.023	1.4
2026	347.1	21,648.0	115,093.5	0.14%	0.054	3.4
2027	347.1	21,648.0	115,093.5	0.32%	0.129	8.1
2028	347.1	21,648.0	115,093.5	0.77%	0.3	19.2
2029	347.1	21,648.0	115,093.5	1.84%	0.7	45.9
2030	347.1	21,648.0	115,093.5	4.39%	1.8	109.5
2031	347.1	21,648.0	115,093.5	10.48%	4.2	261.1
2032	347.1	21,648.0	115,093.5	25.00%	10.0	622.9
Total					17.2	1072.3

The analysis in Table 15 represents our illustrative analysis for this proposed rule, which we put forward for stakeholder review and comment. In Table 16, we present some alternative analysis of the savings. Despite the wide range of alternatives, the resulting range of savings is estimated at about $1.1 billion to about $5.2 billion. As indicated earlier, we solicit comments from stakeholders on our assumptions and methodology. We provide four

alternative assumptions as follows to the assumptions made in Tables 12 through 15:

• We assumed in this section that the number of hours per week that providers spend on prior authorization has not changed since 2006. In Table 16, we allow for an alternative with 4 percent annual growth. This number came from several papers cited in section V. of this proposed rule.

• We assumed in this section that the reduction of hours per week that provider teams spend on prior authorization is a result of a 25 percent reduction for doctors and nurses and a 50 percent reduction for clerical staff. In the Table 16, we provide an alternative analysis assuming a 75 percent reduction for doctors and nurses and a 50 percent reduction for clerical staff. These alternative numbers are not based on published articles or experience but rather meant to span a range of alternatives.

• In this section, we assumed 230,187 physician practices. In Table 16, we also use an alternate assumption of 450,000 physician practices, also discussed in this section.. We modified these numbers by a factor of 50 percent to account for the fact that only half of provider groups accept Medicaid, CHIP, and QHP.

• For purposes of comparison we present the 10-year savings assuming all providers participate as well as the 10-year savings from reduced paperwork assuming a gradual increase in participation from 0 percent in the base year to 25 percent in the tenth year.

In making these assumptions, the goal was to obtain a range of possible alternatives. We have no experience basis to justify any particular assumption and data vary widely in the literature. As can be seen from Table 16, the potential savings range from about $1 billion to about $5 billion. We believe the magnitude of such a number is important for stakeholders when evaluating and commenting on the provisions of this rule. We solicit public comment on the four assumptions and their impact in estimating these savings.

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TABLE 16: Analysis to Savings Arising from Reduced Paperwork in Prior Authorization

Scenario	Assumed Number Physician Practices	Assumed Growth in Hours per Week Spent on Prior Authorization by Staff per Physician Practice	Assumed reduction by Staff in Hours Spent on Prior Authorization	Aggregate Savings in Time Over 10 Years Assuming Gradual Provider Participation (Table 12) (Millions of Hours)	Aggregate Savings of Dollars Over 10 Years Assuming Gradual Increase in Provider Participation (Table 12) (millions of dollars)	Basis of Calculation
(1)	230,187 * 50 percent	0%	25% for nurses, doctors; 50% for clerical	17.2	1.1	Table 15
(2)	230,187 * 50 percent	0%	75% for nurses, doctors; 50% for clerical	35.4	2.6	Table 15 after Table 14 recalculated with 75% replacing 25%
(3)	230,187 * 50 percent	4%	25% for nurses, doctors; 50% for clerical	17.9	1.1	(1) * 1.04
(4)	230,187 * 50 percent	4%	75% for nurses, doctors; 50% for clerical	36.8	2.7	(2) * 1.04
(5)	450,000 * 50 percent	0%	25% for nurses, doctors; 50% for clerical	33.6	2.1	(1) * 450,000 / 230,187
(6)	450,000 * 50 percent	0%	75% for nurses, doctors; 50% for clerical	69.1	5.0	(2) * 450,000 / 230,187
(7)	450,000 * 50 percent	4%	25% for nurses, doctors; 50% for clerical	35.0	2.2	(3) * 450,000 / 230,187
(8)	450,000 * 50 percent	4%	75% for nurses, doctors; 50% for clerical	71.9	5.2	(4) * 450,000 / 230,187

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H. Summary of Costs

In this section, we present a 10-year summary table of costs, an analysis for federal impacts, and the monetized table.

To analyze the cost of this rule to the federal government, we utilize a method of allocating costs by program (Medicaid, CHIP, and QHP issuers on the FFEs). As the cost is shared by the 266 parent organizations, including Medicaid and CHIP state agencies, there is no readily available way to allocate costs per parent organization across programs since the percentage of each parent organization's expenditures on the different programs is not publicly available.

To address this, we utilize the same method that was used in the CMS Interoperability and Patient Access final rule (85 FR 25612). In that final rule, we used the public CMS Medical Loss Ratio (MLR) files, which break out total premiums across the various programs. The advantages and disadvantages of such an approach are fully discussed in that rule, to which we refer readers. At the time this proposed rule is being written, 2019 is the latest available year with published data. Table 17 presents the 2019 MLR data of premiums by program and the resulting percentages by program. We use these percentages to allocate costs by programs. This allocation of cost by program forms a basis to calculate the federal government's cost for the proposed provisions of this rule.

TABLE 17: Allocation of Premium by Program

Program	Premium (Billions $)	Percentage by Program
Total	$207,225,824,345	100.00%
Medicaid/ CHIP	$116,886,191,026	56.41%
Individual Market	$90,339,633,319	43.59%

We can calculate the federal Medicaid payments using the percentages in Table 18.

TABLE 18: Percent of Cost Incurred by the Federal Government for Medicaid Spending

Item	FFS	Managed Care	Total Federal Subsidization (Weighted Average)
Percent breakdown of federal payments to states	52%	48%	
Percent of costs paid in first year	90%	58.44%	74.85%
Percent of costs paid in subsequent years	75%	58.44%	67.05%

In Table 18, the first row shows that 52 percent of federal government payments go to the states for expenditures related to their FFS programs and 48 percent go to states for their Medicaid managed care programs. For state expenditures on Medicaid mechanized claims processing and information retrieval systems, the federal government pays states 90 percent of their expenditures on the design, development, installation, or enhancement of such systems, and 75 percent of their expenditures on the ongoing operation of such systems. States receive an average of 58.44 percent (FMAP) for their managed care program costs. Therefore, the percent of costs paid in the first year by the federal government is 74.85 percent (90 percent * 52 percent + 58.44 percent * 48 percent). The percent of costs paid in later years is 67.05 percent (75 percent * 52 percent + 58.44 percent * 48 percent). By applying these percentages to the total Medicaid costs, we obtain federal costs for the program. These percentages are used to calculate the total dollars going from the federal government to states.

We can now calculate all impacts of this proposed rule by program, government, and QHP issuers. The numerical impacts are presented in Table 19.

TABLE 19: Impacts of this Proposed Rule by Year, Program, and to the Federal Government (Millions $)

		Cost by Program and Year		Cost to Government by Program and Year			Remaining Costs of Rule by Program and year	
Year	Total Cost of Rule by Year	Cost to Medicaid Plans, States, and CHIP	Cost to Individual Market	Total Cost to Gov't by Year	Gov't Payments to Medicaid, States, and CHIP	Gov't Payments (PTC) related to Individual Markets	Remaining Cost to Medicaid by Year	Remaining Costs to Individual Market by year
Totals	1904	1074	830	1090	735	356	340	830
2021	325	184	142	137	137	0	46	142
2022	311	176	136	186	118	68	58	136
2023	158	89	69	95	60	35	29	69
2024	158	89	69	95	60	35	29	69
2025	158	89	69	96	60	36	29	69
2026	158	89	69	96	60	36	29	69
2027	158	89	69	96	60	36	29	69
2028	158	89	69	96	60	36	29	69
2029	158	89	69	96	60	36	29	69
2030	158	89	69	96	60	37	29	69

For Table 19:

• *Cost of Proposed Rule by Year column:* The total cost for years 2021 to 2023 matches the costs in the Collection of Information (section V.) summary table (Table 10).

The total 10-year cost (including payers but excluding PTC payments and savings from prior authorization) is, as shown in Table 19, $1.9 billion. This number uses the primary estimates for the API provisions. The low and high 10-year total costs are $1.0 billion and $2.8 billion, respectively.

• *Cost of Proposed Rule to Payers by Program columns:* We apply the percentages from Table 17 to obtain the cost of the rule to Payers by program (Medicaid, CHIP, and QHP issuers on the FFEs).

• *Cost of Proposed Rule to Government by Program columns:* We apply the percentages of payment by the federal government discussed in Table 18 to obtain the cost by program.

• *PTC Payments:* The government does not reimburse QHPs, neither partially nor totally, neither prospectively nor retroactively, for their expenses in furnishing benefits. However, the government does offer eligible QHP enrollees PTCs to help cover the cost of the plan. QHP issuers on selling on the Exchanges have the option to deal with increased costs of complying with the requirements as proposed in this rule by either temporarily absorbing them (for purposes of market competitiveness), increasing premiums to enrollees, or reducing non-essential health benefits. To the extent that issuers increase premiums for individual market plans on the FFEs, there would be federal PTC impacts. The purpose of the PTC is to assist enrollees in paying premiums. Since PTCs are only available if an individual purchases an individual market plan on an Exchange and the individual has an income between 100 and 400 percent of the Federal Poverty Level, the PTC estimates apply only to Exchange plans. In the PTC estimate, we have accounted for the fact that some issuers have both Exchange and non-Exchange plans, and some issuers have only non-Exchange plans. We reflected these assumptions with global adjustments, so we believe the estimates are reasonable in aggregate.

The methodology to estimate the PTC impact of the of the projected expense burdens is consistent with the method used to estimate the PTC impact in the CMS Interoperability and Patient Access final rule (85 FR 25612). Within the FFE states, the estimated expense burden would impact premium rates in the individual market and is spread across both Exchange and non-Exchange plans. PTCs are only paid in the Exchanges and are calculated as a function of the second lowest cost silver plan and the eligible individuals' income. The estimate of these impacts uses the assumption that the industry would increase the second lowest cost silver plan premium rate in the same amount as the overall premium rate increase as a result of the expense estimate. This assumption allows application of the overall rate increase to the projected PTC payments in the FFE states to estimate the impact to PTC payments.

There are no increases in PTC payments included for 2021 since by the time this proposed rule is projected to be published these rates will already have been determined. The total cost to the government is the sum of payments related to each program. This payment is a transfer from the government to payers for Medicaid, CHIP, and to QHP enrollees.

• *Remaining Cost to Payers columns:* For Medicaid and CHIP, the remaining costs are the difference between total cost to payers and what the federal government pays. For the individual markets, the remaining costs to payers would be the total cost absorbed by the payers and not passed on through premium increases. Since the PTC is paid on behalf of individuals and not the payers, it therefore does not reduce expenses of the payers.

• *Note:* The $1.1 billion savings from reduced paperwork burden for use of

electronic prior authorization (Table 16) is not included in Table 19.

We next explain how the various plans (and states) would bear the costs remaining after federal payments. We follow the same methodology and discussion presented in the CMS Interoperability and Patient Access final rule (85 FR 25612).

TABLE 20: How Payers Could Defray Remaining Costs

Program	Avenues of Dealing with Remaining Costs
QHP Issuers	QHPs generally have the option of absorbing costs (for example, for reasons of market competitiveness), increasing premiums to enrollees, or reducing covered non-essential health benefits. Cost would be spread over all parent organization enrollees in a specified state and the individual market in FFE states. As proposed, small commercial QHP issuers on the FFEs may request an exception to the proposed API provisions. To the extent that QHP issuers increase premiums in 2022 and beyond to offset the cost of complying with this rule, such premium increases would be a transfer from QHP issuers to enrollees and a subsequent transfer from enrollees to the federal government in the form of increased PTC payments.
Medicaid/CHIP	State Medicaid and CHIP agencies would bear the cost (under 10 cents per beneficiary). Medicaid and CHIP managed care plans are fully capitated but may have to defer first year costs. Under certain circumstances, states operating Medicaid and CHIP FFS programs can request an extension or an exemption from the proposed API provisions.

In Table 20, we explain possible ways payers may manage these extra costs. We emphasize that Table 20 lists possibilities. Payers will ultimately make decisions about how to defray these remaining costs based on market dynamics and internal business decisions, and we have no uniform way of predicting what these actual behaviors and responses will be.

Individual Market Plans: Individual market plans have the option of absorbing costs or passing costs to enrollees either in the form of higher premiums or reduced benefits that are not essential health benefits (EHBs). The experience of the Office of the Actuary is that frequently, plans, for reasons of market competitiveness, will absorb costs rather than increase premiums or reduce benefits.

Medicaid and CHIP: Assuming roughly 75 million enrollees nationally, including Medicaid and CHIP FFS programs, Medicaid managed care plans and CHIP managed care entities are adding a cost of under a dollar per beneficiary per year; this contrasts with a total cost per beneficiary per year for the Medicaid and CHIP programs of several thousand dollars.

I. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 21 showing the classification of annualized costs associated with the provisions of this proposed rule for the 10-year period 2021 through 2030. This accounting table is based on Table 19. It includes costs of this proposed rule to providers, Medicaid and CHIP state entities, and issuers offering QHPs on the FFEs. It does not include the potential savings (Tables 14 and 15) of at least $1.1 billion arising from reduced burden due to providers voluntarily complying with electronic prior authorization as discussed in the illustrative earlier in this section.

TABLE 21: ACCOUNTING TABLE (MILLIONS $)

Discount Rate	Annualized Monetized Cost (as positive numbers in 2020 dollars), *Low Estimate*	Annualized Monetized Cost (as positive numbers in 2020 dollars), *Primary Estimate*	Annualized Monetized Cost (as positive numbers in 2020 dollars), *High Estimate*	Period	Who is Impacted
Annualized at 7%	103.5	199.7	295.9	Contract Years 2021-2030	Providers, state Medicaid & CHIP entities; QHP issuers on the FFEs
Annualized at 3%	100.7	194.4	288.0	Contract Years 2021-2030	Providers, state Medicaid & CHIP entities; QHP issuers on the FFEs
Transfers (PTC Payments)					
Discount Rate	**Annualized transfer (In 2020 dollars)**			**Period**	**From whom to whom**
Annualized at 7%	18.1	35.1	52.2	2022-2030	Federal government to enrollees
Annualized at 3%	18.2	35.4	52.5	2022-2030	Federal government to enrollees

J. Regulatory Reform Analysis Under E.O. 13771

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 proposed rule, if finalized, is considered an E.O. 13771 regulatory action. We estimate that the medium (primary) estimates of this proposed rule would generate annual costs of $136.3 million in 2016 dollars when calculated at a 7 percent discount over a perpetual time horizon. (The low estimates would generate $70.6 million in annualized costs, while the high estimates would generate $202.1 million in annualized costs, discounted at 7 percent relative to 2016, over a perpetual time horizon.) Details on the estimated costs of this proposed rule can be found in the preceding analyses.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget (OMB).

List of Subjects

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements, State fair hearings.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Notices, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 156

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), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women, Youth.

45 CFR Part 170

Computer technology, Health, Health care, Health insurance, Health records, Hospitals, Indians, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Public health, Reporting and recordkeeping requirements, Security measures.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services (CMS) proposes to amend 42 CFR chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 431.60 is amended by—
■ a. Revising paragraph (b)(3);
■ b. Adding paragraph (b)(5);
■ c. Revising paragraph (c)(3) introductory text;
■ d. Adding paragraph (c)(3)(iii);
■ e. Revising paragraphs (c)(4) introductory text, (c)(4)(ii)(C), and (e)(2);
■ f. Redesignating paragraph (g) as paragraph (i); and
■ g. Adding new paragraphs (g) and (h).

The revisions and addition read as follows:

§ 431.60 Beneficiary access to and exchange of data

* * * * *

(b) * * *

(3) Clinical data, as defined in the USCDI version 1, if the State maintains any such data, no later than 1 business day after the data are received by the State;

* * * * *

(5) Beginning January 1, 2023, pending and active prior authorization decisions and related clinical documentation and forms for items and services, not including covered outpatient drugs, including the date the prior authorization was approved, the date the authorization ends, as well as the units and services approved and those used to date, no later than 1 business day after a provider initiates a prior authorization request for the beneficiary or there is a change of status for the prior authorization.

(c) * * *

(3) Must comply with the content and vocabulary standards requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable to the data type or data element, unless alternate standards are required by other applicable law, and be conformant with the requirements in paragraph (c)(3)(iii) of this section:

* * * * *

(iii) Beginning January 1, 2023, be conformant with the implementation specifications at 45 CFR 170.215(c)(5) for data specified in paragraphs (b)(1) and (2), 45 CFR 170.215(a)(2) or 45 CFR 170.215(c)(6) for data specified in paragraph (b)(3) of this section, 45 CFR 170.215(c)(7) for data specified in paragraph (b)(4) of this section, and 45 CFR 170.215(c)(6) for data specified in paragraph (b)(5) of this section.

(4) May use an updated version of any standard or all standards and any or all implementation guides or specifications required under paragraphs (b) or (c) of this section, and §§ 431.61, 431.70, 431.80, where:

* * * * *

(ii) * * *

(C) Use of the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data described in paragraph (b) of this section or the data described in §§ 431.61, 431.70, and 431.80 through the required API.

* * * * *

(e) * * *

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which parties seek to access electronic health information, as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

* * * * *

(g) *Privacy policy attestation.* (1) Beginning January 1, 2023, the State must establish, implement, and maintain a process for requesting an attestation from a third-party app developer requesting to retrieve data via the Patient Access API that indicates the app adheres to certain privacy provisions. The State must:

(i) Independently, or through the support of a third party, request a third-party app developer to attest whether:

(A) The app has a privacy policy that is publicly available and accessible at all times, including updated versions, and that is written in plain language, and that the third-party app has affirmatively shared with the beneficiary prior to the beneficiary authorizing the app to access their health information. To ''affirmatively share'' means that the beneficiary had to take an action to indicate they saw the privacy policy, such as click or check a box or boxes.

(B) The app's privacy policy includes, at a minimum:

(*1*) How a beneficiary's health information may be accessed, exchanged, or used by any person or other entity, including whether the beneficiary's health information may be shared or sold at any time (including in the future);

(*2*) A requirement for express consent from a beneficiary before the beneficiary's health information is accessed, exchanged, or used, including receiving express consent before a beneficiary's health information is shared or sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction);

(*3*) If an app will access any other information from a beneficiary's device; and

(*4*) How a beneficiary can discontinue app access to their data and what the app's policy and process is for disposing of a beneficiary's data once the beneficiary has withdrawn consent.

(ii) Include information in the beneficiary resources required in paragraph (f) of this section about the specific content of the State's privacy policy attestation required under this paragraph, and, at a minimum, the timeline for the attestation process, the method for informing the beneficiary about the app developer's response or non-response to the State's request, and the beneficiary's role and rights in this process; and

(iii) Request the attestation at the time the third-party app engages the API and notify the beneficiary as follows:

(A) The State must inform the beneficiary within 24 hours of requesting the attestation from the third-party app developer regarding the status of the attestation—positive, negative, or no response, with a clear explanation of what each means;

(B) If a beneficiary does not respond within 24 hours of when the State sends notice of the attestation status to the beneficiary, the State must proceed with making the beneficiary's data available to the third-party app consistent with the beneficiary's original request.

(2) The State must not discriminate when implementing this requirement, including for the purposes of competitive advantage; the method employed to meet this requirement must be applied equitably across all apps requesting access the Patient Access API.

(h) *Reporting on the use of the Patient Access API.* (1) Beginning March 31, 2023, a State must report to CMS, at the State agency level, by the end of each calendar quarter, based on the previous quarter's data as follows:

(i) The total number of unique beneficiaries whose data are transferred via the Patient Access API to a beneficiary-designated third-party application; and

(ii) The number of unique beneficiaries whose data are transferred via the Patient Access API to a beneficiary designated third-party application more than once.

(2) [Reserved].

* * * * *

■ 3. Section 431.61 is added to read as follows:

§ 431.61 Access to and exchange of health data to providers and payers.

(a) *Application Programming Interface to support data transfer from payers to providers—Provider Access API.*—(1) *Accessible content and API requirements.* Beginning January 1, 2023, a state must implement and maintain a standards-based Application Programming Interface (API) compliant with § 431.60(c), (d), and (e):

(i) *Individual beneficiary data.* The Provider Access API must make available to providers, if requested by the provider, as permitted by the beneficiary per paragraph (a)(3) of this section, and as permitted by applicable law, at a minimum, data maintained by the State with a date of service on or

after January 1, 2016, within one (1) business day of receipt, conformant with the implementation specifications at 45 CFR 170.215(c)(5) for data specified at § 431.60(b)(1) and (2) not including remittances and enrollee cost sharing information, 45 CFR 170.215(a)(2) or 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(3), 45 CFR 170.215(c)(7) for data specified at § 431.60(b)(4), and 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(5); and

(ii) *Bulk data access.* The Provider Access API must be able to share the data specified in paragraph (a)(1)(i) of this section conformant with the implementation specification at 45 CFR 170.215(a)(4) to facilitate sharing the specified data relevant to one or more beneficiary at one time.

(2) *Attribution.* A State must establish, implement, and maintain a process to facilitate generating each provider's current beneficiary roster to enable this payer-to-provider data sharing via the Provider Access API.

(3) *Opt-in.* A State may put a process in place to allow a beneficiary or the beneficiary's personal representative to opt-in to permit the State's use of the Provider Access API for sharing with each of the beneficiary's provider(s) currently providing care, or planning to provide care, the data specified in paragraph (a)(1) of this section.

(4) *Provider resources regarding APIs.* A State must provide on its website and through other appropriate mechanisms through which it ordinarily communicates with providers, educational resources in non-technical, simple, and easy-to-understand language explaining general information concerning how a provider may make a request to the State for beneficiary data using the standards-based Provider Access API required under paragraph (a)(1) of this section, both for individual access and bulk data requests.

(5) *Out-of-network provider access.* A State cannot deny use of, or access to, the Provider Access API based on a provider's contract status.

(b) *Coordination among payers—Payer-to-Payer Data Exchange.* (1) Beginning January 1, 2023, a State must implement and maintain a standards-based API compliant with § 431.60(c), (d), and (e) that makes available to another payer, at a minimum, the data maintained by the state with a date of service on or after January 1, 2016, within one (1) business day of receipt, conformant with the implementation specifications at 45 CFR 170.215(c)(5) for data specified at § 431.60(b)(1) and (2) not including remittances and enrollee cost sharing information, 45 CFR 170.215(a)(2) or 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(3), 45 CFR 170.215(c)(7) for data specified at § 431.60(b)(4), and 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(5). Such information received by a State must be incorporated into the State's records about the current beneficiary.

(2) With the approval and at the direction of a current or former beneficiary or the beneficiary's personal representative, the State must:

(i) Receive all such data for a current beneficiary from any other payer that has provided coverage to the beneficiary within the preceding 5 years;

(ii) At any time a beneficiary is currently enrolled with the State and up to 5 years after disenrollment, send all such data to any other payer that currently covers the beneficiary or to a payer the beneficiary or the beneficiary's personal representative specifically requests receive the data; and

(iii) Send data received from another payer under this paragraph in the electronic form and format it was received.

(c) *Coordination among payers at enrollment—Payer-to-Payer API.* (1) *Accessible content and API requirements.* Beginning January 1, 2023, a State must make the standards-based API specified in paragraph (b)(1) of this section conformant with the implementation specification at 45 CFR 170.215(a)(4) to facilitate sharing the data specified in paragraph (b)(1) of this section relevant to one or more beneficiaries at one time.

(2) *Requesting data exchange.* (i) When a beneficiary enrolls in coverage with the State, the State may request the data from a previous payer through the standards-based API described in paragraph (c)(1) of this section, as permitted by the beneficiary per paragraph (c)(5) of this section, and as permitted by applicable law;

(ii) For any beneficiaries who enroll with the State during the first calendar quarter of each year, the State must request the specified data within one (1) week of the end of the first calendar quarter from any previous payers through the standards-based API described in paragraph (c)(1) of this section, as permitted by the beneficiary per paragraph (c)(5) of this section, and as permitted by applicable law;

(iii) If a State receives a request from another payer to make data available for one or more former beneficiaries who have enrolled with the new payer, the State must respond by making the required data available via the standards-based API described in paragraph (c)(1) of this section within one (1) business day of receiving the request.

(3) *Previous or concurrent payer.* A State must adopt a process to obtain from a new beneficiary the name of the new beneficiary's previous payer as part of the enrollment process, and the name of the new beneficiary's concurrent payer or payers if the beneficiary has coverage through more than one payer, to facilitate data sharing using the Payer-to-Payer API described in paragraph (c)(1) of this section.

(4) *Concurrent payer exchange.* When a beneficiary has concurrent coverage with another payer also subject to CMS regulations on the Payer-to-Payer API, the State must make available to the other payer the data described in paragraph (b)(1) of this section through the standards-based API described in paragraph (c)(1) of this section quarterly.

(5) *Opt-in.* A State must put a process in place to allow a beneficiary or the beneficiary's personal representative to opt-in to permit the State's use of the Payer-to-Payer API data sharing specified in paragraph (c)(1) of this section.

(d) *Obligations.* The requirements under this section do not in any way alter or change a State's obligation as a HIPAA covered entity to comply with regulations regarding standard transactions at 45 CFR part 162.

(e) *Extensions and Exemptions.* (1) *Extension.* (i) A State may submit a written application to request to delay implementation of the requirements in paragraphs (a) through (c) of this section one-time for up to one (1) year with respect to its Medicaid fee-for-service program. The written application must be submitted and approved as part of the State's annual Advance Planning Document for MMIS operations costs and must include:

(A) A narrative justification describing the specific reasons why the State cannot reasonably satisfy the requirement(s) by the compliance date and explaining why those reasons result from circumstances that are unique to States operating Medicaid fee-for service programs;

(B) A report on completed and ongoing State implementation activities that evidence a good faith effort towards compliance; and

(C) A comprehensive plan to meet implementation requirements no later than 1 year after the initial compliance date.

(ii) CMS will grant the State's request if it determines based on the information provided in the State's annual Advance Planning Document for MMIS operations costs that the request

adequately establishes a need to delay implementation, that this need results from circumstances that are unique to States operating Medicaid fee-for-service programs, that the State has made a good faith effort to implement the proposed requirements as soon as possible, and that the State has a clear plan to implement the requirements no later than one (1) year after the proposed compliance date.

(2) *Exemption.* (i) A State operating a Medicaid program under which at least 90 percent of all covered items and services are provided to Medicaid beneficiaries through Medicaid managed care contracts with MCOs, PIHPs, or PAHPs, rather than through a fee-for-service delivery system, or under which at least 90 percent of the State's Medicaid beneficiaries are enrolled in Medicaid managed care organizations as defined in § 438.2, may request that its fee-for-service program be exempted from the requirement(s) in paragraphs (a) through (c) of this section.

(A) A state may submit an exemption request once per calendar year for a one (1) year exemption.

(B) The annual request must be submitted as part of a state's annual Advance Planning Document for MMIS operations costs.

(C) The State's request must include documentation that the State meets the criteria for the exemption, using data from any one of the three most recent and complete calendar years prior to the date the exemption request is made.

(ii) CMS will grant the exemption for a one-year period if the State establishes to CMS's satisfaction that the State meets the criteria for the exemption and has established a plan to ensure there will be efficient electronic access to the same information through alternative means.

■ 4. Section 431.70 is amended by adding paragraph (d) to read as follows:

§ 431.70 Access to published provider directory information.

* * * * *

(d) Beginning January 1, 2023, the Provider Directory API must be conformant with the implementation specification at 45 CFR 170.215(c)(8).

■ 5. Section 431.80 is added to subpart B to read as follows:

§ 431.80 Documentation and prior authorization.

(a) *Requirements to support provider documentation discovery and to support prior authorization.* At a minimum:

(1) *Documentation Requirement Lookup Service (DRLS) Application Programming Interface (API).* Beginning January 1, 2023, a State must implement and maintain a standards-based API compliant with § 431.60(c), (d), and (e):

(i) That is populated with the State's list of covered items and services, not including covered outpatient drugs, for which prior authorization is required, and with the State's documentation requirements for submitting a prior authorization request, including a description of the required documentation; and

(ii) That is conformant with the implementation specifications at 45 CFR 170.215(c)(1) and (2).

(2) *Prior Authorization Support API.* Beginning January 1, 2023, a State must implement and maintain a standards-based API compliant with § 431.60(c), (d), and (e):

(i) That facilitates a HIPAA-compliant prior authorization request and response, including any forms or medical record documentation required by the State for the items or services for which the provider is seeking prior authorization;

(ii) That is conformant with the implementation specification at 45 CFR 170.215(c)(3); and

(iii) That includes in the response whether the State approves (and for how long), denies, or requests more information related to the prior authorization request, along with a standard denial reason code in the case of denial;

(iv) A State must include a specific reason for a denial in the case of a denial with all prior authorization decisions, regardless of the method used to send the prior authorization decision.

(b) *Extensions and Exemptions.* (1) *Extension.* (i) A State may submit a written application to request to delay implementation of the requirements in paragraphs (a)(1) and (2) of this section one-time for up to one (1) year with respect to its Medicaid fee-for-service program. The written application must be submitted and approved as part of the State's annual Advance Planning Document for MMIS operations costs and must include:

(A) A narrative justification describing the specific reasons why the State cannot reasonably satisfy the requirement(s) by the compliance date and explaining why those reasons result from circumstances that are unique to States operating Medicaid fee-for service programs;

(B) A report on completed and ongoing State implementation activities that evidence a good faith effort towards compliance; and

(C) A comprehensive plan to meet implementation requirements no later than 1 year after the initial compliance date.

(ii) CMS will grant the State's request if it determines based on the information provided in the State's annual Advance Planning Document for MMIS operations costs that the request adequately establishes a need to delay implementation, that this need results from circumstances that are unique to States operating Medicaid fee-for-service programs, that the State has made a good faith effort to implement the proposed requirements as soon as possible, and that the State has a clear plan to implement the requirements no later than one (1) year after the proposed compliance date.

(2) *Exemption.* (i) A State operating a Medicaid program under which at least 90 percent of all covered items and services are provided to Medicaid beneficiaries through Medicaid managed care contracts with MCOs, PIHPs, or PAHPs, rather than through a fee-for-service delivery system, or under which at least 90 percent of the State's Medicaid beneficiaries are enrolled in Medicaid managed care organizations as defined in § 438.2, may request that its fee-for-service program be exempted from the requirement(s) in paragraphs (a)(1) and (2) of this section.

(A) A state may submit an exemption request once per calendar year for a one (1) year exemption.

(B) The annual request must be submitted as part of a state's annual Advance Planning Document for MMIS operations costs.

(C) The State's request must include documentation that the State meets the criteria for the exemption, using data from any one of the three most recent and complete calendar years prior to the date the exemption request is made.

(ii) CMS will grant the exemption for a one-year period if the State establishes to CMS's satisfaction that the State meets the criteria for the exemption and has established a plan to ensure there will be efficient electronic access to the same information through alternative means.

■ 6. Section 431.201 is amended by revising the definition of ''Action'' to read as follows:

§ 431.201 Definitions.

* * * * *

Action means:

(1) A termination, suspension of, or reduction in covered benefits or services, including benefits or services for which there is a current approved prior authorization;

(2) A termination, suspension of, or reduction in Medicaid eligibility, or an increase in beneficiary liability, including a determination that a beneficiary must incur a greater amount

of medical expenses in order to establish income eligibility in accordance with § 435.121(e)(4) or § 435.831 of this chapter;

(3) A determination that a beneficiary is subject to an increase in premiums or cost-sharing charges under subpart A of part 447 of this chapter; or

(4) A determination by a skilled nursing facility or nursing facility to transfer or discharge a resident and an adverse determination by a State with regard to the preadmission screening and resident review requirements of section 1919(e)(7) of the Act.

* * * * *

■ 7. Section 431.220 is amended—

■ a. In paragraph (a)(1)(iv) by removing the term ''or'' from the end of the paragraph;

■ b. In paragraph (a)(1)(v) by removing ''.'' from the end of the paragraph and adding in its place ''; or''; and

■ c. By adding paragraph (a)(1)(vi).

The addition reads as follows:

§ 431.220 When a hearing is required.

(a) * * *

(1) * * *

(vi) A prior authorization decision.

* * * * *

PART 435—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 8. The authority citation for part 435 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 9. Section 435.917 is amended by:

■ a. Revising the paragraph headings of paragraphs (a) and (b); and

■ b. Revising paragraph (b)(2).

The revisions read as follows:

§ 435.917 Notice of agency's decision concerning eligibility, benefits, or services.

(a) *Notice of determinations.* * * *

* * * * *

(b) *Content of notice.* * * *

* * * * *

(2) Notice of adverse action including denial, termination or suspension of eligibility or change in benefits or services. Any notice of denial, termination or suspension of Medicaid eligibility or, in the case of beneficiaries receiving medical assistance, denial of or change in benefits or services must be consistent with § 431.210 of this chapter.

* * * * *

PART 438—MANAGED CARE

■ 10. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 11. Section 438.9 is amended by revising paragraph (b)(7) to read as follows:

§ 438.9 Provisions that apply to non-emergency medical transportation PAHPs.

* * * * *

(b) * * *

(7) The PAHP standards in §§ 438.206(b)(1), 438.210, 438.214, 438.224, 438.230, and 438.242, excluding the requirement in § 438.242(b)(7) to comply with § 431.61(a) and (c) of this chapter.

* * * * *

■ 12. Section 438.62 is amended by revising paragraph (b)(1)(vii)(A) introductory text to read as follows:

§ 438.62 Continued services to enrollees.

* * * * *

(b) * * *

(1) * * *

(vii) * * *

(A) The MCO, PIHP, or PAHP must comply with the requirements in paragraph (b)(1)(vi) of this section beginning January 1, 2022 until the start of the rating period beginning on or after January 1, 2023 with regard to data:

* * * * *

■ 13. Section 438.210 is amended by—

■ a. Revising paragraph (d)(1); and

■ b. Adding paragraph (g).

The addition and revision read as follows:

§ 438.210 Coverage and authorization of services.

* * * * *

(d) * * *

(1) *Standard authorization decisions.* For standard authorization decisions, provide notice as expeditiously as the enrollee's condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, and for standard authorization decisions made beginning with the rating period on or after January 1, 2023, may not exceed 7 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days if—

* * * * *

(g) *Public reporting of prior authorization metrics.* Beginning March 31, 2023, the MCO, PIHP, or PAHP must make the following information about plan level prior authorization publicly accessible by posting directly on its website or via publicly accessible hyperlink(s), annually by the end of the first calendar quarter, data, for the prior rating period:

(1) A list of all items and services, not including covered outpatient drugs, that require prior authorization;

(2) The percentage of standard prior authorization requests that were approved, reported separately for items and services, not including covered outpatient drugs;

(3) The percentage of standard prior authorization requests that were denied, reported separately for items and services, not including covered outpatient drugs;

(4) The percentage of standard prior authorization requests that were approved after appeal, reported separately for items and services, not including covered outpatient drugs;

(5) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported separately for items and services, not including covered outpatient drugs;

(6) The percentage of expedited prior authorization requests that were approved, reported separately for items and services, not including covered outpatient drugs; and

(7) The average and median time that elapsed between the submission of a request and a determination by the MA organization, for standard prior authorizations, reported separately for items and services, not including covered outpatient drugs.

■ 14. Section 438.242 is amended by—

■ a. Revising paragraphs (b)(5) introductory text;

■ b. Adding paragraph (b)(5)(ii);

■ c. Revising paragraph (b)(6); and

■ b. Adding paragraphs (b)(7) and (8).

The revisions and additions read as follows:

§ 438.242 Health information systems.

* * * * *

(b) * * *

(5) Subject to paragraph (b)(8) of this section, implement a Patient Access Application Programming Interface (API) as specified in § 431.60 of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP and include:

* * * * *

(ii) Reporting metrics specified at § 431.60(h) of this chapter at the plan level.

(6) Except for § 431.70(d) of this chapter implement, by January 1, 2021, and maintain a publicly accessible standard-based Provider Directory API described at § 431.70 of this chapter, which must include all information specified at § 438.10(h)(1) and (2) of this chapter. The State must require, at a minimum, that each MCO, PIHP, and PAHP comply with § 431.70(d) by the rating period beginning on or after January 1, 2023.

(7) By the rating period beginning on or after January 1, 2023, comply with § 431.61(a) through (d) and § 431.80(a)

of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP.

(8) The following timeframes apply to paragraph (b)(5) of this section:

(i) Except for the requirements at §§ 431.60(b)(5), 431.60(c)(3)(iii), 431.60(g), and 431.60(h) of this chapter, comply with the by the requirements of § 431.60 of this chapter by January 1, 2021.

(ii) Comply with the requirements at §§ 431.60(b)(5), 431.60(c)(3)(iii), and 431.60(g) of this chapter by the rating period beginning on or after January 1, 2023.

(iii) Comply with the reporting requirements at § 431.60(h) of this chapter beginning with the end of the first full quarter of the rating period beginning on or after January 1, 2023 based on the previous quarter's data.

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

■ 15. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 16. Section 440.230 is amended by adding paragraphs (d)(1) and (2) to read as follows:

§ 440.230 Sufficiency of amount, duration, and scope.

* * * * *

(d) * * *

(1) *Prior authorization decision timeframes.* The State Medicaid agency must—

(i) Beginning January 1, 2023, provide notice of prior authorization decisions for items and services, not including covered outpatient drugs, as expeditiously as a beneficiary's health condition requires and under any circumstances not later than 72 hours of receiving a request for an expedited determination and not later than 7 calendar days for standard requests. The timeframe for authorization decisions could be extended by up to 14 calendar days for standard requests if the beneficiary or provider requests an extension, or if the state agency or its authorized representative determines that additional information from the provider is needed to make a decision.

(ii) Provide the beneficiary with notice of the agency's prior authorization decision and fair hearing rights in accordance with § 435.917 and part 431, subpart E of this chapter.

(2) *Public reporting of prior authorization metrics.* Beginning March 31, 2023, the State Medicaid agency must make the following information about State agency level prior authorization decisions publicly accessible by posting directly on its website or via publicly accessible hyperlink(s), annually by the end of the first calendar quarter, data for the prior calendar year:

(i) A list of all items and services, not including covered outpatient drugs, that require prior authorization;

(ii) The percentage of standard prior authorization requests that were approved, reported separately for items and services, not including covered outpatient drugs;

(iii) The percentage of standard prior authorization requests that were denied, reported separately for items and services, not including covered outpatient drugs;

(iv) The percentage of standard prior authorization requests that were approved after appeal, reported separately for items and services, not including covered outpatient drugs;

(v) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported separately for items and services, not including covered outpatient drugs;

(vi) The percentage of expedited prior authorization requests that were approved, reported separately for items and services, not including covered outpatient drugs; and

(vii) The average and median time that elapsed between the submission of a request and a determination by the state Medicaid agency, for standard prior authorizations, reported separately for items and services, not including covered outpatient drugs.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 17. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 18. Section 457.495 is amended by revising paragraph (d) to read as follows:

§ 457.495 State assurance of access to care and procedures to assure quality and appropriateness of care.

* * * * *

(d) *Decisions related to the prior authorization of health services.* (1) That decisions related to the prior authorization of health services are completed in accordance with the medical needs of the patient, but no later than 7 calendar days after the date of receipt of the request for a standard determination and by no later than 72 hours after the date of receipt of the request for an expedited determination. A possible extension of up to 14 days may be permitted if the enrollee requests the extension or if the physician or health plan determines the additional information is needed.

(2) Reserved.

■ 19. Section 457.700 is amended by revising paragraph (c) to read as follows:

§ 457.700 Basis, scope, and applicability.

* * * * *

(c) *Applicability.* The requirements of this subpart apply to separate child health programs and Medicaid expansion programs, except that §§ 457.730, 457.731, and 457.732 do not apply to Medicaid expansion programs. Separate child health programs that provide benefits exclusively through managed care organizations may meet the requirements of §§ 457.730, 457.731, and 457.732 by requiring the managed care organizations to meet the requirements of § 457.1233(d)(2).

■ 20. Section 457.730 is amended by—

■ a. Revising paragraphs (b)(3);

■ b. Adding paragraph (b)(5);

■ c. Revising paragraph (c)(3) introductory text;

■ d. Adding paragraph (c)(3)(iii);

■ e. Revising paragraphs (c)(4) introductory text, (c)(4)(ii)(C), and (e)(2);

■ f. Redesignating paragraph (g) as paragraph (i); and

■ g. Adding new paragraphs (g) and (h).

The revisions and additions read as follows:

§ 457.730 Beneficiary access to and exchange of data.

* * * * *

(b) * * *

(3) Clinical data, as defined in the USCDI version 1, if the State maintains any such data, no later than 1 business day after the data are received by the State;

* * * * *

(5) By January 1, 2023, pending and active prior authorization decisions and related clinical documentation and forms for items and services, not including covered outpatient drugs, including the date the prior authorization was approved, the date the authorization ends, as well as the units and services approved and those used to date, no later than 1 business day after a provider initiates a prior authorization for the beneficiary or there is a change of status for the prior authorization.

(c) * * *

(3) Must comply with the content and vocabulary standard requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable to the data type or data element, unless alternate standards are required by other applicable law, and be conformant with the

requirements in paragraphs (c)(3)(iii) of this section:

* * * * *

(iii) Beginning January 1, 2023, be conformant with the implementation specifications at 45 CFR 170.215(c)(5) for data specified in paragraphs (b)(1) and (2) of this section, 45 CFR 170.215(a)(2) or 45 CFR 170.215(c)(6) for data specified in paragraph (b)(3), 45 CFR 170.215(c)(7) for data specified in (b)(4), and 45 CFR 170.215(c)(6) for data specified in paragraph (b)(5) of this section.

(4) May use an updated version of any standard or all standards and any or all implementation guides or specifications required under paragraphs (b) or (c) of this section, §§ 457.731, 457.732, and 457.760, where:

* * * * *

(ii) * * *

(C) Use of the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data described in paragraph (b) of this section, or the data described in §§ 457.731, 457.732, and 457.760 of this chapter through the required API.

* * * * *

(e) * * *

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which parties seek to access electronic health information, as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

* * * * *

(g) *Privacy policy attestation.* (1) Beginning January 1, 2023, the State must establish, implement, and maintain a process for requesting an attestation from a third-party app developer requesting to retrieve data via the Patient Access API that indicates the app adheres to certain privacy provisions. The State must:

(i) Independently, or through the support of a third party, request a third-party app developer to attest whether:

(A) The app has a privacy policy that is publicly available and accessible at all times, including updated versions, and that is written in plain language, and that the third-party app has affirmatively shared with the beneficiary prior to the beneficiary authorizing app access to their health information. To ''affirmatively share'' means that the beneficiary had to take an action to indicate they saw the privacy policy, such as click or check a box or boxes.

(B) The app's privacy policy includes, at a minimum:

(*1*) How a beneficiary's health information may be accessed, exchanged, or used by any person or other entity, including whether the beneficiary's health information may be shared or sold at any time (including in the future);

(*2*) A requirement for express consent from a beneficiary before the beneficiary's health information is accessed, exchanged, or used, including receiving express consent before a beneficiary's health information is shared or sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction);

(*3*) If an app will access any other information from a beneficiary's device; and

(*4*) How a beneficiary can discontinue app access to their data and what the app's policy and process is for disposing of a beneficiary's data once the beneficiary has withdrawn consent.

(ii) Include information in the beneficiary resources required in paragraph (f) of this section about the specific content of the State's privacy policy attestation required under this paragraph, and, at a minimum, the timeline for the attestation process, the method for informing beneficiary about the app developer's response or non-response to the State's request, and the beneficiary's role and rights in this process; and

(iii) Request the attestation at the time the third-party app engages the API and notify the beneficiary as follows:

(A) The State must inform the beneficiary within 24 hours of requesting the attestation from the third-party app developer regarding the status of the attestation—positive, negative, or no response, with a clear explanation of what each means;

(B) If a beneficiary does not respond within 24 hours of when the State sends notice of the attestation status to the beneficiary, the State must proceed with making the beneficiary's data available to the third-party app consistent with the beneficiary's original request.

(2) The State must not discriminate when implementing this requirement, including for the purposes of competitive advantage; the method employed to meet this requirement must be applied equitably across all apps requesting access to the Patient Access API.

(h) *Reporting on the use of the Patient Access API.* (1) Beginning March 31, 2023, a State must report to CMS, at the State agency level, by the end of each calendar quarter, based on the previous quarter's data as follows:

(i) The total number of unique beneficiaries whose data are transferred via the Patient Access API to a beneficiary-designated third-party application; and

(ii) The number of unique beneficiaries whose data are transferred via the Patient Access API to a beneficiary-designated third-party application more than once.

(2) [Reserved].

* * * * *

■ 21. Section 457.731 is added to subpart G to read as follows:

§ 457.731 Access to and exchange of health data to providers and payers.

(a) *Application Programming Interface to support data transfer from payers to providers—Provider Access API.*—(1) *Accessible content and API requirements.* Beginning January 1, 2023, a State must implement and maintain a standards-based Application Programming Interface (API) compliant with § 457.730(c), (d), and (e):

(i) *Individual beneficiary data.* The Provider Access API must make available to providers, if requested by the provider, as permitted by the beneficiary per paragraph (a)(3) of this section, and as permitted by applicable law, at a minimum, data maintained by the State with a date of service on or after January 1, 2016, within one (1) business day of receipt, conformant with the implementation specifications at 45 CFR 170.215(c)(5) for data specified at § 431.60(b)(1) and (2) of this chapter, not including remittances and enrollee cost sharing information, 45 CFR 170.215(a)(2) or 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(3) of this chapter, 45 CFR 170.215(c)(7) for data specified at § 431.60(b)(4), and 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(5) of this chapter; and

(ii) *Bulk data access.* The Provider Access API must be able to share the data specified in (a)(1)(i) of this section conformant with the implementation specification at 45 CFR 170.215(a)(4) to facilitate sharing the specified data relevant to one or more beneficiaries at one time.

(2) *Attribution.* A State must establish, implement, and maintain a process to facilitate generating each provider's current beneficiary roster to enable this payer-to-provider data sharing via the Provider Access API;

(3) *Opt-in.* A State may put a process in place to allow a beneficiary or the beneficiary's personal representatives to opt-in to permit the State's use of the Provider Access API for sharing with

the each of the beneficiary's provider(s) currently providing care, or planning to provide care, the data specified in paragraph (a)(1) of this section.

(4) *Provider resources regarding APIs.* A State must provide on its website and through other appropriate mechanisms through which it ordinarily communicates with providers, educational resources in non-technical, simple and easy-to-understand language explaining general information concerning how a provider may make a request to the State for beneficiary data using the standards-based Provider Access API required under paragraph (a)(1) of this section, both for individual access and bulk data requests.

(5) *Out-of-network provider access.* A State cannot deny use of, or access to, the Provider Access API based on a provider's contract status.

(b) *Coordination among payers—Payer-to-Payer Data Exchange.* (1) Beginning January 1, 2023, a State must implement and maintain a standards-based API compliant with § 457.730(c), (d), and (e) that makes available to another payer, at a minimum, the data maintained by the State with a date of service on or after January 1, 2016, within one (1) business day of receipt, conformant with the implementation specifications at 45 CFR 170.215(c)(5) for data specified at § 431.60(b)(1) and (2) of this chapter not including remittances and enrollee cost sharing information, 45 CFR 170.215(a)(2) or 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(3) of this chapter, 45 CFR 170.215(c)(7) for data specified at § 431.60(b)(4) of this chapter, and 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(5) of this chapter. Such information received by a State must be incorporated into the State's records about the current beneficiary.

(2) With the approval and at the direction of a current or former beneficiary or the beneficiary's personal representative, the State must:

(i) Receive all such data for a current beneficiary from any other payer that has provided coverage to the beneficiary within the preceding 5 years;

(ii) At any time a beneficiary is currently enrolled with the State and up to 5 years after disenrollment, send all such data to any other payer that currently covers the beneficiary or a payer the beneficiary or the beneficiary's personal representative specifically requests receive the data; and

(iii) Send data received from another payer under this paragraph in the electronic form and format it was received.

(c) *Coordination among payers at enrollment—Payer-to-Payer API.*—(1) *Accessible content and API requirements.* Beginning January 1, 2023, a State must make the standards-based API specified in paragraph (b)(1) of this section conformant with the implementation specification at 45 CFR 170.215(a)(4) to facilitate sharing the data specified in paragraph (b)(1) of this section relevant to one or more beneficiaries at one time.

(2) *Requesting data exchange.* (i) When a beneficiary enrolls in coverage with the State, the State may request the data from a previous payer through the standards-based API described in paragraph (c)(1) of this section, as permitted by the enrollee per paragraph (c)(5) of this section, and as permitted by applicable law;

(ii) For any beneficiaries who enroll with the State during the first calendar quarter of each year, the State must request the specified data within one (1) week of the end of the first calendar quarter from any previous payers through the standards-based API described in paragraph (c)(1) of this section, as permitted by the beneficiary per paragraph (c)(5) of this section, and as permitted by applicable law;

(iii) If a State receives a request from another payer to make data available for one or more former beneficiaries who have enrolled with the new payer, the State must respond by making the required data available via the standards-based API described in paragraph (c)(1) of this section within one (1) business day of receiving the request.

(3) *Previous or concurrent payer.* A State must maintain a process to obtain from a new beneficiary the name of the new beneficiary's previous payer as part of the enrollment process, and concurrent payer if the beneficiary has coverage through more than one payer, to facilitate data sharing using the Payer-to-Payer API described in paragraph (c)(1) of this section.

(4) *Concurrent payer exchange.* When a beneficiary has concurrent coverage with another payer also subject to CMS regulations on the Payer-to-Payer API, the State must make available to the other payer the data described in paragraph (b)(1) of this section through the standards-based API described in paragraph (c)(1) of this section quarterly.

(5) *Opt-in.* A State must put a process in place to allow a beneficiary or the beneficiary's personal representative to opt-in to permit the State's use of the Payer-to-Payer API data sharing specified in paragraph (c)(1) of this section.

(d) *Obligations.* The requirements under this section do not in any way alter or change a State's obligation as a HIPAA covered entity to comply with regulations regarding standard transactions at 45 CFR part 162.

(e) *Extensions and Exemptions*—(1) *Extension.* (i) A State may submit a written application to request to delay implementation of the requirements in paragraphs (a) through (c) of this section one-time for up to one (1) year with respect to its Medicaid fee-for-service program. The written application must be submitted and approved as part of the State's annual Advance Planning Document for MMIS operations costs and must include:

(A) A narrative justification describing the specific reasons why the State cannot reasonably satisfy the requirement(s) by the compliance date and explaining why those reasons result from circumstances that are unique to States operating CHIP fee-for service programs;

(B) A report on completed and ongoing State implementation activities that evidence a good faith effort towards compliance; and

(C) A comprehensive plan to meet implementation requirements no later than 1 year after the initial compliance date.

(ii) CMS will grant the State's request if it determines based on the information provided in the State's annual Advance Planning Document for MMIS operations costs that the request adequately establishes a need to delay implementation, that this need results from circumstances that are unique to States operating CHIP fee-for-service programs, that the State has made a good faith effort to implement the proposed requirements as soon as possible, and that the State has a clear plan to implement the requirements no later than one (1) year after the proposed compliance date.

(2) *Exemption.* (i) A State operating a CHIP program under which at least 90 percent of all covered items and services are provided to beneficiaries through managed care contracts with MCOs, PIHPs, or PAHPs, rather than through a fee-for-service delivery system, or under which at least 90 percent of the State's beneficiaries are enrolled in managed care organizations as defined in § 457.10, may request that its fee-for-service program be exempted from the requirement(s) in paragraphs (a) through (c) of this section.

(A) A state may submit an exemption request once per calendar year for a one (1) year exemption.

(B) The annual request must be submitted as part of a state's annual

Advance Planning Document for MMIS operations costs.

(C) The State's request must include documentation that the State meets the criteria for the exemption, using data from any one of the three most recent and complete calendar years prior to the date the exemption request is made.

(ii) CMS will grant the exemption for a one-year period if the State establishes to CMS's satisfaction that the State meets the criteria for the exemption and has established a plan to ensure there will be efficient electronic access to the same information through alternative means.

(f) *Applicability.* This section is applicable beginning January 1, 2023.

■ 22. Section 457.732 is added to subpart G to read as follows:

§ 457.732 Documentation and prior authorization.

(a) *Requirements to support provider documentation discovery and to support prior authorization.* At a minimum:

(1) *Documentation Requirement Lookup Service (DRLS) Application Programming Interface (API).* Beginning January 1, 2023, a State must implement and maintain a standards-based API compliant with § 457.730(c), (d), and (e) —

(i) That is populated with the State's list of covered items and services, not including covered outpatient drugs, for which prior authorization is required, and with the State's documentation requirements for submitting a prior authorization request, including a description of the required documentation; and

(ii) That is conformant with the implementation specifications at 45 CFR 170.215(c)(1) and (2).

(2) *Prior Authorization Support API.* Beginning January 1, 2023, a State must implement and maintain a standards-based API compliant with § 457.730(c), (d), and (e) —

(i) That facilitates a HIPAA-compliant prior authorization request and response, including any forms or medical record documentation required by the State for the items or services for which the provider is seeking prior authorization;

(ii) That is conformant with the implementation specifications at 45 CFR 170.215(c)(1) and (2).

(iii) That includes in the response whether the State approves (and for how long), denies, or requests more information related to the prior authorization request, along with a denial reason code in the case of denial;

(iv) A State must include a specific reason for a denial in the case of a denial with all prior authorization decisions, regardless of the method used to send the prior authorization decision.

(b) *Extensions and Exemptions.*—(1) *Extension.* (i) A State may submit a written application to request to delay implementation of the requirements in paragraphs (a)(1) and (2) of this section one-time for up to one (1) year with respect to its Medicaid fee-for-service program. The written application must be submitted and approved as part of the State's annual Advance Planning Document for MMIS operations costs and must include:

(A) A narrative justification describing the specific reasons why the State cannot reasonably satisfy the requirement(s) by the compliance date and explaining why those reasons result from circumstances that are unique to States operating CHIP fee-for service programs;

(B) A report on completed and ongoing State implementation activities that evidence a good faith effort towards compliance; and

(C) A comprehensive plan to meet implementation requirements no later than 1 year after the initial compliance date.

(ii) CMS will grant the State's request if it determines based on the information provided in the State's annual Advance Planning Document for MMIS operations costs that the request adequately establishes a need to delay implementation, that this need results from circumstances that are unique to States operating CHIP fee-for-service programs, that the State has made a good faith effort to implement the proposed requirements as soon as possible, and that the State has a clear plan to implement the requirements no later than one (1) year after the proposed compliance date.

(2) *Exemption.* (i) A State operating a CHIP program under which at least 90 percent of all covered items and services are provided to beneficiaries through managed care contracts with MCOs, PIHPs, or PAHPs, rather than through a fee-for-service delivery system, or under which at least 90 percent of the State's beneficiaries are enrolled in managed care organizations as defined in § 457.10, may request that its fee-for-service program be exempted from the requirement(s) in paragraphs (a)(1) and (2) of this section.

(A) A state may submit an exemption request once per calendar year for a one (1) year exemption.

(B) The annual request must be submitted as part of a state's annual Advance Planning Document for MMIS operations costs.

(C) The State's request must include documentation that the State meets the criteria for the exemption, using data from any one of the three most recent and complete calendar years prior to the date the exemption request is made.

(ii) CMS will grant the exemption for a one-year period if the State establishes to CMS's satisfaction that the State meets the criteria for the exemption and has established a plan to ensure there will be efficient electronic access to the same information through alternative means.

(3) *Public reporting of prior authorization metrics.* Beginning March 31, 2023, the State must make the following information about State agency level prior authorization decisions publicly accessible by posting directly on its website or via publicly accessible hyperlink(s), annually by the end of the first calendar quarter, data for the prior calendar year:

(i) A list of all items and services, not including covered outpatient drugs, that require prior authorization;

(ii) The percentage of standard prior authorization requests that were approved, reported separately for items and services, not including covered outpatient drugs;

(iii) The percentage of standard prior authorization requests that were denied, reported separately for items and services, not including covered outpatient drugs;

(iv) The percentage of standard prior authorization requests that were approved after appeal, reported separately for items and services, not including covered outpatient drugs;

(v) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported separately for items and services, not including covered outpatient drugs;

(vi) The percentage of expedited prior authorization requests that were approved, reported separately for items and services, not including covered outpatient drugs; and

(vii) The average and median time that elapsed between the submission of a request and a determination by the State, for standard prior authorizations, reported separately for items and services, not including covered outpatient drugs.

■ 23. Section 457.760 is amended by adding paragraph (d) to read as follows:

§ 457.760 Access to published provider directory information

* * * * *

(d) Beginning January 1, 2023, the Provider Directory API must be conformant with the implementation specification at 45 CFR 170.215(c)(8).

■ 24. Section 457.1233 is amended by—

■ a. Revising paragraph (d)(2) introductory text;

■ b. Adding paragraph (d)(2)(ii);

■ c. Revising paragraph (d)(3); and

■ d. Adding paragraph (d)(4) and (5).

The revisions and additions read as follows:

§ 457.1233 Structure and operations standards.

* * * * *

(d) * * *

(2) Subject to paragraph (d)(5) of this section, each MCO, PIHP, and PAHP must implement a Patient Access Application Programming Interfaces (APIs) as specified in § 457.730 as if such requirements applied directly to the MCO, PIHP, or PAHP, and include:

* * * * *

(ii) Reporting metrics specified at § 457.730(h) at the plan level.

(3) Except for § 457.760(d), implement, by January 1, 2021, and maintain a publicly accessible standards-based Provider Directory API described at § 457.760 of this chapter, which must include all information specified in § 438.10(h)(1) and (2) of this chapter. The state must require, at a minimum, that each MCO, PIHP, and PAHP comply with § 457.760(d) by the rating period beginning on or after January 1, 2023.

(4) By the rating period beginning on or after January 1, 2023, comply with §§ 457.731(a) through (d) and 457.732(a) as if such requirements applied directly to the MCO, PIHP, or PAHP.

(5) The following timeframes apply to paragraph (d)(2) of this section:

(i) Except for the requirement at §§ 457.730(b)(5), 457.730(c)(3)(iii), 457.730(g), and 457.730(h), comply with the by the requirements of § 457.730 by January 1, 2021.

(ii) Comply with the requirements at §§ 457.730(b)(5), 457.730(c)(3)(iii), and 457.730(g) by the rating period beginning on or after January 1, 2023.

(iii) Comply with the reporting requirement at § 457.730(h) beginning with the end of the first full quarter of the rating period beginning on or after January 1, 2023 based on the previous quarter's data.

* * * * *

For the reasons set forth in the preamble, the Department of Health and Human Services (HHS) proposes to amend 45 CFR subtitle A, subchapter B as set forth below:

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 25. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 26. Section 156.221 is amended by—

■ a. Revising paragraph (b)(1)(iii);

■ b. Adding paragraph (b)(1)(iv);

■ c. Revising paragraph (c)(3) introductory text;

■ d. Adding paragraph (c)(3)(iii);

■ e. Revising paragraph (c)(4) introductory text, (c)(4)(ii)(C), (e)(2), and (f)(1) introductory text;

■ f. Adding paragraph (f)(2);

■ g. Redesignating paragraphs (h) and (i) as paragraphs (j) and (k);

■ h. Adding new paragraphs (h) and (i); and

■ i. Revising newly redesignated paragraph (j).

The revisions and addition read as follows:

§ 156.221 Access to and exchange of health data and plan information.

* * * * *

(b) * * *.

(1) * * *

(iii) Clinical data, as defined in the USCDI version 1, if the QHP issuer maintains any such data, no later than 1 business day after data are received by the QHP issuer; and

(iv) Beginning January 1, 2023, pending and active prior authorization decisions and related clinical documentation and forms for items and services, not including prescription drugs, including the date the prior authorization was approved, the date the authorization ends, as well as the units and services approved and those used to date, no later than 1 business day after a provider initiates a prior authorization for the enrollee or there is a change of status for the prior authorization.

* * * * *

(c) * * *

(3) Must comply with the content and vocabulary standard requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable to the data type or data element, unless alternate standards are required by other applicable law, and be conformant with the requirements in paragraph (c)(3)(iii) of this section:

* * * * *

(iii) Beginning January 1, 2023, be conformant with the implementation specifications at § 170.215(c)(5) for data specified at § 156.221(b)(1)(i) and (ii), § 170.215(a)(2) or § 170.215(c)(6) of this subchapter for data specified at §§ 156.221(b)(1)(iii), and 170.215(c)(6) of this subchapter for data specified in paragraph (b)(1)(iv) of this section.

(4) May use an updated version of any standard or all standards and any or all implementation guides or specifications required under paragraphs (b), (c), or (f) of this section, §§ 156.222 or 156.223, where:

* * * * *

(ii) * * *

(C) Use of the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data described in paragraph (b) or (f) of this section or the data described in §§ 156.222 or 156.223 of this chapter through the required API.

* * * * *

(e) * * *

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which parties seek to access electronic health information, as defined at § 171.102 of this subchapter, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

(f) * * *

(1) From January 1, 2022 until December 31, 2022, a QHP issuer on a Federally-facilitated Exchange must maintain a process for the electronic exchange of, at a minimum, the data classes and elements included in the content standard adopted at § 170.213 of this subchapter. Such information received by a QHP issuer on a Federally-facilitated Exchange must be incorporated into the QHP issuer's records about the current enrollee. With the approval and at the direction of a current or former enrollee or the enrollee's personal representative, a QHP issuer on a Federally-facilitated Exchange must:

* * * * *

(2) Beginning January 1, 2023, a QHP issuer on a Federally-facilitated Exchange must implement and maintain an API compliant with § 156.221(c)(1), (c)(2), (c)(3)(i), and (c)(3)(ii), (d), and (e), and that is conformant with the implementation specifications at § 170.215(c)(5) of this chapter for data specified at § 156.221(b)(1)(i) and (ii) not including remittances and enrollee cost sharing information, § 170.215(a)(2) or 170.215(c)(6) of this subchapter for data specified at § 156.221(b)(1)(iii), and § 170.215(c)(6) of this subchapter for

data specified in paragraph (b)(1)(iv). Such information received by a QHP issuer on a Federally-facilitated Exchange must be incorporated into the QHP issuer's records about the current enrollee.

(i) With the approval and at the direction of a current or former enrollee or the enrollee's personal representative, a QHP issuer on a Federally-facilitated Exchange must:

(A) Receive all such data for a current enrollee from any other payer that has provided coverage to the enrollee within the preceding 5 years;

(B) At any time an enrollee is currently enrolled in the plan and up to 5 years after disenrollment, send all such data to any other payer that currently covers the enrollee or a payer the enrollee or the enrollee's personal representative specifically requests receive the data; and

(C) Send data received from another payer under this paragraph (f)(2) of this section in the electronic form and format it was received.

(ii) [Reserved].

* * * * *

(h) *Privacy policy attestation.* (1) Beginning January 1, 2023, a QHP issuer on a Federally-facilitated Exchange must establish, implement, and maintain a process for requesting an attestation from a third-party app developer requesting to retrieve data via the Patient Access API that indicates the app adheres to certain privacy provisions. The QHP issuer on a Federally-facilitated Exchange must:

(i) Independently, or through the support of a third party, request a third-party app developer to attest whether:

(A) The app has a privacy policy that is publicly available and accessible at all times, including updated versions, and that is written in plain language, and that the third-party app has affirmatively shared with the enrollee prior to the enrollee authorizing app access to their health information. To ''affirmatively share'' means that the enrollee had to take an action to indicate they saw the privacy policy, such as click or check a box or boxes.

(B) The app's privacy policy includes, at a minimum:

(*1*) How an enrollee's health information may be accessed, exchanged, or used by any person or other entity, including whether the enrollee's health information may be shared or sold at any time (including in the future);

(*2*) A requirement for express consent from an enrollee before the enrollee's health information is accessed, exchanged, or used, including receiving express consent before an enrollee's health information is shared or sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction);

(*3*) If an app will access any other information from an enrollee's device; and

(*4*) How an enrollee can discontinue app access to their data and what the app's policy and process is for disposing of an enrollee's data once the enrollee has withdrawn consent.

(ii) Include information in the enrollee resources required in paragraph (g) of this section about the specific content of the QHP issuer's privacy policy attestation required under this paragraph, and, at a minimum, the timeline for the attestation process, the method for informing enrollees about the app developer's response or non-response to the QHP issuer's request, and the enrollee's role and rights in this process; and

(iii) Request the attestation at the time the third-party app engages the API and notify the enrollee as follows:

(A) The QHP issuer on a Federally-facilitated Exchange must inform the enrollee within 24 hours of requesting the attestation from the third-party app developer regarding the status of the attestation—positive, negative, or no response, with a clear explanation of what each means;

(B) If an enrollee does not respond within 24 hours of when the QHP issuer send the notice of the attestation status to the enrollee, the QHP issuer must proceed with making the enrollee's data available to the third-party app consistent with the enrollee's original request.

(2) A QHP issuer must not discriminate when implementing this requirement, including for the purposes of competitive advantage; the method employed to meet this requirement must be applied equitably across all apps requesting access the Patient Access API.

(i) *Reporting on the use of the Patient Access API.* (1) Beginning March 31, 2023, a QHP issuer on a Federally-facilitated Exchange must report to HHS, at the issuer level, by the end of each calendar quarter, based on the previous quarter's data:

(i) The total number of unique enrollees whose data are transferred via the Patient Access API to an enrollee designated third-party application; and

(ii) The number of unique enrollees whose data are transferred via the Patient Access API to an enrollee designated third-party application more than once.

(2) [Reserved].

(j) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraphs (a) through (i) of this section, the issuer must include as part of its QHP application a narrative justification describing the reasons why the plan cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance upon enrollees, the current or proposed means of providing health information to enrollees, and solutions and a timeline to achieve compliance with the requirements of this section.

(2) The Federally-facilitated Exchange may grant an exception to the requirements in paragraphs (a) through (i) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals and qualified employers in the State or States in which such Exchange operates.

* * * * *

■ 27. Section 156.222 is added to read as follows:

§ 156.222 Access to and exchange of health data and plan information to providers and payers.

(a) *Application Programming Interface to support data transfer from payers to providers—Provider Access API.* Subject to paragraph (d) of this section:

(1) *Accessible content and API requirements.* Beginning January 1, 2023, a QHP issuer on a Federally-facilitated Exchange must implement and maintain a standards-based Application Programming Interface (API) compliant with § 156.221(c), (d), and (e):

(i) *Individual enrollee data.* The Provider Access API must make available to providers, if requested by the provider, as permitted by the enrollee per paragraph (a)(3) of this section, and as permitted by applicable law, at a minimum, data maintained by the QHP with a date of service on or after January 1, 2016, within one (1) business day of receipt, conformant with the implementation specifications at § 170.215(c)(5) of this subchapter for data specified at § 156.221(b)(1)(i) and (ii), not including remittances and enrollee cost sharing information, § 170.215(a)(2) or (c)(6) of this subchapter for data specified at § 156.221(b)(1)(iii), and § 170.215(c)(6) of this subchapter for data specified in paragraph (b)(1)(iv) of this section; and

(ii) *Bulk data access.* The Provider Access API must be able to share the data described in paragraph (a)(1)(i) of

this section conformant with the implementation specification at § 170.215(a)(4) to facilitate sharing the specified data relevant to one or more QHP enrollees at one time;

(2) *Attribution.* A QHP issuer on a Federally-facilitated Exchange must establish, implement, and maintain a process to facilitate generating each provider's current enrollee rosters to enable payer-to-provider data sharing via the Provider Access API.

(3) *Opt-in.* A QHP issuer on a Federally-facilitated Exchange may put a process in place to allow an enrollee or the enrollee's personal representative to opt-in to permit the QHP's use of the Provider Access API for sharing with each of the enrollee's provider(s) currently providing care, or planning to provide care, the data specified in paragraph (a)(1) of this section.

(4) *Provider resources regarding APIs.* A QHP issuer on a Federally-facilitated Exchange must provide on its website and through other appropriate mechanisms through which it ordinarily communicates with providers, educational resources in non-technical, simple, and easy-to-understand language explaining general information concerning how a provider may make a request to the QHP for QHP enrollee data using the standards-based Provider Access API, required under paragraph (a)(1) of this section, both for individual access and bulk data requests.

(5) *Out-of-network provider access.* A QHP issuer on a Federally-facilitated Exchange cannot deny use of, or access to, the Provider Access API based on a provider's contract status.

(b) *Coordination among payers at enrollment—Payer-to-Payer API.* Subject to paragraph (d) of this section:

(1) *Accessible content and API requirements.* Beginning January 1, 2023 a QHP issuer on a Federally-facilitated Exchange must make the standards-based API specified at § 156.221(f)(2) conformant with the implementation specification at § 170.215(a)(4) of this subchapter to facilitate sharing the data specified at § 156.221(f)(2) relevant to one or more QHP enrollees at one time.

(2) *Requesting data exchange.* (i) When an enrollee enrolls in a QHP on a Federally-facilitated Exchange, the QHP issuer may request the data from the previous payer through the standards-based API described in paragraph (b)(1) of this section, as permitted by the enrollee per paragraph (b)(5) of this section, and as permitted by applicable law.

(ii) For any enrollees who enrolled in a QHP on a Federally-facilitated Exchange during the annual open enrollment period applicable to the Federally-facilitated Exchange, the QHP issuer must request the specified data within one (1) week of the end of the enrollment period from any previous payers through the standards-based API described in paragraph (b)(1) of this section, as permitted by enrollees per paragraph (b)(5) of this section, and as permitted by applicable law;

(iii) If a QHP issuer receives a request from another payer to make data available for one or more former enrollee who have enrolled with the new payer, the QHP issuer must respond by making the required data available via the standards-based API described in paragraph (b)(1) of this section within one (1) business day of receiving the request.

(3) *Previous or concurrent payer.* A QHP issuer on a Federally-facilitated Exchange must maintain a process to obtain from a new QHP enrollee the name of the new QHP enrollee's previous payer, and concurrent payer if the enrollee has coverage through more than one payer, to facilitate data sharing using the Payer-to-Payer API described in paragraph (b)(1) of this section.

(4) *Concurrent payer exchange.* When a QHP enrollee has concurrent coverage with another payer also subject to HHS regulations on the Payer-to-Payer API, the QHP issuer on the Federally-facilitated Exchange must make available to the other payer the data described at § 156.221(f)(2) through the standards-based API described in paragraph (b)(1) of this section quarterly.

(5) *Opt-in.* A QHP issuer on a Federally-facilitated Exchange must put a process in place to allow an enrollee or the enrollee's personal representative to opt-in to permit the QHP issuer to use the Payer-to-Payer API data sharing specified in paragraph (b)(1) of this section.

(c) *Obligations.* The requirements under this section do not in any way alter or change a QHP issuer's obligation as a HIPAA covered entity to comply with regulations regarding standard transactions at 45 CFR part 162.

(d) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraphs (a) or (b) of this section, the issuer must include as part of its QHP application a narrative justification describing the reasons why the plan cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance upon enrollees, the current or proposed means of providing health information to providers and/or payers, and solutions and a timeline to achieve compliance with the requirements of this section.

(2) The Federally-facilitated Exchange may grant an exception to the requirements in paragraphs (a) or (b) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals and qualified employers in the State or States in which such Exchange operates.

■ 28. Section 156.223 is added to read as follows:

§ 156.223 Documentation and prior authorization.

(a) *Requirements to support provider documentation discovery and to support prior authorization.* Subject to paragraph (b) of this section:

(1) *Documentation Requirement Lookup Service (DRLS) Application Programming Interface (API).* Beginning January 1, 2023, a QHP issuer on a Federally-facilitated Exchange must implement and maintain a standards-based API compliant with § 156.221(c), (d), and (e):

(i) That is populated with the QHP issuer's list of covered items and services, not including prescription drugs, for which prior authorization is required, and with the QHP issuer's documentation requirements for submitting a prior authorization request, including a description of the required documentation; and

(ii) That is conformant with the implementation specifications at § 170.215(c)(1) and (2).

(2) *Prior Authorization Support API.* Beginning January 1, 2023, a QHP issuer on a Federally-facilitated Exchange must implement and maintain a standards-based API compliant with § 156.221(c), (d), and (e):

(i) That facilitates a HIPAA-compliant prior authorization request and response, including any other forms or medical record documentation required by the QHP issuer for the items or services for which the provider is seeking prior authorization, conformant with the requirements at § 172.110(a)(3) of this subchapter;

(ii) That is conformant with the implementation specification at § 170.215(c)(3) of this subchapter; and

(iii) That includes in the response whether the QHP issuer approves (and for how long), denies, or requests more information related to the prior authorization request, along with a standard denial reason code in the case of denial;

(iv) A QHP issuer on a Federally-facilitated Exchange must include a specific reason for a denial in the case of a denial with all prior authorization

decisions, regardless of the method used to send the prior authorization decision.

(3) *Public reporting of prior authorization metrics.* Beginning March 31, 2023, a QHP issuer on a Federally-facilitated Exchange must make the following information about the issuer level prior authorization decisions specified, publicly accessible by posting directly on its website or via publicly accessible hyperlink(s), annually by the end of the first calendar quarter, data for the prior calendar year:

(i) A list of all items and services, not including prescription drugs, that require prior authorization;

(ii) The percentage of standard prior authorization requests that were approved, reported separately for items and services, not including prescription drugs;

(iii) The percentage of standard prior authorization requests that were denied, reported separately for items and services, not including prescription drugs;

(iv) The percentage of standard prior authorization requests that were approved after appeal, reported separately for items and services, not including prescription drugs;

(v) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported separately for items and services, not including prescription drugs;

(vi) The percentage of expedited prior authorization requests that were approved, reported separately for items and services, not including prescription drugs; and

(vii) The average and median time that elapsed between the submission of a request and a determination by the issuer, for standard prior authorizations, reported separately for items and services, not including prescription drugs.

(b) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraph (a)(1) and/or (a)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing the reasons why the plan cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance upon enrollees, the current or proposed means of providing health information to providers, and solutions and a timeline to achieve compliance with the requirements of this section.

(2) The Federally-facilitated Exchange may grant an exception to the requirements in paragraph (a) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals and qualified employers in the State or States in which such Exchange operates.

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 29. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj-11; 42 U.S.C 300jj-14; 5 U.S.C. 552.

■ 30. Section 170.215 is amended—

■ a. By revising the section heading;

■ b. In paragraph (a), by adding a paragraph heading;

■ c. In paragraph (b), by revising the paragraph heading; and

■ d. By adding paragraph (c).

The revisions and additions read as follows:

§ 170.215 Application Programming Interface Standards and Implementation Specifications.

* * * * *

(a) *Base Standard and Implementation Specifications.* * * *

* * * * *

(b) *Security Standard.* * * *

(c) *Standards and Implementation Specifications for Health Care Operations.*

(1) *Prior authorization implementation specification.* HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide: Version STU 1.0.0 (incorporated by reference in § 170.299).

(2) *Prior authorization implementation specification.* HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide: Version STU 1.0.0 (incorporated by reference in § 170.299).

(3) *Prior authorization implementation specification.* HL7 FHIR Da Vinci—Prior Authorization Support (PAS) Implementation Guide: Version STU 1.0.0 (incorporated by reference in § 170.299).

(4) *Payer data implementation specification.* HL7 FHIR Da Vinci—Payer Coverage Decision Exchange (PCDE) Implementation Guide: Version STU 1.0.0 (incorporated by reference in § 170.299).

(5) *Payer data implementation specification.* HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide: Version STU 1.0.0 (incorporated by reference in § 170.299).

(6) *Payer data implementation specification.* HL7 FHIR Da Vinci Payer Data Exchange (PDex) Implementation Guide: Version STU 1.0.0 (incorporated by reference in § 170.299).

(7) *Payer data implementation specification.* HL7 FHIR Da Vinci—Payer Data Exchange (PDex) US Drug Formulary Implementation Guide: Version STU 1.0.1 (incorporated by reference in § 170.299).

(8) *Provider directory implementation specification.* HL7 FHIR Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide: Version STU 1.0.0 (incorporated by reference in § 170.299).

■ 31. Section 170.299 is amended by adding paragraphs (f)(35) through (42) to read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(f) * * *

(35) HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version STU 1.0.0, IBR approved for § 170.215(c).

(36) HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version STU 1.0.0, IBR approved for § 170.215(c).

(37) HL7 FHIR® Da Vinci—Prior Authorization Support (PAS) Implementation Guide, Version STU 1.0.0, IBR approved for § 170.215(c).

(38) HL7 FHIR® Da Vinci—Payer Coverage Decision Exchange (PCDE) Implementation Guide, Version STU 1.0.0, IBR approved for § 170.215(c).

(39) HL7 FHIR® Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide, Version STU 1.0.0, IBR approved for § 170.215(c).

(40) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version STU 1.0.0, IBR approved for § 170.215(c).

(41) HL7 FHIR® Da Vinci—Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version STU 1.0.1, IBR approved for § 170.215(c).

(42) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide, Version STU 1.0.0, IBR approved for § 170.215(c).

* * * * *

Dated: December 2, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 10, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–27593 Filed 12–14–20; 11:15 am]

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Part III

Environmental Protection Agency

40 CFR Part 50

Review of the National Ambient Air Quality Standards for Particulate Matter; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2015–0072; FRL–10018–11–OAR]

RIN 2060–AS50

Review of the National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: Based on the Environmental Protection Agency's (EPA's) review of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the Administrator has reached final decisions on the primary and secondary PM NAAQS. With regard to the primary standards meant to protect against fine particle exposures (*i.e.,* annual and 24-hour $PM_{2.5}$ standards), the primary standard meant to protect against coarse particle exposures (*i.e.,* 24-hour PM_{10} standard), and the secondary $PM_{2.5}$ and PM_{10} standards, the EPA is retaining the current standards, without revision.

DATES: This final action is effective December 18, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2015–0072. Incorporated into this docket is a separate docket established for the Integrated Science Assessment (Docket ID No. EPA–HQ–ORD–2014–0859). All documents in the docket are listed in *https://www.regulations.gov/.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. With the exception of such material, publicly available docket materials are available electronically through *https://www.regulations.gov/.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Dr. Lars Perlmutt, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C539–04, Research Triangle Park, NC 27711; telephone: (919) 541–3037; fax: (919) 541–5315; email: *perlmutt.lars@epa.gov.*

SUPPLEMENTARY INFORMATION:

Basis for Immediate Effective Date

In accordance with section 307(d)(1)(V), the Administrator has designated this action as being subject to the rulemaking procedures in section 307(d) of the Clean Air Act (CAA). Section 307(d)(1) of the CAA states that: ''The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies.'' Thus, section 553(d) of the Administrative Procedure Act (APA), which requires publication of a substantive rule to be made ''not less than 30 days before its effective date'' subject to limited exceptions, does not apply to this action. In the alternative, the EPA concludes that it is s consistent with APA section 553(d) to make this action effective December 18, 2020.

Section 553(d)(3) of the APA, 5 U.S.C. 553(d)(3), provides that final rules shall not become effective until 30 days after publication in the **Federal Register** ''except . . . as otherwise provided by the agency for good cause found and published with the rule.'' ''In determining whether good cause exists, an agency should 'balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996) (quoting *United States* v. *Gavrilovic,* 551 F.2d 1099, 1105 (8th Cir. 1977)). The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Id.; see also Gavrilovic,* 551 F.2d at 1104 (quoting legislative history).

The EPA is determining that in light of the nature of this action, good cause exists to make this final action effective immediately because the Agency seeks to provide regulatory certainty as soon as possible and the Administrator's decision to retain the current NAAQS does not change the status quo or impose new obligations on any person or entity. As a result, there is no need to provide parties additional time to adjust their behavior, and no person will be harmed by making the action immediately effective as opposed to delaying the effective date by 30 days. Accordingly, the EPA is making this action effective immediately upon publication.

General Information

Availability of Information Related to This Action

A number of the documents that are relevant to this final decision are available through the EPA's website at *https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards.* These documents include the Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (U.S. EPA, 2016), available at *https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf,* the Integrated Science Assessment for Particulate Matter (U.S. EPA, 2019), available at *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534,* the Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (U.S. EPA, 2020), available at *https://www.epa.gov/naaqs/particulate-matter-pm-standards-policy-assessments-current-review-0,* and the notice of proposed rulemaking, available at *https://www.epa.gov/naaqs/particulate-matter-pm-standards-federal-register-notices-current-review.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

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Executive Summary

This notice presents the Administrator's final decisions to retain the current primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for particulate matter (PM), without revision.

In ambient air, PM is a mixture of substances suspended as small liquid and/or solid particles. Particles in the atmosphere range in size from less than 0.01 to more than 10 micrometers (μm) in diameter. Particulate matter and its precursors are emitted from both anthropogenic sources (*e.g.,* electricity generating units, cars and trucks, agricultural operations) and natural sources (*e.g.,* sea salt, wildland fires, biological aerosols). When describing PM, subscripts are used to denote particle size. For example, $PM_{2.5}$ includes particles with diameters generally less than or equal to 2.5 μm and PM_{10} includes particles with diameters generally less than or equal to 10 μm.

The EPA has established primary (health-based) and secondary (welfare-based) NAAQS for $PM_{2.5}$ and PM_{10}. This includes two primary $PM_{2.5}$ standards, an annual average standard with a level of 12.0 μg/m³ and a 24-hour standard with a 98th percentile form and a level of 35 μg/m³. It also includes a primary PM_{10} standard with a 24-hour averaging time, a 1-expected exceedance form, and a level of 150 μg/m³. Secondary PM standards are set equal to the primary standards, except that the level of the secondary annual $PM_{2.5}$ standard is 15.0 μg/m³. In reaching decisions on these PM standards in the current review, the Administrator has considered the available scientific evidence assessed in the Integrated Science Assessment (ISA), analyses in the Policy Assessment (PA), advice from the Clean Air Scientific Advisory Committee (CASAC), and public comments on the proposal.

For the primary $PM_{2.5}$ standards, the Administrator concludes that there are important uncertainties in the evidence for adverse health effects below the current standards and in the potential for additional public health improvements from reducing ambient $PM_{2.5}$ concentrations below those standards. Based on the available evidence, the Administrator has concluded that the current primary $PM_{2.5}$ standards are requisite to protect public health, with an adequate margin of safety, from effects of $PM_{2.5}$ in ambient air and should be retained, without revision. Therefore, the EPA is retaining those standards (*i.e.,* both the annual and 24-hour standards), without revision.

For the primary PM_{10} standard, the Administrator observes that, while the available health effects evidence has expanded, recent studies are subject to the same types of uncertainties that were judged important in the last review. He concludes that, based on the newly available evidence with its inherent uncertainties, the current primary PM_{10} standard is requisite to protect public health, with an adequate margin of safety, from effects of PM_{10} in ambient air, and should be retained, without revision. Therefore, the EPA is retaining that standard, without revision.

For the secondary standards, the Administrator observes that the expanded evidence for non-ecological welfare effects is consistent with the last review [1] and that updated quantitative analyses show results similar to those in the last review. Based on his consideration of the available evidence and quantitative information, he concludes that the current secondary PM standards are requisite to protect public welfare, against visibility effects and that there is insufficient information to establish distinct

[1] The welfare effects considered in this review include visibility impairment, climate effects, and materials effects. Ecological effects associated with PM, and the adequacy of protection provided by the secondary PM standards for those effects, are being addressed in the separate review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM (U.S. EPA, 2016, section 5.2; U.S. EPA, 2020, section 5.1.1) in recognition of the linkages between oxides of nitrogen, oxides of sulfur, and PM with respect to atmospheric deposition and ecological effects. Addressing the pollutants together enables the EPA to take a comprehensive approach to considering the nature and interactions of the pollutants, which is important for ensuring that all scientific information relevant to ecological effects is thoroughly evaluated. Information on the current review of these secondary NAAQS can be found at *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards.*

secondary PM standards to address materials and climate effects. Therefore, the EPA is retaining those standards, without revision.

These decisions are consistent with the CASAC's consensus advice on the primary 24-hour $PM_{2.5}$ standard, the primary PM_{10} standard, and the secondary standards. The CASAC provided differing views on the primary annual $PM_{2.5}$ standard, with some committee members recommending that the EPA retain the current standard and other members recommending revision of that standard.

I. Background

A. Legislative Requirements

Two sections of the CAA govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those pollutants ''emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare''; ''the presence of which in the ambient air results from numerous or diverse mobile or stationary sources''; and for which he ''plans to issue air quality criteria . . . .'' (42 U.S.C. 7408(a)(1)). Air quality criteria are intended to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air . . . .'' (42 U.S.C. 7408(a)(2)).

Section 109 [42 U.S.C. 7409] directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants for which air quality criteria are issued [42 U.S.C. 7409(a)]. Section 109(b)(1) defines primary standards as ones ''the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [2] Under section 109(b)(2), a secondary standard must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [3]

In setting primary and secondary standards that are ''requisite'' to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001). Likewise, ''[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.'' *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corporation* v. *EPA,* 936 F.3d 597, 623–24 (D.C. Cir. 2019).

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir 1980); *American Petroleum Institute* v. *Costle,* 665 F.2d at 1186; *Coalition of Battery Recyclers Ass'n* v. *EPA,* 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi* v. *EPA,* 744 F.3d 1334, 1353 (D.C. Cir. 2013). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1156 n.51, *Mississippi* v. *EPA,* 744 F.3d at 1351, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s), and the kind and degree of uncertainties. The selection of any particular approach to providing an adequate margin of safety is a policy choice left to the Administrator's judgment. See *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1161–62; *Mississippi* v. *EPA,* 744 F.3d at 1353.

Section 109(d)(1) of the Act requires the review every five years of existing air quality criteria and, if appropriate, the revision of those criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to review every five years and, if appropriate, revise the NAAQS, based on the revised air quality criteria.

Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of ''seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.'' Section 109(d)(2)(B) provides that the independent scientific review committee ''shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate. . . .'' Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board. A number of other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

> Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

[2] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

[3] Under CAA section 302(h) (42 U.S.C. 7602(h)), effects on welfare include, but are not limited to, ''effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

As previously noted, the Supreme Court has held that section 109(b) ''unambiguously bars cost considerations from the NAAQS-setting process.'' *Whitman* v. *Am. Trucking Associations,* 531 U.S. 457, 471 (2001). Accordingly, while some of these issues regarding which Congress has directed the CASAC to advise the Administrator are ones that are relevant to the standard setting process, others are not. Issues that are not relevant to standard setting may be relevant to implementation of the NAAQS once they are established.[4]

B. Related PM Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under sections 110 and 171–190 of the CAA, and related provisions and regulations, states are to submit, for the EPA's approval, state implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the Prevention of Significant Deterioration (PSD) program (CAA sections 160 to 169). In addition, Federal programs provide for nationwide reductions in emissions of PM and other air pollutants through the Federal motor vehicle and motor vehicle fuel control program under title II of the Act (CAA sections 202 to 250), which involves controls for emissions from mobile sources and controls for the fuels used by these sources, and new source performance standards for stationary sources under section 111 of the CAA.

C. History of the PM Air Quality Criteria and Standards

1. Reviews Completed in 1971 and 1987

The EPA first established NAAQS for PM in 1971 (36 FR 8186, April 30, 1971), based on the original Air Quality Criteria Document (AQCD) (DHEW, 1969).[5] The federal reference method (FRM) specified for determining attainment of the original standards was the high-volume sampler, which collects PM up to a nominal size of 25 to 45 μm (referred to as total suspended particulates or TSP). The primary standards were set at 260 μg/m^3, 24-hour average, not to be exceeded more than once per year, and 75 μg/m^3, annual geometric mean. The secondary standards were set at 150 μg/m^3, 24-hour average, not to be exceeded more than once per year, and 60 μg/m^3, annual geometric mean.

In October 1979 (44 FR 56730, October 2, 1979), the EPA announced the first periodic review of the air quality criteria and NAAQS for PM. Revised primary and secondary standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In the 1987 decision, the EPA changed the indicator for particles from TSP to PM_{10},[6] in order to focus on the subset of inhalable particles small enough to penetrate to the thoracic region of the respiratory tract (including the tracheobronchial and alveolar regions), referred to as thoracic particles. The level of the 24-hour standards (primary and secondary) was set at 150 μg/m^3, and the form was one expected exceedance per year, on average over three years. The level of the annual standards (primary and secondary) was set at 50 μg/m^3, and the form was annual arithmetic mean, averaged over three years.

2. Review Completed in 1997

In April 1994, the EPA announced its plans for the second periodic review of the air quality criteria and NAAQS for PM, and in 1997 the EPA promulgated revisions to the NAAQS (62 FR 38652, July 18, 1997). In the 1997 decision, the EPA determined that the fine and coarse fractions of PM_{10} should be considered separately. This determination was based on evidence that serious health effects were associated with short- and long-term exposures to fine particles in areas that met the existing PM_{10} standards. The EPA added new standards, using $PM_{2.5}$ as the indicator for fine particles (with $PM_{2.5}$ referring to particles with a nominal mean aerodynamic diameter less than or equal to 2.5 μm). The new primary standards were as follows: (1) An annual standard with a level of 15.0 μg/m^3, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors;[7] and (2) a 24-hour standard with a level of 65 μg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each monitor within an area. Also, the EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and adopted rules for determining attainment of the new standards. To continue to address the health effects of the coarse fraction of PM_{10} (referred to as thoracic coarse particles or $PM_{10-2.5}$; generally including particles with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm), the EPA retained the primary annual PM_{10} standard and revised the form of the primary 24-hour PM_{10} standard to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by setting them equal in all respects to the primary standards.

Following promulgation of the 1997 p.m. NAAQS, petitions for review were filed by several parties, addressing a broad range of issues. In May 1999, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld the EPA's decision to establish fine particle standards, holding that ''the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards.'' *American Trucking Associations, Inc.* v. *EPA,* 175 F. 3d 1027, 1055–56 (D.C. Cir. 1999). The D.C. Circuit also found ''ample support'' for the EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that the

[4] Some aspects of the CASAC's advice may not be relevant to the EPA's process of setting primary and secondary standards that are requisite to protect public health and welfare. Indeed, were the EPA to consider costs of implementation when reviewing and revising the standards ''it would be grounds for vacating the NAAQS.'' *Whitman,* 531 U.S. at 471 n.4. At the same time, the CAA directs the CASAC to provide advice on ''any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance'' of the NAAQS to the Administrator under section 109(d)(2)(C)(iv). In *Whitman,* the Court clarified that most of that advice would be relevant to implementation but not standard setting, as it ''enable[s] the Administrator to assist the States in carrying out their statutory role as primary *implementers* of the NAAQS.'' *Id.* at 470 (emphasis in original). However, the Court also noted that the CASAC's ''advice concerning certain aspects of 'adverse public health . . . effects' from various attainment strategies is unquestionably pertinent'' to the NAAQS rulemaking record and relevant to the standard setting process. *Id.* at 470 n.2.

[5] Prior to the review initiated in 2007 (see section I.C.4), the AQCD provided the scientific foundation (*i.e.,* the air quality criteria) for the NAAQS. Beginning in that review, the Integrated Science Assessment (ISA) has replaced the AQCD.

[6] PM_{10} refers to particles with a nominal mean aerodynamic diameter less than or equal to 10 μm. More specifically, 10 μm is the aerodynamic diameter for which the efficiency of particle collection is 50 percent.

[7] The 1997 annual $PM_{2.5}$ standard was compared with measurements made at the community-oriented monitoring site recording the highest concentration or, if specific constraints were met, measurements from multiple community-oriented monitoring sites could be averaged (*i.e.,* ''spatial averaging''). In the last review (completed in 2012), the EPA replaced the term ''community-oriented'' monitor with the term ''area-wide'' monitor. Area-wide monitors are those sited at the neighborhood scale or larger, as well as those monitors sited at micro- or middle-scales that are representative of many such locations in the same core-based statistical area (CBSA) (78 FR 3236, January 15, 2013).

EPA had not provided a reasonable explanation justifying use of PM_{10} as an indicator for coarse particles. *American Trucking Associations* v. *EPA,* 175 F. 3d at 1054–55. Pursuant to the D.C. Circuit's decision, the EPA removed the vacated 1997 PM_{10} standards, and the pre-existing 1987 PM_{10} standards remained in place (65 FR 80776, December 22, 2000). The D.C. Circuit also upheld the EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility. *American Trucking Associations* v. *EPA,* 175 F. 3d at 1027.

The D.C. Circuit also addressed more general issues related to the NAAQS, including issues related to the consideration of costs in setting NAAQS and the EPA's approach to establishing the levels of NAAQS. Regarding the cost issue, the court reaffirmed prior rulings holding that in setting NAAQS the EPA is ''not permitted to consider the cost of implementing those standards.'' *American Trucking Associations* v. *EPA,* 175 F. 3d at 1040–41. Regarding the levels of NAAQS, the court held that the EPA's approach to establishing the level of the standards in 1997 (*i.e.,* both for PM and for the ozone NAAQS promulgated on the same day) effected ''an unconstitutional delegation of legislative authority.'' *American Trucking Associations* v. *EPA,* 175 F. 3d at 1034–40. Although the court stated that ''the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable,'' it remanded the rule to the EPA, stating that when the EPA considers these factors for potential non-threshold pollutants ''what EPA lacks is any determinate criterion for drawing lines'' to determine where the standards should be set.

The D.C. Circuit's holdings on the cost and constitutional issues were appealed to the U.S. Supreme Court. In February 2001, the Supreme Court issued a unanimous decision upholding the EPA's position on both the cost and constitutional issues. *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 464, 475–76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be ''requisite'' to protect public health with an adequate margin of safety sufficiently guided the EPA's discretion, affirming the EPA's approach of setting standards that are neither more nor less stringent than necessary.

The Supreme Court remanded the case to the D.C. Circuit for resolution of any remaining issues that had not been addressed in that court's earlier rulings. Id. at 475–76. In a March 2002 decision, the D.C. Circuit rejected all remaining challenges to the standards, holding that the EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not ''arbitrary and capricious.'' *American Trucking Associations* v. *EPA,* 283 F. 3d 355, 369–72 (D.C. Cir. 2002).

3. Review Completed in 2006

In October 1997, the EPA published its plans for the third periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997). After the CASAC and public review of several drafts, the EPA's National Center for Environmental Assessment (NCEA) finalized the AQCD in October 2004 (U.S. EPA, 2004). The EPA's Office of Air Quality Planning and Standards (OAQPS) finalized a Risk Assessment and Staff Paper in December 2005 (Abt Associates, 2005; U.S. EPA, 2005).[8] On December 20, 2005, the EPA announced its proposed decision to revise the NAAQS for PM and solicited public comment on a broad range of options (71 FR 2620, January 17, 2006). On September 21, 2006, the EPA announced its final decisions to revise the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively (71 FR 61144, October 17, 2006). With regard to the primary and secondary standards for fine particles, the EPA revised the level of the 24-hour $PM_{2.5}$ standards to 35 μg/m^3, retained the level of the annual $PM_{2.5}$ standards at 15.0 μg/m^3, and revised the form of the annual $PM_{2.5}$ standards by narrowing the constraints on the optional use of spatial averaging. With regard to the primary and secondary standards for PM_{10}, the EPA retained the 24-hour standards, with levels at 150 μg/m^3, and revoked the annual standards.[9] The Administrator judged that the available evidence generally did not suggest a link between long-term exposure to existing ambient levels of coarse particles and health or welfare effects. In addition, a new reference method was added for the measurement of $PM_{10-2.5}$ in the ambient air in order to provide a basis for approving federal equivalent methods (FEMs) and to promote the gathering of scientific data to support future reviews of the PM NAAQS.

Several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. These petitions addressed the following issues: (1) Selecting the level of the primary annual $PM_{2.5}$ standard; (2) retaining PM_{10} as the indicator of a standard for thoracic coarse particles, retaining the level and form of the 24-hour PM_{10} standard, and revoking the PM_{10} annual standard; and (3) setting the secondary $PM_{2.5}$ standards identical to the primary standards. On February 24, 2009, the D.C. Circuit issued its opinion in the case *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir. 2009). The court remanded the primary annual $PM_{2.5}$ NAAQS to the EPA because the Agency had failed to adequately explain why the standards provided the requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations. *Id. at* 520–27. With regard to the standards for $PM_{10,}$ the court upheld the EPA's decisions to retain the 24-hour PM_{10} standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM_{10} standard. *Id.* at 533–38. With regard to the secondary $PM_{2.5}$ standards, the court remanded the standards to the EPA because the Agency failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *Id.* at 528–32. The EPA responded to the court's remands as part of the next review of the PM NAAQS, which was initiated in 2007.

4. Review Completed in 2012

In June 2007, the EPA initiated the fourth periodic review of the air quality criteria and the PM NAAQS by issuing a call for information (72 FR 35462, June 28, 2007). Based on the NAAQS review process, as revised in 2008 and again in 2009,[10] the EPA held science/policy

[8] Prior to the review initiated in 2007, the Staff Paper presented the EPA staff's considerations and conclusions regarding the adequacy of existing NAAQS and, when appropriate, the potential alternative standards that could be supported by the evidence and information. More recent reviews present this information in the Policy Assessment (PA).

[9] In the 2006 proposal, the EPA proposed to revise the 24-hour PM_{10} standard in part by establishing a new $PM_{10-2.5}$ indicator for thoracic coarse particles (*i.e.,* particles generally between 2.5 and 10 μm in diameter). The EPA proposed to include any ambient mix of $PM_{10-2.5}$ that was dominated by resuspended dust from high density traffic on paved roads and by PM from industrial sources and construction sources. The EPA proposed to exclude any ambient mix of $PM_{10-2.5}$ that was dominated by rural windblown dust and soils and by PM generated from agricultural and mining sources. In the final decision, the existing PM_{10} standard was retained, in part due to an ''inability . . . to effectively and precisely identify which ambient mixes are included in the [$PM_{10-2.5}$] indicator and which are not'' (71 FR 61197, October 17, 2006).

[10] The history of the NAAQS review process, including revisions to the process, is discussed at *https://www.epa.gov/naaqs/historical-information-naaqs-review-process.*

issue workshops on the primary and secondary PM NAAQS (72 FR 34003, June 20, 2007; 72 FR 34005, June 20, 2007), and prepared and released the planning and assessment documents that comprise the review process (*i.e.,* IRP (U.S. EPA, 2008), ISA (U.S. EPA, 2009c), REA planning documents for health and welfare (U.S. EPA, 2009b, U.S. EPA, 2009a), a quantitative health risk assessment (U.S. EPA, 2010a) and an urban-focused visibility assessment (U.S. EPA, 2010b), and PA (U.S. EPA, 2011)). In June 2012, the EPA announced its proposed decision to revise the NAAQS for PM (77 FR 38890, June 29, 2012).

In December 2012, the EPA announced its final decisions to revise the primary NAAQS for PM to provide increased protection of public health (78 FR 3086, January 15, 2013). With regard to primary standards for $PM_{2.5}$, the EPA revised the level of the annual $PM_{2.5}$ standard [11] to 12.0 μg/m^3 and retained the 24-hour $PM_{2.5}$ standard, with its level of 35 μg/m^3. For the primary PM_{10} standard, the EPA retained the 24-hour standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (*i.e.,* $PM_{10-2.5}$). With regard to the secondary PM standards, the EPA generally retained the 24-hour and annual $PM_{2.5}$ standards [12] and the 24-hour PM_{10} standard to address visibility and non-visibility welfare effects.

As with previous reviews, petitioners challenged the EPA's final rule. Petitioners argued that the EPA acted unreasonably in revising the level and form of the annual standard and in amending the monitoring network provisions. On judicial review, the revised standards and monitoring requirements were upheld in all respects. *NAM* v. *EPA,* 750 F.3d 921 (D.C. Cir. 2014).

D. Current Review of the Air Quality Criteria and Standards

In December 2014, the EPA announced the initiation of the current periodic review of the air quality criteria for PM and of the $PM_{2.5}$ and PM_{10} NAAQS and issued a call for information (79 FR 71764, December 3, 2014). From February 9 to February 11, 2015, the EPA's NCEA and OAQPS held a public workshop to inform the planning for the current review of the PM NAAQS (announced in 79 FR 71764, December 3, 2014). Workshop participants, including a wide range of external experts as well as EPA staff representing a variety of areas of expertise (*e.g.,* epidemiology, human and animal toxicology, risk/exposure analysis, atmospheric science, visibility impairment, climate effects), were asked to highlight significant new and emerging PM research, and to make recommendations to the Agency regarding the design and scope of this review. This workshop provided for a public discussion of the key science and policy-relevant issues around which the EPA has structured the current review of the PM NAAQS and of the most meaningful new scientific information that would be available in this review to inform understanding of these issues.

The input received at the workshop guided EPA staff in developing a draft IRP, which was reviewed by the CASAC Particulate Matter Review Panel and discussed on public teleconferences held in May 2016 (81 FR 13362, March 14, 2016) and August 2016 (81 FR 39043, June 15, 2016). Advice from the chartered CASAC, supplemented by the Particulate Matter Review Panel, and input from the public were considered in developing the final IRP (U.S. EPA, 2016). The final IRP discusses the approaches to be taken in developing key scientific, technical, and policy documents in this review and the key policy-relevant issues.

In May 2018, the Administrator issued a memorandum describing a ''back-to-basics'' process for reviewing the NAAQS (Pruitt, 2018). This memo announced the Agency's intention to conduct the current review of the PM NAAQS in such a manner as to ensure that any necessary revisions are finalized by December 2020. Following this memo, on October 10, 2018 the Administrator additionally announced that the role of reviewing the key assessments developed as part of the ongoing review of the PM NAAQS (*i.e.,* drafts of the ISA and PA) would be performed by the seven-member chartered CASAC (*i.e.,* rather than the CASAC Particulate Matter Panel that reviewed the draft IRP).[13]

The EPA released the draft ISA in October 2018 (83 FR 53471, October 23, 2018). The draft ISA was reviewed by the chartered CASAC at a public meeting held in Arlington, VA in December 2018 (83 FR 55529, November 6, 2018) and was discussed on a public teleconference in March 2019 (84 FR 8523, March 8, 2019). The CASAC provided its advice on the draft ISA in a letter to the EPA Administrator dated April 11, 2019 (Cox, 2019b). In that letter, the CASAC's recommendations address both the draft ISA's assessment of the science for PM-related effects and the process under which this review of the PM NAAQS is being conducted.

Regarding the assessment of the evidence, the CASAC letter states that ''the Draft ISA does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to particulate matter (PM)'' (Cox, 2019b, p. 1 of letter). The CASAC recommended that this and other limitations (*i.e.,* ''[i]nadequate evidence for altered causal determinations'' and the need for a ''[c]learer discussion of causality and causal biological mechanisms and pathways'') be remedied in a revised ISA (Cox, 2019b, p. 1 of letter).

Given the Administrator's timeline for this review, as noted above (Pruitt, 2018), the EPA did not prepare a second draft ISA (Wheeler, 2019). Rather, the EPA has taken steps to address the CASAC's comments in the final ISA (U.S. EPA, 2019). In particular, the final ISA includes additional text and a new appendix to clarify the comprehensive and systematic process employed by the EPA to develop the ISA. In addition, several causality determinations were re-examined and, consistent with the CASAC advice, the final ISA reflects a revised causality determination for long-term ultrafine particle (UFP) exposures and nervous system effects (*i.e.,* from ''likely to be causal'' to ''suggestive of, but not sufficient to infer, a causal relationship'').[14] The final ISA also contains additional text to clarify the evidence for biological pathways of particular PM-related effects and the role of that evidence in causality determinations.

Among its comments on the process, the chartered CASAC recommended ''that the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise)'' (Cox, 2019b). The Agency's response to this advice was provided in a letter from the Administrator to the CASAC chair dated

[11] The EPA also eliminated the option for spatial averaging.

[12] Consistent with the primary standard, the EPA eliminated the option for spatial averaging with the annual standard.

[13] The CASAC charter is available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf.* The Administrator's announcement is available at: *https://archive.epa.gov/epa/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee.html.*

[14] Based on the CASAC's comments, the EPA also re-examined the causality determinations for cancer and for nervous system effects following long-term $PM_{2.5}$ exposures. The EPA's consideration of these comments in the final ISA is described in detail in the proposal in sections II.B.1.d (85 FR 24111, April 30, 2020) and II.B.1.e (85 FR 24113, April 30, 2020).

July 25, 2019.[15] In that letter, the Administrator announced his intention to identify a pool of non-member subject matter expert consultants to support the CASAC's review activities for the PM and ozone NAAQS. A **Federal Register** notice requesting the nomination of scientists from a broad range of disciplines ''with demonstrated expertise and research in the field of air pollution related to PM and ozone'' was published in August 2019 (84 FR 38625, August 7, 2019). The Administrator selected consultants from among those nominated, and input from members of this pool of consultants informed the CASAC's review of the draft PA.

The EPA released the draft PA in September 2019 (84 FR 47944, September 11, 2019). The draft PA drew from the assessment of the evidence in the draft ISA. It was reviewed by the chartered CASAC and discussed in October 2019 at a public meeting held in Cary, NC. Public comments were received via a separate public teleconference (84 FR 51555, September 30, 2019). A public meeting to discuss the chartered CASAC letter and response to charge questions on the draft PA was held in Cary, NC in December 2019 (84 FR 58713, November 1, 2019), and the CASAC provided its advice on the draft PA, including its advice on the current primary and secondary PM standards, in a letter to the EPA Administrator dated December 16, 2019 (Cox, 2019a).

With regard to the primary standards, the CASAC recommended retaining the current 24-hour $PM_{2.5}$ and PM_{10} standards but did not reach consensus on the adequacy of the current annual $PM_{2.5}$ standard. With regard to the secondary standards, the CASAC recommended retaining the current standards. The CASAC's advice on the primary and secondary PM standards, and the Administrator's consideration of that advice in reaching proposed decisions, is discussed in detail in sections II.C.2 and II.C.3 (primary $PM_{2.5}$ standards), III.C.2 and III.C.3 (primary PM_{10} standards), and IV.D.2 and IV.D.3 (secondary standards) of the proposal notice (85 FR 24094, April 30, 2020).

The CASAC additionally made a number of recommendations regarding the information and analyses presented in the draft PA. Specifically, the CASAC recommended that a revised PA include: (1) Additional discussion of the current CASAC and NAAQS review process; (2) additional characterization of PM-related emissions, monitoring and air quality information, including uncertainties in that information; (3) additional discussion and examination of uncertainties in the $PM_{2.5}$ health evidence and the risk assessment; (4) updates to reflect changes in the ISA's causality determinations; and (5) additional discussion of the evidence for PM-related welfare effects, including uncertainties (Cox, 2019a, pp. 2–3 in letter). In response to the CASAC's comments, the final PA [16] incorporated a number of changes, as described in detail in section I.C.5 of the proposal (85 FR 24100, April 2020).

Drawing from his consideration of the scientific evidence assessed in the ISA and the analyses in the PA, including uncertainties in the evidence and analyses, and from his consideration of advice from the CASAC, on April 14, 2020 the Administrator proposed to retain all of the primary and secondary PM standards, without revision. These proposed decisions were published in the **Federal Register** on April 30, 2020 (85 FR 24094, April 30, 2020). The EPA held virtual public hearings on the proposal on May 20–22, 2020 and May 27, 2020 (85 FR 26634, May 5, 2020). In total, the EPA received more than 66,000 comments on the proposal from members of the public and various stakeholder groups by the close of the public comment period on June 29, 2020. Major issues raised in the public comments are discussed throughout the preamble of this final action. A more detailed summary of all significant comments, along with the EPA's responses (henceforth ''Response to Comments''), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–0072).

As in prior NAAQS reviews, the EPA is basing its decision in this review on studies and related information included in the air quality criteria, which have undergone CASAC and public review. The studies assessed in the ISA [17] and PA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by the EPA, the CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. Decisions on the NAAQS can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by the EPA but also by the statutorily mandated independent scientific advisory committee, as well as the public review that accompanies this process. Some commenters have referred to and discussed individual scientific studies on the health effects of PM that were not included in the ISA (''new' studies'') and that have not gone through this comprehensive review process. In considering and responding to comments for which such ''new'' studies were cited in support, the EPA has provisionally considered the cited studies in the context of the findings of the ISA. The EPA's provisional consideration of these studies did not and could not provide the kind of in-depth critical review described above, but rather was focused on determining whether they warranted reopening the review of the air quality criteria to enable the EPA, the CASAC, and the public to consider them further.

This approach, and the decision to rely on studies and related information included in the air quality criteria, which have undergone CASAC and public review, is consistent with the EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and the EPA has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. See 71 FR 61144, 61148 (October 17, 2006, final decision on review of NAAQS for particulate matter) for a detailed discussion of this issue and the EPA's past practice.

As discussed in the EPA's 1993 decision not to revise the O_3 NAAQS, ''new'' studies may sometimes be of

[15] Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf.*

[16] Given the Administrator's timeline for this review, as noted above (Pruitt, 2018), the EPA did not prepare a second draft PA. Rather, the CASAC's advice was considered in developing the final PA (U.S. EPA, 2020).

[17] Studies identified for the ISA were based on the review's opening ''call for information'' (79 FR 71764, December 3, 2014), as well as literature searches conducted routinely to identify and evaluate ''studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3). References that are cited in the ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter.*

such significance that it is appropriate to delay a decision in a NAAQS review and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013–13014, March 9, 1993). In the present case, the EPA's provisional consideration of ''new'' studies concludes that, taken in context, the ''new'' information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare effects of PM in ambient air made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted.

Accordingly, the EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone rigorous review by the EPA, CASAC and the public. The EPA will consider these ''new'' studies for inclusion in the air quality criteria for the next PM NAAQS review, which the EPA expects to begin soon after the conclusion of this review and which will provide the opportunity to fully assess these studies through a more rigorous review process involving the EPA, CASAC, and the public.

E. Air Quality Information

This section provides a summary of basic information related to PM ambient air quality. It summarizes information on the distribution of particle size in ambient air (I.E.1), sources and emissions contributing to PM in the ambient air (I.E.2), ambient PM concentrations and trends in the U.S. (I.E.3), and background PM (I.E.4). Additional detail on PM air quality can be found in Chapter 2 of the Policy Assessment (U.S. EPA, 2020; PA) and section I.D of the proposal (85 FR 24100, April 30, 2020).

1. Distribution of Particle Size in Ambient Air

In ambient air, PM is a mixture of substances suspended as small liquid and/or solid particles (U.S. EPA, 2019, section 2.2) and distinct health and welfare effects have been linked with exposures to particles of different sizes. Particles in the atmosphere range in size from less than 0.01 to more than 10 μm in diameter (U.S. EPA, 2019, section 2.2).The EPA defines $PM_{2.5}$, also referred to as fine particles, as particles with aerodynamic diameters generally less than or equal to 2.5 μm. The size range for $PM_{10-2.5}$, also called coarse or thoracic coarse particles, includes those particles with aerodynamic diameters generally greater than 2.5 μm and less than or equal to 10 μm. PM_{10}, which is comprised of both fine and coarse fractions, includes those particles with aerodynamic diameters generally less than or equal to 10 μm. In addition, UFP are often defined as particles with a diameter of less than 0.1 μm based on physical size, thermal diffusivity or electrical mobility (U.S. EPA, 2019, section 2.2). Atmospheric lifetimes are generally longest for $PM_{2.5}$, which often remains in the atmosphere for days to weeks (U.S. EPA, 2019, Table 2–1) before being removed by wet or dry deposition, while atmospheric lifetimes for UFP and $PM_{10-2.5}$ are shorter and are generally removed from the atmosphere within hours, through wet or dry deposition (U.S. EPA, 2019, Table 2–1; 85 FR 24100, April 30, 2020).

2. Sources and Emissions Contributing to PM in the Ambient Air

PM is composed of both primary (directly emitted particles) and secondary particles. Primary PM is derived from direct particle emissions from specific PM sources while secondary PM originates from gas-phase chemical compounds present in the atmosphere that have participated in new particle formation or condensed onto existing particles (U.S. EPA, 2019, section 2.3). As discussed further in the ISA (U.S. EPA, 2019, section 2.3.2.1), secondary PM is formed in the atmosphere by photochemical oxidation reactions of both inorganic and organic gas-phase precursors. Sources and emissions of PM are discussed in more detail the PA (U.S. EPA, 2020, section 2.1.1) and in the proposal (85 FR 24101, April 30, 2020).

3. Ambient Concentrations and Trends

This section summarizes available information on recent ambient PM concentrations in the U.S. and on trends in PM air quality. Sections I.E.3.a and I.E.3.b summarize information on $PM_{2.5}$ mass and components, respectively. Section I.E.3.c summarizes information on PM_{10}. Sections I.E.3.d and I.E.3.e summarize the more limited information on $PM_{10-2.5}$ and UFP, respectively. Additional detail on PM air quality and trends can be found in the PA (U.S. EPA, 2020, section 2.3) and in the proposal (85 FR 24100, April 30, 2020).

a. $PM_{2.5}$ Mass

At monitoring sites in the U.S., annual $PM_{2.5}$ concentrations from 2015 to 2017 averaged 8.0 μg/m³ (and ranged from 3.0 to 18.2 μg/m³) and the 98th percentiles of 24-hour concentrations averaged 20.9 μg/m³ (and ranged from 9.2 to 111 μg/m³) (U.S. EPA, 2020, section 2.3.2.1). The highest ambient $PM_{2.5}$ concentrations occur in the west, particularly in California and the Pacific northwest (U.S. EPA, 2020, Figure 2–8). Much of the eastern U.S. has lower ambient concentrations, with annual average concentrations generally at or below 12.0 μg/m³ and 98th percentiles of 24-hour concentrations generally at or below 30 μg/m³ (U.S. EPA, 2020, section 2.3.2).

Recent ambient $PM_{2.5}$ concentrations reflect the substantial reductions that have occurred across much of the U.S. (U.S. EPA, 2020, section 2.3.2.1). From 2000 to 2017, national annual average $PM_{2.5}$ concentrations have declined from 13.5 μg/m³ to 8.0 μg/m³, a 41% decrease (U.S. EPA, 2020, section 2.3.2.1).[18] These declines have occurred at urban and rural monitoring sites, although urban $PM_{2.5}$ concentrations remain consistently higher than those in rural areas (Chan et al., 2018) due to the impact of local sources in urban areas. Analyses at individual monitoring sites indicate that declines in ambient $PM_{2.5}$ concentrations have been most consistent across the eastern U.S. and in parts of coastal California, where both annual average and 98th percentiles of 24-hour concentrations have declined significantly (U.S. EPA, 2020, section 2.3.2.1). In contrast, trends in ambient $PM_{2.5}$ concentrations have been less consistent over much of the western U.S., with no significant changes since 2000 observed at some sites in the Pacific northwest, the northern Rockies and plains, and the southwest, particularly for 98th percentiles of 24-hour concentrations (U.S. EPA, 2020, section 2.3.2.1).

The recent deployment of $PM_{2.5}$ monitors near major roads in large urban areas provides information on $PM_{2.5}$ concentrations near an important emissions source. Of the 25 CBSAs with valid design values at near-road monitoring sites,[19] 52% measured the highest annual design value at the near-road site while 24% measured the highest 24-hour design value at the near-road site (U.S. EPA, 2020, section 2.3.2.2). Of the CBSAs with highest annual design values at near-road sites, those design values were, on average, 0.7 μg/m³ higher than at the highest measuring non-near-road sites (range is 0.1 to 2.0 μg/m³ higher at near-road sites). Although most near-road monitoring sites do not have sufficient data to evaluate long-term trends in

[18] See *https://www.epa.gov/air-trends/particulate-matter-pm25-trends* and *https://www.epa.gov/air-trends/particulate-matter-pm25-trends#pmnat* for more information.

[19] A design value is considered valid if it meets the data handling requirements given in 40 CFR Appendix N to part 50.

near-road $PM_{2.5}$ concentrations, analyses of the data at one near-road-like site in Elizabeth, NJ,[20] show that the annual average near-road increment has generally decreased between 1999 and 2017 from about 2.0 μg/m³ to about 1.3 μg/m³ (U.S. EPA, 2020, section 2.3.2.2).

b. $PM_{2.5}$ Components

Based on recent air quality data, the major chemical components of $PM_{2.5}$ have distinct spatial distributions. Sulfate concentrations tend to be highest in the eastern U.S., while in the Ohio Valley, Salt Lake Valley, and California nitrate concentrations are highest, and relatively high concentrations of organic carbon are widespread across most of the continental U.S. (U.S. EPA, 2020, section 2.3.2.3). Elemental carbon, crustal material, and sea salt are found to have the highest concentrations in the northeast U.S., southwest U.S., and coastal areas, respectively.

An examination of $PM_{2.5}$ composition trends can provide insight into the factors contributing to overall reductions in ambient $PM_{2.5}$ concentrations. The biggest change in $PM_{2.5}$ composition that has occurred in recent years is the reduction in sulfate concentrations due to reductions in SO_2 emissions. Between 2000 and 2015, the nationwide annual average sulfate concentration decreased by 17% at urban sites and 20% at rural sites. This change in sulfate concentrations is most evident in the eastern U.S. and has resulted in organic matter or nitrate now being the greatest contributor to $PM_{2.5}$ mass in many locations (U.S. EPA, 2019, Figure 2–19). The overall reduction in sulfate concentrations has contributed substantially to the decrease in national average $PM_{2.5}$ concentrations as well as the decline in the fraction of PM_{10} mass accounted for by $PM_{2.5}$ (U.S. EPA, 2019, section 2.5.1.1.6; U.S. EPA, 2020, section 2.3.1).

c. PM_{10}

At monitoring sites in the U.S., the 2015–2017 average of 2nd highest 24-hour PM_{10} concentration was 56 μg/m³ (ranging from 18 to 173 μg/m³) (U.S. EPA, 2020, section 2.3.2.4).[21] The highest PM_{10} concentrations tend to occur in the western U.S. Seasonal analyses indicate that ambient PM_{10} concentrations are generally higher in the summer months than at other times of year, though the most extreme high concentration events are more likely in the spring (U.S. EPA, 2019, Table 2–5). This is due to fact that the major PM_{10} emission sources, dust and agriculture, are more active during the warmer and drier periods of the year.

Recent ambient PM_{10} concentrations reflect reductions that have occurred across much of the U.S. (U.S. EPA, 2020, section 2.3.2.4). From 2000 to 2017, annual second highest 24-hour PM_{10} concentrations have declined by about 30% (U.S. EPA, 2020, section 2.3.2.4).[22] These PM_{10} concentrations have generally declined in the eastern U.S., while concentrations in much of the midwest and western U.S. have remained unchanged or increased since 2000 (U.S. EPA, 2020, section 2.3.2.4). Analyses at individual monitoring sites indicate that annual average PM_{10} concentrations have also declined at most sites across the U.S., with much of the decrease in the eastern U.S. associated with reductions in $PM_{2.5}$ concentrations.

d. $PM_{10-2.5}$

Since the last review, the availability of $PM_{10-2.5}$ ambient concentration data has greatly increased because of additions to the $PM_{10-2.5}$ monitoring capabilities to the national monitoring network. As illustrated in the PA (U.S. EPA, 2020, section 2.3.2.5), annual average and 98th percentile $PM_{10-2.5}$ concentrations exhibit less distinct differences between the eastern and western U.S. than for either $PM_{2.5}$ or PM_{10}. Additionally, compared to $PM_{2.5}$ and PM_{10}, changes in $PM_{10-2.5}$ concentrations have been small in magnitude and inconsistent in direction (U.S. EPA, 2020, section 2.3.2.5).

e. UFP

Compared to $PM_{2.5}$ mass, there is relatively little data on U.S. particle number concentrations, which are dominated by UFP. Based on measurements in two urban areas (New York City, Buffalo) and at a background site (Steuben County) in New York, urban particle number counts were several times higher than at the background site (U.S. EPA, 2020, section 2.3.2.6; U.S. EPA, 2019, Figure 2–18). The highest particle number counts in an urban area with multiple sites (Buffalo) were observed at a near-road location.

Long-term trends in UFP are not routinely available at U.S. monitoring sites. At one site in Illinois with long-term data available, the annual average particle number concentration declined between 2000 and 2017, closely matching the reductions in annual $PM_{2.5}$ mass over that same period (U.S. EPA, 2020, section 2.3.2.6). In addition, a small number of published studies have examined UFP trends over time. While limited, these studies also suggest that UFP number concentrations have declined over time along with decreases in $PM_{2.5}$ (U.S. EPA, 2020, section 2.3.2.6).

4. Background PM

In this review, background PM is defined as all particles that are formed by sources or processes that cannot be influenced by actions within the jurisdiction of concern. U.S. background PM is defined as any PM formed from emissions other than U.S. anthropogenic (*i.e.,* manmade) emissions. Potential sources of U.S. background PM include both natural sources (*i.e.,* PM that would exist in the absence of any anthropogenic emissions of PM or PM precursors) and transboundary sources originating outside U.S. borders. Background PM is discussed in more detail in the PA (U.S. EPA, 2020, section 2.4) and in the proposal (85 FR 24102, April 30, 2020). At annual and national scales, estimated background PM concentrations in the U.S. are small compared to contributions from domestic anthropogenic emissions.[23] For example, based on zero-out modeling in the last review of the PM NAAQS, annual background $PM_{2.5}$ concentrations were estimated to range from 0.5–3 μg/m³ across the sites examined. In addition, speciated monitoring data from IMPROVE sites can provide some insights into how contributions from different sources, including sources of background PM, may have changed over time. Such data suggests the estimates of background concentrations using speciated monitoring data from IMPROVE monitors are around 1–3 μg/m³, and have not changed significantly since the last review. Contributions to background PM in the U.S. result

[20] The Elizabeth Lab site in Elizabeth, NJ is situated approximately 30 meters from travel lanes of the Interchange 13 toll plaza of the New Jersey Turnpike and within 200 meters of travel lanes for Interstate 278 and the New Jersey Turnpike.

[21] The form of the current 24-hour PM_{10} standard is one-expected-exceedance, averaged over three years.

[22] For more information, see *https://www.epa.gov/air-trends/particulate-matter-pm10-trends#pmnat.*

[23] Sources that contribute to natural background PM include dust from the wind erosion of natural surfaces, sea salt, wildland fires, primary biological aerosol particles such as bacteria and pollen, oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce secondary organic aerosols (SOA), and geogenic sources such as sulfate formed from volcanic production of SO_2 and oceanic production of dimethyl-sulfide (U.S. EPA, 2020, section 2.4). While most of these sources release or contribute predominantly to fine aerosol, some sources including windblown dust, and sea salt also produce particles in the coarse size range (U.S. EPA, 2019, section 2.3.3).

mainly from sources within North America. Contributions from intercontinental events have also been documented (*e.g.,* transport from dust storms occurring in deserts in North Africa and Asia), but these events are less frequent and represent a relatively small fraction of background PM in most places.

II. Rationale for Decisions on the Primary $PM_{2.5}$ Standards

This section presents the rationale for the Administrator's decision to retain the current primary $PM_{2.5}$ standards. This decision is based on a thorough review in the ISA of the latest scientific information, published through December 2017,[24] on human health effects associated with long-and short-term exposures to $PM_{2.5}$ in the ambient air. This decision also takes into account analyses in the PA of policy-relevant information from the ISA, as well as information on air quality; the analyses of human health risks in the PA; CASAC advice; and consideration of public comments received on the proposal.

Section II.A provides background on the general approach for this review and the basis for the existing standard, and also presents brief summaries of key aspects of the currently available health effects and risk information. Section II.B summarizes the proposed conclusions and CASAC advice, addresses public comments received on the proposal and presents the Administrator's conclusions on the adequacy of the current standard, drawing on consideration of the scientific evidence and quantitative risk information, advice from the CASAC, and comments from the public. Section II.C summarizes the Administrator's decision on the primary $PM_{2.5}$ standards.

A. Introduction

As in prior reviews, the general approach to reviewing the current primary $PM_{2.5}$ standards is based, most fundamentally, on using the EPA's assessment of current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding primary $PM_{2.5}$ standards that protects public health with an adequate margin of safety. In drawing conclusions with regard to the primary $PM_{2.5}$ standards, the final decision on the adequacy of the standard is largely a public health policy judgment to be made by the Administrator. The Administrator's final decision draws upon scientific information and analyses about health effects, population risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and risk analyses. The approach to informing these judgments, discussed more fully below, generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the CAA and with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish primary standards that, in his judgment, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health including the health of sensitive groups.[25] The four basic elements of the NAAQS (indicator, averaging time, form, and level) are considered collectively in evaluating the health protection afforded by a standard.

In evaluating the appropriateness of retaining or revising the current primary $PM_{2.5}$ standards, the EPA has adopted an approach that builds upon the general approach used in the last review and reflects the body of evidence of information now available. As summarized in section II.A.1 below, the Administrator's decisions in the prior review were based on an integration of information on health effects associated with exposure to $PM_{2.5}$ with information on the public health significance of key health effects, as well as on policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety and on consideration of advice from the CASAC and public comments. These decisions were also informed by air quality and related analyses and quantitative risk information.

Similarly, in this review, as described in the PA, the proposal, and elsewhere in this document, we draw on the current evidence and quantitative assessments of public health risk of $PM_{2.5}$ in ambient air. The past and current approaches are both based, most fundamentally, on the EPA's assessments of the current scientific information and associated quantitative analyses. The EPA's assessments are primarily documented in the ISA and PA, which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 83 FR 55529, November 6, 2018; 84 FR 8523, March 8, 2019; 84 FR 47944, September 11, 2019; 84 FR 51555, September 30, 2019; 84 FR 58713, September 30, 2019). To bridge the gap between the scientific assessments of the ISA and quantitative assessments of the PA and the judgments required of the Administrator in determining whether the current standard remains requisite to protect public health with an adequate margin of safety, the PA evaluates the policy implications of the current evidence in the ISA and of the quantitative analyses in the PA.

In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review, including most particularly that which has been critically analyzed and characterized in the current ISA. We additionally consider the quantitative risk information described in the PA that estimated population-level health risks associated with ambient $PM_{2.5}$ concentrations that have been adjusted to simulate air quality scenarios of policy interest (*e.g.,* ''just meeting'' the current standards) in multiple study areas. The evidence-based discussions presented below (and summarized more fully in the proposal) draw upon evidence from studies evaluating health effects related to exposures to $PM_{2.5}$, as discussed in the ISA. The risk-based discussions also presented below (and summarized more fully in the proposal) have been drawn from the quantitative analyses for $PM_{2.5}$, as discussed in the PA. Sections II.A.2 and II.A.3 below provide an overview for the current health effects evidence related to short- and long-term exposures to $PM_{2.5}$ and quantitative risk information with a focus on specific policy-relevant questions identified for these categories of information in the PA.

[24] In addition to the review's opening ''call for information'' (79 FR 71764, December 3, 2014), ''the current ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3). References that are cited in the ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter.*

[25] As noted in section I.A above, such protection is specified for the sensitive group of individuals and not to a single person in the sensitive group (see S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 [1970]).

1. Background on the Current Standards

The last review of the primary PM NAAQS was completed in 2012 (78 FR 3086, January 15, 2013). As noted above (section I.C.4), in the last review the EPA lowered the level of the primary annual $PM_{2.5}$ standard from 15.0 to 12.0 μg/m³,[26] and retained the existing 24-hour $PM_{2.5}$ standard with its level of 35 μg/m³. The 2012 decision to strengthen the suite of primary $PM_{2.5}$ standards was based on the prior Administrator's consideration of the extensive body of scientific evidence assessed in the 2009 ISA (U.S. EPA, 2009c); the quantitative risk analyses presented in the 2010 health risk assessment (U.S. EPA, 2010a); the advice and recommendations of the CASAC (Samet, 2009; Samet, 2010c; Samet, 2010b); and public comments on the proposed rule (78 FR 3086, January 15, 2013; U.S. EPA, 2012). In particular, she noted the ''strong and generally robust body of evidence of serious health effect associated with both long- and short-term exposures to $PM_{2.5}$'' (78 FR 3120, January 15, 2013). This included epidemiological studies reporting health effect associations based on long-term average $PM_{2.5}$ concentrations ranging from about 15.0 μg/m³ or above (*i.e.,* at or above the level of the then-existing annual standard) to concentrations ''significantly below the level of the annual standard'' (78 FR 3120, January 15, 2013). Based on her ''confidence in the association between exposure to $PM_{2.5}$ and serious public health effects, combined with evidence of such an association in areas that would meet the current standards'' (78 FR 3120, January 15, 2013), the prior Administrator concluded that revision of the suite of primary $PM_{2.5}$ standards was necessary in order to provide increased public health protection.

The prior Administrator next considered what specific revisions to the existing primary $PM_{2.5}$ standards were appropriate, given the available evidence and quantitative risk information. She considered both the annual and 24-hour $PM_{2.5}$ standards, focusing on the basic elements of those standards (*i.e.,* indicator, averaging time, form, and level). With regard to the indicator, the EPA recognized that the health studies available during the last review continued to link adverse health outcomes (*e.g.,* premature mortality, hospital admissions, emergency department visits) with long- and short-term exposures to $PM_{2.5}$ (78 FR 3121, January 15, 2013). In assessing the appropriateness of $PM_{2.5}$ mass as the indicator, the EPA also considered the available scientific evidence and information available related to ultrafine particles[27] [28] and PM components,[29] noting the significant uncertainties and limitations associated with the evidence, as well as the availability of monitoring data. Consistent with the considerations and conclusions in the 2011 PA, the CASAC advised that it was appropriate to consider retaining $PM_{2.5}$ as the indicator for fine particles. In light of the evidence and the CASAC's advice, the prior Administrator concluded that it was ''appropriate to retain $PM_{2.5}$ as the indicator for fine particles'' (78 FR 3123, January 15, 2013).

With regard to averaging time, in the last review, the EPA considered issues related to the appropriate averaging time for $PM_{2.5}$ standards, with a focus on evaluating support for the existing annual and 24-hour averaging times and for potential alternative averaging times based on sub-daily or seasonal metrics. Based on the evidence assessed in the 2009 ISA, the 2011 PA noted that the overwhelming majority of studies utilized annual (or multi-year) or 24-hour PM averaging periods (U.S. EPA, 2011, section 2.3.2). Given this evidence-base, and limitations in the data for alternatives, the 2011 PA reached the overall conclusions that the available information provided strong support for considering retaining the existing annual and 24-hour averaging times (U.S. EPA, 2011, p. 2–58). The CASAC agreed that these conclusions were reasonable (Samet, 2010a, p. 2–58). The prior Administrator concurred with the CASAC's advice. Specifically, she judged that it was ''appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards to protect against health effects associated with long- and short-term exposure periods'' (78 FR 3124, January 15, 2013).

With regard to form, the EPA first noted that the form of the annual $PM_{2.5}$ standard was established in 1997 as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors.[30] That is, the level of the annual standard was to be compared to measurements made at each community-oriented monitoring site, or if criteria were met, measurements from multiple community-oriented monitoring sites could be averaged together (*i.e.,* spatial averaging)[31] (62 FR 38671–38672, July 18, 1997). In the 1997 review, the EPA also established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of 24-hour concentrations at each monitor within an area (*i.e.,* no spatial averaging), averaged over three years (62 FR 38671–38674, July 18, 1997). In the 2006 review, the EPA retained these standard forms but tightened the criteria for using spatial averaging with the annual standard (71 FR 61167, October 17, 2006).[32]

At the time of the last review, the EPA again considered the form of the standard with a focus on the issue of spatial averaging. An analysis of air quality and population demographic information indicated that the highest $PM_{2.5}$ concentrations in a given area tended to be measured at monitors in locations where the surrounding populations were more likely to live below the poverty line and to include larger percentages of racial and ethnic minorities (U.S. EPA, 2011, p. 2–60). Based on this analysis, the 2011 PA concluded that spatial averaging could result in disproportionate impacts in at-risk populations and populations with

[26] The Agency also eliminated spatial averaging provisions as part of the form of the annual standard.

[27] In the last review, the ISA defined ultrafine particles (UFP) as generally including particles with a mobility diameter less than or equal to 0.1 μm. Mobility diameter is defined as the diameter of a particle having the same diffusivity or electrical mobility in air as the particle of interest and is often used to characterize particles of 0.5 μm or smaller (U.S. EPA, 2009c, pp. 3–2 to 3–3).

[28] The 2011 PA noted the limited body of evidence assessed in the 2009 ISA (summarized in U.S. EPA, 2009c, section 2.3.5 and Table 2–6) and the limited monitoring information available to characterized ambient concentrations of UFP (U.S. EPA, 2011, section 1.3.2).

[29] The 2009 ISA concluded that ''the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes'' (U.S. EPA, 2009c, pp. 2–26 and 6–212; 78 FR 3123, January 15, 2013). The 2011 PA further noted that ''many different constituents of the fine particle mixture as well as groups of components associated with specific source categories of fine particles are linked to adverse health effects'' (U.S. EPA, 2011, p. 2–55; 78 FR 3123, January 15, 2013).

[30] In the last review, the EPA replaced the term ''community-oriented'' monitor with the term ''area-wide'' monitor (U.S. EPA, 2020, section 1.3). *Area-wide* monitors are those sited at the neighborhood scale or larger, as well as those monitors sited at micro- or middle scales that are representative of many such locations in the same core-based statistical area (CBSA; 78 FR 3236, January 15, 2013). CBSAs are required to have at least one area-wide monitor sited in the area of expected maximum $PM_{2.5}$ concentration.

[31] The original criteria for spatial averaging included: (1) The annual mean concentration at each site shall be within 20% of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.6 for each calendar quarter (62 FR 38671–38672, July 18, 1997).

[32] Specifically, the Administrator revised spatial averaging criteria such that ''(1) [t]he annual mean concentration at each site shall be within 10 percent of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.9 for each calendar quarter'' (71 FR 61167, October 17, 2006).

lower socioeconomic status (SES). Therefore, the PA concluded that it was appropriate to consider revising the form of the annual $PM_{2.5}$ standard such that it did not allow for the use of spatial averaging across monitors (U.S. EPA, 2011, p. 2–60). The CASAC agreed with the PA conclusions that it was ''reasonable'' for the EPA to eliminate the spatial averaging provisions (Samet, 2010c, p. 2).

With regard to the form of the annual $PM_{2.5}$ standard, the prior Administrator concluded that public health would not be protected with an adequate margin of safety in all locations if disproportionately higher $PM_{2.5}$ concentrations in low income and minority communities were averaged together with lower concentrations measured at other sites in a larger urban area. Therefore, she concluded that the form of the annual $PM_{2.5}$ standard should be revised to eliminate spatial averaging provisions (78 FR 3124, January 15, 2013).

With regard to the form of the 24-hour $PM_{2.5}$ standard, the EPA recognized that the existing 98th percentile form was originally selected to provide a balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs.[33] Updated air quality analyses in the last review provided additional support for the increased stability of the 98th percentile $PM_{2.5}$ concentration, compared to the 99th percentile (U.S. EPA, 2011, Figure 2–2, p. 2–62). Consistent with the PA conclusions based on this analysis, the prior Administrator concluded that it was appropriate to retain the 98th percentile form for the 24-hour $PM_{2.5}$ standard (78 FR 3127, January 15, 2013).

With regard to alternative levels of the annual and 24-hour $PM_{2.5}$ standards, in the last review, the EPA considered the public health protection provided by the standards, taken together, against mortality and morbidity effects associated with long- or short-term $PM_{2.5}$ exposures. This approach recognized that it is appropriate to consider the protection provided by attaining the air quality needed to meet the suite of standards, and that there is no bright line clearly directing the choice of levels. Rather, the choice of what is appropriate is a public health policy judgment entrusted to the Administrator. See *Mississippi,* 744 F.3d at 1358, *Lead Industries Ass'n,* 647 F.2d at 1147.

In selecting the levels of the annual and 24-hour $PM_{2.5}$ standards, the prior Administrator placed the greatest emphasis on health endpoints for which the evidence was strongest, based on the assessment of the evidence in the ISA and on the ISA's causality determinations (U.S. EPA, 2009c, section 2.3.1). She particularly noted that the evidence was sufficient to conclude a causal relationship exists between $PM_{2.5}$ exposures and mortality and cardiovascular effects (*i.e.,* for both long- and short-term exposures) and that the evidence was sufficient to conclude a causal relationship is ''likely'' to exist between $PM_{2.5}$ exposures and respiratory effects (*i.e.,* for both long- and short-term exposures). She also noted additional, but more limited, evidence for a broader range of health endpoints, including evidence ''suggestive of a causal relationship'' between long-term exposures and developmental and reproductive effects as well as carcinogenic effects (78 FR 3158, January 15, 2013).

To inform her decisions on an appropriate level for the annual standard, the Administrator considered the degree to which epidemiological studies indicate confidence in the reported health effect associations over distributions of $PM_{2.5}$ concentrations in ambient air. She noted that a level of 12.0 μg/m³ was below the long-term mean $PM_{2.5}$ concentrations reported in key epidemiological studies that provided evidence of an array of serious health effects (78 FR 3161, January 15, 2013). She further noted that 12.0 μg/m³ generally corresponded to the lower portions (*i.e.,* about the 25th percentile) of distributions of health events in the limited number of epidemiological studies for which population-level information was available. A level of 12.0 μg/m³ also reflected placing some weight on studies of reproductive and developmental effects, for which the evidence was more uncertain (78 FR 3161–3162, January 15, 2013).

Given the uncertainties remaining in the scientific evidence, the Administrator judged that an annual standard level below 12.0 μg/m³ was not supported. She specifically noted uncertainties related to understanding the relative toxicity of the different components in the fine particle mixture, the role of $PM_{2.5}$ in the complex ambient mixture, exposure measurement error in epidemiological studies, and the nature and magnitude of estimated risks at relatively low ambient $PM_{2.5}$ concentrations. Furthermore, she noted that epidemiological studies had reported heterogeneity in effect estimates both within and between cities and in geographic regions of the U.S. She recognized that this heterogeneity may be attributed, in part, to difference in $PM_{2.5}$ composition in different regions and cities. With regard to evidence for reproductive and developmental effects, the prior Administrator recognized that there were a number of limitations associated with this body of evidence, including the limited number of studies evaluating such effects; uncertainties related to identifying the relevant exposure time periods of concern, and limited toxicologic evidence providing information on the mode of action(s) or biological plausibility for an association between long-term $PM_{2.5}$ exposures and adverse birth outcomes. On balance, she found that the available evidence, interpreted in light of these remaining uncertainties, did not justify an annual standard level set below 12.0 μg/m³ as being requisite to protect public health with an adequate margin of safety (*i.e.,* a standard with a lower level would have been more stringent than necessary).

In conjunction with a revised annual standard with a level of 12.0 μg/m³, the prior Administrator concluded that the evidence supported retaining the 35 μg/m³ level of the 24-hour $PM_{2.5}$ standard. She noted that the existing 24-hour standard, with its 35 μg/m³ level and 98th percentile form, would provide supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong seasonal sources and for areas with $PM_{2.5}$-related effects that may be associated with shorter than daily exposure periods (78 FR 3163, January 15, 2013). Thus, she concluded that the available evidence and information, considered together with its inherent uncertainties and limitations, supported an annual standard with a level of 12.0 μg/m³ combined with a 24-hour standard with a level of 35 μg/m³.

2. Overview of Health Effects Evidence

In this section, we provide an overview of the policy-relevant aspects of the health effects evidence available for consideration in this review. Section II.B of the proposal provides a detailed summary of key information contained in the ISA (U.S. EPA, 2019) and in the PA (U.S. EPA, 2020) on the health effects associated with $PM_{2.5}$ exposures, and the related public health implications, focusing particularly on the information most relevant to consideration of effects associated with the presence of $PM_{2.5}$ in ambient air. The subsections below briefly

[33] See *ATA III,* 283 F.3d at 374–76 which concludes that it is legitimate for the EPA to consider overall stability of the standard and its resulting promotion of overall effectiveness of NAAQS control programs in setting a standard that is requisite to protect the public health.

summarize the information discussed in more detail in section II.B of the proposal (85 FR 24106 to 24114, April 30, 2020).

a. Nature of Effects

Drawing from the assessment of the evidence in the ISA (U.S. EPA, 2019), and the summaries of that assessment in the PA (U.S. EPA, 2020), the sections below summarize the evidence for relationships between long- or short-term $PM_{2.5}$ exposures and mortality (II.A.2.a.i), cardiovascular effects (II.A.2.a.ii), respiratory effects (II.A.2.a.iii), cancer (II.A.2.a.iv), nervous system effects (II.A.2.a.v), and other effects (II.A.2.a.vi). For these outcomes, the ISA concludes that the evidence supports either a ''causal'' or a ''likely to be causal'' relationship with $PM_{2.5}$ exposures.[34]

i. Mortality

Long-Term $PM_{2.5}$ Exposures

In the last review, the 2009 ISA reported that the evidence was ''sufficient to conclude that the relationship between long-term $PM_{2.5}$ exposures and mortality is causal'' (U.S. EPA, 2009c, p. 7–96). The strongest evidence supporting this conclusion was provided by epidemiological studies, particularly those examining two seminal cohorts, the American Cancer Society (ACS) cohort and the Harvard Six Cities cohort. Analyses of the Harvard Six Cities cohort included demonstrations that reductions in ambient $PM_{2.5}$ concentrations are associated with reduced mortality risk (Laden et al., 2006) and with increases in life expectancy (Pope et al., 2009). Further support was provided by other cohort studies conducted in North America and Europe that reported positive associations between long-term $PM_{2.5}$ exposures and risk of mortality (U.S. EPA, 2009c).

Recent cohort studies, which have become available since the 2009 ISA, continue to provide consistent evidence of positive associations between long-term $PM_{2.5}$ exposures and mortality. These studies add support for associations with total and non-accidental mortality,[35] as well as with specific causes of death, including cardiovascular disease and respiratory disease (U.S. EPA, 2019, section 11.2.2). Many of these recent studies have extended the follow-up periods originally evaluated in the ACS and Harvard Six Cities cohort studies and continue to observe positive associations between long-term $PM_{2.5}$ exposures and mortality (U.S. EPA, 2019, section 11.2.2.1, Figures 11–18 and 11–19). Adding to recent evaluations of the ACS and Six Cities cohorts, studies conducted with other cohorts also show consistent, positive associations between long-term $PM_{2.5}$ exposure and mortality across various demographic groups (*e.g.,* age, sex, occupation), spatial and temporal extents, exposure assessment metrics, and statistical techniques (U.S. EPA, 2019, sections 11.2.2.1 and 11.2.5). This includes some of the largest cohort studies conducted to date, with analyses of the U.S. Medicare cohort that include nearly 61 million enrollees (Di et al., 2017b) and studies that control for a range of individual and ecological covariates.

A recent series of accountability studies has additionally tested the hypothesis that past reductions in ambient $PM_{2.5}$ concentrations have been associated with increased life expectancy or a decreased mortality rate (U.S. EPA, 2019, section 11.2.2.5). Pope et al. (2009) conducted a cross-sectional analysis using air quality data from 51 metropolitan areas across the U.S., beginning in the 1970s through the early 2000s, and found that a 10 $\mu g/m^3$ decrease in long-term $PM_{2.5}$ concentration was associated with a 0.61-year increase in life expectancy. In a subsequent analysis, the authors extended the period of analysis to include 2000 to 2007 (Correia et al., 2013), a time period with lower ambient $PM_{2.5}$ concentrations. In this follow-up study, a decrease in long-term $PM_{2.5}$ concentrations continued to be associated with an increase in life expectancy, though the magnitude of the increase was smaller than during the earlier time period (*i.e.,* a 10 $\mu g/m^3$ decrease in long-term $PM_{2.5}$ concentration was associated with a 0.35-year increase in life expectancy). Additional studies conducted in the U.S. or Europe similarly report that reductions in ambient $PM_{2.5}$ are associated with improvements in longevity (U.S. EPA, 2019, section 11.2.2.5).

The ISA concludes that positive associations between long-term $PM_{2.5}$ exposures and mortality are robust across analyses examining a variety of study designs (*e.g.,* U.S. EPA, 2019, section 11.2.2.4), approaches to estimating $PM_{2.5}$ exposures (U.S. EPA, 2019, section 11.2.5.1), approaches to controlling for confounders (U.S. EPA, 2019, sections 11.2.3 and 11.2.5), geographic regions and populations, and temporal periods (U.S. EPA, 2019, sections 11.2.2.5 and 11.2.5.3). Recent evidence further demonstrates that associations with mortality remain robust in copollutant analyses (U.S. EPA, 2019, section 11.2.3), and that associations persist in analyses restricted to long-term exposures below 12 $\mu g/m^3$ (Di et al., 2017b) or 10 $\mu g/m^3$ (Shi et al., 2016).

Another important consideration in characterizing the potential for additional public health improvements associated with changes in $PM_{2.5}$ exposure is whether concentration-response relationships are linear across the range of concentrations or if nonlinear relationships exist along any part of this range. Several recent studies examine this issue, and continue to provide evidence of linear, no-threshold relationships between long-term $PM_{2.5}$ exposures and all-cause and cause-specific mortality (U.S. EPA, 2019, section 11.2.4). However, interpreting the shapes of these relationships, particularly at $PM_{2.5}$ concentrations near the lower end of the air quality distribution, can be complicated by relatively low data density in the lower concentration range, the possible influence of exposure measurement error, and variability among individuals with respect to air pollution health effects. These sources of variability and uncertainty tend to smooth and ''linearize'' population-level concentration-response functions, and thus could obscure the existence of a threshold or nonlinear relationship (85 FR 24107, April 30, 2020).

The biological plausibility of $PM_{2.5}$-attributable mortality is supported by the coherence of effects across scientific disciplines (*i.e.,* animal toxicologic, controlled human exposure studies, and epidemiologic). The ISA outlines the available evidence for plausible pathways by which inhalation exposure to $PM_{2.5}$ could progress from initial events (*e.g.,* respiratory tract inflammation, autonomic nervous system modulation) to endpoints relevant to population outcomes, particularly those related to cardiovascular diseases such as ischemic heart disease, stroke and atherosclerosis (U.S. EPA, 2019, section 6.2.1), and to metabolic disease and diabetes (U.S. EPA, 2019, section 7.2.1). The ISA notes ''more limited evidence from respiratory morbidity'' (U.S. EPA, 2019, p. 11–101) to support the biological plausibility of mortality due

[34] In this review of the PM NAAQS, the EPA considers the full body of health evidence, placing the greatest emphasis on the health effects for which the evidence has been judged in the ISA to demonstrate a ''causal'' or a ''likely to be causal'' relationship with PM exposures.

[35] The majority of these studies examined non-accidental mortality outcomes, though some Medicare studies lack cause-specific death information and, therefore, examine total mortality.

to long-term $PM_{2.5}$ exposures (U.S. EPA, 2019, section 11.2.1).

Taken together, recent studies reaffirm and further strengthen the body of evidence from the 2009 ISA for the relationship between long-term $PM_{2.5}$ exposure and mortality. Recent epidemiological studies consistently report positive associations with mortality across different geographic locations, populations, and analytic approaches. Recent experimental and epidemiological evidence for cardiovascular effects, and respiratory effects to a more limited degree, supports the plausibility of mortality due to long-term $PM_{2.5}$ exposures. The 2019 ISA concludes that, ''collectively, this body of evidence is sufficient to conclude that a causal relationship exists between long-term $PM_{2.5}$ exposure and total mortality'' (U.S. EPA, 2019, section 11.2.7; p. 11–102).

Short-Term $PM_{2.5}$ Exposures

The 2009 ISA concluded that ''a causal relationship exists between short-term exposure to $PM_{2.5}$ and mortality'' (U.S. EPA, 2009c). This conclusion was based on the evaluation of both multi- and single-city epidemiological studies that consistently reported positive associations between short-term $PM_{2.5}$ exposure and non-accidental mortality. Examination of the potential confounding effects of gaseous copollutants was limited, though evidence from single-city studies indicated that gaseous copollutants have minimal effect on the $PM_{2.5}$-mortality relationship (*i.e.,* associations remain robust to inclusion of other pollutants in copollutant models). The evaluation of cause-specific mortality found that effect estimates were larger in magnitude, but also had larger confidence intervals, for respiratory mortality compared to cardiovascular mortality. Although the largest mortality risk estimates were for respiratory mortality, the interpretation of the results was complicated by the limited coherence from studies of respiratory morbidity. However, the evidence from studies of cardiovascular morbidity provided both coherence and biological plausibility for the relationship between short-term $PM_{2.5}$ exposure and cardiovascular mortality.

Recent multicity studies evaluated since the 2009 ISA continue to provide evidence of primarily positive associations between daily $PM_{2.5}$ exposures and mortality, with percent increases in total mortality ranging from 0.19% (Lippmann et al., 2013) to 2.80% (Kloog et al., 2013) [36] at lags of 0 to 1 days in single-pollutant models. Whereas most studies rely on assigning exposures using data from ambient monitors, associations are also reported in recent studies that employ hybrid modeling approaches using additional $PM_{2.5}$ data (*i.e.,* from satellites, land use information, and modeling, in addition to monitors), allowing for the inclusion of more rural locations in analyses (Kloog et al., 2013, Shi et al., 2016, Lee et al., 2015).

Some recent studies have expanded the examination of potential confounders (*e.g.,* U.S. EPA, 2019, section 11.1.5.1) to include not only copollutants, but also systematic evaluations of the potential impact of inadequate control from long-term temporal trends and weather. Associations between short-term $PM_{2.5}$ exposures and mortality remain positive and relatively unchanged in copollutant models with both gaseous pollutants and $PM_{10-2.5}$ (U.S. EPA, 2019, Section 11.1.4). Additionally, the low (r <0.4) to moderate correlations (r = 0.4–0.7) between $PM_{2.5}$ and gaseous pollutants and $PM_{10-2.5}$ increase the confidence in $PM_{2.5}$ having an independent effect on mortality (U.S. EPA, 2019, section 11.1.4).

The generally positive associations reported with mortality are supported by a small group of studies employing causal inference or quasi-experimental statistical approaches (U.S. EPA, 2019, section 11.1.2.1). For example, a recent study examined whether a specific regulatory action in Tokyo, Japan (*i.e.,* a diesel emission control ordinance) resulted in a subsequent reduction in daily mortality (Yorifuji et al., 2016). The authors report a reduction in mortality in Tokyo due to the ordinance, compared to Osaka, which did not have a similar diesel emission control ordinance in place.

Positive associations with total mortality are further supported by analyses reporting positive associations with cause-specific mortality, including cardiovascular and respiratory mortality (U.S. EPA, 2019, section 11.1.3). For cause-specific mortality, there has been only a limited assessment of potential copollutant confounding, though initial evidence indicates that associations remain positive and relatively unchanged in models with gaseous pollutants and $PM_{10-2.5}$. The evidence for ischemic events and heart failure, as detailed in the assessment of cardiovascular morbidity (U.S. EPA, 2019, chapter 6), provides biological plausibility for $PM_{2.5}$-related cardiovascular mortality, which comprises the largest percentage of total mortality (*i.e.,* ~33%) (U.S. National Institutes of Health, 2013). Although there is evidence for exacerbations of chronic obstructive pulmonary disease (COPD) and asthma, the collective body of evidence for respiratory effects, particularly from controlled human exposure studies, provides only limited support for the biological plausibility of $PM_{2.5}$-related respiratory mortality (U.S. EPA, 2019, chapter 5).

In the 2009 ISA, one of the main uncertainties identified was the regional and city-to-city heterogeneity in $PM_{2.5}$-mortality associations. Recent studies examine both city-specific as well as regional characteristics to identify the underlying contextual factors that could contribute to this heterogeneity (U.S. EPA, 2019, section 11.1.6.3). Collectively, these studies indicate that the heterogeneity in $PM_{2.5}$-mortality risk estimates cannot be attributed to one factor, but instead to a combination of factors including, but not limited to, PM composition and sources as well as community characteristics that could influence exposures (U.S. EPA, 2019, section 11.1.12).

A few recent studies have conducted analyses comparing the traditional 24-hour average exposure metric with a sub-daily metric (*i.e.,* 1-hour max). These initial studies provide evidence of a similar pattern of associations for both the 24-hour average and 1-hour max metric, with the association larger in magnitude for the 24-hour average metric (U.S. EPA, 2019, section 11.1.8.1).

Recent multicity studies indicate that positive and statistically significant associations with mortality persist in analyses restricted to short-term $PM_{2.5}$ exposures below 35 μg/m³ (Lee et al., 2015),[37] below 30 μg/m³ (Shi et al., 2016), and below 25 μg/m³ (Di et al., 2017a). Additional studies examine the shape of the concentration-response relationship and whether a threshold exists specifically for $PM_{2.5}$ (U.S. EPA, 2019, section 11.1.10). These studies have used various statistical approaches and consistently found linear relationships with no evidence of a threshold. Recent analyses provide initial evidence indicating that $PM_{2.5}$-mortality associations persist and may be stronger (*i.e.,* a steeper slope) at lower

[36] As detailed in the ISA, risk estimates are for a 10 μg/m³ increase in 24-hour average $PM_{2.5}$ concentrations, unless otherwise noted (U.S. EPA, 2019, Preface).

[37] Lee et al. (2015) also report that positive and statistically significant associations between short-term $PM_{2.5}$ exposures and mortality persist in analyses restricted to areas with long-term concentrations below 12 μg/m³.

concentrations (*e.g.,* Di et al., 2017a; U.S. EPA, 2019, Figure 11–12). However, given the limited data available at the lower end of the distribution of ambient $PM_{2.5}$ concentrations, the shape of the concentration-response curve remains uncertain at these low concentrations and, to date, studies have not conducted extensive analyses exploring alternatives to linearity when examining the shape of the $PM_{2.5}$-mortality concentration-response relationship.

Overall, recent epidemiological studies build upon and extend the conclusions of the 2009 ISA for the relationship between short-term $PM_{2.5}$ exposures and total mortality. Supporting evidence for $PM_{2.5}$-related cardiovascular morbidity, and more limited evidence from respiratory morbidity, provides biological plausibility for mortality due to short-term $PM_{2.5}$ exposures. The primarily positive associations observed across studies conducted in diverse geographic locations is further supported by the results from copollutant analyses indicating robust associations, along with evidence from analyses of the concentration-response relationship. The 2019 ISA states that, collectively, ''this body of evidence is sufficient to conclude that a causal relationship exists between short-term $PM_{2.5}$ exposure and total mortality'' (U.S. EPA, 2019, p. 11–58).

ii. Cardiovascular Effects

Long-Term $PM_{2.5}$ Exposures

The scientific evidence reviewed in the 2009 ISA was ''sufficient to infer a causal relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects'' (U.S. EPA, 2009c). The strongest line of evidence comprised findings from several large epidemiological studies of U.S. cohorts that consistently showed positive associations between long-term $PM_{2.5}$ exposure and cardiovascular mortality (Pope et al., 2004, Krewski et al., 2009, Miller et al., 2007, Laden et al., 2006). Studies of long-term $PM_{2.5}$ exposure and cardiovascular morbidity were limited in number. Biological plausibility and coherence with the epidemiological findings were provided by studies using genetic mouse models of atherosclerosis demonstrating enhanced atherosclerotic plaque development and inflammation, as well as changes in measures of impaired heart function, following 4- to 6-month exposures to $PM_{2.5}$ concentrated ambient particles (CAPs), and by a limited number of studies reporting CAPs-induced effects on coagulation factors, vascular reactivity, and worsening of experimentally induced hypertension in mice (U.S. EPA, 2009c).

Studies conducted since the last review continue to support the relationship between long-term exposure to $PM_{2.5}$ and cardiovascular effects. As discussed above, results from recent U.S. and Canadian cohort studies consistently report positive associations between long-term $PM_{2.5}$ exposure and cardiovascular mortality (U.S. EPA, 2019, Figure 6–19) in evaluations conducted at varying spatial scales and employing a variety of exposure assessment and statistical methods (U.S. EPA, 2019, section 6.2.10). Positive associations between long-term $PM_{2.5}$ exposures and cardiovascular mortality are generally robust in copollutant models adjusted for ozone, NO_2, $PM_{10-2.5}$, or SO_2. In addition, most of the results from analyses examining the shape of the concentration-response relationship for cardiovascular mortality support a linear relationship with long-term $PM_{2.5}$ exposures and do not identify a threshold below which effects do not occur (U.S. EPA, 2019, section 6.2.16, Table 6–52).[38]

The available evidence examining the relationship between long-term $PM_{2.5}$ exposure and cardiovascular morbidity has greatly expanded since the 2009 ISA, with positive associations reported in several cohorts examining a range of cardiovascular outcomes (U.S. EPA, 2019, section 6.2). Though results for cardiovascular morbidity are less consistent than those for cardiovascular mortality (U.S. EPA, 2019, section 6.2), recent studies provide some evidence for associations between long-term $PM_{2.5}$ exposures and the progression of cardiovascular disease, including cardiovascular morbidity (*e.g.,* coronary heart disease, stroke) and atherosclerosis progression (*e.g.,* coronary artery calcification) (U.S. EPA, 2019, sections 6.2.2. to 6.2.9). Associations reported in such studies are supported by toxicologic evidence for increased plaque progression in mice following long-term exposure to $PM_{2.5}$ collected from multiple locations across the U.S. (U.S. EPA, 2019, section 6.2.4.2). A small number of epidemiological studies also report positive associations between long-term $PM_{2.5}$ exposure and heart failure, changes in blood pressure, and hypertension (U.S. EPA, 2019, sections 6.2.5 and 6.2.7). Associations with heart failure are supported by animal toxicologic studies demonstrating decreased cardiac contractility and function, and increased coronary artery wall thickness following long-term $PM_{2.5}$ exposure (U.S. EPA, 2019, section 6.2.5.2). Similarly, a limited number of animal toxicologic studies demonstrating a relationship between long-term exposure to $PM_{2.5}$ and consistent increases in blood pressure in rats and mice are coherent with epidemiological studies reporting positive associations between long-term exposure to $PM_{2.5}$ and hypertension. Further, a recent animal toxicologic study also demonstrates increased plaque progression in mice following long-term exposure to $PM_{2.5}$ and provides coherent results with epidemiological evidence reporting positive associations between long-term exposure to $PM_{2.5}$ and indicators of atherosclerosis (U.S. EPA, 2019, section 6.2.4.2).

Longitudinal epidemiological analyses also report positive associations with markers of systemic inflammation (U.S. EPA, 2019, section 6.2.11), coagulation (U.S. EPA, 2019, section 6.2.12), and endothelial dysfunction (U.S. EPA, 2019, section 6.2.13). These results are coherent with animal toxicologic studies generally reporting increased markers of systemic inflammation, oxidative stress, and endothelial dysfunction (U.S. EPA, 2019, section 6.2.12.2 and 6.2.14).

In summary, the 2019 ISA concludes that there is consistent evidence from multiple epidemiological studies illustrating that long-term exposure to $PM_{2.5}$ is associated with mortality from cardiovascular causes. Associations with CHD, stroke and atherosclerosis progression were observed in several additional epidemiological studies providing coherence with the mortality findings. Results from copollutant models generally support an independent effect of $PM_{2.5}$ exposure on mortality. Additional evidence of the independent effect of $PM_{2.5}$ on the cardiovascular system is provided by experimental studies in animals, which support the biological plausibility of pathways by which long-term exposure to $PM_{2.5}$ could potentially result in outcomes such as CHD, stroke, CHF and cardiovascular mortality. The combination of epidemiological and experimental evidence results in the ISA conclusion that ''a causal relationship exists between long-term exposure to $PM_{2.5}$ and cardiovascular effects'' (U.S. EPA, 2019, p. 6–222).

Short-Term $PM_{2.5}$ Exposures

The 2009 ISA concluded that ''a causal relationship exists between short-

[38] As noted above for mortality, uncertainty in the shape of the concentration-response relationship increases near the upper and lower ends of the concentration distribution where the data are limited.

term exposure to $PM_{2.5}$ and cardiovascular effects'' (U.S. EPA, 2009c). The strongest evidence in the 2009 ISA was from epidemiological studies of emergency department visits and hospital admissions for ischemic heart disease (IHD) and heart failure (HF), with supporting evidence from epidemiological studies of cardiovascular mortality (U.S. EPA, 2009c). Animal toxicologic studies reported evidence of reduced myocardial blood flow during ischemia and studies indicating altered vascular reactivity (*i.e.,* vascular function), which provided coherence and biological plausibility for the effects observed in epidemiological studies. In addition, both animal toxicologic and epidemiological panel studies reported effects of $PM_{2.5}$ exposure on ST segment depression, an electrocardiogram change that potentially indicates ischemia.[39] Key uncertainties from the last review included inconsistent results across disciplines with respect to the relationship between short-term exposure to $PM_{2.5}$ and changes in blood pressure, blood coagulation markers, and markers of systemic inflammation. In addition, while the 2009 ISA identified a growing body of evidence from controlled human exposure and animal toxicologic studies, uncertainties remained with respect to biological plausibility.

A large body of recent evidence confirms and extends the evidence from the 2009 ISA supporting the relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects. This includes generally positive associations observed in multicity epidemiological studies of emergency department visits and hospital admissions for IHD, HF, and combined cardiovascular-related endpoints. In particular, nationwide studies of older adults (65 years and older) report positive associations between $PM_{2.5}$ exposures and hospital admissions for HF (U.S. EPA, 2019, section 6.1.3.1). Single-city epidemiological studies contribute some support, though associations reported are less consistently positive than in multicity studies, and include a number of studies reporting null associations (U.S. EPA, 2019, sections 6.1.2 and 6.1.3).

In addition, a number of more recent controlled human exposure, animal toxicologic, and epidemiological panel studies provide evidence that $PM_{2.5}$ exposure could plausibly result in IHD or HF through pathways that include endothelial dysfunction, arterial thrombosis, and arrhythmia (U.S. EPA, 2019, section 6.1.1). The most consistent evidence from recent controlled human exposure studies is for endothelial dysfunction, as measured by changes in brachial artery diameter or flow mediated dilation (U.S. EPA, 2019, section 6.1.13.2). These studies report variable results regarding the timing of the effect and the mechanism by which reduced blood flow occurs (*i.e.,* availability of vs. sensitivity to nitric oxide). Some controlled human exposure studies using $PM_{2.5}$ CAPs report evidence for small increases in blood pressure (U.S. EPA, 2019, section 6.1.6.3). In addition, although not entirely consistent, there is also some evidence across controlled human exposure studies for conduction abnormalities/arrhythmia (U.S. EPA, 2019, section 6.1.4.3), changes in heart rate variability (HRV) (U.S. EPA, 2019, section 6.1.10.2), changes in hemostasis that could promote clot formation (U.S. EPA, 2019, section 6.1.12.2), and increases in inflammatory cells and markers (U.S. EPA, 2019, section 6.1.11.2). Thus, when taken as a whole, controlled human exposure studies are coherent with epidemiological studies in that they provide evidence that short-term exposures to $PM_{2.5}$ may result in the types of cardiovascular endpoints that could lead to emergency department visits and hospital admissions for IHD or HF.

Animal toxicologic studies published since the 2009 ISA also support a relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects. A recent study demonstrating decreased cardiac contractility and left ventricular pressure in mice is coherent with the results of epidemiological studies that report associations between short-term $PM_{2.5}$ exposure and heart failure (U.S. EPA, 2019, section 6.1.3.3). In addition, similar to results of controlled human exposure studies, there is generally consistent evidence in animal toxicologic studies for indicators of endothelial dysfunction (U.S. EPA, 2019, section 6.1.13.3). Studies in animals also provide evidence for changes in a number of other cardiovascular endpoints following short-term $PM_{2.5}$ exposure. Although not entirely consistent, these studies provide some evidence of conduction abnormalities and arrhythmia (U.S. EPA, 2019, section 6.1.4.4), changes in HRV (U.S. EPA, 2019, section 6.1.10.3), changes in blood pressure (U.S. EPA, 2019, section 6.1.6.4), and evidence for systemic inflammation and oxidative stress (U.S. EPA, 2019, section 6.1.11.3).

In summary, recent evidence supports the conclusions reported in the 2009 ISA indicating relationships between short-term $PM_{2.5}$ exposures and hospital admissions and ED visits for IHD and HF, along with cardiovascular mortality. Epidemiological studies reporting robust associations in copollutant models are supported by direct evidence from controlled human exposure and animal toxicologic studies reporting independent effects of $PM_{2.5}$ exposures on endothelial dysfunction as well as endpoints indicating impaired cardiac function, increased risk of arrhythmia, changes in HRV, increases in BP, and increases in indicators of systemic inflammation, oxidative stress, and coagulation (U.S. EPA, 2019, section 6.1.16). Epidemiological panel studies, although not entirely consistent, provide some evidence that $PM_{2.5}$ exposures are associated with cardiovascular effects, including increased risk of arrhythmia, decreases in HRV, increases in BP, and ST segment depression. Overall, the results from epidemiological panel, controlled human exposure, and animal toxicologic studies (in particular those related to endothelial dysfunction, impaired cardiac function, ST segment depression, thrombosis, conduction abnormalities, and changes in blood pressure) provide coherence and biological plausibility for the consistent results from epidemiological studies reporting positive associations between short-term $PM_{2.5}$ exposures and IHD and HF, and ultimately cardiovascular mortality. The 2019 ISA concludes that, overall, ''there continues to be sufficient evidence to conclude that a causal relationship exists between short-term $PM_{2.5}$ exposure and cardiovascular effects'' (U.S. EPA, 2019, p. 6–138).

iii. Respiratory Effects

Long-Term $PM_{2.5}$ Exposures

The 2009 ISA concluded that ''a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and respiratory effects'' (U.S. EPA, 2009c). This conclusion was based mainly on epidemiological evidence demonstrating associations between long-term $PM_{2.5}$ exposure and changes in lung function or lung function growth in children. Biological plausibility was provided by a single animal toxicologic study examining pre- and post-natal exposure to $PM_{2.5}$ CAPs, which found impaired lung development. Epidemiological evidence for associations between long-term $PM_{2.5}$ exposure and other respiratory outcomes, such as the

[39] Some animal studies included in the 2009 ISA examined exposures to mixtures, such as motor vehicle exhaust or woodsmoke. In these studies, it was unclear if the resulting cardiovascular effects could be attributed specifically to the particulate components of the mixture.

development of asthma, allergic disease, and COPD; respiratory infection; and the severity of disease was limited, both in the number of studies available and the consistency of the results. Experimental evidence for other outcomes was also limited, with one animal toxicologic study reporting that long-term exposure to $PM_{2.5}$ CAPs results in morphological changes in the nasal airways of healthy animals. Other animal studies examined exposure to mixtures, such as motor vehicle exhaust and woodsmoke, and effects were not attributed specifically to the particulate components of the mixture.

Recent cohort studies provide additional support for the relationship between long-term $PM_{2.5}$ exposure and decrements in lung function growth (as a measure of lung development), indicating a robust and consistent association across study locations, exposure assessment methods, and time periods (U.S. EPA, 2019, section 5.2.13). This relationship is further supported by a recent retrospective study that reports an association between declining $PM_{2.5}$ concentrations and improvements in lung function growth in children (U.S. EPA, 2019, section 5.2.11). Epidemiological studies also examined asthma development in children (U.S. EPA, 2019, section 5.2.3), with recent prospective cohort studies reporting generally positive associations, though several are imprecise (*i.e.,* they report wide confidence intervals). Supporting evidence is provided by studies reporting associations with asthma prevalence in children, with childhood wheeze, and with exhaled nitric oxide, a marker of pulmonary inflammation (U.S. EPA, 2019, section 5.2.13). A recent animal toxicologic study showing the development of an allergic phenotype and an increase in a marker of airway responsiveness supports the biological plausibility of the development of allergic asthma (U.S. EPA, 2019, section 5.2.13). Other epidemiological studies report a $PM_{2.5}$-related acceleration of lung function decline in adults, while improvement in lung function was observed with declining $PM_{2.5}$ concentrations (U.S. EPA, 2019, section 5.2.11). A recent longitudinal study found declining $PM_{2.5}$ concentrations are also associated with an improvement in chronic bronchitis symptoms in children, strengthening evidence reported in the 2009 ISA for a relationship between increased chronic bronchitis symptoms and long-term $PM_{2.5}$ exposure (U.S. EPA, 2019, section 5.2.11). A common uncertainty across the epidemiological evidence is the lack of examination of copollutants to assess the potential for confounding. While there is some evidence that associations remain robust in models with gaseous pollutants, a number of these studies examining copollutant confounding were conducted in Asia, and thus have limited generalizability due to high annual pollutant concentrations.

When taken together, the 2019 ISA concludes that ''the collective evidence is sufficient to conclude a likely to be causal relationship between long-term $PM_{2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019, p. 5–220).

Short-Term $PM_{2.5}$ Exposures

The 2009 ISA (U.S. EPA, 2009c) concluded that a ''causal relationship is likely to exist'' between short-term $PM_{2.5}$ exposure and respiratory effects. This conclusion was based mainly on the epidemiological evidence demonstrating positive associations with various respiratory effects. Specifically, the 2009 ISA described epidemiological evidence as consistently showing $PM_{2.5}$-associated increases in hospital admissions and emergency department visits for COPD and respiratory infection among adults or people of all ages, as well as increases in respiratory mortality. These results were supported by studies reporting associations with increased respiratory symptoms and decreases in lung function in children with asthma, though the available epidemiological evidence was inconsistent for hospital admissions or emergency department visits for asthma. Studies examining copollutant models showed that $PM_{2.5}$ associations with respiratory effects were robust to inclusion of CO or SO_2 in the model, but often were attenuated (though still positive) with inclusion of O_3 or NO_2. In addition to the copollutant models, evidence supporting an independent effect of $PM_{2.5}$ exposure on the respiratory system was provided by animal toxicologic studies of $PM_{2.5}$ CAPs demonstrating changes in some pulmonary function parameters, as well as inflammation, oxidative stress, injury, enhanced allergic responses, and reduced host defenses. Many of these effects have been implicated in the pathophysiology for asthma exacerbation, COPD exacerbation, or respiratory infection. In the few controlled human exposure studies conducted in individuals with asthma or COPD, $PM_{2.5}$ exposure mostly had no effect on respiratory symptoms, lung function, or pulmonary inflammation. Available studies in healthy people also did not clearly find respiratory effects following short-term $PM_{2.5}$ exposures.

Recent epidemiological studies provide evidence for a relationship between short-term $PM_{2.5}$ exposure and several respiratory-related endpoints, including asthma exacerbation (U.S. EPA, 2019, section 5.1.2.1), COPD exacerbation (U.S. EPA, 2019, section 5.1.4.1), and combined respiratory-related diseases (U.S. EPA, 2019, section 5.1.6), particularly from studies examining emergency department visits and hospital admissions. The generally positive associations between short-term $PM_{2.5}$ exposure and asthma and COPD emergency department visits and hospital admissions are supported by epidemiological studies demonstrating associations with other respiratory-related effects such as symptoms and medication use that are indicative of asthma and COPD exacerbations (U.S. EPA, 2019, sections 5.1.2.2 and 5.4.1.2). The collective body of epidemiological evidence for asthma exacerbation is more consistent in children than in adults. Additionally, epidemiological studies examining the relationship between short-term $PM_{2.5}$ exposure and respiratory mortality provide evidence of consistent positive associations, demonstrating a continuum of effects (U.S. EPA, 2019, section 5.1.9).

Building on the studies evaluated in the 2009 ISA, recent epidemiological studies expand the assessment of potential copollutant confounding. There is some evidence that $PM_{2.5}$ associations with asthma exacerbation, combined respiratory-related diseases, and respiratory mortality remain relatively unchanged in copollutant models with gaseous pollutants (*i.e.,* O_3, NO_2, SO_2, with more limited evidence for CO) and other particle sizes (*i.e.,* $PM_{10-2.5}$) (U.S. EPA, 2019, section 5.1.10.1).

Insight into whether there is an independent effect of $PM_{2.5}$ on respiratory health is provided by findings from animal toxicologic studies. Specifically, short-term exposure to $PM_{2.5}$ has been shown to enhance asthma-related responses in an animal model of allergic airways disease and lung injury and inflammation in an animal model of COPD (U.S. EPA, 2019, sections 5.1.2.4.4 and 5.1.4.4.3). The experimental evidence provides biological plausibility for some respiratory-related endpoints, including limited evidence of altered host defense and greater susceptibility to bacterial infection as well as consistent evidence of respiratory irritant effects. Animal toxicologic evidence for other respiratory effects is inconsistent and controlled human exposure studies

provide limited evidence of respiratory effects (U.S. EPA, 2019, section 5.1.12).

The 2019 ISA concludes that ''[t]he strongest evidence of an effect of short-term $PM_{2.5}$ exposure on respiratory effects is provided by epidemiological studies of asthma and COPD exacerbation. While animal toxicologic studies provide biological plausibility for these findings, some uncertainty remains with respect to the independence of $PM_{2.5}$ effects'' (U.S. EPA, 2019, p. 5–155). When taken together, the ISA concludes that this evidence ''is sufficient to conclude a likely to be causal relationship between short-term $PM_{2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019, p. 5–155).

iv. Cancer

The 2009 ISA concluded that the overall body of evidence was ''suggestive of a causal relationship between relevant $PM_{2.5}$ exposures and cancer'' (U.S. EPA, 2009c). This conclusion was based primarily on positive associations observed in a limited number of epidemiological studies of lung cancer mortality. The few epidemiological studies that had evaluated $PM_{2.5}$ exposure and lung cancer incidence or cancers of other organs and systems generally did not show evidence of an association. Toxicologic studies did not focus on exposures to specific PM size fractions, but rather investigated the effects of exposures to total ambient PM, or other source-based PM such as wood smoke. Collectively, results of in vitro studies were consistent with the larger body of evidence demonstrating that ambient PM and PM from specific combustion sources are mutagenic and genotoxic. However, animal inhalation studies found little evidence of tumor formation in response to chronic exposures. A small number of studies provided preliminary evidence that PM exposure can lead to changes in methylation of DNA, which may contribute to biological events related to cancer.

Since the 2009 ISA, additional cohort studies provide evidence that long-term $PM_{2.5}$ exposure is positively associated with lung cancer mortality and with lung cancer incidence, and provide initial evidence for an association with reduced cancer survival (U.S. EPA, 2019, section 10.2.5), with limited evidence of cancer in other organ systems. Reanalyses of the ACS cohort using different years of $PM_{2.5}$ data and follow-up, along with various exposure assignment approaches, provide consistent evidence of positive associations between long-term $PM_{2.5}$ exposure and lung cancer mortality (U.S. EPA, 2019, Figure 10–3). Additional support for positive associations with lung cancer mortality is provided by recent epidemiological studies using individual-level data to control for smoking status, in studies of people who have never smoked), and in analyses of cohorts that relied upon proxy measures to account for smoking status (U.S. EPA, 2019, section 10.2.5.1.1). Although studies that evaluate lung cancer incidence, including studies of people who have never smoked, are limited in number, recent studies generally report positive associations with long-term $PM_{2.5}$ exposures (U.S. EPA, 2019, section 10.2.5.1.2). In addition, a subset of the studies focusing on lung cancer incidence also examined histological subtypes, providing some evidence of positive associations for adenocarcinomas, the predominate subtype of lung cancer observed in people who have never smoked (U.S. EPA, 2019, section 10.2.5.1.2). Associations between long-term $PM_{2.5}$ exposure and lung cancer incidence were found to remain relatively unchanged, though in some cases confidence intervals widened, in analyses that attempted to reduce exposure measurement error by accounting for length of time at residential address or by examining different exposure assignment approaches (U.S. EPA, 2019, section 10.2.5.1.2).

To date, relatively few studies have evaluated the potential for copollutant confounding of the relationship between long-term $PM_{2.5}$ exposure and lung cancer mortality or incidence. The small number of such studies have generally focused on O_3 and report that $PM_{2.5}$ associations remain relatively unchanged in copollutant models (U.S. EPA, 2019, section 10.2.5.1.3). However, available studies have not systematically evaluated the potential for copollutant confounding by other gaseous pollutants or by other particle size fractions (U.S. EPA, 2019, section 10.2.5.1.3). Compared to total (non-accidental) mortality (discussed above), fewer studies have examined the shape of the concentration-response curve for cause-specific mortality outcomes, including lung cancer. Several of these studies have reported no evidence of deviations from linearity in the shape of the concentration-response relationship (Lepeule et al., 2012; Raaschou-Nielsen et al., 2013; Puett et al., 2014), though authors provided only limited discussions of results (U.S. EPA, 2019, section 10.2.5.1.4).

In support of the biological plausibility of an independent effect of $PM_{2.5}$ on cancer, the 2019 ISA notes evidence from recent experimental studies demonstrating that $PM_{2.5}$ exposure can lead to a range of effects indicative of mutagenicity, genotoxicity, and carcinogenicity, as well as epigenetic effects (U.S. EPA, 2019, section 10.2.7). For example, both in vitro and in vivo toxicologic studies have shown that $PM_{2.5}$ exposure can result in DNA damage (U.S. EPA, 2019, section 10.2.2). Although such effects do not necessarily equate to carcinogenicity, the evidence that PM exposure can damage DNA, and elicit mutations, provides support for the plausibility of epidemiological associations with lung cancer mortality and incidence. Additional supporting studies indicate the occurrence of micronuclei formation and chromosomal abnormalities (U.S. EPA, 2019, section 10.2.2.3), and differential expression of genes that may be relevant to cancer pathogenesis, following PM exposures. Experimental and epidemiological studies that examine epigenetic effects indicate changes in DNA methylation, providing some support for $PM_{2.5}$ exposure contributing to genomic instability (U.S. EPA, 2019, section 10.2.3).

Epidemiological evidence for associations between $PM_{2.5}$ exposure and lung cancer mortality and incidence, together with evidence supporting the biological plausibility of such associations, contributes to the 2019 ISA's conclusion that the evidence ''is sufficient to conclude there is a likely to be causal relationship between long-term $PM_{2.5}$ exposure and cancer'' (U.S. EPA, 2019, p. 10–77).

In its letter to the Administrator on the draft ISA, the CASAC states that ''the Draft ISA does not present adequate evidence to conclude that there is likely to be a causal relationship between long-term $PM_{2.5}$ exposure and . . . cancer'' (Cox, 2019a, p. 1 of letter). The CASAC specifically states that this causality determination ''relies largely on epidemiology studies that . . . do not provide exposure time frames that are appropriate for cancer causation and that there are no animal studies showing direct effects of $PM_{2.5}$ on cancer formation'' (Cox, 2019a, p. 20 of consensus responses).

With respect to the latency period, it is well recognized that ''air pollution exposures experienced over an extended historical time period are likely more relevant to the etiology of lung cancer than air pollution exposures experienced in the more recent past'' (Turner et al. 2011). However, many epidemiological studies conducted within the U.S. that examine long-term

$PM_{2.5}$ exposure and lung cancer incidence and lung cancer mortality rely on more recent air quality data because routine $PM_{2.5}$ monitoring did not start until 1999–2000. An exception to this is the ACS study that had $PM_{2.5}$ concentration data from two time periods, 1979–1983 and from 1999–2000. Turner et al. (2011), conducted a comparison of $PM_{2.5}$ concentrations between these two time periods and found that they were highly correlated (r >0.7), with the relative rank order of metropolitan statistical areas (MSAs) by $PM_{2.5}$ concentrations being ''generally retained over time.'' Therefore, areas where $PM_{2.5}$ concentrations were high remained high over decades (or were low and remained low) relative to other locations. Long-term exposure epidemiological studies rely on spatial contrasts between locations; therefore, if a location with high $PM_{2.5}$ concentrations continues to have high concentrations over decades relative to other locations a relationship between the $PM_{2.5}$ exposure and cancer should persist. This was confirmed in a sensitivity analysis conducted by Turner et al. (2011), where the authors reported a similar hazard ratio (HR) for lung cancer mortality for participants assigned exposure to $PM_{2.5}$ (1979–1983) and $PM_{2.5}$ (1999–2000) in two separate analyses.

While experimental studies showing a direct effect of $PM_{2.5}$ on cancer formation were limited to an animal model of urethane-induced tumor initiation, a large number of experimental studies report that $PM_{2.5}$ exhibits several key characteristics of carcinogens, as indicated by genotoxic effects, oxidative stress, electrophilicity, and epigenetic alterations, all of which provide biological plausibility that $PM_{2.5}$ exposure can contribute to cancer development. The experimental evidence, in combination with multiple recent and previously evaluated epidemiological studies examining the relationship between long-term $PM_{2.5}$ exposure and both lung cancer incidence and lung cancer mortality that reported generally positive associations across different cohorts, exposure assignment methods, and in analyses of never smokers further addresses uncertainties identified in the 2009 ISA. Therefore, upon re-evaluating the causality determination for cancer, when considering CASAC comments on the draft ISA and applying the causal framework as described (U.S. EPA, 2015; U.S. EPA, 2019, section A.3.2.1), the EPA continues to conclude in the 2019 ISA that the evidence for long-term $PM_{2.5}$ exposure and cancer supports a ''likely to be causal relationship'' (U.S. EPA, 2019, p. 10–77).

v. Nervous System Effects

Reflecting the very limited evidence available in the last review, the 2009 ISA did not make a causality determination for long-term $PM_{2.5}$ exposures and nervous system effects (U.S. EPA, 2009c). Since the last review, this body of evidence has grown substantially (U.S. EPA, 2019, section 8.2). Recent studies in adult animals report that long-term $PM_{2.5}$ exposures can lead to morphologic changes in the hippocampus and to impaired learning and memory. This evidence is consistent with epidemiological studies reporting that long-term $PM_{2.5}$ exposure is associated with reduced cognitive function (U.S. EPA, 2019, section 8.2.5). Further, while the evidence is limited, early markers of Alzheimer's disease pathology have been reported in rodents following long-term exposure to $PM_{2.5}$ CAPs. These findings support reported associations with neurodegenerative changes in the brain (*i.e.,* decreased brain volume), all-cause dementia, and hospitalization for Alzheimer's disease in a small number of epidemiological studies (U.S. EPA, 2019, section 8.2.6). Additionally, loss of dopaminergic neurons in the substantia nigra, a hallmark of Parkinson's disease, has been reported in mice following long-term $PM_{2.5}$ exposures (U.S. EPA, 2019, section 8.2.4), though epidemiological studies provide only limited support for associations with Parkinson's disease (U.S. EPA, 2019, section 8.2.6). Overall, the lack of consideration of copollutant confounding introduces some uncertainty in the interpretation of epidemiological studies of nervous system effects, but this uncertainty is partly addressed by the evidence for an independent effect of $PM_{2.5}$ exposures provided by experimental animal studies.

In addition to the findings described above, which are most relevant to older adults, several recent studies of neurodevelopmental effects in children have also been conducted. Epidemiological studies provided limited evidence of an association between $PM_{2.5}$ exposure during pregnancy and childhood on cognitive and motor development (U.S. EPA, 2019, section 8.2.5.2). While some studies report positive associations between long-term exposure to $PM_{2.5}$ during the prenatal period and autism spectrum disorder (ASD) (U.S. EPA, 2019, section 8.2.7.2). Interpretation of these epidemiological studies is limited due to the small number of studies, their lack of control for potential confounding by copollutants, and uncertainty regarding the critical exposure windows. Biological plausibility is provided for the ASD findings by a study in mice that found inflammatory and morphologic changes in the corpus collosum and hippocampus, as well as ventriculomegaly (*i.e.,* enlarged lateral ventricles) in young mice following prenatal exposure to $PM_{2.5}$ CAPs.

Taken together, the 2019 ISA concludes that the strongest evidence of an effect of long-term exposure to $PM_{2.5}$ on the nervous system is provided by toxicologic studies that show inflammation, oxidative stress, morphologic changes, and neurodegeneration in multiple brain regions following long-term exposure of adult animals to $PM_{2.5}$ CAPs. These findings are coherent with epidemiological studies reporting consistent associations with cognitive decrements and with all-cause dementia. The ISA determines that ''[o]verall, the collective evidence is sufficient to conclude a likely to be causal relationship between long-term $PM_{2.5}$ exposure and nervous system effects'' (U.S. EPA, 2019, p. 8–61).

In its letter to the Administrator on the draft ISA, the CASAC states that ''the Draft ISA does not present adequate evidence to conclude that there is likely to be a causal relationship between long-term $PM_{2.5}$ exposure and nervous system effects'' (Cox, 2019a, p. 1 of letter). The CASAC specifically states that ''[f]or a likely causal conclusion, there would have to be evidence of health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the overall evidence'' (Cox, 2019a, p. 20 of consensus responses). These uncertainties in the eyes of CASAC reflect that animal toxicologic studies ''have largely been done by a single group,'' and for epidemiological studies that examined brain volume that ''brain volumes can vary . . . between normal people'' and the results from studies of cognitive function were ''largely non-statistically significant'' (Cox, 2019a, p. 20 of consensus responses).

With these concerns in mind, and as noted in the proposed rule (85 FR 24114, April 30, 2020), the EPA re-evaluated the evidence and note that animal toxicologic studies were conducted in ''multiple research groups [and show a range of effects including] inflammation, oxidative stress, morphologic changes, and neurodegeneration in multiple brain regions following long-term exposure of adult animals to $PM_{2.5}$ CAPs'' (U.S. EPA, 2019, p. 8–61). The results from the

animal toxicologic studies ''are coherent with a number of epidemiological studies reporting consistent associations with cognitive decrements and with all-cause dementia'' (U.S. EPA, 2019, p. 8–61). Additionally, as discussed in the Preamble to the ISAs (U.S. EPA, 2015):

''. . . the U.S. EPA emphasizes the importance of examining the pattern of results across various studies and does not focus solely on statistical significance or the magnitude of the direction of the association as criteria of study reliability. Statistical significance is influenced by a variety of factors including, but not limited to, the size of the study, exposure and outcome measurement error, and statistical model specifications. Statistical significance . . . is just one of the means of evaluating confidence in the observed relationship and assessing the probability of chance as an explanation. Other indicators of reliability such as the consistency and coherence of a body of studies as well as other confirming data may be used to justify reliance on the results of a body of epidemiologic studies, even if results in individual studies lack statistical significance . . . [Therefore, the U.S. EPA] . . . does not limit its focus or consideration to statistically significant results in epidemiologic studies.''

Therefore, upon re-evaluating the causality determination, when considering the CASAC comments on the draft ISA and applying the causal framework as described (U.S. EPA, 2015; U.S. EPA, 2019, section A.3.2.1), the EPA continues to conclude in the 2019 ISA that the evidence for long-term $PM_{2.5}$ exposure and nervous system effects supports a ''likely to be causal relationship'' (U.S. EPA, 2019, p. 8–61).

vi. Other Effects

For other categories of health effects and $PM_{2.5}$ exposures,[40] the currently available evidence is ''suggestive of, but not sufficient to infer, a causal relationship,'' mainly due to inconsistent evidence across specific outcomes and uncertainties regarding exposure measurement error, the potential for confounding, and potential modes of action (U.S. EPA, 2019, sections 7.1.4, 7.2.10, 8.1.6, and 9.1.5). These causality determinations are revised from ''inadequate to infer a causal relationship'' or not evaluated in the 2009 ISA this review; however, the ''suggestive of, but not sufficient to infer, a causal relationship'' causality determinations reflect continued uncertainties in the evidence.

[40] The other categories evaluated in the ISA include nervous system effects and short-term exposures; metabolic effects; reproduction and fertility; and pregnancy and birth outcomes (U.S. EPA, 2019, Table ES–1).

b. At-Risk Populations

In this review, we use the term ''at-risk populations'' to describe populations with a quality or characteristic in common (*e.g.,* a specific pre-existing illness or specific lifestage) that contributes to them having a greater likelihood of experiencing $PM_{2.5}$-related health effects. In the current review, consistent with the last review, the 2019 ISA cites extensive evidence indicating that ''both the general population as well as specific populations and lifestages are at risk for $PM_{2.5}$-related health effects'' (U.S. EPA, 2019, p. 12–1). For example, in support of its ''causal'' and ''likely to be causal'' determinations, the ISA cites substantial evidence for: PM-related mortality and cardiovascular effects in older adults (U.S. EPA, 2019, sections 11.1, 11.2, 6.1, and 6.2); PM-related cardiovascular effects in people with pre-existing cardiovascular disease (U.S. EPA, 2019, section 6.1); PM-related respiratory effects in people with pre-existing respiratory disease, particularly asthma exacerbations in children (U.S. EPA, 2019, section 5.1); and PM-related impairments in lung function growth and asthma development in children (U.S. EPA, 2019, sections 5.1 and 5.2; 12.5.1.1).

The ISA additionally notes that stratified analyses (*i.e.,* analyses that directly compare PM-related health effects across groups) provide support for racial and ethnic differences in $PM_{2.5}$ exposures and in $PM_{2.5}$-related health risk (U.S. EPA, 2019, section 12.5.4). Drawing from such studies, the ISA concludes that ''[t]here is strong evidence demonstrating that black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic white populations'' and that ''there is consistent evidence across multiple studies demonstrating an increase in risk for nonwhite populations'' (U.S. EPA, 2019, p. 12–38). Stratified analyses focusing on other groups also suggest that populations with pre-existing cardiovascular or respiratory disease, populations that are overweight or obese, populations that have particular genetic variants, populations that are of low socioeconomic status, and current/former smokers could be at increased risk for $PM_{2.5}$-related adverse health effects (U.S. EPA, 2019, Chapter 12).

Thus, the groups at greater risk of $PM_{2.5}$-related health effects represent a substantial portion of the total U.S. population. In evaluating the primary $PM_{2.5}$ standards, an important consideration is the potential for additional public health improvements in these populations.

c. Evidence-Based Considerations

The sections below summarize the PA's evaluation of the $PM_{2.5}$ exposure concentrations that have been examined in controlled human exposure studies, animal toxicology studies, and epidemiological studies.

i. $PM_{2.5}$ Concentrations Evaluated in Experimental Studies

Evidence for a particular $PM_{2.5}$-related health outcome is strengthened when results from experimental studies demonstrate biologically plausible mechanisms through which adverse human health outcomes could occur (U.S. EPA, 2015, p. 20). Two types of experimental studies are of particular importance in understanding the effects of PM exposures: Controlled human exposure and animal toxicologic studies. In such studies, investigators expose human volunteers or laboratory animals, respectively, to known concentrations of air pollutants under carefully regulated environmental conditions and activity levels. Thus, controlled human exposure and animal toxicology studies can provide information on the health effects of experimentally administered pollutant exposures under well-controlled laboratory conditions (U.S. EPA, 2015, p. 11).

Controlled human exposure studies have reported that $PM_{2.5}$ exposures lasting from less than one hour up to five hours can impact cardiovascular function (U.S. EPA, 2019, section 6.1). The most consistent evidence from these studies is for impaired vascular function (U.S. EPA, 2019, section 6.1.13.2). Table 3–2 in the PA (U.S. EPA, 2020) summarizes information from the ISA on available controlled human exposure studies that evaluate effects on markers of cardiovascular function following exposures to $PM_{2.5}$. Most of the controlled human exposure studies in Table 3–2 of the PA have evaluated average $PM_{2.5}$ exposure concentrations at or above about 100 $\mu g/m^3$, with exposure durations typically up to about two hours. Statistically significant effects on one or more indicators of cardiovascular function are often, though not always, reported following 2-hour exposures to average $PM_{2.5}$ concentrations at and above about 120 $\mu g/m^3$, with less consistent evidence for effects following exposures to lower concentrations. Impaired vascular function, the effect identified in the ISA as the most consistent across studies (U.S. EPA, 2019, section 6.1.13.2), is shown following 2-hour

exposures to $PM_{2.5}$ concentrations at and above 149 μg/m³. Mixed results are reported in the few studies that evaluate longer exposure durations (*i.e.,* longer than 2 hours) and lower $PM_{2.5}$ concentrations (U.S. EPA, 2020, section 3.2.3.1).

To provide some insight into what these studies may indicate regarding the primary $PM_{2.5}$ standards, analyses in the PA examine monitored 2-hour $PM_{2.5}$ concentrations at sites meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). At these sites, most 2-hour concentrations are below 11 μg/m³, and they almost never exceed 32 μg/m³. Even the highest 2-hour concentrations remain well-below the exposure concentrations consistently shown to cause effects in controlled human exposure studies (*i.e.,* 99.9th percentile of 2-hour concentrations is 68 μg/m³ during the warm season). Thus, while controlled human exposure studies support the plausibility of the serious cardiovascular effects that have been linked with ambient $PM_{2.5}$ exposures (U.S. EPA, 2019, Chapter 6), the PA notes that the $PM_{2.5}$ exposures evaluated in most of these studies are well-above the ambient concentrations typically measured in locations meeting the current primary standards (U.S. EPA, 2020, section 3.2.3.2.1).

With respect to animal toxicology studies, the ISA relies on animal toxicology studies to support the plausibility of a wide range of $PM_{2.5}$-related health effects. While animal toxicology studies often examine more severe health outcomes and longer exposure durations than controlled human exposure studies, there is uncertainty in extrapolating the effects seen in animals, and the $PM_{2.5}$ exposures and doses that cause those effects, to human populations.

As with controlled human exposure studies, most of the animal toxicology studies assessed in the ISA have examined effects following exposures to $PM_{2.5}$ concentrations well-above the concentrations likely to be allowed by the current $PM_{2.5}$ standards. Such studies have generally examined short-term exposures to $PM_{2.5}$ concentrations from 100 to >1,000 μg/m³ and long-term exposures to concentrations from 66 to >400 μg/m³ (*e.g.,* see U.S. EPA, 2019, Table 1–2). Two exceptions are a study reporting impaired lung development following long-term exposures (*i.e.,* 24 hours per day for several months prenatally and postnatally) to an average $PM_{2.5}$ concentration of 16.8 μg/m³ (Mauad et al., 2008) and a study reporting increased carcinogenic potential following long-term exposures (*i.e.,* 2 months) to an average $PM_{2.5}$ concentration of 17.7 μg/m³ (Cangerana Pereira et al., 2011). These two studies report serious effects following long-term exposures to $PM_{2.5}$ concentrations close to the ambient concentrations reported in some $PM_{2.5}$ epidemiological studies (U.S. EPA, 2019, Table 1–2), though still above the ambient concentrations likely to occur in areas meeting the current primary standards. Thus, as is the case with controlled human exposure studies, animal toxicology studies support the plausibility of various adverse effects that have been linked to ambient $PM_{2.5}$ exposures (U.S. EPA, 2019), but have not evaluated $PM_{2.5}$ exposures likely to occur in areas meeting the current primary standards.

ii. Ambient Concentrations in Locations of Epidemiological Studies

As summarized above in section II.A.2.a, epidemiological studies examining associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity represent a large part of the evidence base supporting several of the ISA's ''causal'' and ''likely to be causal'' determinations for cardiovascular effects, respiratory effects, cancer, and mortality. The PA considers what information from these epidemiological studies may indicate regarding primary $PM_{2.5}$ standards. The use of information from epidemiological studies to inform conclusions on the primary $PM_{2.5}$ standards is complicated by the fact that such studies evaluate associations between distributions of ambient $PM_{2.5}$ and health outcomes, but do not identify the specific exposures that cause reported effects. Rather, health effects can occur over the entire distributions of ambient $PM_{2.5}$ concentrations evaluated, and epidemiological studies do not identify a population-level threshold below which it can be concluded with confidence that PM-associated health effects do not occur (U.S. EPA, 2020, section 3.2.3.2). Therefore, the PA evaluates the $PM_{2.5}$ air quality distributions over which epidemiological studies support health effect associations. As discussed further in the PA (U.S. EPA, 2020, section 3.2.3.2.1), studies of daily $PM_{2.5}$ exposures examine associations between day-to-day variation in $PM_{2.5}$ concentrations and health outcomes, often over several years. While there can be considerable variability in daily exposures over a multi-year study period, most of the estimated exposures reflect days with ambient $PM_{2.5}$ concentrations around the middle of the air quality distributions examined (*i.e.,* ''typical'' days rather than days with extremely high or extremely low concentrations). Similarly, for studies of annual $PM_{2.5}$ exposures, most of the estimated exposures reflect annual average $PM_{2.5}$ concentrations around the middle of the air quality distributions examined. In both cases, epidemiological studies provide the strongest support for reported health effect associations for this middle portion of the $PM_{2.5}$ air quality distribution, which corresponds to the bulk of the underlying data, rather than the extreme upper or lower ends of the distribution. Consistent with this, and as noted in the PA (U.S. EPA, 2020, section 3.2.1.1), several epidemiological studies report that associations persist in analyses that exclude the upper portions of the distributions of estimated $PM_{2.5}$ exposures, indicating that ''peak'' $PM_{2.5}$ exposures are not disproportionately responsible for reported health effect associations.

Thus, in considering $PM_{2.5}$ air quality data from epidemiological studies, the PA evaluates study-reported means (or medians) of daily and annual average $PM_{2.5}$ concentrations as proxies for the middle portions of the air quality distributions that support reported associations. In Figure 3–7, the PA highlights the overall mean (or median) $PM_{2.5}$ concentrations reported in key U.S. and Canadian epidemiological studies that use ground-based monitors alone to estimate long- or short-term $PM_{2.5}$ exposures. In Figure 3–8, the PA also considers the emerging body of studies that use hybrid modeling methods to estimate long- or short-term $PM_{2.5}$ exposures. Hybrid methods incorporate data from several sources, often including satellites and models, in addition to ground-based monitors.

Epidemiological studies using hybrid methods are generally new in this review. These modeling methods have improved the ability to estimate $PM_{2.5}$ exposure for populations throughout the conterminous U.S. compared with the earlier approaches based on monitoring data alone. Excellent performance in cross-validation tests suggests that hybrid methods are reliable for estimating $PM_{2.5}$ exposure in many applications. As discussed in Chapter 3 of the PA, good agreement in health study results between monitor- and model-based methods for urban areas (McGuinn et al., 2017) and general consistency in results for the conterminous U.S. (Jerrett et al., 2017; Di et al., 2016) also suggests that the fields are reliable for use in health studies. However, there are also important limitations associated with the modeled fields that should be kept in mind. First, performance evaluations

for the methods are weighted toward densely monitored urban areas at the scales of representation of the monitoring networks. Predictions at different scales or in sparsely monitored areas are relatively untested. Second, studies have reported heterogeneity in performance with relatively weak performance in parts of the western U.S., at low concentrations, at greater distance to monitors, and under conditions where the reliability and availability of key input datasets (*e.g.,* satellite retrievals and air quality modeling) are limited. Lastly, differences in predictions among different hybrid methods have also been reported and tend to be most important under conditions with the performance issues just noted. Differences in predictions can be related to the different approaches used to create long-term $PM_{2.5}$ fields (*e.g.,* averaging daily $PM_{2.5}$ fields vs. developing long-term average fields), which can be impacted by variability in monitoring schedules, and the spatial scale at which these fields are created. Future work to further characterize the performance of modeled fields will be useful in informing our understanding of the implications of using these fields to estimate $PM_{2.5}$ exposures in health studies (U.S. EPA, 2020, section 2.3.3.1.4).

In assessing how the overall mean (or median) $PM_{2.5}$ concentrations reported in key epidemiological studies can inform conclusions on the primary $PM_{2.5}$ standards, there are some important considerations. As noted in the PA, study-reported $PM_{2.5}$ concentrations reflect the averages of daily or annual $PM_{2.5}$ air quality concentrations or exposure estimates in the study population over the years examined by the study, and are not the same as the $PM_{2.5}$ design values used by the EPA to determine whether areas meet or violate the PM NAAQS (U.S. EPA, 2020, section 3.2.3.2.1). Overall mean $PM_{2.5}$ concentrations in key studies reflect averaging of short- or long-term $PM_{2.5}$ exposure estimates across locations (*i.e.,* across multiple monitors or across modeled grid cells) and over time (*i.e.,* over several years). In contrast, to determine whether areas meet or violate the NAAQS, the EPA measures air pollution concentrations at individual monitors (*i.e.,* concentrations are not averaged across monitors) and calculates design values at monitors meeting appropriate data quality and completeness criteria. For the annual $PM_{2.5}$ standard, design values are calculated as the annual arithmetic mean $PM_{2.5}$ concentration, averaged over 3 years (described in Appendix N of 40 CFR part 50). For an area to meet the NAAQS, all valid design values in that area, including the highest monitored values, must be at or below the level of the standard.

In the context of epidemiological studies that use ground-based monitors, analyses of recent air quality in U.S. CBSAs indicate that maximum annual $PM_{2.5}$ design values for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7). This comparison is more difficult for epidemiological studies that use hybrid methods. To try to address this issue, the PA also considered a second approach to evaluating information from epidemiological studies. In this approach, the PA calculated study area air quality metrics similar to $PM_{2.5}$ design values (*i.e.,* referred to in the PA as pseudo-design values; U.S. EPA, 2020, section 3.2.3.2.2) and considered the degree to which such metrics indicate that study area air quality would likely have met or violated the current standards during study periods. This approach was generally not well received by commenters during the review of the PA.

3. Overview of Risk and Exposure Assessment Information

Beyond the consideration of the scientific evidence, discussed above in section II.A.2, the EPA also considers the extent to which new or updated quantitative analyses of $PM_{2.5}$ air quality, exposure, or health risks could inform conclusions on the adequacy of the public health protection provided by the current primary $PM_{2.5}$ standards. Conducting such quantitative analyses, if appropriate, could inform judgments about the potential for additional public health improvements associated with $PM_{2.5}$ exposure and related health effects and could help to place the evidence for specific effects into a broader public health context.

To this end, the PA includes a risk assessment that estimates population-level health risks associated with $PM_{2.5}$ air quality that has been adjusted to simulate air quality scenarios of policy interest (*e.g.,* ''just meeting'' the current standards). The general approach to estimating $PM_{2.5}$-associated health risks combines concentration-response functions from epidemiological studies with model-based $PM_{2.5}$ air quality surfaces, baseline health incidence data, and population demographics for 47 urban study areas (U.S. EPA, 2020, section 3.3, Figure 3–10 and Appendix C).

The risk assessment estimates that the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S. For example, when air quality in the 47 study areas is adjusted to simulate just meeting the current standards, the risk assessment estimates from about 16,000 to 17,000 long-term $PM_{2.5}$ exposure-related deaths from ischemic heart disease in a single year (*i.e.,* confidence intervals range from about 12,000 to 21,000 deaths).[41] Compared to the current annual standard, meeting a revised annual standard with a lower level is estimated to reduce $PM_{2.5}$-associated health risks by about 7 to 9% for a level of 11.0 $\mu g/m^3$, 14 to 18% for a level of 10.0 $\mu g/m^3$, and 21 to 27% for a level of 9.0 $\mu g/m^3$.

Uncertainty in risk estimates (*e.g.,* in the size of risk estimates) can result from a number of factors, including assumptions about the shape of the concentration-response relationship with mortality at low ambient PM concentrations, the potential for confounding and/or exposure measurement error in the underlying epidemiological studies, and the methods used to adjust $PM_{2.5}$ air quality. The PA characterizes these and other sources of uncertainty in risk estimates using a combination of quantitative and qualitative approaches (U.S. EPA, 2020, Appendix C, section C.3). As detailed further below in II.B.1, some members of CASAC advised that the risk assessment estimates did not provide useful information about whether the current standard is protective, while other members thought they were useful to understand potential impacts of alternative standards.

B. Conclusions on the Primary $PM_{2.5}$ Standards

In drawing conclusions on the adequacy of the current primary $PM_{2.5}$ standards, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the evidence base, information, and policy judgments that were the foundation of the last review and reflects upon the body of evidence and information newly available in this review. In so doing, he considered the large body of evidence presented and assessed in the ISA (U.S.

[41] For the only other cause-specific mortality endpoint evaluated (*i.e.,* lung cancer), substantially fewer deaths were estimated (U.S. EPA, 2020, section 3.3.2, *e.g.,* Figure 3–5). Risk estimates were not generated for other ''likely to be causal'' outcome categories (*i.e.,* respiratory effects, nervous system effects).

EPA, 2019), the policy-relevant and risk-based conclusions and rationales as presented in the PA (U.S. EPA, 2020), views expressed by CASAC, and public comments. The Administrator has taken into account both evidence- and risk-based considerations in developing final conclusions on the adequacy of the current primary $PM_{2.5}$ standards. Evidence-based considerations include the assessment of epidemiological, animal toxicologic, and controlled human exposure studies evaluating long- or short-term exposures to $PM_{2.5}$ and the integration of evidence across each of these disciplines. These considerations, as assessed in the ISA (U.S. EPA, 2019), focus on the policy-relevant considerations, as discussed in II.A.2 above and in the PA (U.S. EPA, 2020, section 3.2.1). Risk-based considerations draw from the results of the quantitative analyses and policy-relevant considerations as discussed in II.A.3 above and in the PA (U.S. EPA, 2020, section 3.3.2).

Section II.B.1 summarizes the advice and recommendations of the CASAC. Section II.B.2 below summarizes the basis for the Administrator's proposed decision, drawing from section II.C.3 of the proposal, and section II.B.3 addresses public comments on the proposed decision. The Administrator's conclusions in this review regarding the adequacy of the current primary standard and whether any revisions are appropriate are described in section II.B.4.

1. CASAC Advice in This Review

With regard to the process for reviewing the PM NAAQS, the CASAC requested the opportunity to review a second draft ISA (Cox, 2019b, p. 1 of letter) and recommended that ''the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise)'' (Cox, 2019b, p. 2 of letter). As discussed above in section I.D, the Agency's responses to these recommendations were described in a letter from the Administrator to the CASAC chair (Wheeler, 2019).

As part of its review of the draft PA, the CASAC provided advice on the adequacy of the public health protection afforded by the current primary $PM_{2.5}$ standards.[42] Its advice is documented in a letter sent to the EPA Administrator (Cox, 2019a). In this letter, the committee recommended retaining the current 24-hour $PM_{2.5}$ standard but did not reach consensus on whether the scientific and technical information support retaining or revising the current annual standard. In particular, though the CASAC agreed that there is a long-standing body of health evidence supporting relationships between $PM_{2.5}$ exposures and various health outcomes, including mortality and serious morbidity effects, individual CASAC members ''differ[ed] in their assessments of the causal and policy significance of these associations'' (Cox, 2019a, p. 8 of consensus responses). Drawing from this evidence, ''some CASAC members'' expressed support for retaining the current annual standard while ''other members'' expressed support for revising that standard in order to increase public health protection (Cox, 2019a, p.1 of letter). These views are summarized below.

The CASAC members who supported retaining the current annual standard expressed the view that substantial uncertainty remains in the evidence for associations between $PM_{2.5}$ exposures and mortality or serious morbidity effects. These committee members asserted that ''such associations can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias'' (Cox, 2019a, p. 8 of consensus responses). They noted that associations do not necessarily reflect causal effects, and they contended that recent epidemiological studies reporting positive associations at lower estimated exposure concentrations mainly confirm what was anticipated or already assumed in setting the 2012 NAAQS. In particular, they concluded that such studies have some of the same limitations as prior studies and do not provide new information calling into question the existing standard. They further asserted that ''accountability studies provide potentially crucial information about whether and how much decreasing $PM_{2.5}$ causes decreases in future health effects'' (Cox, 2019a, p. 10), and they cited recent reviews (*i.e.,* Henneman et al., 2017; Burns et al., 2019) to support their position that in such studies, ''reductions of $PM_{2.5}$ concentrations have not clearly reduced mortality risks'' (Cox, 2019a, p. 8 of consensus responses). Thus, the committee members who supported retaining the current annual standard advise that, ''while the data on associations should certainly be carefully considered, this data should not be interpreted more strongly than warranted based on its methodological limitations'' (Cox, 2019a, p. 8 of consensus responses).

These members of the CASAC further concluded that the $PM_{2.5}$ risk assessment does not provide a valid basis for revising the current standards. This conclusion was based on concerns that (1) ''the risk assessment treats regression coefficients as causal coefficients with no justification or validation provided for this decision;'' (2) the estimated regression concentration-response functions ''have not been adequately adjusted to correct for confounding, errors in exposure estimates and other covariates, model uncertainty, and heterogeneity in individual biological (causal) [concentration-response] functions;'' (3) the estimated concentration-response functions ''do not contain quantitative uncertainty bands that reflect model uncertainty or effects of exposure and covariate estimation errors;'' and (4) ''no regression diagnostics are provided justifying the use of proportional hazards . . . and other modeling assumptions'' (Cox, 2019a, p. 9 of consensus responses). These committee members also contended that details regarding the derivation of concentration-response functions, including specification of the beta values and functional forms, were not well-documented, hampering the ability of readers to evaluate these design details. Thus, these members ''think that the risk characterization does not provide useful information about whether the current standard is protective'' (Cox, 2019a, p. 11 of consensus responses).

Drawing from their evaluation of the evidence and the risk assessment, these committee members concluded that ''the Draft PM PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current 2012 $PM_{2.5}$ annual standard'' (Cox, 2019a, p.1 of letter).

In contrast, ''[o]ther members of CASAC conclude[d] that the weight of the evidence, particularly reflecting recent epidemiology studies showing positive associations between $PM_{2.5}$ and health effects at estimated annual average $PM_{2.5}$ concentrations below the current standard, does reasonably call into question the adequacy of the 2012 annual $PM_{2.5}$ [standard] to protect public health with an adequate margin of safety'' (Cox, 2019a, p.1 of letter). The committee members who supported this conclusion noted that the body of health evidence for $PM_{2.5}$ not only includes the repeated demonstration of associations in epidemiological studies, but also includes support for biological

[42] The CASAC also provided advice on the draft ISA's assessment of the scientific evidence (Cox, 2019b). That advice, and the resulting changes made in the final ISA and final PA, are summarized in section II.B.3 of the proposal (85 FR 24114, April 30, 2020).

plausibility established by controlled human exposure and animal toxicology studies. They pointed to recent studies demonstrating that the associations between $PM_{2.5}$ and health effects occur in a diversity of locations, in different time periods, with different populations, and using different exposure estimation and statistical methods. They concluded that ''the entire body of evidence for PM health effects justifies the causality determinations made in the Draft PM ISA'' (Cox, 2019a, p. 8 of consensus responses).

The members of the CASAC who supported revising the current annual standard particularly emphasized recent findings of associations with $PM_{2.5}$ in areas with average long-term $PM_{2.5}$ concentrations below the level of the annual standard and studies that show positive associations even when estimated exposures above 12 μg/m³ are excluded from analyses. They found it ''highly unlikely'' that the extensive body of evidence indicating positive associations at low estimated exposures could be fully explained by confounding or by other non-causal explanations (Cox, 2019a, p. 8 of consensus responses). They additionally concluded that ''the risk characterization does provide a useful attempt to understand the potential impacts of alternate standards on public health risks'' (Cox, 2019a, p. 11 of consensus responses). These committee members concluded that the evidence available in this review reasonably calls into question the protection provided by the current primary $PM_{2.5}$ standards and supports revising the annual standard to increase that protection (Cox, 2019a).

2. Basis for Proposed Decision

On April 14, 2020, the Administrator proposed to retain the current primary $PM_{2.5}$ standards. This proposal was published in the **Federal Register** on April 30, 2020 (85 FR 24094, April 30, 2020). In reaching his proposed decision to retain the current $PM_{2.5}$ standards (*i.e.,* annual and 24-hour $PM_{2.5}$ standards), the Administrator considered the assessment of the available evidence and conclusions reached in the ISA (U.S. EPA, 2019); the analyses in the PA (U.S. EPA, 2020), including uncertainties in the evidence and analyses; and the advice and recommendations from the CASAC. These considerations are summarized briefly below and discussed in detail in the proposal notice (85 FR 24094, April 30, 2020).

As described further in section II.A.2 of the proposal, the Administrator's consideration of the public health protection provided by the current primary $PM_{2.5}$ standards were based on his consideration of the combination of the annual and 24-hour standards, including the indicators ($PM_{2.5}$), averaging times, forms (arithmetic mean and 98th percentile, averaged over three years), and levels (12.0 μg/m³, 35 μg/m³) of those standards.

The Administrator's proposed decision noted that one of the methodological limitations highlighted by the CASAC members who support retaining the annual standard (see section II.B.1 above) is that associations reported in epidemiological studies are not necessarily indicative of causal relationships and such associations ''can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias'' (Cox, 2019a, p.8). In the proposed decision, the Administrator recognized that epidemiological studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, and they do not identify particular $PM_{2.5}$ exposures that cause effects, as noted in the PA (U.S. EPA, 2020, section 3.1.2). The Administrator's proposed decision noted that experimental studies do provide evidence for health effects following particular $PM_{2.5}$ exposures under carefully controlled laboratory conditions and further notes that the evidence for a given $PM_{2.5}$-related health outcome is strengthened when results from experimental studies demonstrate biologically plausibility mechanisms through which such an outcome could occur. In the proposed decision, therefore, the Administrator expressed greatest confidence in the potential for $PM_{2.5}$ exposures to cause adverse effects at concentrations supported by multiple types of studies, including experimental studies as well as epidemiological studies.

In the proposed decision, in light of this approach to considering the evidence, the Administrator recognized that controlled human exposure and animal toxicology studies report a wide range of effects, many of which are plausibly linked to the serious cardiovascular and respiratory outcomes reported in epidemiological studies (including mortality), though he noted that the $PM_{2.5}$ exposures examined in these studies are above the concentrations typically measured in areas meeting the current annual and 24-hour standards (U.S. EPA, 2020, section 3.2.3.1). The Administrator was cautious about placing too much weight on reported $PM_{2.5}$ health effect associations for air quality meeting the current annual and 24-hour standards. He concluded in the proposed decision that such associations alone, without supporting experimental evidence at similar $PM_{2.5}$ considerations, left important questions unanswered regarding the degree to which the typical $PM_{2.5}$ exposures likely to occur in areas meeting the current standard could cause the mortality and morbidity outcomes reported in epidemiological studies. Given this concern, the Administrator noted in the proposal that he did not think that recent epidemiological studies reporting health effect associations at $PM_{2.5}$ air quality concentrations likely to have met the current primary standards support revising those standards. Rather, he judged that the overall body of evidence, including controlled human exposure and animal toxicologic studies, in addition to epidemiological studies, indicated continuing uncertainty in the degree to which adverse effects could result from $PM_{2.5}$ exposure in areas meeting the current annual and 24-hour standards.

The Administrator also considered the emerging body of evidence from accountability studies examining past reductions in ambient $PM_{2.5}$, and the degree to which those reductions resulted in public health improvements, but also recognized that interpreting such studies in the context of the current primary $PM_{2.5}$ standards was complicated by the fact that some of the available accountability studies have not evaluated $PM_{2.5}$ specifically, did not show changes in $PM_{2.5}$ air quality, or have not been able to disentangled health impacts of the interventions from background trends in health. The Administrator also recognized that the small number of available studies that do report public health improvements following past declines in ambient $PM_{2.5}$ have not examined air quality meeting the current standard. Together with the Administrator's concerns regarding the lack of experimental studies examining $PM_{2.5}$ exposures typical of areas meeting the current standards, the lack of demonstrated health improvements in areas with air quality meeting the current standards led him to conclude, at the time of proposal, that there was considerable uncertainty in the potential for increased public health protection from further reductions in ambient $PM_{2.5}$ concentrations beyond those achieved under the current primary $PM_{2.5}$ standards.

In addition to the evidence, the Administrator also considered the potential implications of the risk assessment for his proposed decision, noting that all risk assessments have limitations. He noted that such limitations in risk estimates can result

from uncertainty in the shapes of concentration-response functions, particularly at low concentrations; uncertainties in the methods used to adjust air quality; and uncertainty in estimating risks for populations, locations and air quality distributions different from those examined in the underlying epidemiological study. The Administrator noted agreement with some members of the CASAC who expressed concerns regarding limitations in the epidemiological evidence, which provides key inputs to the risk assessment. Thus, he judged it appropriate to place little weight on quantitative estimates of $PM_{2.5}$-associated mortality risk in reaching proposed conclusions on the primary $PM_{2.5}$ standards.

In reaching his proposed decision to retain the current primary $PM_{2.5}$ standards, the Administrator concluded that the scientific evidence assessed in the ISA (U.S. EPA, 2019), and the analyses based on that evidence in the PA (U.S. EPA, 2020), do not call into question the public health protection provided by the current annual and 24-hour $PM_{2.5}$ standards. In particular, the Administrator judged that there is considerable uncertainty in the potential for additional public health improvements from reducing ambient $PM_{2.5}$ below the concentrations achieved under the current primary standards and, therefore, that standards more stringent than the current standards (*e.g.,* with lower levels) are not supported. That is, he judged that such standards would be more than requisite to protect the public health with an adequate margin of safety. This judgment reflected his consideration of the uncertainties in the potential implications of recent epidemiological studies due in part to the lack of supporting evidence from experimental studies and accountability studies conducted at $PM_{2.5}$ concentrations meeting the current standards.

In addition, based on the Administrator's review of the science, including experimental and accountability studies conducted at levels just above the current standard, he judged that the degree of public health protection provided by the current standard is not greater than warranted. This judgment, together with the fact that no CASAC member expressed support for a less stringent standard, led the Administrator to conclude that standards less stringent than the current standards (*e.g.,* with higher levels) are also not supported.

Thus, based on his consideration of the available scientific evidence and technical information and his consideration of advice from the CASAC, the Administrator proposed to conclude that the current suite of primary standards, including the current indicators ($PM_{2.5}$), averaging times (annual and 24-hour), forms (arithmetic mean and 98th percentile, averaged over three years) and levels (12.0 μg/m^3, 35 μg/m^3), remain requisite to protect the public health. As discussed in detail in the proposal (85 FR 24094, April 30, 2020), this proposed conclusion reflected his judgment that limitations in the science lead to considerable uncertainty regarding the potential public health implications of revising the existing suite of $PM_{2.5}$ standards. Therefore, the Administrator proposed to retain the current standards, without revision.

3. Comments on the Proposed Decision

Overall, the EPA received a large number of unique public comments on the proposed decision to retain the annual and 24-hour $PM_{2.5}$ standards. These comments generally fall into one of two broad groups that expressed sharply divergent views. The first group is comprised of the many commenters, representing industries and industry groups, some state and local governments, and independent organizations, that support the Administrator's proposed decision to retain the primary $PM_{2.5}$ standards. The second group of commenters are those who asserted that the current primary $PM_{2.5}$ standards are not sufficient to protect public health with an adequate margin of safety. These commenters disagree with the EPA's proposed decision to retain the current $PM_{2.5}$ standards and generally recommend a revised annual standard of between 8–10 μg/m^3 and a revised 24-hour standard between a range of 25–30 μg/m^3. Among those calling for revisions to the current primary $PM_{2.5}$ standards were commenters representing national public health, medical, and environmental nongovernmental organization, tribes and tribal groups, some state and local governments and independent organizations and individuals.

We address the key public comments received on the proposal (85 FR 24094, April 30, 2020) and present the EPA's responses to those comments below. A more detailed summary of all significant comments, along with the EPA's responses (henceforth ''Response to Comments''), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–0072). This document is available for review in the docket for this rulemaking and through the EPA's NAAQS website (*https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*).

With respect to the various elements of the standards, the EPA received very few comments related to indicator and none advocate for revising the current $PM_{2.5}$ indicator for fine particles. Those who express explicit support for retaining the current $PM_{2.5}$ indicator generally endorse the rationale put forward in the PA. The EPA agrees with these commenters, noting that the scientific evidence in this review, as in the last review, continues to provide strong support for health effects following short- and long-term $PM_{2.5}$ exposures and that the available information remains too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components or to support a distinct standard for the ultrafine fraction.

The EPA also received very few comments on averaging time and form. Those who did provide comments are mostly affiliated with public health organizations and environmental advocacy groups and generally discuss the need for future evaluation of the form and averaging time of the current 24-hour standard (98th percentile, averaged over three years). These commenters, acknowledging the current limitations and uncertainties in the available evidence, suggest that in future reviews the EPA should evaluate how well the current form of the 24-hour standard protects against potential sub-daily exposures based on new epidemiological and experimental evidence that considers sub-daily exposures, but these commenters support retaining the current indicators, averaging times, and forms.

The EPA acknowledges the comments related to averaging time and form of the 24-hour standard and agrees that the current information does not support a revision to the averaging time or form. The EPA will continue to evaluate the form and averaging time of the current 24-hour standard in future reviews based on any new relevant information.

With respect to the level of the 24-hour standard, commenters supporting revision generally support a revised level in the range of 25–30 μg/m^3. They contend the available scientific evidence supports that lower levels within this range are required to protect public health, including the health of at-risk populations, with an adequate margin of safety, and that lower levels within this range will provide additional margin of safety. The commenters cite controlled human exposure studies that assess short-term exposures (*i.e.,* 2 to 5 hours) and epidemiological studies that report

associations between adverse health effects and concentrations below the current standard level as supporting the need for this revision. They further add that while revising the 24-hour level to 25 μg/m³ would offer more health protection than 30 μg/m³, it would still not reduce the risk of adverse health outcomes to zero.

With respect to the level of the annual $PM_{2.5}$ standard, numerous comments were received that specifically focus on the Administrator's consideration of epidemiological evidence in this review. Commenters who support revision generally disagree with the Administrator's conclusions and judgments about the uncertainties in the epidemiological evidence and suggest that these studies support revision of the $PM_{2.5}$ annual standard to a level of 8–10 μg/m³. These commenters state that uncertainties in the epidemiological studies, alone, do not negate positive associations seen in studies using diverse study designs and capturing large geographic and population domains. These commenters note that the possibility of confounders and the other referenced uncertainties have been investigated and found not to be material given the overall strength and consistency of results from varying approaches. The commenters who support revising the primary $PM_{2.5}$ standards generally place substantial weight on epidemiologic evidence from multi-city U.S. and Canadian studies that captured a larger geographic domain and population size, and were included in the ISA and in the study-related analyses in the PA (U.S. EPA, 2020). Further, they also cite epidemiological studies in the ISA (U.S. EPA, 2019) that performed restricted/truncated analyses with populations living in areas of lower $PM_{2.5}$ concentrations and contend that associations still exist in these studies at the concentrations below the levels of the current annual and daily standards. Moreover, they state that there was no evidence for an ambient concentration threshold for adverse health effects at the lowest observed levels of either annual or 24-hour $PM_{2.5}$ concentrations.

The EPA disagrees with these commenters. First, the EPA notes that, consistent with past practices, the foremost consideration is the adequacy of the public health protection as provided by the combination of the annual and 24-hour standards together. The annual standard limits ''typical'' daily $PM_{2.5}$ concentrations that make up the bulk of the distribution, while the 24-hour standard adds supplemental protection against ''peak'' daily $PM_{2.5}$ concentrations. In the judgment of the Administrator, therefore, the current annual standard (arithmetic mean, averaged over three years) remains appropriate for targeting protection against the annual and daily $PM_{2.5}$ exposures around the middle portion of the $PM_{2.5}$ air quality distribution, while the current 24-hour standard (98th percentile, averaged over three years) continues to provide an appropriate balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs (U.S. EPA, 2020, section 3.5.2.3). Further, the Administrator notes that changes in $PM_{2.5}$ air quality to meet an annual standard would likely result not only in lower short- and long-term $PM_{2.5}$ concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak $PM_{2.5}$ concentrations. Similarly, the Administrator recognizes that changes in air quality to meet a 24-hour standard, would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also in lower annual average $PM_{2.5}$ concentrations.

Thus, in considering the adequacy of the 24-hour standard, an important consideration is whether additional protection is needed against short-term exposures to peak $PM_{2.5}$ concentrations. In examining the scientific evidence, the EPA notes that controlled human exposure studies do provide evidence for health effects following single, short-term $PM_{2.5}$ exposures to concentrations. These types of exposures correspond best to those to ambient exposures that might be experienced in the upper end of the $PM_{2.5}$ air quality distribution in the U.S. (*i.e.,* ''peak'' concentrations). However, and as noted above in section II.A.2.c.i, most of these studies examine exposure concentrations considerably higher than are typically measured in areas meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). In particular, controlled human exposure studies often report statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $PM_{2.5}$ concentrations at and above 120 μg/m³ (at and above 149 μg/m³ for vascular impairment, the effect shown to be most consistent across studies). Commenters did specifically note one study (Hemmingsen et al., 2015b) and contend that this study shows significant effects on some outcomes at lower concentrations, following 5-hour exposures to 24 μg/m³. The PA notes that this study does not report effects consistent with other studies in the ISA that evaluate longer exposure durations (*i.e.,* longer than 2 hours) and lower $PM_{2.5}$ concentrations (*e.g.,* Bräuner et al., 2008 and Hemmingsen et al., 2015a). Furthermore, analyses in the PA show that the exposure concentrations included in this study are not observed in areas meeting the current standards (U.S. EPA, 2020, Figure A–2), suggesting that the current standards provide protection against these exposure concentrations. To provide insight into what these studies may indicate regarding the primary $PM_{2.5}$ standards, the PA (U.S. EPA, 2020, p.3–49) notes that 2-hour ambient concentrations of $PM_{2.5}$ at monitoring sites meeting the current standards almost never exceed 32 μg/m³. In fact, even the extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations at sites meeting the current standards remains well-below the $PM_{2.5}$ exposure concentrations consistently shown in controlled human exposure studies to elicit effects (*i.e.,* 99.9th percentile of 2-hour concentrations at these sites is 68 μg/m³ during the warm season). Thus, available $PM_{2.5}$ controlled human exposure studies do not indicate the need for additional protection against exposures to peak $PM_{2.5}$ concentrations, beyond the protection provided by the combination of the current 24-hour standard and the current annual standard (U.S. EPA, 2020, section 3.2.3.1). With respect to the epidemiological evidence and as noted above in section II.A.2.c.ii, the information from such studies is most applicable to examining potential health impacts associated with typical (*i.e.,* average or mean) exposures and thus are most applicable in informing decisions on the annual standard (with its arithmetic mean form). Furthermore, as noted above, the available epidemiological studies do not indicate that associations in these studies are strongly influenced by exposures to peak concentrations in the air quality distribution, and thus do not indicate the need for additional protection against short-term exposures to peak $PM_{2.5}$ concentrations. As discussed above, the annual standard provides protection against the typical 24-hour and annual $PM_{2.5}$ exposures. Thus, in the context of a 24-hour standard that is meant to provide supplemental protection (*i.e.,* beyond that provided by the annual standard alone) against short-term exposures to peak $PM_{2.5}$ concentrations, the available evidence supports the Administrator's proposed conclusion to retain the current 24-hour standard with its level of 35 μg/m³.

With respect to commenters that support revision of the annual standard,

the EPA recognizes that there are a large number of studies, many of which include a variety of study populations and geographic locations, that show positive associations between mortality and morbidity and short-term and long-term $PM_{2.5}$ exposure. Furthermore, the EPA recognizes that while uncertainties exist, when the epidemiological evidence is viewed together in the context of the full body of evidence, the scientific information supports that exposure to $PM_{2.5}$ may cause adverse health effects (U.S.EPA, 2019, section 1.7.3, Table 1–4). Therefore, the EPA does not dispute commenters that note epidemiological studies support the conclusion that exposure to $PM_{2.5}$ is associated with morbidity and mortality.

However, while the epidemiological evidence when considered together with the full body of evidence supports health effects associated with $PM_{2.5}$ exposure, the EPA recognizes that important uncertainties and limitations in the health effects evidence remain. Epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in associations between cities and geographic regions within the U.S. Heterogeneity in the associations observed across $PM_{2.5}$ epidemiological studies may be due in part to exposure error related to measurement-related issues, the use of central fixed-site monitors to represent population exposure to $PM_{2.5}$, models used in lieu of or to supplement ambient measurements, limitations in hybrid models and our limited understanding of factors that may influence exposures (*e.g.,* topography, the built environment, weather, source characteristics, ventilation usage, personal activity patterns, photochemistry) (U.S. EPA, 2020, p.3–25), all of which can introduce bias and/or increased uncertainty is associated health effects estimates. Heterogeneity is expected when the methods or underlying distribution of covariates vary across studies (U.S. EPA, 2019, p. 6–221). In addition, where $PM_{2.5}$ and other pollutants (*e.g.,* ozone, nitrogen dioxide, and carbon monoxide) are correlated, it can be difficult to distinguish whether attenuation of effects in some studies results from copollutant confounding or collinearity with other pollutants in the ambient mixture (U.S. EPA, 2019, section 1.5.1). The EPA also recognizes that methodological study designs to address confounding, such as causal inference methods, are an emerging field of study (U.S. EPA, 2019, section 11.2.2.4 or U.S. EPA, 2020, p. 3–24). The Administrator weighs these uncertainties in the reported associations of $PM_{2.5}$ concentrations in the studies and considers them in the context of the entire body of evidence before the Agency when reviewing the standards.

Additionally, while epidemiological studies indicate associations between exposure to $PM_{2.5}$ and health effects, they do not identify particular $PM_{2.5}$ exposures that cause effects (section II.A.2.c.ii above and U.S. EPA, 2020, section 3.1.2). Further, using information from epidemiological studies to inform decisions on $PM_{2.5}$ standards is complicated by the recognition that no population threshold, below which it can be concluded with confidence that $PM_{2.5}$-related effects do not occur, can be discerned from the available evidence. As a result, any general approach to reaching decisions on what standards are appropriate necessarily requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards. This includes consideration of how to weigh the uncertainties in the reported associations in the epidemiological studies and the uncertainties in quantitative estimates of risk, in the context of the entire body of evidence before the Agency. Such approaches are consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

Commenters who support revising the $PM_{2.5}$ standards further contend that the Administrator has arbitrarily rejected an established practice of relying on epidemiological studies and of setting the standard below the long-term mean $PM_{2.5}$ concentrations reported in each of the studies that provide evidence of an array of serious health effects. The commenters state that in declaring that the latest epidemiological studies cannot justify a decision to strengthen the PM NAAQS, the Administrator has rejected—without acknowledgment or explanation—the EPA's long history of relying on such research as the basis for its primary standards.

As recognized in this and previous PM NAAQS reviews, including those completed in 2006 and 2012, evidence of an association in any epidemiological study is ''strongest at and around the long-term average where the data in the study are most concentrated.'' In the PA (U.S. EPA, 2020, section 3.2.3.2.1), the EPA assessed air quality distributions reported in key epidemiological studies included in the ISA, with a focus on characterizing the long-term average or mean $PM_{2.5}$ concentrations. In doing this, key studies [43] were identified that examined short- and long-term exposure and showed positive associations with either mortality or morbidity health outcomes. The studies either estimated $PM_{2.5}$ exposure using ground-based monitored data or using hybrid modeling data, which incorporate data from several sources, often including satellites and models, as well as ground-based monitors (U.S. EPA, 2020, section 2.3.3). The PA notes some important considerations in using study reported concentrations to inform conclusions on the primary $PM_{2.5}$ standards. In particular, it notes that the overall mean $PM_{2.5}$ concentrations reported by key epidemiological studies are not the same as the ambient concentrations used by the EPA to determine whether areas meet or violate the PM NAAQS. Mean $PM_{2.5}$ concentrations in key studies reflect averaging of short- or long-term $PM_{2.5}$ exposure estimates across locations (*i.e.,* across multiple monitors or across modeled grid cells) and over time (*i.e.,* over several years). In contrast, to determine whether areas meet or violate the PM NAAQS, the EPA measures air pollution concentrations at individual monitors (*i.e.,* concentrations are not averaged across monitors) and calculates design values [44] at monitors meeting appropriate data quality and completeness criteria.[45] For an area to meet the NAAQS, all valid design values in that area, including the highest annual and highest 24-hour monitoring values, must be at or below the standards. As a result, study reported mean concentration values are generally lower than the design value of the highest monitor in an area, which determines compliance.

The PA first presents results from key epidemiological studies that used ground-based monitoring data to estimate population exposure (U.S. EPA, 2020, section 3.2.3.2.1). Study reported mean (or medians) [46] were

[43] Studies included were multi-city studies in Canada and the U.S. that examined health endpoints with 'causal' or 'likely to be causal' determinations in the ISA.

[44] A design value is a statistic that summarizes the air quality data for a given area in terms of the indicator, averaging time, and form of the standard. Design values can be compared to the level of the standard and are typically used to designate areas as meeting or not meeting the standard and assess progress towards meeting the NAAQS.

[45] For the annual $PM_{2.5}$ standard, design values are calculated as the annual arithmetic mean $PM_{2.5}$ concentration, averaged over 3 years (described in appendix N of 40 CFR part 50). For the 24-hour standard, design values are calculated as the 98th percentile of the annual distribution of the 24-hour $PM_{2.5}$ concentrations, averaged over three years.

[46] Some epidemiological studies report median versus mean air quality concentrations offering that

examined from the air quality distributions reported in key epidemiological studies included in the ISA exposures (U.S. EPA, 2020, Figure 3–7). The PA noted that these values are most useful in the context of considering the level of the primary $PM_{2.5}$ annual standard. This is because the mean concentration values from these studies, which include studies examining both short- and long-term exposures, represent ''typical'' or mean exposures, which are most relevant to the form and averaging time of the annual standard, and not as relevant to the daily standard, whose form and averaging time focuses on protecting against peak concentrations. Further, the PA noted that in using these data it should be recognized that these mean concentrations are generally below the design values in the corresponding areas. In fact, analyses included in the PA of recent air quality in U.S. CBSAs indicate that maximum annual $PM_{2.5}$ design values for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7). As noted in the PA, the difference between the maximum annual design value and the average concentrations in an area will depend on a number of factors including the numbers of monitors, monitor citing characteristics, and the distribution of ambient $PM_{2.5}$ concentrations. The PA also recognized that the recent requirement for $PM_{2.5}$ monitoring at near-road locations in large urban areas may further increase the ratios of maximum annual design values to average concentrations in some areas (U.S. EPA, 2020, section 3.2.3.2.1).

As detailed more in section II.A.2.c.ii, the PA next presents data from the epidemiological studies that used hybrid modeling approaches to estimate exposures (U.S. EPA, 2020, Figure 3–8). While studies using hybrid modeling approaches provide valid methods to estimate exposures in epidemiological studies and can expand the characterization of $PM_{2.5}$ exposures in areas with sparse monitoring networks, these exposure estimation methods provide additional challenges to comparing study reported mean concentrations to the annual standard level. In these studies, $PM_{2.5}$ concentrations are typically estimated based on a hybrid approach of ''fusing'' data from air quality models, satellites and ground-based monitors. As such, the reported mean concentrations in an area (*e.g.,* county or zip-code) from these studies are calculated using the estimated concentrations from thousands of grid cells across the area. Generally, this means a larger number of lower concentration grid cells being included in the calculation of the mean, resulting in a mean concentration even further below the design value of the highest monitor in the area (which is used for determining whether the area is meeting the current standard) and even further below the mean concentration reported in epidemiological studies utilizing ground-based monitors to estimate exposure.

It is also important to note that the performance of these hybrid modeling approaches in estimating $PM_{2.5}$ concentrations, which are being used as surrogates for population exposure in the epidemiological study, depends on the availability of monitoring data, air quality model and the ability of the satellite to estimate ground level concentration and, thus, varies by location. Factors that contribute to poorer model performance often coincide with relatively low ambient $PM_{2.5}$ concentrations (U.S. EPA 2020, 2.3.3) Thus, uncertainty in hybrid model predictions becomes an increasingly important issue as lower predicted concentrations are considered. This additional source of uncertainty is an important consideration, particularly when all grid cell estimates are being used to calculate the study mean concentration, and further adds to why using study reported mean concentrations from epidemiological studies that use hybrid approaches to inform conclusions on the primary $PM_{2.5}$ standards is a challenge.

Given all of this, the EPA concludes that the overall mean $PM_{2.5}$ concentrations in hybrid modeling studies are more difficult to directly compare to design values than ground-based monitoring concentrations in the context of setting a standard level. In fact, recognizing this challenge, the PA tried to assess information from hybrid modelling studies by calculating ''pseudo-design values'' in locations of the key epidemiological studies (U.S. EPA, 2020, section 3.2.3.2.2), as noted above in section II.A.2.c.ii and detailed further in section II.C.1.a.ii of the proposal (85 FR 24117, April 30, 2020). However, this analysis and the associated approach were highly criticized by most commenters, with none suggesting the methodology be carried forward in the review. While the EPA believes that the PA's ''pseudo-design value'' approach was a step in the right direction, the specific methodology itself needs further development.

Given these considerations, and in light of the comments received, the EPA believes it is reasonable to focus on study reported mean (or median) concentrations [47] from key U.S.[48] epidemiological studies that used ground-based monitors when considering information most comparable to the current annual standard, while also weighing the uncertainties associated with these studies and considering support provided by other lines of evidence. Based on the information shown in Figure 3–7 of the PA (U.S. EPA, 2020), the mean concentrations in 19 of the 21 these studies were equal to or greater than the level of the current annual standard of 12 μg/m³. There were two studies, both included in last review, for which the mean concentration (11.8 μg/m³; Peng et al., 2009) or median concentration (10.7 μg/m³ (Central Region); Zeger et al., 2008 [49]) was somewhat below 12 μg/m³. While these studies were included in the last review, the air quality distributions were not used by the prior Administrator in making a judgment on the level of the standard. The reported study mean concentration for one other study was 12 μg/m³ (Kioumourtzoglou et al., 2016). The mean [50] of the study reported means (or medians) of these 21 studies is 13.5 μg/m³, a concentration level above the current level of the primary annual standard of 12 μg/m³. Additionally, based on analyses in the PA, it would be expected that most of the design values (the metric most relevant for comparison to the standard level) in the areas included in these studies would be greater than 12 μg/m³ [51] (section II.A.2.c.ii above and U.S.

median is a better metric since it is less skewed by outlying concentrations. In most studies, the mean and median concentrations are very similar and are generally used here interchangeably.

[47] Some epidemiological studies report median versus mean air quality concentrations offering that median is a better metric since it is less skewed by outlying concentrations. In most studies, the mean and median concentrations are very similar and are generally used here interchangeably.

[48] Given how air quality monitors in other countries differ from the U.S. EPA FRM monitors discussed here, a focus on U.S. studies ensures that the results most closely compare to the data being used for calculating the design values and for compliance of the standard.

[49] We note that in this study the population was divided into regions of the country, with statistically significant associations in the Central and Eastern Regions and with median long-term $PM_{2.5}$ concentrations of: Central: 10.7 μg/m³; Western: 13.1 μg/m³ and Eastern: 14.0 μg/m³.

[50] The median of the study reported mean (or median) $PM_{2.5}$ concentrations is 13.3 μg/m³.

[51] Recent air quality in U.S. CBSAs in the PA indicate that maximum annual $PM_{2.5}$ design values

Continued

EPA 2020, Appendix B, section B.7). This is also supported by the pseudo-design value analysis in Figure 3–9 of the PA (U.S. EPA, 2020).

Therefore, although recognizing that the proposal identified certain concerns about the proper weight to be placed on epidemiological studies, the EPA finds that its assessment of the mean concentrations of the key short-term and long-term epidemiological studies in the U.S. that use ground-based monitoring (*i.e.,* those studies that can provide information most directly comparable to the current annual standard) is fundamentally consistent with the assessment in the last review, which established the current primary $PM_{2.5}$ standards.

Some commenters supporting revision of the primary $PM_{2.5}$ standards contend that the quantitative risk assessment finds the number of avoided deaths resulting from retention of the standards will likely number in the many thousands, and a substantial reduction in these events could be achieved by a more stringent $PM_{2.5}$ standard. While commenters who support revising the $PM_{2.5}$ standards support the recommendation of the PA to use the evidence-based approach, as opposed to the risk-based approach, as a basis for ascertaining whether and how to revise the primary standards, the commenters state that the risk assessment does provide qualitative support to revise the standards.

With regard to the quantitative risk assessment described by some commenters as showing health impacts that would be avoided by a more stringent standard, the EPA notes that these analyses utilize epidemiological study effect estimates as concentration-response functions to predict the occurrence of primarily premature mortality under different air quality conditions (characterized by the metric used in the epidemiological study). While the epidemiological studies that are inputs to the quantitative risk assessment are part of the evidence base that supports the conclusion of a ''causal'' or ''likely to be causal'' determination in the ISA (U.S. EPA, 2019), there are uncertainties inherent in the derivation of estimates of health effects (*e.g.,* total mortality or ischemic heart disease mortality) ascribed to $PM_{2.5}$ exposures using effect estimates from these studies. For example, the PA recognized several important uncertainties associated with aspects of the quantitative risk assessment approach and that the EPA concluded to have a medium or greater magnitude on risk estimates (U.S. EPA, 2020, section C.3.1 and table C–32). These uncertainties limit the applicability of the risk results for selecting a specific standard. Uncertainties in the shapes of concentration-response functions, particularly at low concentrations; uncertainties in the methods used to adjust air quality; and uncertainty in estimating risks for populations, locations and air quality distributions different from those examined in the underlying epidemiological study all limit utility (U.S. EPA, 2020, section 3.3.2.4). Further, the approach to weighing evidence-based and risk-based considerations is not a new approach and as in previous reviews, the selection of a specific approach to reaching final decisions on the primary $PM_{2.5}$ standards will reflect the judgments of the Administrator as to what weight to place on the various types of information available in the current review. The EPA notes that in the previous review, evidence-based considerations were given greater weight in the selection of standard levels than risk-based approaches (*e.g.,* 78 FR 3086, 3098–99, January 15, 2013) due to a recognition of similar limitations.

Some commenters who support the Administrator's rationale to retain the $PM_{2.5}$ standards contend that, due to uncertainties in extrapolating health effects observed in animal toxicology studies to humans, animal toxicology studies are of limited regarding the adequacy of the current standard. On the other hand, commenters who support revisions to the current suite of $PM_{2.5}$ standards generally contend that for experimental studies the Administrator: (1) Inappropriately tied the concept of biological plausibility to a specific concentration; (2) incorrectly interpreted animal/controlled human exposure studies; (3) ignored the limitations of experimental studies in relation to informing NAAQS levels and (4) gave inadequate weight to all of the evidence because the Administrator saw no absolute corroboration from clinical and accountability studies. The commenters emphasize their view that experimental studies provide important information regarding biological plausibility of numerous health effects (*e.g.,* cardiovascular, respiratory, nervous system, and cancer effects) associated with $PM_{2.5}$ exposure. Therefore, the commenters contend that experimental studies provide biological plausibility for human health effects linked to PM exposure in epidemiological studies and when viewed together, support revision of the current $PM_{2.5}$ standards.

The EPA notes that controlled human exposures studies provide crucial evidence in assessing whether protection is provided for short-term exposure concentrations consistently shown to elicit effects. In examining the controlled human exposure studies, the PA notes these studies provide evidence for health effects following single, short-term $PM_{2.5}$ exposures to concentrations, and thus, can be useful to assess whether these effects are likely to occur in the upper end of the $PM_{2.5}$ air quality distribution in the U.S. (*i.e.,* ''peak'' concentrations) (U.S. EPA, 2020, section 3.2.3.1). As noted by the commenters, most of these studies examine exposure concentrations considerably higher than are typically measured in areas meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). As detailed in section II.A.2.c.i above, even the extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations at sites meeting the current standards remains well-below the $PM_{2.5}$ exposure concentrations consistently shown to elicit effects. Further, human exposure studies have not reported health effects at $PM_{2.5}$ air quality concentrations likely to be seen in areas meeting the current primary $PM_{2.5}$ standards. As such, these studies do not call into question the protection provided by the current primary $PM_{2.5}$ standards.

Additionally, with respect to the experimental evidence, the EPA agrees that animal toxicologic studies can be useful in understanding and supporting the biological plausibility of various effects linked to $PM_{2.5}$ exposures. However, it is important to remember that for this body of evidence there is uncertainty in extrapolating from effects in animals to those in human populations. As such, animal toxicology studies are of limited utility in directly informing conclusions on the appropriate level of the standard. Thus, the available evidence from animal toxicologic studies do not call into question the protection provided by the current primary $PM_{2.5}$ standards.

Further, the ISA assesses both human exposures studies and animal toxicologic studies to evaluate the biological plausibility of various effects linked to $PM_{2.5}$ exposures, and thus, we agree with the commenters on the importance of experimental evidence on this account. Within the ISA's weight of evidence evaluation, which is based on the integration of findings from various lines of evidence, considerations in making causality determinations

for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7).

include: ''determining whether laboratory studies of humans and animals, in combination with epidemiological studies, inform the biological mechanisms by which PM can impart health effects and provide evidence demonstrating that PM exposure can independently cause a health effect'' (U.S. EPA, 2019, p. ES–8). However, the ISA also notes that the strength of the $PM_{2.5}$ exposure-health effects relationship varies depending on the exposure duration (*i.e.,* short- or long-term) and broad health effects category (*e.g.,* cardiovascular effects, respiratory effects) examined, and that across the broad health effects categories examined, the evidence supporting biological plausibility varies. Additionally, while assessing plausible biological pathways is an important step in evaluating causality determinations, the degree of biological plausibility for different mechanisms and end points can also vary depending on the evidence available. As a result, without a more clear linkage between concentrations below the current standard levels and adverse health effects, the Administrator noted in the proposal that he was ''cautious about placing too much weight on reported $PM_{2.5}$ health effect associations'' observed in epidemiological studies (85 FR 24119, April 30, 2020). As discussed in the proposal, the Administrator's proposed decision was based on his evaluation of ''the overall body of evidence, including controlled human exposure and animal toxicologic studies, in addition to epidemiological studies'' (85 FR 24120, April 30, 2020). Thus, the experimental evidence does not suggest that the epidemiological evidence must be viewed differently than the Administrator has viewed such evidence in his proposed decision to retain the current primary standards.

Some commenters who support retaining the current primary $PM_{2.5}$ standards assert that the currently available accountability studies do not demonstrate that further reduction of the PM NAAQS would achieve a measurable improvement in public health. In contrast, commenters opposing the Administrator's proposed decision to retain the $PM_{2.5}$ standards criticize the Administrator's heavy reliance on accountability studies to guide his decision, while emphasizing that accountability studies are just one line of evidence to inform causality. The commenters acknowledge the importance of well-designed and conducted accountability studies but warn that accountability studies measuring past interventions that are highly localized may have actual effects too small to be reliably measured. Considering the limitations of the accountability studies, including findings leading to false negative results, such studies are not considered essential for the proof of evidence required by statute, according to these commenters.

The EPA agrees with the commenters that well-designed and conducted accountability studies can be informative and should be considered as one line of evidence, recognizing that that these studies offer insight into examples of how public health has responded to implementation of $PM_{2.5}$ reduction strategies. As discussed in the PA (U.S. EPA, 2020, section 3.2.3.2.1) and in section III.C.3 of the proposal (85 FR 24120, April 30, 2020), the EPA notes the availability of several such accountability studies and other retrospective health studies examining periods of declining $PM_{2.5}$ concentrations. As indicated in Table 3–3 of the PA (U.S. EPA, 2020), these studies conducted in the U.S. indicate that declines in ambient $PM_{2.5}$ concentrations over a period of years have been associated with decreases in mortality rates and increases in life expectancy, improvements in respiratory development, and decreased incidence of respiratory disease in children. When considering the overall means in these studies (*i.e.,* the part of the air quality distribution over which the studies provide the strongest support for reported health effect associations), we find that ''starting'' annual average $PM_{2.5}$ concentrations (*i.e.,* mean concentration prior to reductions being evaluated) range from 13.2–31.5 $\mu g/m^3$ and ''ending'' concentrations ranging from 11.6–17.8 $\mu g/m^3$. As such, the EPA notes that these retrospective studies tend to focus on time periods during which ambient $PM_{2.5}$ concentrations were substantially higher than those measured more recently, as well as ''starting'' annual average $PM_{2.5}$ concentrations above those allowed by the current primary $PM_{2.5}$ standards. As a result, the EPA believes that while these studies do provide evidence of public health improvements as ambient $PM_{2.5}$ has declined over time, no current studies have examined public health improvements following reductions in ambient $PM_{2.5}$ concentrations in areas where the ''starting'' concentration met the current primary standards. Thus, while acknowledging that this is an emerging field of study for $PM_{2.5}$-related health effects, the available evidence supports the Administrator's recognition that currently, there is a lack of accountability studies that clearly demonstrate that revising the current primary $PM_{2.5}$ standards would result in public health improvements.

Commenters opposed to the Administrator's proposed decision to retain the $PM_{2.5}$ standards contend that the EPA's proposed decision is a violation of the CAA because it fails to consider sensitive populations and contains no margin of safety for them, as required under the CAA. In particular, these commenters pointed to evidence drawn from epidemiological studies that included specific at-risk groups in their study design and results.

The EPA disagrees with these comments. As discussed above, the Administrator's proposed decision to retain the current primary $PM_{2.5}$ standards followed the same general approach used in previous reviews for reaching conclusions on what standards are appropriate. As such, the Administrator recognized that judgments of how to translate information available from epidemiological studies into a basis for appropriate standards must be considered in conjunction with the uncertainties in the epidemiological studies and in the context of the entire body of evidence before the Agency. This approach recognizes that the Administrator's judgment is particularly important for a pollutant where a population threshold cannot be clearly discerned with confidence from the evidence and where clinical evidence does not demonstrate health effects at typical ambient concentrations that meet the current standards. This approach is also consistent with the CAA requirement to set standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

With respect to protection of at-risk populations, the EPA has carefully evaluated and considered evidence of effects in at-risk populations. Unlike some of the other NAAQS reviews where the epidemiological evidence may be less complete, this PM NAAQS review has the benefit of having an ISA that considered many epidemiological studies that assessed impacts for populations considered at-risk (*e.g.,* populations of older adults, children, or those with preexisting conditions, like cardiovascular disease). In addition, some of the key epidemiology studies that the EPA assessed (included in Figure 3–7 of the PA) also specifically focused on and evaluated at-risk populations, including epidemiology studies that assessed morbidity and mortality associations for age-specific

populations (*e.g.,* Medicare populations), as well as epidemiology studies that evaluated associations between $PM_{2.5}$ exposure and specific health endpoints, like hospital admissions for cardiovascular effects in populations age 65 and older. The Agency takes note that it considered these studies to inform its review of the primary $PM_{2.5}$ standards, which include at-risk populations, as well as other studies in the full body of scientific evidence in evaluating effects associated with long or short-term $PM_{2.5}$ exposures (*i.e.,* premature mortality, cardiovascular effects, cancer, and respiratory effects).

More specifically, in weighing the scientific evidence to inform his decision on requisite $PM_{2.5}$ standards with an adequate margin of safety, including protection for at-risk populations, the Administrator's proposed conclusions recognized that epidemiological studies, many of which by design include at-risk populations, examine associations between distributions of $PM_{2.5}$ air quality and health outcomes. Further, in noting that epidemiological studies do not identify particular $PM_{2.5}$ exposures that cause effects, the PA focused on the reported mean concentrations from key epidemiological studies with the aim of providing a potential translation of information from epidemiological studies into the basis for consideration on standard levels (U.S. EPA, 2020, section 3.1.2). As discussed in more detail above, for the mean concentrations of the key epidemiological studies in the U.S. that use ground-based monitoring (*i.e.,* those studies that can provide information most directly comparable to the current annual standard), the majority of studies have long-term mean (or median) concentrations above the current NAAQS (12.0 μg/m^3), with the mean of the study reported means or medians equal to 13.5 μg/m^3, a concentration level above the current level of the primary annual standard of 12 μg/m^3. The EPA notes that study reported mean (or median) concentration values are generally 10–20% lower than the design value of the highest monitor in an area, which determines compliance, and suggesting that that the current level of the standard provides even more protection than is suggested by the reported means.[52] In the proposal, the Administrator recognized that important uncertainties and limitations do remain in the epidemiological evidence and the Administrator weighed these uncertainties, while also considering support provided by other lines of evidence, in judging whether the current standards are requisite with an adequate margin of safety. The Administrator further considered the emerging body of evidence from accountability studies examining past reductions in ambient $PM_{2.5}$ and the degree to which those reductions have resulted in public health improvements. As discussed above, such studies have focused on time periods during which ambient $PM_{2.5}$ concentrations were substantially higher than those measured more recently and therefore do not demonstrate public health improvements attributable to reduction in ambient $PM_{2.5}$ at concentrations below the current standard.

Thus, the Administrator judged that the overall body of evidence indicates continued uncertainty in the degree to which adverse effects could result from $PM_{2.5}$ exposures in areas meeting the current annual and 24-hour standards. Additionally, the current annual standard is below the lowest ''starting'' concentration in the available accountability studies (*i.e.,* 13.2 μg/m^3) and below the reported mean concentration in the majority of the key U.S. epidemiological studies using ground-based monitoring data[53] (*i.e.,* mean of the reported means was 13.5 μg/m^3). In addition, concentrations in areas meeting the current 24-hour and annual standards remain well-below the $PM_{2.5}$ exposure concentrations consistently shown to elicit effects in controlled human exposure studies. In specifically assessing his proposed decision, the Administrator noted that more stringent standards would be more than requisite to protect public health with an adequate margin of safety.

4. Administrator's Conclusions

This section summarizes the Administrator's conclusions and final decisions related to the current primary $PM_{2.5}$ standards and presents his decision to retain those standards, without revision. As described above (section I.D) and in section II.A.2 of the proposal (85 FR 24105, April 30, 2020), the Administrator's approach to considering the adequacy of the current standards focuses on evaluating the public health protection afforded by the annual and 24-hour standards, taken together, against mortality and morbidity associated with long- or short-term $PM_{2.5}$ exposures. This approach recognizes that changes in $PM_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $PM_{2.5}$ concentrations and that the protection provided by the suite of standards results from the combination of all of the elements of those standards (*i.e.,* indicator, averaging time, form, level). Thus, the Administrator's consideration of the public health protection provided by the current primary $PM_{2.5}$ standards is based on his consideration of the combination of the annual and 24-hour standards, including the indicators ($PM_{2.5}$), averaging times, forms (arithmetic mean and 98th percentile, averaged over three years), and levels (12.0 μg/m^3, 35 μg/m^3) of those standards.

In establishing primary standards under the Act that are ''requisite'' to protect public health with an adequate margin of safety, the Administrator is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. He recognizes that the requirement to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified. However, the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficiently protective, but not more stringent than necessary.

Given these requirements, the Administrator's final decision in this review is a public health policy judgment drawing upon scientific and technical information examining the health effects of $PM_{2.5}$ exposures, including how to consider the range and magnitude of uncertainties inherent in that information. This public health policy judgment is based on an interpretation of the scientific and technical information that neither overstates nor understates its strengths and limitations, nor the appropriate inferences to be drawn, and is informed by the Administrator's consideration of advice from the CASAC and public comments received on the proposal notice.

As an initial matter, the Administrator recognizes that, with regard to effects classified as having evidence of a causal

[52] Analyses of recent air quality in U.S. CBSAs indicate that maximum annual $PM_{2.5}$ design values for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7).

[53] As discussed above, the means from these studies are most relatable to the level of the annual standard. However, because the reported means in these studies are based on averaging the monitored concentration across an area, they are lower than the design value for that same area, since attainment of the standard is based on the measurements at the highest monitor (and not the average across multiple monitors.)

or likely causal relationship with long or short-term $PM_{2.5}$ exposures (*i.e.,* premature mortality, cardiovascular effects, cancer, and respiratory effects), the EPA considered the full range of studies evaluating these effects, including studies of at-risk populations, to inform its review of the primary $PM_{2.5}$ standards. Thus, the Administrator notes that his judgment in this final decision reflects placing the greatest weight on evidence of effects for which the ISA determined there is a causal or likely causal relationship with long- and short-term $PM_{2.5}$ exposures.

With respect to the indicator, the Administrator recognizes that the scientific evidence in this review, as in the last review, continues to provide strong support for health effects following short- and long-term $PM_{2.5}$ exposures. He notes the PA conclusion that the available information continues to support the $PM_{2.5}$ mass-based indicator and remains too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components, and too limited to support a distinct standard for the ultrafine fraction. Further, the Administrator notes that the EPA received very few comments on the indicator, with no commenters advocating for revising the current $PM_{2.5}$ indicator for fine particles. Thus, as proposed, the Administrator concludes that it is appropriate to retain $PM_{2.5}$ as the indicator for the primary standards for fine particulates.

With respect to averaging time and form, the Administrator notes that the scientific evidence continues to provide strong support for health effects associations with both long-term (*e.g.,* annual or multi-year) and short-term (*e.g.,* mostly 24-hour) exposures to $PM_{2.5}$ and, consistent with the conclusions in the PA, judges that the current evidence does not support considering alternatives (U.S. EPA, 2020, section 3.5.2). The Administrator also notes that very few comments were received related to averaging time and form and none directly advocated for changing the form or averaging time. In the current review, epidemiological and controlled human exposure studies have examined a variety of $PM_{2.5}$ exposure durations. Epidemiological studies continue to provide strong support for health effects associated with short-term $PM_{2.5}$ exposures based on 24-hour $PM_{2.5}$ averaging periods, and the EPA notes that associations with sub-daily estimates are less consistent and, in some cases, smaller in magnitude (U.S. EPA, 2019, section 1.5.2.1; U.S. EPA, 2020, section 3.5.2.2). In addition, controlled human exposure and panel-based studies of sub-daily exposures typically examine subclinical effects, as the commenters acknowledge, rather than the more serious population-level effects that have been reported to be associated with 24-hour exposures (*e.g.,* mortality, hospitalizations). Taken together, the ISA concludes that epidemiological studies do not indicate that sub-daily averaging periods are more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019, section 1.5.2.1). Additionally, while recent controlled human exposure studies provide consistent evidence for cardiovascular effects following $PM_{2.5}$ exposures for less than 24 hours (*i.e.,* <30 minutes to 5 hours), exposure concentrations in these studies are well-above the ambient concentrations typically measured in locations meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). Thus, these studies also do not suggest the need for additional protection against sub-daily $PM_{2.5}$ exposures, beyond that provided by the current primary standards. Therefore, the Administrator's judgment is that the current 24-hour averaging time remains appropriate.

In relation to the form of the 24-hour standard (98th percentile, averaged over three years), the Administrator notes that epidemiological studies continue to provide strong support for health effect associations with short-term (*e.g.,* mostly 24-hour) $PM_{2.5}$ exposures (U.S. EPA, 2020, section 3.5.2.3) and that controlled human exposure studies provide evidence for health effects following single short-term ''peak'' $PM_{2.5}$ exposures. Thus, the evidence supports retaining a standard focused on providing supplemental protection against short-term peak exposures and supports a 98th percentile form for a 24-hour standard. The Administrator further notes that this form also provides an appropriate balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs (U.S. EPA, 2020, section 3.5.2.3). As such, the Administrator concludes, as proposed, to retain the form and averaging time of the current 24-hour standard (98th percentile, averaged over three years) and annual standard (annual average, averaged over three years).

The Administrator also proposed to retain the current levels of the 24-hour standard (98th percentile, averaged over three years) at 35 $\mu g/m^3$ and annual standard (annual average, averaged over 3 years) at 12 $\mu g/m^3$. The majority of the comments received focused on this proposed decision to retain the current levels of both standards. In reaching his final decision regarding the level of the standards, the Administrator considered the large body of evidence presented and assessed in the ISA (U.S. EPA, 2019), the policy-relevant and risk-based conclusions and rationales as presented in the PA (U.S. EPA, 2020), views expressed by the CASAC, and public comments. In particular, in considering the ISA and PA, he considers key epidemiological studies that evaluate associations between $PM_{2.5}$ air quality distributions and mortality and morbidity, including key ''accountability studies''; the availability of experimental studies to support biological plausibility; controlled human exposure studies examining effects following short-term $PM_{2.5}$ exposures; air quality analyses; and the important uncertainties and limitations associated with this information.

As an initial matter, the Administrator recognizes that the current annual standard is most effective in controlling $PM_{2.5}$ concentrations near the middle of the air quality distribution (*i.e.,* around the mean of the distribution), but can also provide some control over short-term peak $PM_{2.5}$ concentrations. On the other hand, the 24-hour standard, with its 98th percentile form, is most effective at limiting peak 24-hour $PM_{2.5}$ concentrations, but in doing so will also have an effect on annual average $PM_{2.5}$ concentrations. Thus, while either standard could be viewed as providing some measure of protection against both average exposures and peak exposures, the 24-hour and annual standards are not expected to be equally effective at limiting both types of exposures. Thus, consistent with previous reviews, the Administrator's consideration of the public health protection provided by the current primary $PM_{2.5}$ standards is based on his consideration of the combination of the annual and 24-hour standards. Specifically, he recognizes that the annual standard is more likely to appropriately limit the ''typical'' daily and annual exposures that are most strongly associated with the health effects observed in epidemiological studies. The Administrator concludes that an annual standard (arithmetic mean, averaged over three years) remains appropriate for targeting protection against the annual and daily $PM_{2.5}$ exposures around the middle portion of the $PM_{2.5}$ air quality distribution. Further, recognizing that the 24-hour standard (with its 98th percentile form) is more directly tied to short-term peak $PM_{2.5}$ concentrations, and thus more likely to appropriately limit exposures to such concentrations, the Administrator concludes that the

current 24-hour standard (98th percentile, averaged over three years) remains appropriate to provide a balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs. However, the Administrator recognizes that changes in $PM_{2.5}$ air quality to meet an annual standard would likely result not only in lower short- and long-term $PM_{2.5}$ concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak $PM_{2.5}$ concentrations. The Administrator further recognizes that changes in air quality to meet a 24-hour standard, with a 98th percentile form, would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also in lower annual average $PM_{2.5}$ concentrations.

Thus, in considering the adequacy of the 24-hour standard, the Administrator notes the importance of considering whether additional protection is needed against short-term exposures to peak $PM_{2.5}$ concentrations. In examining the scientific evidence, he notes that controlled human exposure studies provide evidence for health effects following single, short-term $PM_{2.5}$ exposures to concentrations. These types of exposures correspond best to those to ambient exposures that might be experienced in the upper end of the $PM_{2.5}$ air quality distribution in the U.S. (*i.e.,* ''peak'' concentrations). However, most of these studies examine exposure concentrations considerably higher than are typically measured in areas meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). In particular, controlled human exposure studies often report statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $PM_{2.5}$ concentrations at and above 120 $\mu g/m^3$ (at and above 149 $\mu g/m^3$ for vascular impairment, the effect shown to be most consistent across studies). To provide insight into what these studies may indicate regarding the primary $PM_{2.5}$ standards, the PA (U.S. EPA, 2020, p.3–49) notes that 2-hour ambient concentrations of $PM_{2.5}$ at monitoring sites meeting the current standards almost never exceed 32 $\mu g/m^3$. In fact, even the extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations at sites meeting the current standards remains well-below the $PM_{2.5}$ exposure concentrations consistently shown in controlled human exposure studies to elicit effects (*i.e.,* 99.9th percentile of 2-hour concentrations at these sites is 68 $\mu g/m^3$ during the warm season). Additionally, the Administrator notes the limited utility of the animal toxicologic studies in directly informing conclusions on the appropriate level of the standard given the uncertainty in extrapolating from effects in animals to those in human populations. Thus, the available experimental evidence does not indicate the need for additional protection against exposures to peak $PM_{2.5}$ concentrations, beyond the protection provided by the combination of the current 24-hour standard and the current annual standard (U.S. EPA, 2020, section 3.2.3.1).

With respect to the epidemiological evidence, the Administrator notes that the available epidemiological studies do not indicate that associations in those studies are strongly influenced by exposures to peak concentrations in the air quality distribution and thus do not indicate the need for additional protection against short-term exposures to peak $PM_{2.5}$ concentrations (U.S. EPA 2020, section 3.5.1). Lastly, the Administrator notes CASAC consensus support for retaining the current 24-hour standard. Thus, the Administrator concludes that the 24-hour standard with its level of 35 $\mu g/m^3$ is adequate to provide supplemental protection (*i.e.,* beyond that provided by the annual standard alone) against short-term exposures to peak $PM_{2.5}$ concentrations.

In reviewing the level of the annual standard, the Administrator recognizes that the annual standard, with its form based on the arithmetic mean concentration, is most appropriately meant to limit the ''typical'' daily and annual exposures that are most strongly associated with the health effects observed in epidemiological studies. However, the Administrator also recognizes that while epidemiological studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, they do not identify particular $PM_{2.5}$ exposures that cause effects and thus, they cannot alone identify a specific level at which the standard should be set, as such a determination necessarily requires the Administrator's judgment. Thus, any approach that uses epidemiological information in reaching decisions on what standards are appropriate necessarily requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards. This includes consideration of how to weigh the uncertainties in the reported associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity in the epidemiological studies. Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

The Administrator recognizes that important uncertainties and limitations that were present in epidemiological studies in previous reviews, remain in the current review. As discussed above, these uncertainties include exposure measurement error; potential confounding by copollutants; increasing uncertainty of associations at lower $PM_{2.5}$ concentrations; and heterogeneity of effects across different cities or regions. The Administrator also recognizes the advice given by the CASAC on this matter. As discussed above (section II.B.1), the CASAC members who support retaining the annual standard expressed their concerns with available $PM_{2.5}$ epidemiological studies. They assert that recent epidemiological studies do not provide a sufficient basis for revising the current standards. They also identify several key concerns regarding the associations reported in $PM_{2.5}$ epidemiological studies and conclude that ''while the data on associations should certainly be carefully considered, this data should not be interpreted more strongly than warranted based on its methodological limitations'' (Cox, 2019a, p. 8 consensus responses).

Taking into consideration the views expressed by these CASAC members, the Administrator recognizes that epidemiological studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, and they do not identify particular $PM_{2.5}$ exposures that cause effects (U.S. EPA, 2020, section 3.1.2). While the Administrator remains concerned about placing too much weight on epidemiological studies to inform conclusions on the adequacy of the current primary standards, he notes that several commenters advocated for using the epidemiological studies in a manner they characterized as similar to the last review, to determine the level of the annual standard. The previous PM NAAQS review completed in 2012 noted that the evidence of an association in any epidemiological study is ''strongest at and around the long-term average where the data in the study are most concentrated'' (78 FR 3140, January 15, 2013). Accordingly, the Administrator notes the characterization of study reported short-term and long-term mean $PM_{2.5}$ concentrations (section II.A.2.c.ii). As discussed in more detail above in section II.B.3 in responding to comments, when assessing the mean concentrations of the key short-term and

long-term epidemiological studies in the U.S. that use ground-based monitoring (*i.e.,* those studies that can provide information most directly comparable to the current annual standard), the majority of studies (*i.e.,* 19 out of 21) have mean concentrations at or above the level of the current annual standard (12.0 μg/m^3), with the mean of the study reported means or medians equal to 13.5 μg/m^3, a concentration level above the current level of the primary annual standard of 12 μg/m^3.[54] The Administrator further notes his caution in directly comparing the reported study mean values to the standard level given that, as discussed in more detail above, study-reported mean concentrations, by design, are generally lower than the design value of the highest monitor in an area, which determines compliance. In fact, analyses of recent air quality in U.S. CBSAs indicate that maximum annual $PM_{2.5}$ design values for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7). He further notes his concern in placing too much weight on any one epidemiological study but instead feels that it is more appropriate to focus on the body of studies together and therefore takes note of the calculation of the mean of study-reported means (or medians). Thus, in summary, while the Administrator is cautious about placing too much weight on the epidemiological evidence on its own, he notes: (1) The reported mean concentration in the majority of the key U.S. epidemiological studies using ground-based monitoring data are above the level of the current annual standard; (2) the mean of the reported study means (or medians) (*i.e.,* 13.5 μg/m^3) is above the level of the current standard;[55] (3) air quality analyses show the study means to be lower than their corresponding design values by 10–20%; and (4) that these analyses must be considered in light of uncertainties inherent in the epidemiological evidence. When taken together, the Administrator judges that, even if he were to place greater weight on the epidemiological evidence, this information would not call into question the adequacy of the current standards.

In addition to the evidence, the Administrator also considers the potential implications of the risk assessment. He notes that all risk assessments have limitations and that he remains concerned about the uncertainties in the underlying epidemiological data used in the risk assessment. The Administrator also notes that in previous reviews, these uncertainties and limitations have often resulted in less weight being placed on quantitative estimates of risk than on the underlying scientific evidence itself (*e.g.,* 78 FR 3086, 3098–99, January 15, 2013). These uncertainties and limitations have included uncertainty in the shapes of concentration-response functions, particularly at low concentrations; uncertainties in the methods used to adjust air quality; and uncertainty in estimating risks for populations, locations and air quality distributions different from those examined in the underlying epidemiological study (U.S. EPA, 2020, section 3.3.2.4). Additionally, the Administrator notes similar concern expressed by members of the CASAC who support retaining the current standards; they highlighted similar uncertainties and limitations in the risk assessment (Cox, 2019a). In light of all of this, the Administrator judges it appropriate to place little weight on quantitative estimates of $PM_{2.5}$-associated mortality risk in reaching conclusions about the level of the primary $PM_{2.5}$ standards.

The Administrator additionally considers the emerging body of evidence from accountability studies examining past reductions in ambient $PM_{2.5}$, and the degree to which those reductions have resulted in public health improvements. The Administrator agrees with public commenters who note that well-designed and conducted accountability studies can be informative. However, the Administrator also recognizes that interpreting such studies in the context of the current primary $PM_{2.5}$ standards is complicated by the fact that some of the available studies have not evaluated $PM_{2.5}$ specifically (*e.g.,* as opposed to PM_{10} or total suspended particulates), did not show changes in $PM_{2.5}$ air quality, or have not been able to disentangle health impacts of the interventions from background trends in health (U.S. EPA, 2020, section 3.5.1). He further recognizes that the small number of available studies that do report public health improvements following past declines in ambient $PM_{2.5}$ have not examined air quality meeting the current standards (U.S. EPA, 2020, Table 3–3). This includes recent U.S. studies that report increased life expectancy, decreased mortality, and decreased respiratory effects following past declines in ambient $PM_{2.5}$ concentrations. Such studies have examined ''starting'' annual average $PM_{2.5}$ concentrations (*i.e.,* prior to the reductions being evaluated) ranging from about 13.2 to >20 mg/m^3 (*i.e.,* U.S. EPA, 2020, Table 3–3). Given the lack of available accountability studies reporting public health improvements attributable to reductions in ambient $PM_{2.5}$ in locations meeting the current standards, together with his broader concerns regarding the lack of experimental studies examining $PM_{2.5}$ exposures typical of areas meeting the current standards (discussed above), the Administrator judges that there is considerable uncertainty in the potential for increased public health protection from further reductions in ambient $PM_{2.5}$ concentrations beyond those achieved under the current primary $PM_{2.5}$ standards.

When the above considerations are taken together, the Administrator concludes that the scientific evidence that has become available since the last review of the PM NAAQS, together with the analyses in the PA based on that evidence and consideration of CASAC advice and public comments, does not call into question the adequacy of the public health protection provided by the current annual and 24-hour $PM_{2.5}$ standards. In particular, the Administrator judges that there is considerable uncertainty in the potential for additional public health improvements from reducing ambient $PM_{2.5}$ concentrations below the concentrations achieved under the current primary standards and, therefore, that standards more stringent than the current standards (*e.g.,* with lower levels) are not supported. That is, he judges that such standards would be more than requisite to protect the public health with an adequate margin of safety. This judgment reflects the Administrator's consideration of the uncertainties in the potential implications of the lower end of the air quality distributions from the epidemiological studies due in part to the lack of supporting evidence from experimental studies and retrospective accountability studies conducted at $PM_{2.5}$ concentrations meeting the current standards.

In reaching this conclusion, the Administrator notes that the current standards provide an adequate margin of safety. With respect to the annual standard, the level of 12 μg/m^3 is below the lowest ''starting'' concentration (*i.e.,*

[54] There were two studies, both included in the last review, for which the mean concentration (11.8 μg/m^3; Peng et al., 2009) or median concentration (10.7 μg/m^3 (Central Region); Zeger et al., 2008) was somewhat below 12 μg/m^3.

[55] The median of the study reported mean (or median) $PM_{2.5}$ concentrations is 13.3 μg/m^3, which is also above the level of the current standard.

13.2 μg/m³) in the available accountability studies that show public health improvements attributable to reductions in ambient $PM_{2.5}$. In addition, while the Administrator places less weight on the epidemiological evidence for the purposes of selecting a standard, he notes that the current level of the annual standard is below the reported mean (and median) concentrations in the majority of the key U.S. epidemiological studies using ground-based monitoring data [56] (noting that these means tend to be 10–20% lower than their corresponding area design values which is the more relevant metric when considering the level of the standard) and below the mean of the reported means (or medians) of these studies (*i.e.,* 13.5 μg/m³). In addition, the Administrator recognizes that concentrations in areas meeting the current 24-hour and annual standards remain well-below the $PM_{2.5}$ exposure concentrations consistently shown to elicit effects in human exposure studies.

In addition, based on the Administrator's review of the science, including controlled human exposure studies examining effects following short-term $PM_{2.5}$ exposures, the epidemiological studies described above, and accountability studies conducted at levels just above the current standard, he judges that the degree of public health protection provided by the current standard is not greater than warranted. This judgment, together with the fact that no CASAC member expressed support for a less stringent standard, leads the Administrator to conclude that standards less stringent than the current standards (*e.g.,* with higher levels) are also not supported.

When the above information is taken together, the Administrator concludes that the available scientific evidence and technical information continue to support the current annual and 24-hour $PM_{2.5}$ standards. This conclusion reflects the fact that important limitations in the evidence remain. The Administrator concludes that these limitations lead to considerable uncertainty regarding the potential public health implications of revising the existing suite of $PM_{2.5}$ standards. Given this uncertainty, and the advice from some CASAC members, he concludes that the current suite of primary standards, including the current indicators ($PM_{2.5}$), averaging times (annual and 24-hour), forms (arithmetic mean and 98th percentile, averaged over three years) and levels (12.0 μg/m³, 35 μg/m³), when taken together, remain requisite to protect the public health. Therefore, the Administrator reaches the final conclusion that the current suite of primary $PM_{2.5}$ standards is requisite to protect public health from fine particles with an adequate margin of safety, including the health of at-risk populations, and is retaining the standards, without revision.

C. Decision on the Primary $PM_{2.5}$ Standards

For the reasons discussed above and taking into account information and assessments presented in the ISA and PA, the advice from the CASAC, and consideration of public comments, the Administrator concludes that the current annual and 24-hour primary $PM_{2.5}$ standards are requisite to protect public health from fine particles with an adequate margin of safety, including the health of at-risk populations, and is retaining the current standards without revision.

III. Rationale for Decisions on the Primary PM_{10} Standard

This section presents the rationale for the Administrator's decision to retain the existing primary PM_{10} standard. This decision is based on a thorough review of the latest scientific information, published through December 2017,[57] and assessed in the ISA, on human health effects associated with $PM_{10-2.5}$ in ambient air. This decision also accounts for considerations in the PA of the policy-relevant information, CASAC advice, and consideration of public comments received on the proposal.

Section III.A provides background on the general approach for this review and the basis for the existing standard, and also presents a brief summary of key aspects of the currently available health effects information. Section III.B summarizes the CASAC advice and the Administrator's proposed decision to retain the existing primary PM_{10} standard, addresses public comments received on the proposal, and presents the Administrator's conclusions on the adequacy of the current standard, drawing on consideration of information in the ISA and the PA information, advice from the CASAC, and comments from the public. Section III.C summarizes the Administrator's decision on the primary PM_{10} standard.

A. Introduction

As in prior reviews, the general approach to reviewing the current primary PM_{10} standard is based, most fundamentally, on using the EPA's assessment of the current scientific evidence to inform the Administrator's judgment regarding a primary PM_{10} standard that protects public health with an adequate margin of safety. In drawing conclusions with regard to the primary PM_{10} standard, the final decision on the adequacy of the current standard is largely a public health policy judgment to be made by the Administrator. The Administrator's final decision draws upon the scientific information about health effects, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence. The approach to informing these judgments, discussed more fully below, is based on the recognition that the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions in the CAA and with how the EPA and the courts have interpreted the Act. These provisions require the Administrator to establish primary standards that, in his judgment, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health including the health of sensitive groups. The four basic elements of the NAAQS (indicator, averaging time, form, and level) are considered collectively in evaluating the health protection afforded by a standard.

In evaluating the appropriateness of retaining or revising the current primary

[56] As discussed above, the means from these studies are most relatable to the level of the annual standard. However, because the reported means in these studies are based on averaging the monitored concentration across an area, they tend to be lower than the design value for that same area, since attainment of the standard is based on the measurements at the highest monitor (and not the average across multiple monitors.)

[57] In addition to the review's opening ''call for information'' (79 FR 71764, December 3, 2014), ''the current ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3). References that are cited in the ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter.*

PM_{10} standard, the EPA has adopted an approach which is similar to that used in the last review and which reflects the body of evidence and information now available. As summarized in section III.A.1 below, the Administrator's decisions in the prior review were based on an integration of information on health effects associated with exposure to $PM_{10-2.5}$, on the public health significance of key health effects, on policy judgments as to whether the standard is requisite to protect public health with an adequate margin of safety, and on consideration of the CASAC advice and public comments.

Similarly, in this review, as described in the PA, the proposal, and elsewhere in this document, we draw on the current evidence pertaining to the public health risk of $PM_{10-2.5}$ in ambient air. The past and current approaches are both based, most fundamentally, on the EPA's assessment of the current scientific and technical information. The EPA's assessments are primarily documented in the ISA and the PA, which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 84 FR 47944, September 11, 2019). To bridge the gap between the scientific assessment of the ISA and the judgments required of the Administrator in determining whether the current standard is requisite to protect public health with an adequate margin of safety, the PA evaluates the policy implications of the current evidence in the ISA.

In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review, including most particularly that which has been critically analyzed and characterized in the current ISA. The evidence-based discussions presented below in section III.A.2 (and summarized more fully in the proposal) draw upon evidence from studies evaluating health effects related to exposures to $PM_{10-2.5}$, as discussed in the ISA.

1. Background on the Current Standard

The last review of the PM NAAQS was completed in 2012 (78 FR 3086, January 15, 2013). In that review, the EPA retained the existing primary 24-hour PM_{10} standard, with its level of 150 μg/m³ and its one-expected-exceedance form on average over three years, to continue to provide public health protection against exposures to $PM_{10-2.5}$. In support of this decision, the prior Administrator emphasized her consideration of three issues: (1) The extent to which it was appropriate to retain a standard that provides some measure of protection against all $PM_{10-2.5}$ (regardless of composition or source of origin), (2) the extent to which a standard with a PM_{10} indicator can provide protection against exposures to $PM_{10-2.5}$, and (3) the degree of public protection provided by the existing PM_{10} standard.

First, the prior Administrator judged that the evidence provided ''ample support for a standard that protects against exposures to all thoracic coarse particles, regardless of their location or source of origin'' (78 FR 3176, January 15, 2013). In support of this, she noted that the epidemiological studies had reported positive associations between $PM_{10-2.5}$ and mortality or morbidity in a large number of cities across North America, Europe, and Asia, encompassing a variety of environments where $PM_{10-2.5}$ sources and composition were expected to vary widely. Though most of the available studies examined associations in urban areas, the Administrator noted that some studies had also found associations between mortality and morbidity and relatively high ambient concentrations of particles of non-urban crustal origin. In the last review, in considering this body of evidence, and consistent with the CASAC's advice, the Administrator concluded that it was appropriate to maintain a standard that provides some measure of protection against exposures to all thoracic coarse particles, regardless of their composition, location, or source of origin (78 FR 3176, January 15, 2013).

With regard to the appropriateness of retaining a PM_{10} indicator for a standard meant to protect against exposures to $PM_{10-2.5}$ in ambient air, the prior Administrator noted that PM_{10} mass included both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$). As a result, the concentration of thoracic coarse particles ($PM_{10-2.5}$) allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. Because $PM_{2.5}$ concentrations tend to be higher in urban areas than in rural areas, she observed that a PM_{10} standard would generally allow lower $PM_{10-2.5}$ concentrations in urban areas than in rural areas. She judged it appropriate to maintain such a standard given that much of the evidence for $PM_{10-2.5}$ toxicity, particularly at relatively low particle concentrations, came from study locations where thoracic coarse particles were of urban origin, and given that contaminants in urban areas would increase $PM_{10-2.5}$ particle toxicity. Therefore, in the last review, the Administrator concluded that it remained appropriate to maintain a standard that requires lower concentrations of $PM_{10-2.5}$ in ambient air in urban areas, where the strongest evidence was for associations between mortality and morbidity, and allows higher concentrations of $PM_{10-2.5}$ in non-urban areas, where the evidence of public health concerns was less certain. The Administrator concluded that the varying concentrations of coarse particles that would be permitted in urban versus non-urban areas under the 24-hour PM_{10} standard, based the varying levels of $PM_{2.5}$ present, appropriately reflected the differences in the strength of evidence regarding the health effects of coarse particles.

With regard to evaluating the degree of public health protection provided by the current primary PM_{10} standard, with its level of 150 μg/m³ and its one-expected-exceedance form on average over three years, the Administrator recognized that the available scientific evidence and air quality information was much more limited for $PM_{10-2.5}$ than for $PM_{2.5}$. In particular, the strongest evidence for $PM_{10-2.5}$-related health effects was for cardiovascular effects, respiratory effects, and premature mortality following short-term exposures. For each of these categories of effects, the 2009 ISA concluded that the evidence was ''suggestive of a causal relationship'' (U.S. EPA, 2009c, section 2.3.3). The Administrator noted the significant uncertainties and limitations associated with the $PM_{10-2.5}$ scientific evidence leading to these causal determinations and questioned whether additional public health improvements would be achieved by revising the existing primary PM_{10} standard. She specifically took note of several uncertainties and limitations, including the following:

- There were a limited number of epidemiological studies that employed copollutant models to address the potential for confounding, particularly by $PM_{2.5}$, that would further the understanding of the extent to which $PM_{10-2.5}$ itself, rather than copollutants, contributed to the reported health effects.
- The plausibility of the associations between $PM_{10-2.5}$ and mortality and morbidity reported in epidemiological studies was uncertain given the limited number of experimental studies providing support for these associations.
- Limitations in $PM_{10-2.5}$ monitoring data (*i.e.,* limited data available from FRM/FEM sampling methods) and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies resulted in uncertainties in the ambient $PM_{10-2.5}$ concentrations at which the reported

effects occur, increasing uncertainty in estimates of the extent to which changes in ambient $PM_{10-2.5}$ concentrations would likely impact public health.

• While $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were generally positive, most were not statistically significant, even in single pollutant models. This included effect estimates reported in some study locations where the ambient PM_{10} concentrations were above those allowed by the current 24-hour PM_{10} standard.

• The composition of $PM_{10-2.5}$, and the effects associated with specific components, were also key uncertainties in the evidence. With a lack of information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across study locations was difficult to characterize.

In considering these uncertainties and limitations, the prior Administrator particularly took note of degree of uncertainty associated with the extent to which health effects reported in the epidemiological studies are due to $PM_{10-2.5}$ itself, as opposed to one or more copollutants, especially $PM_{2.5}$. This uncertainty reflects the relatively small number of studies available for $PM_{10-2.5}$ in ambient air that had evaluated copollutant models, and the very limited evidence from controlled human exposure studies supporting the plausibility of adverse health effects attributable to $PM_{10-2.5}$ at ambient concentrations.

When considering the available evidence overall, the prior Administrator concluded that the degree of public health protection provided by the current PM_{10} standard against exposures to $PM_{10-2.5}$ should be maintained (*i.e.,* neither increased nor decreased). Her judgment that a more stringent standard to provide additional protection was not necessary was supported by her consideration of the uncertainties in the overall body of evidence. Her judgment that a less stringent standard was not needed and that the degree of public health protection provided by the current standard was not greater than warranted was supported by the positive and statistically significant associations with mortality observed in some single-city study locations that were likely to have violated the current PM_{10} standard. Therefore, the prior Administrator concluded that the existing 24-hour standard, with its one-expected exceedance form on average over three years and a level of 150 $\mu g/m^3$, was requisite to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. In light of this conclusion, the EPA retained the existing primary PM_{10} standard.

2. Overview of Health Effects Evidence

In this section, we provide an overview of the policy-relevant aspects of the $PM_{10-2.5}$-related health effects evidence available for consideration in this review. Section III.B of the proposal provides a detailed summary of key information contained in the ISA and the PA on the health effects associated with $PM_{10-2.5}$ exposures, and the related public health implications. As described in the proposal, the ISA does not identify any $PM_{10-2.5}$-related health outcomes for which the evidence supports either a ''causal'' or ''likely to be causal relationship'' (85 FR 24122, April 30, 2020). Therefore, for $PM_{10-2.5}$, we consider the evidence determined to be ''suggestive of, but not sufficient to infer, a causal relationship,'' recognizing the greater uncertainty in such evidence.[58]

While studies conducted since the time of the last review have strengthened support for relationships between $PM_{10-2.5}$ exposures and some key health outcomes, several key uncertainties from the last review have, to date, ''still not been addressed'' (U.S. EPA, 2019, section 1.4.2, p. 1–41). For example, in the last review, epidemiological studies relied on a number of methods to estimate $PM_{10-2.5}$ exposures, but the methods had not been systematically compared to evaluate spatial and temporal correlations in exposure estimates. Methods employed by these studies included: (1) Calculating the difference between PM_{10} and $PM_{2.5}$ at co-located monitors, (2) calculating the difference between county-wide averages of monitored PM_{10} and $PM_{2.5}$ based on monitors that are not necessarily co-located, and (3) direct measurement of $PM_{10-2.5}$ using a dichotomous sampler (U.S. EPA, 2019, section 1.4.2). More recent epidemiological studies, available since the last review, continue to use these approaches to estimate $PM_{10-2.5}$ concentrations. Some recent studies estimate long-term $PM_{10-2.5}$ exposures as the difference between PM_{10} and $PM_{2.5}$ concentrations based on information from spatiotemporal or land use regression (LUR) models, in addition to monitors. As in the last review, the methods used to estimate $PM_{10-2.5}$ concentrations have not been systematically evaluated (U.S. EPA, 2019, section 3.3.1.1), contributing to the uncertainty regarding spatial and temporal correlations in $PM_{10-2.5}$ concentrations across methods and in $PM_{10-2.5}$ exposure estimates used in epidemiological studies (U.S. EPA, 2019, sections 2.5.1.2.3 and 2.5.2.2.3). Given the greater spatial and temporal variability of $PM_{10-2.5}$ and fewer $PM_{10-2.5}$ monitoring sites compared to $PM_{2.5}$, this uncertainty is particularly important for the coarse size fraction.

In addition to the uncertainty associated with $PM_{10-2.5}$ exposure estimates in the epidemiological studies, information in the current review remains limited with regard to the potential for confounding by copollutants and provides limited support for the biological plausibility of serious effects following $PM_{10-2.5}$ exposures; both of these limitations continue to contribute broadly to uncertainty in the $PM_{10-2.5}$ health evidence. Uncertainty related to potential confounding is related to the relatively few epidemiological studies that have evaluated $PM_{10-2.5}$ health effect associations in copollutant models with both gaseous pollutants and other PM size fractions. Uncertainty related to the biological plausibility of serious effects caused by $PM_{10-2.5}$ exposures results from the limited number of controlled human exposure and animal toxicology[59] studies that have evaluated the health effects of experimental $PM_{10-2.5}$ inhalation exposures. The evidence supporting the ISA's ''suggestive'' causality determinations for $PM_{10-2.5}$ and health effects, including the uncertainties in the evidence, are summarized in the sections below.

a. Nature of Effects

i. Mortality

With regard to long-term $PM_{10-2.5}$ exposure and mortality, very few studies were available at the time of the last review. As such, the 2009 ISA concluded that the evidence was ''inadequate to determine if a causal relationship exists'' (U.S. EPA, 2009c). Since the time of the last review, there is limited new evidence and many of the limitations noted in the 2012 review persist. In the current review, some recent cohort studies conducted in the U.S. and Europe reported positive associations between long-term $PM_{10-2.5}$ exposure and total (nonaccidental) mortality, though results are

[58] As noted in the Preamble to the ISA, ''suggestive'' evidence is ''limited, and chance, confounding, and other biases cannot be ruled out'' (U.S. EPA, 2015, Table II).

[59] Compared to humans, smaller fractions of inhaled $PM_{10-2.5}$ penetrate into the thoracic regions of rats and mice (U.S. EPA, 2019, section 4.1.6), contributing to the relatively limited evaluation $PM_{10-2.5}$ exposures in animal studies.

inconsistent across studies (U.S. EPA, 2019, Table 11–11). The examination of copollutant models in these studies remains limited, and when copollutants are included, $PM_{10-2.5}$ effect estimates are often attenuated after adjusting for $PM_{2.5}$ (U.S. EPA, 2019, Table 11–11). These studies employed a number of approaches for estimating $PM_{10-2.5}$ exposures, including direct measurements from dichotomous samplers, calculating the difference between PM_{10} and $PM_{2.5}$ measured at co-located monitors, and calculating the difference of area-wide PM_{10} and $PM_{2.5}$ concentrations. As discussed above as a limitation in the last review, temporal and spatial correlations between these approaches still have not been evaluated, contributing to uncertainty regarding the potential for exposure measurement error (U.S. EPA, 2019, section 3.3.1.1, Table 11–11). The 2019 ISA concludes that this uncertainty ''reduces the confidence in the associations observed across studies'' (U.S. EPA, 2020, p. 11–125) and that the evidence for long-term $PM_{10-2.5}$ exposures and cardiovascular effects, respiratory morbidity, and metabolic disease provide limited biological plausibility for $PM_{10-2.5}$-related mortality (U.S. EPA, 2019, sections 11.4.1 and 11.4). Taken together, the 2019 ISA concludes that ''this body of evidence is suggestive, but not sufficient to infer, that a causal relationship exists between long-term $PM_{10-2.5}$ exposure and total mortality'' (U.S. EPA, 2019, p. 11–125).

With regard to short-term $PM_{10-2.5}$ exposures and mortality, the 2009 ISA concluded that the evidence is ''suggestive of a causal relationship between short-term exposure to $PM_{10-2.5}$ and mortality'' (U.S. EPA, 2009c). Since the last review, multicity epidemiological studies conducted primarily in Europe and Asia continue to provide consistent evidence of positive associations between short-term $PM_{10-2.5}$ exposure and total (nonaccidental) mortality (U.S. EPA, 2019, Table 11–9). These studies contribute to increasing confidence in the relationship between the short-term $PM_{10-2.5}$ exposures and mortality, however, the use of varying approaches to estimate $PM_{10-2.5}$ exposures continue to contribute uncertainty to the associations observed. Additionally, the 2019 ISA notes than an analysis by Adar et al. (2014) indicates ''possible evidence of publications bias, which was not observed for $PM_{2.5}$'' (U.S. EPA, 2019, section 11.3.2, p. 11–106). Studies newly available in this review expand the assessment of potential copollutant confounding of the short-term $PM_{10-2.5}$-mortality relationship and provide evidence that $PM_{10-2.5}$ associations generally remain positive in copollutant models, although associations are attenuated in some instances (U.S. EPA, 2019, section 11.3.4.1, Figure 11–28, Table 11–10). The 2019 ISA concludes that, overall, the assessment of potential copollutant confounding is limited by a lack of information on the correlation between $PM_{10-2.5}$ and gaseous pollutants and the small number of locations where copollutant analyses have been conducted. Associations with cause-specific mortality provide some support for associations with total (nonaccidental) mortality, though associations with cause-specific mortality, particularly respiratory mortality, are more uncertain (*i.e.,* wider confidence intervals) and less consistent (U.S. EPA, 2019, section 11.3.7). As discussed further below, the ISA concludes that evidence for $PM_{10-2.5}$-related cardiovascular and respiratory effects provides only limited support for the biological plausibility of a relationship between short-term $PM_{10-2.5}$ exposure and cause-specific mortality (U.S. EPA, 2019, section 11.3.7). Based on the overall evidence, the 2019 ISA concludes that ''this body of evidence is suggestive, but not sufficient to infer, that a causal relationship exists between short-term $PM_{10-2.5}$ exposure and total mortality'' (U.S. EPA, 2019, p. 11–120).

ii. Cardiovascular Effects

With regard to long-term exposures, the evidence available in the last review describing the relationship between long-term exposure to $PM_{10-2.5}$ and cardiovascular effects was characterized in the 2009 ISA as ''inadequate to infer the presence or absence of a causal relationship.'' The limited number of epidemiological studies available at that time reported contradictory results and experimental evidence demonstrating an effect of $PM_{10-2.5}$ on the cardiovascular system was lacking (U.S. EPA, 2019, section 6.4).

The evidence of long-term $PM_{10-2.5}$ exposures and cardiovascular mortality remains limited, with no consistent pattern of associations across studies, and as discussed above, uncertainty from the use of various approaches for estimating $PM_{10-2.5}$ concentrations (U.S. EPA, 2019, Table 6–70). The evidence for associations between $PM_{10-2.5}$ and cardiovascular morbidity has grown and, while results across studies are not entirely consistent, some epidemiological studies report positive associations with IHD and myocardial infarction (MI) (U.S. EPA, 2019, Figure 6–34); stroke (U.S. EPA, 2019, Figure 6–35); atherosclerosis (U.S. EPA, 2019, section 6.4.5); venous thromboembolism (VTE) (U.S. EPA, 2019, section 6.4.7); and blood pressure and hypertension (U.S. EPA, 2019, section 6.4.6). With respect to copollutant confounding, the effect estimates for $PM_{10-2.5}$-cardiovascular mortality are often attenuated, but remain positive, in copollutant models adjusted for $PM_{2.5}$. For cardiovascular morbidity outcomes, associations are inconsistent in copollutant models that adjust for $PM_{2.5}$, NO_2, and chronic noise pollution (U.S. EPA, 2019, p. 6–276). The 2019 ISA concluded that ''evidence from experimental animal studies is of insufficient quantity to establish biological plausibility'' (U.S. EPA, 2019, p. 6–277). Despite this substantial data gap in the toxicologic evidence for long-term $PM_{10-2.5}$ exposures and based largely on the observation of positive associations in some high-quality epidemiological studies, the ISA concludes that ''evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10-2.5}$ exposure and cardiovascular effects'' (U.S. EPA, 2019, p. 6–277).

With regard to short-term $PM_{10-2.5}$ exposures and cardiovascular effects, the 2009 ISA found the available evidence was ''suggestive of a causal relationship,'' based primarily on several epidemiological studies reporting associations between short-term $PM_{10-2.5}$ exposure and cardiovascular effects, including IHD hospitalizations, supraventricular ectopy, and changes in heart rate variability (HRV). In addition, studies found increases in cardiovascular disease emergency department visits and hospital admissions linked to dust storm events resulting in high concentrations of crustal material. However, the 2009 ISA noted the potential for exposure measurement error and copollutant confounding in these studies. Moreover, there was only limited evidence of cardiovascular effects from a small number of controlled human exposure and animal toxicologic studies that examined $PM_{10-2.5}$ exposures (U.S. EPA, 2009c, section 6.2.12.2). Therefore, the potential for exposure measurement error and copollutant confounding, along with the limited evidence of biological plausibility for cardiovascular effects following inhalation exposure, contributed uncertainty to the scientific evidence available at the time of the last review (U.S. EPA, 2009c, section 6.3.13).

The evidence related to short-term $PM_{10-2.5}$ exposure and cardiovascular

effects has somewhat expanded since the last review, but a number of important uncertainties persist. The 2019 ISA notes that there are a small number of epidemiological studies reporting positive associations between short-term $PM_{10-2.5}$ exposures and cardiovascular morbidity. There continues to be limited evidence, however, to suggest that these associations are biologically plausible, or independent of copollutant confounding. Additionally, the ISA concludes that it remains unclear how the approaches used to estimate $PM_{10-2.5}$ concentrations in epidemiological studies may impact exposure measurement error. The 2019 ISA concludes that overall ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between short-term $PM_{10-2.5}$ exposures and cardiovascular effects'' (U.S. EPA, 2019, p. 6–254).

iii. Respiratory Effects

With regard to short-term $PM_{10-2.5}$ exposures and respiratory effects, the 2009 ISA concluded that, based on a small number of epidemiological studies observing some respiratory effects and limited evidence to support biological plausibility, the relationship is ''suggestive of a causal relationship.'' Epidemiological findings were consistent for respiratory infection and combined respiratory-related diseases, but not for COPD. Studies were characterized by overall uncertainty in the exposure assignment approach and limited information regarding potential copollutant confounding. Controlled human exposure studies of short-term $PM_{10-2.5}$ exposures found no lung function decrements and inconsistent evidence of pulmonary inflammation. Animal toxicologic studies were limited to those that used non-inhalation (*e.g.,* intra-tracheal instillation) routes of $PM_{10-2.5}$ exposure.

Recently available epidemiological studies link short-term $PM_{10-2.5}$ exposure with asthma exacerbation and respiratory mortality. Some associations remained positive in copollutant models including $PM_{2.5}$ or gaseous pollutants, although associations were attenuated in some studies of mortality. Limited evidence is available that observes positive associations with other respiratory outcomes, including COPD exacerbation, respiratory infection, and combined respiratory-related diseases (U.S. EPA, 2019, Table 5–36). The lack of systematic evaluation of the various methods used to estimate $PM_{10-2.5}$ concentrations and the resulting spatial and temporal variability in $PM_{10-2.5}$ concentrations compared to $PM_{2.5}$ continues to be an uncertainty in this evidence (U.S. EPA, 2019, sections 2.5.1.2.3 and 3.3.1.1). Based on the overall evidence, the 2019 ISA concludes that the ''evidence is suggestive of, but not sufficient to infer, a causal relationship between short-term $PM_{10-2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019, p. 5–270).

iv. Cancer

In the last review, little information was available from studies of cancer following inhalation exposures to $PM_{10-2.5}$. Thus, the 2009 ISA concluded that the evidence was ''inadequate to assess the relationship between long-term $PM_{10-2.5}$ exposures and cancer'' (U.S. EPA, 2009c). Since the last review, the available studies of long-term $PM_{10-2.5}$ exposure and cancer remain limited, with a few recent epidemiological studies that report positive, but imprecise, associations with lung cancer incidence. Uncertainty remains in these studies due to exposure measurement error from the use of $PM_{10-2.5}$ predictions that have not been validated by monitored $PM_{10-2.5}$ concentrations (U.S. EPA, 2019, sections 3.3.2.3 and 10.3.4). Very few experimental studies of $PM_{10-2.5}$ exposures have been conducted, although the available studies indicate that $PM_{10-2.5}$ exhibits genotoxicity and oxidative stress, two key characteristics of carcinogens. While limited, these studies provide some evidence of biological plausibility for the findings in a small number of epidemiological studies (U.S. EPA, 2019, section 10.3.4). Taken together, the small number of available epidemiological and experimental studies, along with uncertainty related to exposure measurement error, contribute to the 2019 ISA conclusion that ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10-2.5}$ exposure and cancer'' (U.S. EPA, 2019, p. 10–87).

v. Metabolic Effects

The 2009 ISA did not make a causality determination for $PM_{10-2.5}$-related metabolic effects. Since the last review, one epidemiological study shows an association between long-term $PM_{10-2.5}$ exposure and incident diabetes, while additional cross-sectional studies report associations with effects on glucose or insulin homeostasis (U.S. EPA, 2019, section 7.4). Uncertainties with this evidence include the potential for copollutant confounding and exposure measurement error (U.S. EPA, 2019, Tables 7–14 7–15). There is limited evidence to support biological plausibility of metabolic effects, although a cross-sectional study that investigated biomarkers of insulin resistance and systemic and peripheral inflammation may support a pathway leading to type 2 diabetes (U.S. EPA, 2019, sections 7.4.1 and 7.4.3). Based on the somewhat expanded evidence available in this review, the 2019 ISA concludes that ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between [long]-term $PM_{10-2.5}$ exposures and metabolic effects'' (U.S. EPA, 2019, p. 7–56).

vi. Nervous System Effects

The 2009 ISA did not make a causal determination for $PM_{10-2.5}$ exposures and nervous system effects. Newly available evidence since that time includes epidemiological studies that report associations between long-term $PM_{10-2.5}$ exposures and impaired cognition and anxiety in adults in longitudinal analyses (U.S. EPA, 2019, Table 8–25, section 8.4.5). Associations of long-term $PM_{10-2.5}$ exposure with neurodevelopmental effects are not consistently reported in children (U.S. EPA, 2019, section 8.4.4 and 8.4.5). Uncertainties in these studies include the potential for copollutant confounding, given that no studies examined copollutant models (U.S. EPA, 2019, section 8.4.5), and exposure measurement error based on the various methods used across studies to estimate $PM_{10-2.5}$ concentrations (U.S. EPA, 2019, Table 8–25). Additionally, there is very limited animal toxicologic evidence to provide support for biological plausibility of nervous system effects (U.S. EPA, 2019, sections 8.4.1 and 8.4.5). Considering the available studies and associated limitations, the 2019 ISA concludes that ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10-2.5}$ exposure and nervous system effects'' (U.S. EPA, 2019, p. 8–75).

B. Conclusions on the Primary PM_{10} Standard

In drawing conclusions on the adequacy of the current primary PM_{10} standard, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the evidence base, information, and policy judgments that were the foundation of the last review and reflects upon the body of evidence and information newly available in this review. In so doing, the Administrator has taken into account the evidence-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence from animal

toxicologic, controlled human exposure studies, and epidemiological studies evaluating health effects related to exposures to $PM_{10-2.5}$ as presented in the ISA and discussed in section III.A.2. In addition to the evidence, the Administrator has weighed a range of policy-relevant considerations as discussed in the PA and summarized in sections III.B and III.C of the proposal and summarized in section III.B.2 below. These considerations, along with the advice from the CASAC (section III.B.1) and public comments (section III.B.3), are discussed below. A more detailed summary of all significant comments, along with the EPA's responses (henceforth ''Response to Comments''), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–0072). This document is available for review in the docket for this rulemaking and through the EPA's NAAQS website (*https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*). The Administrator's conclusions in this review regarding the adequacy of the current primary PM_{10} standard and whether any revisions are appropriate are described in section III.B.4.

1. CASAC Advice in This Review

As a part of the review of the draft PA, the CASAC has provided advice on the adequacy of the public health protection afforded by the current primary PM_{10} standard. As for $PM_{2.5}$ (section II.B.1 above), the CASAC's advice is documented in a letter sent to the EPA Administrator (Cox, 2019a).

In its comments on the draft PA, the CASAC concurs with the draft PA's overall preliminary conclusions that it is appropriate to consider retaining the current primary PM_{10} standard without revision. The CASAC agrees with the draft PA ''that key uncertainties identified in the last review remain'' (Cox, 2019a, p. 13 of consensus responses) and that ''none of the identified health outcomes linked to $PM_{10-2.5}$'' were judged to be causal or likely causal. (Cox, 2019a, p. 12 of consensus responses). To reduce these uncertainties in future reviews, the CASAC recommends improvements to $PM_{10-2.5}$ exposure assessment, including a more extensive network for direct monitoring of the $PM_{10-2.5}$ fraction (Cox, 2019a, p. 13 of consensus responses). The CASAC also recommends additional controlled human exposure and animal toxicology studies of the $PM_{10-2.5}$ fraction to improve the understanding of biological causal mechanisms and pathway (Cox, 2019a, p. 13 of consensus responses). Overall, the CASAC agrees with the EPA that ''. . . the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard and that evidence supports consideration of retaining the current standard in this review'' (Cox, 2019a, p. 3 of letter).

2. Basis for the Proposed Decision

At the time of the proposal, the Administrator carefully considered the assessment of the current evidence and conclusions reached in the ISA, considerations and staff conclusions and associated rationales presented in the PA, and the advice and recommendations of the CASAC (85 FR 24125, April 30, 2020). In reaching his proposed decision on the primary PM_{10} standard, the Administrator first noted the decision to retain the primary PM_{10} standard in the last review recognized that epidemiological studies had reported positive associations between $PM_{10-2.5}$ and mortality and morbidity in cities across North America, Europe, and Asia. The studies encompassed a variety of environments where $PM_{10-2.5}$ sources and composition were expected to vary widely. Although many of the studies examined associations between $PM_{10-2.5}$ and health effects in urban areas, some of the studies also linked mortality and morbidity with relatively high ambient concentrations of particles of non-urban crustal origin. Drawing on this information, the EPA judged that it was appropriate to maintain a standard that provides some measure of protection against exposures to $PM_{10-2.5}$, regardless of location, source of origin, or particle composition (78 FR 3176, January 15, 2013).

The Administrator noted that the evidence for several $PM_{10-2.5}$-related health effects, particularly for long-term exposures, has expanded since the time of the last review. Recently available epidemiological studies conducted in North America, Europe, and Asia continue to report positive associations with mortality and morbidity in cities where $PM_{10-2.5}$ sources and composition are expected to vary widely, but uncertainties remain with respect to the methods used to assign exposure in the studies. While the Administrator recognized that important uncertainties persist in the scientific evidence, as described below and in section III.A.2 above, he also recognized that $PM_{10-2.5}$ exposures may be associated with a broader range of health effects that have been linked with $PM_{10-2.5}$ exposures. These studies provide an important part of the body of evidence supporting the ISA's revised causality determinations, including new determinations, for long-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer (U.S. EPA, 2019; U.S. EPA, 2020, section 4.2). Drawing on this information, the Administrator proposed to conclude that the scientific studies available since the last review continue to support a primary PM_{10} standard that provides some measure of public health protection against $PM_{10-2.5}$ exposures, regardless of location, source of origin, or particle composition.

With regard to the uncertainties in the scientific evidence, the Administrator noted that the decision in the last review highlighted limitations in the estimates of ambient $PM_{10-2.5}$ concentrations used in epidemiological studies, the limited evaluation of copollutant models to address potential confounding, and the limited number of experimental studies to support biologically plausible pathways for $PM_{10-2.5}$-related health effects. These and other limitations raised questions as to whether additional public health improvements would be achieved by revising the existing PM_{10} standard.

Despite some additional new evidence available in this review, the Administrator recognized that, similar to the last review, uncertainties remain in the scientific evidence for $PM_{10-2.5}$-related health effects. As summarized above (section III.A.2), these include uncertainties in the $PM_{10-2.5}$ exposure estimates used in epidemiological studies, in the independence of $PM_{10-2.5}$ health effect associations, and in support for the biologic plausibility of $PM_{10-2.5}$-related effects from controlled human exposure and animal toxicologic studies (U.S. EPA, 2020, section 4.2). These uncertainties contributed to the conclusions in the 2019 ISA that the evidence for key $PM_{10-2.5}$ health effects is ''suggestive of, but not sufficient to infer'' causal relationships (U.S. EPA, 2019). In light of his emphasis on evidence supporting ''causal'' or ''likely to be causal'' relationships in the current review, the Administrator judged that the evidence of health effects associated with $PM_{10-2.5}$ in ambient air provides an uncertain scientific foundation for making decisions for standard setting. As such, he further judged that, consistent with the last review, limitations in the evidence raise questions as to whether additional public health protections would be achieved by revising the existing PM_{10} standard.

In reaching his proposed conclusions on the primary PM_{10} standard, the Administrator additionally considered the advice and recommendations from the CASAC. As described above (section III.B.1), the CASAC recognized the

uncertainties in the evidence for $PM_{10-2.5}$-related health effects, stating that ''key uncertainties identified in the last review remain'' (Cox, 2019a, p. 13 of consensus responses). Given these uncertainties, the CASAC agreed with the PA conclusion that the evidence available in this review ''does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard'' (Cox, 2019a, p. 3 of letter). The CASAC further recommended that this evidence ''supports consideration of retaining the current standard in this review'' (Cox, 2019a, p. 3 of letter).

In considering the information above, the Administrator proposed to conclude that the available scientific evidence continues to support a PM_{10} standard to provide some measure of protection against $PM_{10-2.5}$ exposures. This conclusion reflected the expanded evidence available in this review for health effects from $PM_{10-2.5}$ exposures. However, important uncertainties and limitations in the evidence remain. Consistent with the decision in the last review, the Administrator proposed to conclude that these limitations contribute to considerable uncertainty regarding the potential public health implications of revising the existing PM_{10} standard. Given this uncertainty, and consistent with the advice from the CASAC, the Administrator proposed to conclude that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard. Therefore, he proposed to retain the primary PM_{10} standard, without revision.

3. Comments on the Proposed Decision

Of the public comments received on the proposal, very few commenters provided comments on the primary PM_{10} standard. Of those commenters who did provide comments on the primary PM_{10} standard, the majority supported the Administrator's proposed decision to retain the current primary PM_{10} standard, without revision. This group includes primarily industries and industry groups. All of these commenters generally note their agreements with the rationale provided in the proposal and the CASAC concurrence with the PA conclusion that the current evidence does not support revision to the standard. Most also cite the EPA and CASAC statements that the newly available information in this review does not call into question the adequacy of the current standard. The EPA agrees with these comments and with the CASAC advice regarding the adequacy of the current primary standard and the lack of support for revision of the standard.

Some commenters disagreed with the Administrator's proposed conclusion to retain the current primary PM_{10} standard, primarily focusing their comments on the need for revisions to the form of the standard or the level of the standard. With regard to comments on the form of the standard, some commenters assert that the EPA should revise the standard by adopting a separate form (or a ''compliance threshold'' in their words)—the 99th percentile, averaged over three years—for the primary PM_{10} standard for continuous monitors, which provide data every day, while maintaining the current form of the standard (one exceedance, averaged over three years) for 1-in-6 samplers, given the widespread use of continuous monitoring and to ease the burden of demonstrating exceptional events. These commenters, in support of their comment, contend that the 99th percentile would effectively change the form from the 2nd high to the 4th high and would allow no more than three exceedances per year, averaged over three years. These commenters additionally highlight the EPA's decision in the 1997 review to adopt a 99th percentile form, averaged over three years, citing to advantages of a percentile-based form in the Administrator's rationale in that review. The comments further assert that a 99th percentile form for the primary PM_{10} standard is still more conservative than the form for other short-term NAAQS (*e.g.,* $PM_{2.5}$ and NO_2).

First, the EPA has long recognized that the form is an integral part of the NAAQS and must be selected together with the other elements of the NAAQS to ensure the appropriate stringency and requisite degree of public health protection. Thus, if the EPA were to change the form according to the monitoring method it would be establishing two different NAAQS, varying based on the monitoring method. The EPA has not done this to date, did not propose such an approach, and declines to adopt it for the final rule, as we believe such a decision in this final rule is beyond the scope of the proposal, and that each PM standard should have a single form, indicator, level and averaging time, chosen by the Administrator as necessary and appropriate. While certain continuous monitors may be established and approved as a Federal Equivalent Method (FEM) for PM_{10}, as an alternative to a Federal Reference Method (FRM), the use of an FEM is intended as an alternative means of determining compliance with the NAAQS, not as authorizing a different NAAQS.

Even if the commenters had asked that the change in form be made without regard to monitoring method, the EPA does not believe such a change would be warranted. The change in form for continuous monitors suggested by the commenters, without also lowering the level of such a standard, would allow more exceedances and thereby markedly reduce the public health protection provided against exposures to $PM_{10-2.5}$ in ambient air. These commenters have not provided new evidence or analyses to support their conclusion that an appropriate degree of public health protection could be achieved by allowing the use of an alternative form (*i.e.,* 99th percentile), while retaining the other elements of the standard.

With regard to the commenters' assertion that an alternate form of the standard would ease the burden of demonstrating exceptional events, the EPA first recognizes, consistent with the CAA, that it may be appropriate to exclude monitoring data influenced by ''exceptional'' events when making certain regulatory determinations. However, the EPA notes that the cost of implementation of the standards may not be considered by the EPA in reviewing the standards [60] and further the EPA believes it is unnecessary to alter the standard for the purpose of reducing the burden of demonstrating exceptional events. The EPA continues to update and develop documentation and tools to facilitate the implementation of the 2016 Exceptional Events Rule, including new documents intended to assist air agencies with the development of demonstrations for specific types of exceptional events. Moreover, with regard to the commenters' specific concerns for wildfires or high winds, the EPA released updated guidance documents on the preparation of exceptional event demonstrations related to wildfires in September 2016, high wind dust events in April 2019, and prescribed fires in August 2019. These guidance documents outline the regulatory requirements and provide examples for air agencies preparing demonstrations for wildfires, high wind dust, and prescribed fire events.

For all of the reasons discussed above, the EPA does not agree with the commenters that the form of the primary PM_{10} standard should be revised to a 99th percentile for continuous monitors.

[60] See generally *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001).

Some commenters who disagreed with the proposal to retain the current standard advocate for revision to the primary PM_{10} standard to protect public health with an adequate margin of safety. In their recommendations for revising the standard, some commenters contend that the current standard, with its indicator of PM_{10} to target exposures to $PM_{10-2.5}$, has become less protective as ambient concentrations of $PM_{2.5}$ have been reduced with revisions to that standard. These commenters assert that the current primary PM_{10} standard allows increased exposure to $PM_{10-2.5}$ in ambient air because retaining the primary PM_{10} would allow proportionately more $PM_{10-2.5}$ mass as the $PM_{2.5}$ standard has been revised downward. Moreover, in support of their recommendations, the commenters note that the available evidence of $PM_{10-2.5}$-related health effects has been expanded and strengthened since the time of the last review. Taken together, the commenters contend that the primary PM_{10} standard should be revised and failure to do so would be arbitrary and capricious.

We disagree with the commenters that the primary PM_{10} standard should be revised because reductions in ambient concentrations of $PM_{2.5}$ result in a less protective PM_{10} standard. As an initial matter, we note that overall, ambient concentrations of both PM_{10} and $PM_{2.5}$ have declined significantly over time. Ambient concentrations of PM_{10} have declined by 46% across the U.S. from 2000 to 2019,[61] while $PM_{2.5}$ concentrations in ambient air have declined by 43% during this same time period.[62] While trends data is not currently available for $PM_{10-2.5}$ concentrations in ambient air, the expanded availability of monitoring data from the NCore network in this review can provide insight into the relative contributions of fine and coarse PM to total PM_{10} concentrations.

The 2019 ISA provides a comparison of the relative contribution of $PM_{2.5}$ and $PM_{10-2.5}$ to PM_{10} concentrations by region and season using the more comprehensive monitoring data from the NCore network available in this review (U.S. EPA, 2019, section 2.5.1.1.4). The data indicate that, for urban areas, there are roughly equivalent amounts of $PM_{2.5}$ and $PM_{10-2.5}$ contributing to PM_{10} in ambient air, while rural locations have a slightly higher contribution of $PM_{10-2.5}$ contributing to PM_{10} concentrations than $PM_{2.5}$ (U.S. EPA, 2019, section 2.5.1.1.4, Table 2–7). There is generally a greater contribution from the $PM_{2.5}$ fraction in the East and a greater contribution from the $PM_{10-2.5}$ fraction in the West and Midwest. However, as described in the 2019 ISA, PM_{10} has become considerably coarser across the U.S. compared to similar observations in the 2009 ISA (U.S. EPA, 2019, section 2.5.1.1.4; U.S. EPA, 2009c).

The EPA recognizes that when the primary annual $PM_{2.5}$ standard was revised from 15 μg/m³ to 12 μg/m³ while leaving the 24-hour $PM_{2.5}$ standards unchanged at 35 μg/m³ and the 24-hour PM_{10} standard unchanged at 150 μg/m³, the $PM_{10-2.5}$ fraction of PM_{10} could increase in some areas as the $PM_{2.5}$ fraction decreases. Moreover, the EPA recognizes that in most areas of the country $PM_{2.5}$ and PM_{10} concentrations have declined and are well below their respective 24-hour standards, which may also allow the relative ratio of $PM_{2.5}$ to $PM_{10-2.5}$ to vary. In considering the available health effects evidence in this review, there continue to be significant uncertainties and limitations that make it difficult to fully assess the public health implications of revising the primary PM_{10} standard even considering the possibility for additional variability in the relative ratio of $PM_{2.5}$ to $PM_{10-2.5}$ in current PM_{10} air quality across the U.S. As described in detail above in section III.A.2 and in the proposal (85 FR 24125, April 30, 2020), these uncertainties contribute to the determinations in the 2019 ISA that the evidence for key $PM_{10-2.5}$ health effects is ''suggestive of, but not sufficient to infer, a causal relationship'' (U.S. EPA, 2019). Beyond these uncertainties, the EPA also notes that, while the NCore monitoring network has been expanded since the time of the last review, epidemiological studies available in this review do not use $PM_{10-2.5}$ NCore data in evaluating associations between $PM_{10-2.5}$ in ambient air and long- or short-term exposures. In the absence of such evidence, the public health implications of changes in ambient PM_{10} concentrations as $PM_{2.5}$ concentrations decrease remain unclear. Therefore, the EPA continues to recognize this as an area for future research, to address the existing uncertainties (U.S. EPA, 2020, section 4.5), and inform future reviews of the PM NAAQS.

Taken together, at the time of proposal, the Administrator concluded that these and other limitations in the $PM_{10-2.5}$ evidence raised questions as to whether additional public health improvements would be achieved by revising the existing PM_{10} standard. Therefore, the EPA does not agree with the commenters that the currently available air quality information or scientific evidence support revisions to the primary PM_{10} standard in this review.

4. Administrator's Conclusions

Having carefully considered advice from the CASAC and the public comments, as discussed above, the Administrator believes that the fundamental scientific conclusions on health effects of $PM_{10-2.5}$ in ambient air that were reached in the ISA and summarized in the PA remain valid. Additionally, the Administrator believes the judgments he proposed (85 FR 24125, April 30, 2020) with regard to the evidence remain appropriate. Further, in considering the adequacy of the current primary PM_{10} standard in this review, the Administrator has carefully considered the policy-relevant evidence and conclusions contained in the ISA; the rationale and conclusions presented in the PA; the advice and recommendations from the CASAC; and public comments, as addressed in section III.B.3 above. In the discussion below, the Administrator gives weight to the PA conclusions, with which the CASAC has concurred, as summarized in section III.D of the proposal, and takes note of the key aspects of the rationale for those conclusions that contribute to his decision in this review. After giving careful consideration to all of this information, the Administrator believes that the conclusions and policy judgments supporting his proposed decision remain valid, and that the current primary PM_{10} standard provides requisite protection of public health with an adequate margin of safety and should be retained.

In considering the PA evaluations and conclusions, the Administrator specifically notes that, while the health effects evidence is somewhat expanded since the last review, the overall conclusions are generally consistent with what was considered in the last review (U.S. EPA, 2020, section 4.4). In so doing, he additionally notes that the CASAC supports retaining the current standard, agreeing with the EPA that ''the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard'' (Cox, 2019a, p. 3 of letter). As noted below, the newly available evidence for several $PM_{10-2.5}$-related health effects has

[61] PM_{10} concentrations presented as the annual second maximum 24-hour concentration (in μg/m³) at 262 sites in the U.S. For more information, see: *https://www.epa.gov/air-trends/particulate-matter-pm10-trends.*

[62] $PM_{2.5}$ concentrations presented as the seasonally-weighted annual average concentration (in μg/m³) at 406 sites in the U.S. For more information, see: *https://www.epa.gov/air-trends/particulate-matter-pm25-trends.*

expanded since the last review, in particular for long-term exposures. The Administrator recognizes, however, that there are a number of uncertainties and limitations associated with the available information, as described in the proposal (85 FR 24125, April 30, 2020) and below.

With regard to the current evidence on $PM_{10-2.5}$-related health effects, the Administrator takes note of recent epidemiological studies that continue to report positive associations with mortality and morbidity in cities across North America, Europe, and Asia, where $PM_{10-2.5}$ sources and composition are expected to vary widely. While significant uncertainties remain, as described below, the Administrator recognizes that this expanded body of evidence has broadened the range of effects that have been linked with $PM_{10-2.5}$ exposures. These studies provide an important part of the scientific foundation supporting the ISA's revised causality determinations (and new determinations) for long-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer (U.S. EPA, 2019; U.S. EPA, 2020, section 4.2). Drawing from his consideration of this evidence, the Administrator concludes that the scientific information available since the time of the last review supports a decision to maintain a primary PM_{10} standard to provide public health protection against $PM_{10-2.5}$ exposures, regardless of location, source of origin, or particle composition.

With regard to uncertainties in the evidence, the Administrator first notes that a number of limitations were identified in the last review related to: (1) Estimates of ambient $PM_{10-2.5}$ concentrations used in epidemiological studies; (2) limited evaluation of copollutant models to address the potential for confounding; and (3) limited experimental studies supporting biological plausibility for $PM_{10-2.5}$-related effects. In the current review, despite the expanded body of evidence for $PM_{10-2.5}$ exposures and health effects, the Administrator recognizes that similar uncertainties remain. As summarized in section III.B.1 above and in responding to public comments, uncertainties in the current review continue to include those associated with the exposure estimates used in epidemiological studies, the independence of the $PM_{10-2.5}$ health effect associations, and the biologically plausible pathways for $PM_{10-2.5}$ health effects (U.S. EPA, 2020, section 4.2). These uncertainties contribute to the 2019 ISA determinations that the evidence is ''suggestive of, but not sufficient to infer'' causal relationships (U.S. EPA, 2019). In light of his emphasis on evidence supporting ''causal'' or ''likely to be causal'' relationships (sections II.A.2 and III.A.2 above), recognizing that the NAAQS should allow for a margin of safety but finding that there is too much uncertainty that a more stringent standard would improve public health, the Administrator judges that the available evidence provides support for his conclusion that the current standard provides the requisite level of protection from the effects of $PM_{10-2.5}$.

In making this judgment, the Administrator considers whether this level of protection is more than what is requisite and whether a less stringent standard would be appropriate to consider. He notes that there continues to be uncertainty associated with the evidence, for example exposure measurement error, as reflected by the ''suggestive of, but not sufficient to infer'' causal determinations. The Administrator recognizes that the CAA requirement that primary standards provide an adequate margin of safety, as summarized in section I.A above, is intended to address uncertainties associated with inconclusive scientific evidence and technical information, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Based on all of the considerations noted here, and considering the current body of evidence, including uncertainties and limitations, the Administrator concludes that a less stringent standard would not provide the requisite protection of public health, including an adequate margin of safety.

The Administrator also considers whether the level of protection associated with the current standard is less than what is requisite and whether a more stringent standard would be appropriate to consider. In so doing, the Administrator considers, as discussed above, the level of protection offered from exposures for which public health implications are less clear. In so doing, he again notes the significant uncertainties and limitations that persist in the scientific evidence in this review. In particular, he notes limitations in the approaches used to estimate ambient $PM_{10-2.5}$ concentrations in epidemiological studies, limited examination of the potential for confounding by co-occurring pollutants, and limited support for the biological plausibility of the serious effects reported in many epidemiological studies that are reflected by the ''suggestive of, but not sufficient to infer'' causal determinations. Thus, in light of the currently available information, including the uncertainties and limitations of the evidence base available to inform his judgments regarding protection against $PM_{10-2.5}$-related effects, the Administrator does not find it appropriate to increase the stringency of the standard in order to provide the requisite public health protection. Rather, he judges it appropriate to maintain the level of protection provided by the current PM_{10} standard for $PM_{10-2.5}$ exposures and he does not judge the available information and the associated uncertainties to indicate the need for a greater level of public health protection.

In reaching his conclusions on the primary PM_{10} standard, the Administrator also considers advice from the CASAC, including that regarding uncertainties that remain in this review (summarized in section III.B.1 above). In their comments, the CASAC noted that uncertainties persist in the evidence for $PM_{10-2.5}$-related health effects, stating that ''key uncertainties identified in the last review remain'' (Cox, 2019a, p. 13 of consensus responses). In considering these comments, the Administrator takes note of the CASAC consideration of the uncertainties related to the evidence and its conclusion that ''evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard'' (Cox, 2019a, p. 3 of letter). The Administrator further notes the CASAC overall conclusion in this review that the current evidence ''supports consideration of retaining the current standard in this review'' (Cox, 2019a, p. 3 of letter).

Thus, in light of the currently available information, including uncertainties and limitations in the evidence base available to inform his judgments regarding public health protection, as well as CASAC advice, the Administrator does not find it appropriate to revise the standard. Rather, he judges it appropriate to retain the primary PM_{10} standard to provide the requisite degree of public health protection against $PM_{10-2.5}$ exposures, regardless of location, source of origin, or particle composition.

With regard to the uncertainties identified above, the Administrator notes that his final decision in this review is a public health policy judgment that draws upon scientific information, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the information. Accordingly, he recognizes that his decision requires judgments based on

the interpretation of the evidence that neither overstates nor understates the strength or limitations of the evidence nor the appropriate inferences to be drawn. He recognizes, as described in section I.A above, that the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficient but not more stringent than necessary to protect public health, including the health of sensitive groups with an adequate margin of safety.

Recognizing and building upon all of the above considerations and judgments, the Administrator has reached his conclusion in the current review. As an initial matter, he recognizes the control exerted by the current primary PM_{10} standard against exposures to $PM_{10-2.5}$ in ambient air. With regard to key aspects of the specific elements of a standard, the Administrator recognizes continued support in the current evidence base for PM_{10} as the indicator for the standard. In so doing, he notes that such an indicator provides protection from exposure to all coarse PM, regardless of location, source of origin, or particle composition. Similarly, with regard to averaging time, form, and level of the standard, the Administrator takes note of uncertainties in the available evidence and information and continues to find that the current standard, as defined by its current elements, is requisite. He has additionally considered the public comments regarding revisions to these elements of the standard and continues to judge that the existing level and the existing form, in all its aspects, together with the other elements of the existing standard provide an appropriate level of public health protection.

For all of the reasons discussed above, and recognizing the CASAC conclusion that the current evidence provides support for retaining the current standard, the Administrator concludes that the current primary PM_{10} standard (in all of its elements) is requisite to protect public health with an adequate margin of safety from effects of $PM_{10-2.5}$ in ambient air, and should be retained without revision.

C. Decision on the Primary PM_{10} Standard

For the reasons discussed above and taking into account information and assessments presented in the ISA and PA, the advice from the CASAC, and consideration of public comments, the Administrator concludes that the current primary PM_{10} standard is requisite to protect public health with an adequate margin of safety, including the health of at-risk populations, and is retaining the current standard without revision.

IV. Rationale for the Decision on the Secondary PM Standards

This section presents the rationale for the Administrator's decision to retain the current secondary PM standards, without revision. This decision is based on a thorough review of the latest scientific information generally published through December 2017,[63] as presented in the ISA, on non-ecological public welfare effects associated with PM and pertaining to the presence of PM in ambient air, specifically visibility, climate, and materials effects. This decision also accounts for analyses in the PA of policy-relevant information from the ISA and quantitative analyses of air quality related to visibility impairment; CASAC advice; and consideration of public comments received on the proposal.

The EPA is separately reviewing the ecological effects associated with PM in conjunction with reviews of other pollutants that, along with PM, contribute jointly to atmospheric deposition. As explained in both the PM IRP (U.S. EPA, 2016, p. 1–17) and the IRP for review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM (U.S. EPA, 2017, p. 1–1), and discussed in the proposal for this review (85 FR 24127, April 30, 2020), in recognition of the linkages between oxides of nitrogen, oxides of sulfur, and PM with respect to atmospheric deposition, and with respect to the ecological effects, the reviews of the ecological effects evidence and the secondary standards for these pollutants are being conducted together. Addressing the pollutants together enables the EPA to take a comprehensive approach to considering the nature and interactions of the pollutants, which is important for ensuring that all scientific information relevant to ecological effects is thoroughly evaluated. This combined review of the ecological criteria for oxides of nitrogen, oxides of sulfur, and particulate matter is ongoing.[64]

Section IV.A provides background on the general approach for this review and the basis for the existing secondary PM standards, and also presents brief summaries of key aspects of the currently available welfare effects evidence and quantitative information. Section IV.B summarizes the proposed conclusions and CASAC advice, addresses public comments received on the proposal, and presents the Administrator's conclusions on the adequacy of the current standards, drawing on consideration of this information, advice from the CASAC, and comments from the public. Section IV.C summarizes the Administrator's decision on the secondary PM standards.

A. Introduction

As in prior reviews, the general approach to reviewing the current secondary standards is based, most fundamentally, on using the EPA's assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding secondary standards for PM that are requisite to protect the public welfare from known or anticipated adverse effects associated with the presence of PM in the ambient air. The EPA's assessments are primarily documented in the ISA and PA, both of which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 84 FR 47944, September 11, 2019). To bridge the gap between the scientific assessments of the ISA and judgments required of the Administrator in determining whether the current standards provide the requisite welfare protection, the PA evaluates the policy implications of the assessment of the current evidence in the ISA and of the quantitative air quality information documented in the PA. In evaluating the public welfare protection afforded by the current standards, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

The secondary standard is to ''specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator . . . is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air'' (CAA, section 109(b)(2)). The secondary

[63] In addition to the review's opening ''call for information'' (79 FR 71764, December 3, 2014), ''the current ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3). References that are cited in the ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter.*

[64] The final ISA was released in October 2020: *https://www.epa.gov/isa/integrated-science-assessment-isa-oxides-nitrogen-oxides-sulfur-and-particulate-matter.*

standard is not meant to protect against all known or anticipated PM-related effects, but rather those that are judged to be adverse to the public welfare, and a bright-line determination of adversity is not required in judging what is requisite (78 FR 3212, January 15, 2013; 80 FR 65376, October 26, 2015). Thus, the level of protection from known or anticipated adverse effects to public welfare that is requisite for the secondary standard is a public welfare policy judgment to be made by the Administrator. In exercising that judgment, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that the standards be set at a zero-risk level, but rather at a level that reduces risk to protect the public welfare from known or anticipated adverse effects. In reaching conclusions on the standards, the Administrator's final decision draws upon the scientific information and analyses about welfare effects, environmental exposure and risks, and associated public welfare significance, as well as judgment about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and quantitative analyses. The approach to informing these judgments is based on the recognition that the available evidence generally reflects a continuum, consisting of levels at which scientists generally agree that effects are likely to occur, through lower levels at which the likelihood and magnitude of the responses become increasingly uncertain. This approach is consistent with the requirements of the CAA and with how the EPA and the courts have historically interpreted the Act.

In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review, including most particularly that which has been critically analyzed and characterized in the current ISA. We additionally consider the quantitative information described in the PA that estimated visibility impairment associated with current air quality conditions in areas with monitoring data that met completeness criteria (U.S. EPA, 2020, chapter 5). The evidence-based discussions presented below (and summarized more fully in the proposal) draw upon evidence from studies evaluating visibility, climate, and materials effects related to PM in ambient air, as discussed in the ISA. The quantitative-based discussions also presented below (and summarized more fully in the proposal) have been drawn from the quantitative analyses for PM-related visibility impairment, as discussed in the PA.

1. Background on the Current Standards

In the last review, completed in 2012,[65] the EPA retained the secondary 24-hour $PM_{2.5}$ standard, with its level of 35 μg/m³, and the 24-hour PM_{10} standard, with its level of 150 μg/m³ (78 FR 3228, January 15, 2013). The EPA also retained the level, set at 15 μg/m³, and averaging time of the secondary annual $PM_{2.5}$ standard, while revising the form. With regard to the form of the annual $PM_{2.5}$ standard, the EPA removed the option for spatial averaging (78 FR 3228, January 15, 2013). Key aspects of the Administrator's decisions on the secondary PM standards in the last review for non-visibility effects and visibility effects are described below. In the previous PM NAAQS review, the prior Administrator concluded that there was insufficient information available to base a national ambient air quality standard on climate impacts associated with ambient air concentrations of PM or its constituents (78 FR 3225–3226, January 15, 2013; U.S. EPA, 2011, section 5.2.3). In reaching this decision, the prior Administrator considered the scientific evidence, noting the 2009 ISA conclusion ''that a causal relationship exists between PM and effects on climate'' and that aerosols[66] alter climate processes directly through radiative forcing and by indirect effects on cloud brightness, changes in precipitation, and possible changes in cloud lifetimes (U.S. EPA, 2009c, section 9.3.10). She also noted that the major aerosol components with the potential to affect climate processes (*i.e.,* black carbon (BC), organic carbon (OC), sulfates, nitrates and mineral dusts) vary in their reflectivity, forcing efficiencies, and direction of climate forcing (U.S. EPA, 2009c, section 9.3.10). The prior Administrator recognized the strong evidence indicating that aerosols affect climate and further considered what the available information indicated regarding the adequacy of protection provided by the secondary PM standards. In particular, she noted that a number of uncertainties in the scientific information (*i.e.,* the spatial and temporal heterogeneity of PM components that contribute to climate forcing, uncertainties in the measurement of aerosol components, inadequate consideration of aerosol impacts in climate modeling, insufficient data on local and regional microclimate variations and heterogeneity of cloud formations) affected our ability to conduct a quantitative analysis to determine a distinct secondary standard based on climate.

In the last review, the prior Administrator concluded that that it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address PM-related materials effects (78 FR 3225–3226, January 15, 2013; U.S. EPA, 2011, p. 5–29). In reaching this conclusion, she considered materials effects associated with the deposition of PM (*i.e.,* dry and wet deposition), including both physical damage (materials effects) and aesthetic qualities (soiling effects). She noted the 2009 ISA conclusion that evidence was ''sufficient to conclude that a causal relationship exists between PM and effects on materials'' (U.S. EPA, 2009c, sections 2.5.4 and 9.5.4), but also recognized that the 2011 PA noted that quantitative relationships were lacking between particle size, concentrations, and frequency of repainting and repair of surfaces and that considerable uncertainty exists in the contributions of co-occurring pollutants to materials damage and soiling processes (U.S. EPA, 2011, p. 5–29).

In considering non-visibility welfare effects in the last review, as discussed above, the prior Administrator concluded that, while it is important to maintain an appropriate degree of control of fine and coarse particles to address non-visibility welfare effects, ''[i]n the absence of information that would support any different standards . . . it is appropriate to retain the

[65] The 2012 decision on the adequacy of the secondary PM standards was based on consideration of the protection provided by those standards for visibility and for the non-visibility effects of materials damage, climate effects and ecological effects. As noted earlier, the current review of the public welfare protection provided by the secondary PM standards against ecological effects is occurring in the separate, on-going review of the secondary NAAQS for oxides of nitrogen and oxides of sulfur (U.S. EPA, 2016, Chapter 1, section 5.2; U.S. EPA, 2020, Chapter 1, section 5.1.1). Thus, the consideration of ecological effects in the 2012 review is not discussed here.

[66] In the climate sciences research community, PM is encompassed by what is typically referred to as aerosol. An aerosol is defined as a solid or liquid suspended in a gas, but PM refers to the solid or liquid phase of an aerosol. In this review of the secondary PM NAAQS the discussion on climate effects of PM uses the term PM throughout for consistency with the ISA (U.S. EPA, 2019) as well as to emphasize that the climate processes altered by aerosols are generally altered by the PM portion of the aerosol. Exceptions to this practice include the discussion of climate effects in the last review, when aerosol was used when discussing suspended aerosol particles, and for certain acronyms that are widely used by the climate community that include the term aerosol (*e.g.,* aerosol optical depth, or AOD).

existing suite of secondary standards'' (78 FR 3225–3226, January 15, 2013). Her decision was consistent with the CASAC advice related to non-visibility effects. Specifically, the CASAC agreed with the 2011 PA conclusions that, while these effects are important, ''there is not currently a strong technical basis to support revisions of the current standards to protect against these other welfare effects'' (Samet, 2010a, p. 5). Thus, in considering non-visibility welfare effects, the prior Administrator concluded that it was appropriate to retain all aspects of the existing 24-hour $PM_{2.5}$ and PM_{10} secondary standards. With regard to the secondary annual $PM_{2.5}$ standard, she concluded that it was appropriate to retain a level of 15.0 μg/m³ while revising only the form of the standard to remove the option for spatial averaging (78 FR 3225–3226, January 15, 2013).

Having reached the conclusion it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address non-visibility PM-related welfare effects, the prior Administrator next considered the level of protection that would be requisite to protect public welfare against PM-related visibility impairment and whether to adopt a distinct secondary standard to achieve this level of protection. In reaching her final decision that the existing 24-hour $PM_{2.5}$ standard provides sufficient protection against PM-related visibility impairment (78 FR 3228, January 15, 2013), she considered the evidence assessed in the 2009 ISA (U.S. EPA, 2009c) and the analyses included in the Urban-Focused Visibility Assessment (2010 UFVA; U.S. EPA, 2010b) and the 2011 PA (U.S. EPA, 2011). She also considered the degree of protection for visibility that would be provided by the existing secondary standard, focusing specifically on the secondary 24-hour $PM_{2.5}$ standard with its level of 35 μg/m³. These considerations, and the prior Administrator's conclusions regarding visibility are summarized below and discussed in more detail in the proposal (85 FR 24128–24129, April 30, 2020).

In the last review, the ISA concluded that, ''collectively, the evidence is sufficient to conclude that a causal relationship exists between PM and visibility impairment'' (U.S. EPA, 2009c, p. 2–28). In consideration of the potential public welfare implication of various degrees of PM-related visibility impairment, the prior Administrator considered the available visibility preference studies that were part of the overall body of evidence in the 2009 ISA and reviewed as a part of the 2010 UFVA. These preference studies provided information about the potential public welfare implications of visibility impairment from surveys in which participants were asked questions about their preferences or the values they placed on various visibility conditions, as displayed to them in scenic photographs or in images with a range of known light extinction levels.[67]

In noting the relationship between PM concentrations and PM-related light extinction, the prior Administrator focused on identifying an adequate level of protection against visibility-related welfare effects. She first concluded that a standard in terms of a $PM_{2.5}$ visibility index would provide a measure of protection against PM-related light extinction that directly takes into account the factors (*i.e.,* PM species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in ambient air and PM-related visibility impairment. A $PM_{2.5}$ visibility index standard would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by directly incorporating the effects of differences of $PM_{2.5}$ composition and relative humidity. In defining a target level of protection in terms of a $PM_{2.5}$ visibility index, as discussed below, she considered specific elements of the index, including the basis for its derivation, as well as an appropriate averaging time, level, and form.

The prior Administrator concluded that it was appropriate to use an adjusted version of the original IMPROVE algorithm,[68] in conjunction with monthly average relative humidity data based on long-term climatological means, as the basis for deriving a visibility index. In so concluding, she noted the CASAC conclusion on the reasonableness of reliance on a $PM_{2.5}$ light extinction indicator calculated from $PM_{2.5}$ chemical composition and relative humidity, and she recognized that the mass monitoring methods available at that time were unable to measure the full water content of ambient $PM_{2.5}$ and did not provide information on the composition of $PM_{2.5}$, both of which contribute to visibility impacts (77 FR 38980, June 29, 2012). As noted at the time of the proposal, the prior Administrator recognized that suitable equipment and performance-based verification procedures did not then exist for direct measurement of light extinction and could not be developed within the time frame of the review (77 FR 38980–38981, June 29, 2012).

The prior Administrator concluded that a 24-hour averaging time would be appropriate for a visibility index (78 FR 3226, January 15, 2013). Although she recognized that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with relatively high humidity, are more directly related to the short-term nature of the perception of PM-related visibility impairment and relevant exposure periods for segments of the viewing public than a 24-hour averaging time, she also noted that there were data quality uncertainties associated with the instruments used to provide the hourly $PM_{2.5}$ mass measurements required for an averaging time shorter than 24 hours. She also considered the results of analyses that compared 24-hour and 4-hour averaging times for calculating the index. These analyses showed good correlation between 24-hour and 4-hour average $PM_{2.5}$ light extinction, as evidenced by reasonably high city-specific and pooled R-squared values, generally in the range of over 0.6 to over 0.8. Based on these analyses and the 2011 PA conclusions regarding them, the prior Administrator concluded that a 24-hour averaging time would be a reasonable and appropriate surrogate for a sub-daily averaging time.

The statistical form of the index, 3-year average of annual 90th percentile values, was based on the prior Administrator's consideration of the analyses conducted in the 2011 UFVA of three different statistics and consistency of this statistical form with the Regional Haze Program, which targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas. Moreover, the prior Administrator noted that a 3-year average form provided stability from the occasional effect of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year (78 FR 3198, January 15, 2013; U.S. EPA,

[67] Preference studies were available in four urban areas in the last review. Three western preference studies were available, including one in Denver, Colorado (Ely et al., 1991), one in the lower Fraser River valley near Vancouver, British Columbia, Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates, 2001), and a replicate study with 26 participants was also conducted for Washington, DC (Smith and Howell, 2009). More details about these studies are available in Appendix D of the PA.

[68] The revised IMPROVE algorithm (Pitchford et al., 2007) uses major PM chemical composition measurements and relative humidity estimates to calculate light extinction. For more information about the derivation of and input data required for the original and revised IMPROVE algorithms, see 78 FR 3168–3177, January 15, 2013.

2011, p. 4–58).[69] The Administrator also noted that the available studies on people's preferences did not address frequency of occurrence of different levels of visibility and did not identify a basis for a different target for urban areas than that for Class I areas (U.S. EPA, 2011, p. 4–59). These considerations led the prior Administrator to conclude that 90th percentile form was the most appropriate annual statistic to be averaged across three years (78 FR 3226, January 15, 2013).

In selecting a level for the index, the prior Administrator considered the ''candidate protection levels'' (CPLs)[70] identified in the 2011 PA based on the visibility preference studies, ranging from 20 to 30 deciviews (dv),[71] while noting the uncertainties and limitations in these public preference studies.[72] She concluded that that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain. Therefore, she concluded that it was appropriate to set a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index at 30 dv (78 FR 3226–3227, January 15, 2013).

Based on her considerations and conclusions summarized above, the prior Administrator concluded that the protection provided by a secondary standard based on a 3-year visibility metric, defined in terms of a $PM_{2.5}$ visibility index with a 24-hour averaging time, a 90th percentile form averaged over 3 years, and a level of 30 dv, would be requisite to protect public welfare with regard to visual air quality (78 FR 3227, January 15, 2013). Having reached this conclusion, she next determined whether an additional distinct secondary standard in terms of a visibility index was needed given the degree of protection from visibility impairment afforded by the existing secondary standards. Specifically, she noted that the air quality analyses showed that all areas meeting the existing 24-hour $PM_{2.5}$ standard, with its level of 35 μg/m^3, had visual air quality at least as good as 30 dv, based on the visibility index defined above (Kelly et al., 2012b, Kelly et al., 2012a). Thus, the secondary 24-hour $PM_{2.5}$ standard would likely be controlling relative to a 24-hour visibility index set at a level of 30 dv. Additionally, areas would be unlikely to exceed the target level of protection for visibility of 30 dv without also exceeding the existing secondary 24-hour standard. Thus, the prior Administrator judged that the 24-hour $PM_{2.5}$ standard ''provides sufficient protection in all areas against the effects of visibility impairment—*i.e.,* that the existing 24-hour $PM_{2.5}$ standard would provide *at least* the target level of protection for visual air quality of 30 dv which [she] judges appropriate'' (78 FR 3227, January 15, 2013). She further judged that ''[s]ince sufficient protection from visibility impairment would be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection for some areas of the country . . . adoption of such a distinct secondary standard is not needed to provide requisite protection for both visibility and nonvisibility related welfare effects'' (78 FR 3228, January 15, 2013).

2. Overview of Welfare Effects Evidence

In this section, we provide an overview of the policy-relevant aspects of the welfare effects evidence available for consideration in this review. Sections IV.B and IV.C of the proposal provide a detailed summary of key information contained in the ISA and in the PA on the visibility and non-visibility welfare effects associated with PM in ambient air, and the related public welfare implications (85 FR 24129, April 30, 2020). The subsections below briefly summarize the nature of PM-related visibility and non-visibility effects.

a. Nature of Effects

The evidence base available in the current review includes decades of research on visibility impairment, climate effects, and materials effects associated with PM (U.S. EPA, 2004, 2009c, 2019). Visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being (U.S. EPA, 2009c, section 9.2). The strongest evidence for PM-related visibility impairment comes from the fundamental relationship between light extinction and PM mass (U.S. EPA, 2009c), as well as studies of the public perception of visibility impairment (U.S. EPA, 2010b), which confirm a well-established ''causal relationship exists between PM and visibility impairment'' (U.S. EPA, 2009c, p. 2–28). Beyond its effects on visibility, the 2009 ISA also identified a causal relationship ''between PM and climate effects, including both direct effects of radiative forcing and indirect effects that involve cloud and feedbacks that influence precipitation formation and cloud lifetimes'' (U.S. EPA, 2009, p. 2–29). The evidence also supports a causal relationship between PM and effects on materials, including soiling effects and materials damage (U.S. EPA, 2009, p. 2–31).

The evidence newly available in this review is consistent with the evidence available at the time of the last review and supports the conclusions of causal relationships between PM and visibility, climate, and materials effects (U.S. EPA, 2019, chapter 13). Evidence newly available in this review augments the previously available evidence of the relationship between PM and visibility impairment (U.S. EPA, 2019, section 13.2), climate effects (U.S. EPA, 2019, section 13.3), and materials effects (U.S. EPA, 2019, section 13.4).

i. Visibility

Visibility refers to the visual quality of a human's view with respect to color rendition and contrast definition. It is the ability to perceive landscape form, colors, and textures. Visibility involves optical and psychophysical properties involving human perception, judgment, and interpretation. Light between the observer and the object can be scattered into or out of the sight path and absorbed by PM or gases in the sight path. Consistent with conclusions of causality in the last review, the 2019 ISA concludes that ''the evidence is sufficient to conclude that a causal relationship exists between PM and visibility impairment'' (U.S. EPA, 2019, section 13.2.6). These conclusions are based on the strong and consistent evidence that ambient PM can impair visibility in both urban and remote areas (U.S. EPA, 2019, section 13.1; U.S. EPA, 2009c, section 9.2.5).

The fundamental relationship between light extinction and PM mass, and the EPA's understanding of this relationship, has changed little since the

[69] The EPA recognized that a percentile form averaged over multiple years offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard, thus reducing the potential for disruption of programs implementing the standard and reducing the potential for disruption of the protections provided by those programs.

[70] For comparison, 20 dv, 25 dv, and 30 dv are equivalent to 64, 112, and 191 megameters (Mm^{-1}), respectively.

[71] Deciview (dv) refers to a scale for characterizing visibility that is defined directly in terms of light extinction. The deciview scale is frequently used in the scientific and regulatory literature on visibility.

[72] Uncertainties and limitations in the public preference studies included the small number of stated preference studies available; the relatively small number of study participants and the extent to which the study participants may not be representative of the broader study area population in some of the studies; and the variations in the specific materials and methods used in each study.

2009 ISA (U.S. EPA, 2009c). The combined effect of light scattering and absorption by particles and gases is characterized as light extinction, *i.e.,* the fraction of light that is scattered or absorbed per unit of distance in the atmosphere. Light extinction is measured in units of 1/distance, which is often expressed in the technical literature as visibility per megameter (abbreviated Mm^{-1}). Higher values of light extinction (usually given in units of Mm^{-1} or dv) correspond to lower visibility. When PM is present in the air, its contribution to light extinction is typically much greater than that of gases (U.S. EPA, 2019, section 13.2.1). The impact of PM on light scattering depends on particle size and composition, as well as relative humidity. All particles scatter light, as described by the Mie theory, which relates light scattering to particle size, shape, and index of refraction (U.S. EPA, 2019, section 13.2.3; Van de Hulst, 1981; Mie, 1908). Fine particles scatter more light than coarse particles on a per unit mass basis and include sulfates, nitrates, organics, light-absorbing carbon, and soil (Malm et al., 1994). Hygroscopic particles like ammonium sulfate, ammonium nitrate, and sea salt increase in size as relative humidity increases, leading to increased light scattering (U.S. EPA, 2019, section 13.2.3).

As at the time of the last review, direct measurements of PM light extinction, scattering, and absorption continue to be considered more accurate for quantifying visibility than PM mass-based estimates because measurements do not depend on assumptions about particle characteristics (*e.g.,* size, shape, density, component mixture, etc.) (U.S. EPA, 2019, section 13.2.2.2). Measurements of light extinction can be made with high time resolution, allowing for characterization of sub-daily temporal patterns of visibility impairment. A number of measurement methods have been used for visibility impairment (*e.g.,* transmissometers, integrating nephelometers, teleradiometers, telephotometers, and photography and photographic modeling), although each of these methods has its own strengths and limitations (U.S. EPA, 2019, Table 13–1). As recognized in the last review, there are no common performance-based criteria to evaluate these methods and none have been deployed broadly across the U.S. for routine measurement of visibility impairment.

In the absence of a robust monitoring network for the routine measurement of light extinction across the U.S., estimation of light extinction based on existing PM monitoring can be used. The theoretical relationship between light extinction and PM characteristics, as derived from Mie theory (U.S. EPA, 2019, Equation 13.5), and can be used to estimate light extinction by combining mass scattering efficiencies of particles with particle concentrations (U.S. EPA, 2019, section 13.2.3; U.S. EPA, 2009c, sections 9.2.2.2 and 9.2.3.1). This estimation of light extinction is consistent with the method used in the last review. The algorithm used to estimate light extinction, known as the IMPROVE algorithm,[73] provides for the estimation of light extinction (b_{ext}), in units of Mm^{-1}, using routinely monitored components of fine ($PM_{2.5}$) and coarse ($PM_{10-2.5}$) PM. Relative humidity data are also needed to estimate the contribution by liquid water that is in solution with the hygroscopic components of PM. To estimate each component's contribution to light extinction, their concentrations are multiplied by extinction coefficients and are additionally multiplied by a water growth factor that accounts for their expansion with moisture. Both the extinction efficiency coefficients and water growth factors of the IMPROVE algorithm have been developed by a combination of empirical assessment and theoretical calculation using particle size distributions associated with each of the major aerosol components (U.S. EPA, 2019, section 13.2.3.1, section 13.2.3.3).

At the time of the last review, two versions of the IMPROVE algorithm were available in the literature—the *original IMPROVE algorithm* (Malm and Hand, 2007; Ryan et al., 2005; Lowenthal and Kumar, 2004) and the *revised IMPROVE algorithm* (Pitchford et al., 2007). As described in detail in the proposal (85 FR 24130, April 30, 2020) and the ISA (U.S. EPA, 2019, section 13.2.3), the algorithm has been further evaluated and refined since the time of the last review (Lowenthal and Kumar, 2016), particularly for PM characteristics and relative humidity in remote areas. All three versions of the IMPROVE algorithm were considered in evaluating visibility impairment in this review.

Consistent with the evidence available at the time of the last review, our understanding of public perception of visibility impairment comes from visibility preference studies conducted in four areas in North America.[74] The detailed methodology for these studies are described in the proposal (85 FR 24131, April 30, 2020), the 2019 ISA (U.S. EPA, 2019), and the 2009 ISA (U.S. EPA, 2009c). In summary, the study participants were queried regarding multiple images that were either photographs of the same location and scenery that had been taken on different days on which measured extinction data were available or digitized photographs onto which a uniform ''haze'' had been superimposed. Results of the studies indicated a wide range of judgments on what study participants considered to be acceptable visibility across the different study areas, depending on the setting depicted in each photograph. Based on the results of the four cities, a range encompassing the $PM_{2.5}$ visibility index values from images that were judged to be acceptable by at least 50 percent of study participants across all four of the urban preference studies was identified (U.S. EPA, 2010b, p. 4–24; U.S. EPA, 2020, Figure 5–2). Much lower visibility (considerably more haze resulting in higher values of light extinction) was considered acceptable in Washington, DC, than was in Denver, and 30 dv reflected the level of impairment that was determined to be ''acceptable'' by at least 50 percent of study participants (78 FR 3226–3227, January 15, 2013). As noted in the proposal (85 FR 24131, April 30, 2020), the evidence base for public preferences of visibility impairment has not been augmented since the last review. There are no new visibility preference studies that have been conducted in the U.S. since the time of the last review and there is very little new information available regarding acceptable levels of visibility impairment in the U.S.

ii. Climate

The current evidence continues to support the conclusion of a causal relationship between PM and climate effects (U.S. EPA, 2019, section 13.3.9). Since the last review, climate impacts and been extensively studied and recent research reinforces and strengthens the evidence evaluated in the 2009 ISA. New evidence provides greater specificity about the details of radiative

[73] The algorithm is referred to as the IMPROVE algorithm as it was developed specifically to use monitoring data generated at IMPROVE network sites and with equipment specifically designed to support the IMPROVE program and was evaluated using IMPROVE optical measurements at the subset of monitoring sites that make those measurements (Malm et al., 1994).

[74] Preference studies were available in four urban areas in the last review: Denver, Colorado (Ely et al., 1991), Vancouver, British Columbia, Canada (Pryor, 1996), Phoenix, Arizona (BBC Research & Consulting, 2003), and Washington, DC (Abt Associates, 2011; Smith and Howell, 2009).

forcing effects[75] and increases the understanding of additional climate impacts driven by PM radiative effects. The Intergovernmental Panel on Climate Change (IPCC) assesses the role of anthropogenic activity in past and future climate change, and since the last review, has issued the Fifth IPCC Assessment Report (AR5; IPCC, 2013) which summarizes any key scientific advances in understanding the climate effects of PM since the previous report. As in the last review, the ISA draws substantially on the IPCC report to summarize climate effects. As discussed in more detail in the proposal (85 FR 24131, April 30, 2020), the general conclusions are similar between the IPCC AR4 and AR5 reports with regard to effects of PM on global climate. Consistent with the evidence available in the last review, the key components, including sulfate, nitrate, organic carbon (OC), black carbon (BC), and dust, that contribute to climate processes vary in their reflectivity, forcing efficiencies, and direction of forcing. Since the last review, the evidence base has expanded with respect to the mechanisms of climate responses and feedbacks to PM radiative forcing; however, the new literature published since the last review does not reduce the considerable uncertainties that continue to exist related these mechanisms.

As described in the proposal (85 FR 24133, April 30, 2020), PM has a very heterogeneous distribution globally and patterns of forcing tend to correlate with PM loading, with the greatest forcings centralized over continental regions. The climate response to this PM forcing, however, is more complicated since the perturbation to one climate variable (*e.g.,* temperature, cloud cover, precipitation) can lead to a cascade of effects on other variables. While the initial PM radiative forcing may be concentrated regionally, the eventual climate response can be much broader spatially or be concentrated in remote regions, and may be quite complex, affecting multiple climate variable with possible differences in the direction of the forcing in different regions or for different variables (U.S. EPA, 2019, section 13.3.6). The complex climate system interactions lead to variation among climate models, which have suggested a range of factors which can influence large-scale meteorological processes and may affect temperature, including local feedback effects involving soil moisture and cloud cover, changes in the hygroscopicity of the PM, and interactions with clouds (U.S. EPA, 2019, section 13.3.7). Further research is needed to better characterize the effects of PM on regional climate in the U.S. before PM climate effects can be quantified.

iii. Materials

Consistent with the last review, the current evidence continues to support the conclusion that there is a causal relationship between PM deposition and materials effects. Effects of deposited PM, particularly sulfates and nitrates, to materials include both physical damage and impaired aesthetic qualities, generally involving soiling and/or corrosion (U.S. EPA, 2019, section 13.4.2; 85 FR 24133, April 30, 2020). Because of their electrolytic, hygroscopic, and acidic properties and their ability to sorb corrosive gases, particles contribute to materials damage by adding to the effects of natural weathering processes, by potentially promoting or accelerating the corrosion of metals, degradation of painted surfaces, deterioration of building materials, and weakening of material components.[76] There is a limited amount of new data for consideration in this review from studies primarily conducted outside of the U.S. on buildings and other items of cultural heritage. However, these studies involved concentrations PM in ambient air greater than those typically observed in the U.S. (U.S. EPA, 2019, section 13.4).

Building on the evidence available in the 2009 ISA, and as described in detail in the proposal (85 FR 24134, April 30, 2020) and in the 2019 ISA (U.S. EPA, 2019, section 13.4), research has progressed on: (1) The theoretical understanding of soiling of items of cultural heritage; (2) the quantification of degradation rates and further characterization of factors that influence damage of stone materials; (3) materials damage from PM components besides sulfate and black carbon and atmospheric gases besides SO_2; (4) methods for evaluating soiling of materials by PM mixtures; (5) PM-attributable damage to other materials, including glass and photovoltaic panels; (6) development of dose-response relationships for soiling of building materials; and (7) damage functions to quantify material decay as a function of pollutant type and load. While the evidence of PM-related materials effects has expanded somewhat since the last review, there remains insufficient evidence to relate soiling or damage to specific PM levels in ambient air or to establish a quantitative relationship between PM and materials degradation. The current evidence is generally similar to the evidence available in the last review, including associated limitations and uncertainties and a lack of evidence to inform quantitative relationships between PM and materials effects, therefore leading to similar conclusions about the PM-related effects on materials.

3. Overview of Air Quality and Quantitative Information

a. Visibility Effects

In the current review, quantitative analyses were conducted to further our understanding of the relationship between recent air quality and calculated light extinction. As at the time of the last review, these analyses explored this relationship as an estimate of visibility impairment in terms of the 24-hour $PM_{2.5}$ standard and the visibility index. Generally, the results of the updated analyses are similar to those based on the data available at the time of the last review (U.S. EPA, 2020, section 5.2.1.1). Compared to the last review, updated analyses incorporate several refinements, including: (1) The evaluation of three versions of the IMPROVE equation[77] to calculate light extinction (U.S. EPA, 2020, Appendix D, Equations D–1 through D–3) in order to better understand the influence of variability in equation inputs;[78] (2) the

[75] Radiative forcing (RF) for a given atmospheric constituent is defined as the perturbation in net radiative flux, at the tropopause (or the top of the atmosphere) caused by that constituent, in watts per square meter (Wm^{-2}), after allowing for temperatures in the stratosphere to adjust to the perturbation but holding all other climate responses constant, including surface and tropospheric temperatures (Fiore et al., 2015; Myhre et al., 2013). A positive forcing indicates net energy trapped in the Earth system and suggests warming of the Earth's surface, whereas a negative forcing indicates net loss of energy and suggests cooling (U.S. EPA, 2019, section 13.3.2.2).

[76] As discussed in the ISA (U.S. EPA, 2019, section 13.4.1), corrosion typically involves reactions of acidic PM (*i.e.,* acidic sulfate or nitrate) with material surfaces, but gases like SO_2 and nitric acid (HNO_3) also contribute. Because ''the impacts of gaseous and particulate N and S wet deposition cannot be clearly distinguished'' (U.S. EPA, 2019, p. 13–1), the assessment of the evidence in the ISA considers the combined impacts.

[77] Given the lack of new information to inform a different visibility metric, the metric used in the updated analyses is that defined by the EPA in the last review as the target level of protection for visibility (discussed above in section IV.A.1): A $PM_{2.5}$ visibility index with a 24-hour averaging time, a 90th percentile form averaged over 3 years, and a level of 30 dv (U.S. EPA, 2020, section 5.2.1.2).

[78] While the $PM_{2.5}$ monitoring network has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations, there continue to be data quality uncertainties associated with providing hourly $PM_{2.5}$ mass and component measurements that could be input into IMPROVE equation calculations for sub-daily visibility impairment estimates. As detailed in the PA, there are uncertainties associated with the precision and

use of 24-hour relative humidity data, rather than monthly average relative humidity as was used in the last review (U.S. EPA, 2020, section 5.2.1.2, Appendix D); and (3) the inclusion of the coarse fraction in the estimation of light extinction in the subset of areas with $PM_{10-2.5}$ monitoring data available for the time period of interest (U.S. EPA, 2020, section 5.2.1.2, Appendix D). The analyses in the current review are updated from the last review and include 67 monitoring sites that measure $PM_{2.5}$, including 20 sites that measure both PM_{10} and $PM_{2.5}$, that are geographically distributed across the U.S. in both urban and rural areas (U.S. EPA, 2020, Appendix D, Figure D–1).

In areas that meet the current 24-hour $PM_{2.5}$ standard for the 2015–2017 time period, all sites have light extinction estimates at or below 27 dv using the original and revised IMPROVE equations (and most areas are below 25 dv; U.S. EPA, 2020, section 5.2.1.2). In the one location that exceeds the current 24-hour $PM_{2.5}$ standard, light extinction estimates are at or below 27 dv (U.S. EPA, 2020, Figure 5–3). These findings are consistent with the findings of the analysis in the last review with older air quality data (Kelly et al., 2012b; 78 FR 3201, January 15, 2013).

Using the recently modified IMPROVE equation from Lowenthal and Kumar (2016), new in this review, the resulting 3-year visibility index is slightly higher at all of the sites compared to the original and revised IMPROVE equation estimates (U.S. EPA, 2020, Figure 5–4). These higher estimates are to be expected, given the higher OC multiplier included in the IMPROVE equation from Lowenthal and Kumar (2016), which reflects the use of data from remote areas with higher concentrations of organic PM when validating the equation. As such, it is important to note that the Lowenthal and Kumar (2016) version of the equation may overestimate light extinction in non-remote areas, including the urban areas in the updated analyses in this review.

Nevertheless, when light extinction is calculated using the Lowenthal and Kumar (2016) equation for those sites that meet the current 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is generally at or below 30 dv. The one exception to this is a site in Fairbanks, Alaska that just meets the current 24-hour $PM_{2.5}$ standard in 2015–2017 and has a 3-year visibility index value just above 30 dv, rounding to 31 dv (compared to 27 dv when light extinction is calculated with the original IMPROVE equations) (U.S. EPA, 2020, Appendix D, Table D–3). The unique conditions at this urban site (*e.g.,* higher OC concentrations, much lower temperatures, and the complete lack of sunlight for long periods) that affect quantitative relationships between OC, OM and visibility (*e.g.,* Hand et al., 2012; Hand et al., 2013) may differ considerably from those under which the Lowenthal and Kumar (2016) equation has been evaluated, making the most appropriate approach for characterizing light extinction in this area unclear.

At the time of the last review, the EPA noted that $PM_{2.5}$ is the size fraction of PM responsible for most of the visibility impairment in urban areas (77 FR 38980, June 29, 2012). Data available at the time of the last review suggested that $PM_{10-2.5}$ was a minor contributor to visibility impairment (U.S. EPA, 2010b), although this fraction may be responsible for a larger contribution in some areas in the desert southwestern region of the U.S. However, at the time of the last review, there was very little data available from $PM_{10-2.5}$ monitors to quantify the contribution of coarse PM to calculated light extinction.

Since the last review, the expansion of $PM_{10-2.5}$ monitoring efforts has increased the availability of data for use in estimating light extinction. As such, both $PM_{2.5}$ and $PM_{10-2.5}$ concentrations can be included as inputs in the equations in the updated analyses in this review. For 2015–2017, 20 of the 67 $PM_{2.5}$ sites analyzed have collocated $PM_{10-2.5}$ monitoring data available. These 20 sites meet both the 24-hour $PM_{2.5}$ and 24-hour PM_{10} standards. All of these sites have 3-year visibility metrics at or below 30 dv regardless of whether light extinction is calculated with or without the coarse fraction, and for all three versions of the IMPROVE equation. Generally, the coarse fraction contribution to light extinction is minimal, contributing less than 1 dv to the 3-year visibility metric. The 20 locations with collocated $PM_{2.5}$ and $PM_{10-2.5}$ monitoring data available in this review would be expected to have relatively low concentrations of coarse PM. In areas with higher concentrations of coarse PM, such as the southwestern U.S., the coarse fraction may be a more important contributor to light extinction and visibility impairment than in the locations included in the updated analyses in this review.

Overall, the results of the updated analyses in this review are consistent with those in the last review. The 3-year visibility metric is generally at or below 27 dv in areas that meet the current secondary standards, with only small differences observed for the three versions of the IMPROVE equation. Though such differences are modest, the IMPROVE equation from Lowenthal and Kumar (2016) results in higher light extinction values, which were expected given the higher OC multiplier in the equation and its validation using data from remote areas far away from emission sources. There are only small differences in estimates of light extinction when the coarse fraction is included in the equation, although a somewhat larger coarse fraction contribution to light extinction would be expected in areas with higher concentrations of coarse PM. Overall, the updated analyses indicate that the current secondary PM standards provide a degree of protection against visibility impairment similar to the target level of protection identified in the last review, in terms of a 3-year visibility index.

b. Non-Visibility Effects

Consistent with the evidence available at the time of the last review, and as described in detail in the PA (U.S. EPA, 2020, section 5.2.2.2), the data remain insufficient to conduct quantitative analyses for PM effects on climate and materials. For PM-related climate effects, as explained in more detail in the proposal (85 FR 24131–24133, 24136, April 30, 2020), our understanding of PM-related climate effects is still limited by significant key uncertainties. The newly available evidence does not appreciably improve our understanding of the spatial and temporal heterogeneity of PM components that contribute to climate forcing (U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). Significant uncertainties also persist related to quantifying the contributions of PM and PM components to the direct and indirect effects on climate forcing, such as changes to the pattern of rainfall, changes to wind patterns, and effects on vertical mixing in the atmosphere (U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). Additionally, while improvements have been made to climate models since the time of the last review, the models continue to exhibit variability in estimates of the PM-related climate effects on regional scales (*e.g.,* ~100 km) compared to simulations at the global scale (U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). While our understanding of

bias of 24-hour $PM_{2.5}$ measurements (U.S. EPA, 2020, p. 2–18), as well as to the fractional uncertainty associated with 24-hour PM component measurements (U.S. EPA, 2020, p. 2–21). Given the uncertainties present when evaluating data quality on a 24-hour basis, the uncertainty associated with sub-daily measurements may be even greater. Therefore, the inputs to these light extinction calculations are based on 24-hour average measurements of $PM_{2.5}$ mass and components, rather than sub-daily information.

climate forcing on a global scale is somewhat expanded since the last review, significant limitations remain to quantifying potential adverse PM-related climate effects in the U.S. and how they would vary in response to incremental changes in PM concentrations across the U.S. As such, while new research is available on climate forcing on a global scale, the remaining limitations and uncertainties are significant, and the new global scale research does not translate directly for use at regional spatial scales. Therefore, the evidence does not provide a clear understanding at the necessary spatial scales for quantifying the relationship between PM mass in ambient air and the associated climate-related effects in the U.S. that would be most relevant to informing consideration of a national PM standard on climate in this review (U.S. EPA, 2020, section 5.2.2.2.1; U.S. EPA, 2019, section 13.3).

For PM-related materials effects, as explained in more detail in the proposal (85 FR 24133–24134, 24137, April 30, 2020), the available evidence has been somewhat expanded to include additional information about the soiling process and the types of materials impacted by PM. This evidence provides some limited information to inform dose-response relationships and damage functions associated with PM, although most of these studies were conducted outside of the U.S. where PM concentrations in ambient air are typically above those observed in the U.S. (U.S. EPA, 2020, section 5.2.2.1.2; U.S. EPA, 2019, section 13.4). The evidence available in this review also includes studies examining effects of PM on the energy efficiency of solar panels and passive cooling building materials, although the evidence remains insufficient to establish quantitative relationships between PM in ambient air and these or other materials effects (U.S. EPA, 2020, section 5.2.2.1.2). While the available evidence is somewhat expanded since the time of the last review, quantitative relationships have not been established for PM-related soiling and corrosion and frequency of cleaning or repair that would help inform our understanding of the public welfare implications of materials effects (U.S. EPA, 2020, section 5.2.2.2.2; U.S. EPA, 2019, section 13.4). Therefore, there is insufficient information to inform quantitative analyses assessing materials effects to inform a consideration of a national PM standard on materials in this review (U.S. EPA, 2020, section 5.2.2.2.2; U.S. EPA, 2019, section 13.4).

B. Conclusions on the Secondary Standards

In drawing conclusions on the adequacy of the current secondary PM standards, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the evidence base, information, and policy judgments that were the foundation of the last review and reflects upon the body of information and evidence available in this review. In so doing, the Administrator has taken into account both evidence-based and quantitative information-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence from studies evaluating welfare effects related to visibility, climate, and materials associated with PM in ambient air as discussed in the PA (summarized in sections IV..B, V.C, and IV.D.1 of the proposal, and section IV.A.2 above). The quantitative information-based considerations draw from the results of the quantitative analyses of visibility impairment presented in the PA (as summarized in section IV.D.1 of the proposal and section IV.A.3 above) and consideration of these results in the PA.

Consideration of the evidence and quantitative information in the PA and by the Administrator is framed by consideration of a series of policy-relevant questions. Section IV.B.2 below summarizes the rationale for the Administrator's proposed decision, drawing from section IV.D.3 of the proposal. The advice and recommendations of the CASAC and public comments on the proposed decision are addressed below in sections IV.D.2 and IV.D.3, respectively. The Administrator's conclusions in this review regarding the adequacy of the secondary PM standards and whether any revisions are appropriate are described in section IV.D.4.

1. CASAC Advice in This Review

In comments on the draft PA, the CASAC concurred with the staff's overall preliminary conclusions that it is appropriate to consider retaining the current secondary standards without revision (Cox, 2019a). The CASAC ''finds much of the information . . . on visibility and materials effects of $PM_{2.5}$ to be useful, while recognizing that uncertainties and controversies remain about the best ways to evaluate these effects'' (Cox, 2019a, p. 13 of consensus responses). Regarding climate, while the CASAC agreed that research on PM-related effects has expanded since the last review, it also concluded that ''there are still significant uncertainties associated with the accurate measurement of PM to the direct and indirect effects of PM on climate'' (Cox, 2019a, pp. 13–14 of consensus responses). The committee recommended that the EPA summarize the ''current scientific knowledge and quantitative modeling results for effects of reducing $PM_{2.5}$'' on several climate-related outcomes (Cox, 2019a, p. 14 of consensus responses), while also recognizing that ''it is appropriate to acknowledge uncertainties in climate change impacts and resulting welfare impacts in the United States of reductions in $PM_{2.5}$ levels'' (Cox, 2019a, p. 14 of consensus responses). When considering the overall body of scientific information for PM-related effects on visibility, climate, and materials, the CASAC agreed that ''the available evidence does not call into question the protection afforded by the current secondary PM standards and concurs that they should be retained'' (Cox, 2019a, p. 3 of letter).

2. Basis for the Proposed Decision

At the time of the proposal, the Administrator carefully considered the assessment of the current evidence and conclusions reached in the ISA; the currently available quantitative information, including associated limitations and uncertainties, described in detail and characterized in the PA; considerations and staff conclusions and associated rationales presented in the PA; and the advice and recommendations from the CASAC (85 FR 24137, April 30, 2020).

In reaching his proposed decision on the secondary PM standards, the Administrator first recognized the longstanding body of evidence for PM-related visibility impairment. The Administrator recognized that visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being. In so doing, and consistent with the approach used in the last review (section IV.A.1 above), the Administrator first defined a target level of protection in terms of a PM visibility index that accounts for the factors that influence the relationship between PM in ambient air and visibility (*i.e.,* size fraction, species composition, and relative humidity). He then considered air quality analyses examining the relationship between this PM visibility index and the current 24-hour $PM_{2.5}$ and 24-hour PM_{10} standards in areas that

met data completeness criteria for inclusion in the analyses.[79]

To identify a target level of protection, the Administrator first defined the specific characteristics of the visibility index, noting that in the last review, the EPA used an index based on estimates of light extinction by $PM_{2.5}$ components calculated using the IMPROVE algorithm. As described in section IV.A.2 above, the IMPROVE algorithm estimates light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$,[80] along with estimates of relative humidity. The Administrator recognized that, despite revisions to the IMPROVE algorithm since the last review (U.S. EPA, 2020, section 5.2.1.1), our fundamental understanding of the relationship between PM in ambient air and light extinction has changed little and that the various IMPROVE algorithms can appropriately reflect this relationship across the U.S. In the absence of a robust monitoring network to measure light extinction (85 FR 24130, 24135, April 30, 2020), the Administrator judged that estimated light extinction, as calculated using the IMPROVE algorithms, continued to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment in the current review.

In further defining the characteristics of a visibility index based on estimates of light extinction, the Administrator considered the appropriate averaging time, form, and level of the index. The Administrator judged that the decisions made in the last review with regard to averaging time and form remain reasonable. In the last review, a 24-hour averaging time was judged to be an appropriate surrogate for the sub-daily periods relevant for visual perception,[81] recognizing the relatively strong correlations between 24-hour and sub-daily (*i.e.,* 4-hour) average $PM_{2.5}$ light extinction and that this longer averaging time may be less influenced by atypical conditions and/or atypical instrument performance (78 FR 3226, January 15, 2013). In the decision to set the form as the 3-year average of annual 90th percentile values in the last review, it was noted that: (1) A 3-year average provided stability from the occasional effect of interannual meteorological variability (78 FR 3198, January 15, 2013); (2) the 90th percentile corresponds to the 20 percent worst days for visibility, which are targeted in Class I areas by the Regional Haze program; and (3) available studies on people's visibility preferences did not identify a basis for a different target than that identified for Class I areas (U.S. EPA, 2011, p. 4–59). Recognizing that the information available in the current review is similar to that available in the last review, at the time of proposal the Administrator judged that these decisions remain reasonable, and it remains appropriate to define a visibility index based on estimated light extinction in terms of a 24-hour averaging time and a form based on the 3-year average of annual 90th percentile values.

At the time of the last review, the level of the visibility index was set at 30 dv, based on the upper end of the range of levels of visibility impairment judged to be acceptable by at least 50% of study participants in the available visibility preference studies (U.S. EPA, 2020, section 5.2.1.1). (78 FR 3226–27, January 15, 2013; 85 FR 24131 April 30, 2020).[82] In the last review, the Administrator concluded that the substantial degree of variability and uncertainty in the public preference studies should be reflected in a target protection level at the upper end of the 20 dv to 30 dv range of CPLs. Therefore, she concluded that it was appropriate to set a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index at 30 dv (78 FR 3226–27, January 15, 2013).

In considering the preference studies in this review, the Administrator first noted that, as a part of the last review, a range of levels was identified for the $PM_{2.5}$ visibility index based on an aggregated evaluation of the results of these studies that reflected variability in levels of visibility that were considered acceptable in the four study areas (U.S. EPA, 2010b). Because no visibility preference studies have been conducted in the U.S. since the last review, and given the general lack of new preference studies over the last several reviews, the Administrator proposed to conclude that the range considered in the last review remained appropriate to consider in the current review.

The Administrator highlighted the following uncertainties and limitations in the underlying public preference studies (U.S. EPA, 2020, section 5.2.1.1), consistent with those identified in the last review:

- The available studies may not capture the full range of visibility preferences in the U.S. population, particularly given the potential for preferences to vary based on the visibility conditions commonly encountered and the types of scenes being viewed.
- The available preference studies were conducted 15 to 30 years ago and may not reflect visibility preferences in the U.S. population today.
- The available preference studies have used a variety of methods, potentially influencing responses as to what level of visibility impairment is deemed acceptable.
- Factors that are not captured by the methods used in available preference studies may influence people's judgments on acceptable visibility, including the duration of visibility impairment, the time of day during which light extinction is greatest, and the frequency of episodes of visibility impairment.

After considering these preference studies, along with their inherent uncertainties and limitations, the Administrator judged in the proposal that a level of 30 dv continued to be an appropriate target level of protection for the visibility index in the current review.[83]

Having defined a target level of protection in terms of a visibility index based on the elements described above, (*i.e.,* with a 24-hour averaging time; a 3-year average of the annual 90th

[79] As described in detail in section IV.A.3.a above, the EPA's updated quantitative analyses in this review included 67 areas that met data completeness criteria for inclusion in the analyses (see U.S. EPA, 2020, Appendix D for details of the criteria). Of those monitoring locations that met the data completeness criteria, all but one location met the current secondary $PM_{2.5}$ standard (U.S. EPA, 2020, Table D–7).

[80] In the last review, the focus was on $PM_{2.5}$ components given their prominent role in PM-related visibility impairment in urban areas and the limited data available for $PM_{10-2.5}$ (77 FR 38980, June 29, 2010; U.S. EPA, 2020, section 5.2.1.2).

[81] While the $PM_{2.5}$ monitoring network has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations, there continue to be data quality uncertainties associated with providing hourly $PM_{2.5}$ mass and component measurements that could be input into IMPROVE equation calculations for sub-daily visibility impairment estimates. As detailed in the PA, there are uncertainties associated with the precision and bias of 24-hour $PM_{2.5}$ measurements (U.S. EPA, 2020, p. 2–18), as well as to the fractional uncertainty associated with 24-hour PM component measurements (U.S. EPA, 2020, p. 2–21). Given the uncertainties present when evaluating data quality on a 24-hour basis, the uncertainty associated with sub-daily measurements may be even greater. Therefore, the inputs to these light extinction calculations are based on 24-hour average measurements of $PM_{2.5}$ mass and components, rather than sub-daily information.

[82] Based on the preference studies, the 2011 PA identified a range of levels from 20 to 30 deciviews (dv) as being a reasonable range of ''candidate protection levels'' or ''CPLs'' for a visibility index (U.S. EPA, 2011, p. 4–61; U.S. EPA, 2020, section 5.2.1.1).

[83] As noted above, in the last review, the Administrator explained that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain (78 FR 3216, January 15, 2013).

percentile form; and a level of 30 dv), the Administrator next considered the degree of protection from visibility impairment afforded by the existing secondary standards. In so doing, he considered the updated analyses of PM-related visibility impairment (U.S. EPA, 2020, section 5.2.1.2), specifically noting the improvements over the analyses in the last review, in particular the use of multiple versions of the IMPROVE algorithm, including the version incorporating revisions since the last review (85 FR 24135–24136, April 30, 2020). The analyses in this review expand upon our understanding of how variation in equation inputs impacts calculated light extinction (U.S. EPA, 2020, Appendix D) and also better characterizes the influence of the coarse fraction on light extinction for the subset of sites with available $PM_{10-2.5}$ monitoring data (U.S. EPA, 2020, section 5.2.1.2).

The Administrator noted that the results of the updated analyses are consistent with the results from the last review, regardless of the IMPROVE equation used. The results of the analyses demonstrated that, in areas meeting the 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is at or below about 30 dv,[84] and is below 25 dv in most of the areas. In those locations with $PM_{10-2.5}$ monitoring data available, which met both the current 24-hour $PM_{2.5}$ and 24-hour PM_{10} standards, 3-year visibility metrics were at or below 30 dv regardless of if the coarse fraction was included in the calculation (U.S. EPA, 2020, section 5.2.1.2). In considering these updated analyses, the Administrator proposed to conclude that the scientific and quantitative information available in this review support the adequacy of the current secondary $PM_{2.5}$ and PM_{10} standards to protect against PM-related visibility impairment.

With respect to non-visibility welfare effects, the Administrator considered the evidence related to climate and materials effects and proposed to conclude that it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address non-visibility PM-related welfare effects. With regard to climate, the Administrator recognized that a number of improvements and refinements have been made to climate models since the last review, while also noting that significant limitations continue to exist in quantifying the contributions of the direct and indirect effects of PM and PM components on climate forcing (85 FR 24139, April 30, 2020; U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). The Administrator also recognized that climate models continue to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (*e.g.,* ~100 km) compared to simulations at global scales (85 FR 24139, April 30, 2020; U.S. EPA, 2020, section 5.2.2.1.1 and 5.4). In considering this uncertainty, the Administrator proposed to conclude that the scientific information available in the current review remains insufficient to quantify the impacts of ambient PM on climate in the U.S. with confidence (85 FR 34139, April 30, 2020; U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4) and that there is insufficient information available in this review to base a national ambient air quality standard on climate impacts.

With respect to materials effects, the Administrator recognized that deposition of fine or coarse particles can result in physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the effects of weathering processes and by promoting the corrosion of metals, the degradation of painted surfaces, the deterioration of building materials, and the weakening of material components. The Administrator, while recognizing that some new evidence of PM-related materials effects is available in this review, noted that this evidence is primarily from studies conducted outside of the U.S. with PM concentrations that are higher than those typically observed in ambient air in the U.S. (U.S. EPA, 2019, section 13.4). Consistent with the information available at the time of the last review, the Administrator recognized a limited amount of information available on the quantitative relationships between PM and materials effects in the U.S., and uncertainties in the degree to which those effects could be adverse to public welfare. Therefore, at the time of proposal, the Administrator judged that the scientific information available in this review remains insufficient to quantify the public welfare impacts of PM in ambient air on materials with confidence and that there is insufficient information available in this review to support a distinct national ambient standard based on materials effects.

Thus, based on consideration of the scientific and quantitative information available in this review, with its uncertainties and limitations, and information that might inform his public welfare judgments, as well as consideration of advice from the CASAC, including their concurrence with the PA conclusions that the current evidence does not support revision of the secondary PM standards (discussed in section IV.B.1 above). The Administrator proposed to conclude that it is appropriate to retain the current secondary PM standards without revision based on his judgment that the current secondary PM standards are requisite to protect against PM-related effects on visibility and that there is insufficient information available in this review to base a national ambient air quality standard for PM on climate and materials impacts.

3. Comments on the Proposed Decision

Of the public comments received on the proposal, very few were specific to the secondary PM standards. Of those commenters who did provide comments on the secondary PM standards, the majority support the Administrator's proposed decision to retain the current standards. Some commenters disagree with the Administrator's proposed conclusion to retain the current secondary standards, primarily focusing their comments on the need for a revised standard to protect against visibility impairment. In addition to the comments addressed in this notice, the EPA has prepared a Response to Comments document that addresses other specific comments related to setting the secondary PM standards. This document is available for review in the docket for this rulemaking and through the EPA's NAAQS website (*https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*).

Of the comments addressing the proposed decision, many of the commenters support the Administrator's proposed decision to retain the current secondary PM standards, without revision. This group includes industries and industry groups and state and local governments and organizations. All of these commenters generally note their agreement with the rationale provided in the proposal and with the views expressed by the CASAC that the current evidence does not support revision to the standards. Most also cite the EPA and CASAC statements that the scientific evidence and quantitative information in this review has not substantially altered our previous

[84] As discussed above and in the PA (U.S. EPA, 2020, section 5.2.1.2), one site in Fairbanks, Alaska just meets the current 24-hour $PM_{2.5}$ standard and has a 3-year visibility index value of 27 dv based on the original IMPROVE equation and 31 dv based on the Lowenthal and Kumar (2016) equation. At this site, use of the Lowenthal and Kumar (2016) equation may not be appropriate given that PM composition and meteorological conditions may differ considerably from those under which revisions to the equation have been validated.

understanding of the effects of PM on visibility, climate, and materials beyond what was previously examined and does not call into question the adequacy of the current standards. They all find the proposed decision to retain the current standards to be well supported and a reasonable exercise of the Administrator's public welfare policy judgment under the CAA. The EPA agrees with these comments and with the CASAC advice regarding the adequacy of the current secondary PM standards and the lack of support for revision of these standards.

Of the commenters who disagree with the proposal to retain the current standards, nearly all of these commenters recommend more stringent standards, primarily to protect against visibility impairment. These comments were submitted primarily by national public health, medical, and environmental nongovernmental organizations, and some individuals. The commenters who recommend strengthening the standards state their support for revisions to provide greater public welfare protection, generally claiming that the current standards are inadequate and do not provide the requisite protection against known or anticipated welfare effects. Additionally, some of the commenters who disagree with the proposal did not specifically recommend revising the current standards, but instead recommend additional research to address key uncertainties and limitations in the available scientific and quantitative information that would inform decisions regarding a national standard to protect against PM-related non-visibility and visibility effects.

The EPA received relatively few comments on the proposed decision that it is not appropriate to establish any distinct secondary PM standards to address PM-related climate effects. The majority of the comments that were received agree with the EPA that the currently available information is not sufficient for supporting quantitative analyses for the climate effects of PM in ambient air. These commenters support the Administrator's proposed decision not to set a distinct standard for climate. Several commenters note, however, that the EPA should frequently reconsider the available evidence and quantitative information and should revise the standard as necessary to provide requisite protection against PM-related climate effects. The EPA agrees with the commenters that quantitative analyses of the relationship between PM and climate effects are not supported by the available information in this review, and new information about PM-related welfare effects, including climate, will be assessed consistent with CAA requirements in the next review of the PM NAAQS.

There were also very few commenters who commented on the proposed decision that it is not appropriate to establish any distinct secondary PM standards to address PM-related material effects. As with comments on climate effects, commenters generally agree with the EPA that the evidence is not sufficient to support quantitative analyses for PM-related materials effects. However, some commenters contend that the EPA failed to consider the following information: (1) Studies conducted outside of the U.S. on the cost of soiling of materials that are also found in the U.S.; (2) recent work related to soiling of photovoltaic modules and other surfaces, and; (3) quantitative relationships between PM in ambient air and materials effects used in several studies. These commenters further assert that the EPA failed to specify a level of air quality that protects against adverse effects of PM on materials and failed to propose a standard that provides requisite protection against materials effects attributable to PM.

We disagree with the commenters that the EPA failed to consider the relevant scientific information about materials effects available in this review. As an initial matter, the ISA considered and included studies related to materials effects of PM, including studies conducted in and outside of the U.S., on newly studied materials including photovoltaic modules that were published prior to the cutoff date for the literature search.[85] These include the Besson et al. (2017) study referenced by the commenters (U.S. EPA, 2019, section 13.4.2). The Grøntoft et al. (2019) study referenced by the same commenters was published after the cutoff date for the literature search. However, the EPA has provisionally considered new studies, including the new studies highlighted by the commenters, in the context of the findings of the ISA (see Appendix in Response to Comments document).[86] Based on this provisional consideration, the EPA concludes that the new studies are not sufficient to alter the conclusions reached in the ISA regarding PM and materials effects.

Moreover, we disagree with the commenters that the EPA failed to consider quantitative information from studies available in this review. As detailed in section 5.2.2.1.2 of the PA, a number of new studies are available that apply new methods to characterize PM-related effects on previously studied materials; however, the evidence remains insufficient to relate soiling or damage to specific levels of PM in ambient air or to establish quantitative relationships between PM and materials degradation. The uncertainties in the evidence identified in the last review persist in the evidence in the current review, with significant uncertainties and limitations to establishing quantitative relationships between particle size, concentration, chemical components, and frequency of painting or repair of materials. While some new evidence is available in this review, overall, the data are insufficient to conduct quantitative analyses for PM-related materials effects. Quantitative relationships have not been established between characteristics of PM and frequency of repainting or cleaning of materials, including photovoltaic panels and other energy-efficient materials, that would help inform our understanding of the public welfare implications of soiling (U.S. EPA, 2020, section 5.2.2.2.2; U.S. EPA, 2019, section 13.4). Similarly, the information does not support quantitative analyses between microbial deterioration of surfaces and the contribution of carbonaceous PM to the formation of black crusts that contribute to soiling (U.S. EPA, 2020, section 5.2.2.2.2; U.S. EPA, 2019, section 13.4). We also note that quantitative relationships are difficult to assess, in particular those characterized using damage functions as these approaches depend on human perception of the level of soiling deemed to be acceptable and evidence in this area remains limited in the current review (U.S. EPA, 2020, section 5.2.2.1.2). Additionally, we note the CASAC's concurrence with conclusions in the PA that uncertainties remain about the best way to evaluate materials effects of PM in ambient air (Cox, 2019a, p. 13 of consensus responses). Further, no new studies are available in this review to link human perception of reduced aesthetic appeal of buildings

[85] As noted earlier in section IV, ''the current ISA identified and evaluated studies and reports that that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3).

[86] As discussed in section I.D, the EPA has provisionally considered studies that were highlighted by commenters and that were published after the ISA. These studies are generally consistent with the evidence assessed in the ISA, and they do not materially alter our understanding of the scientific evidence or the Agency's conclusions based on that evidence or warrant reopening of the air quality criteria.

and other objects to materials effects and PM in ambient air. Finally, uncertainties remain about deposition rates of PM in ambient air to surfaces and the interaction of PM with copollutants on these surfaces (U.S. EPA, 2020, p. 5–34).

As summarized above and in the proposal, the evidence in this review for PM effects on materials is not substantively changed from that in the last review. There continues to be a lack of evidence related to materials effects that establishes quantitative relationships and supports quantitative analyses of PM-related materials soiling or damage. While the information available in this review continues to support a causal relationship between PM in ambient air and materials effects (U.S. EPA, 2019, section 13.4), the EPA is unable to relate soiling or damage to specific levels of PM in ambient air and is unable to evaluate or consider a level of air quality to protect against such materials effects. Although the EPA did not propose a distinct level of air quality or a national standard based on air quality impacts (85 FR 24139, April 30, 2020), we did identify data gaps that prevented us from doing so. The EPA identified a number of key uncertainties and areas of future research (U.S. EPA, 2020, p. 5–42) that may inform consideration of the materials effects of PM in ambient air in future reviews of the PM NAAQS.

Commenters who disagreed with the Administrator's proposed decision to retain the current secondary PM standards provided a number of comments on the scientific evidence and quantitative analyses for visibility impairment. These commenters criticize various aspects of the EPA's proposal to retain the standards, including specific aspects of the visibility index, the target level of protection identified by the Administrator, and the appropriateness of a single national standard for purposes of protecting against PM-related visibility impairment. In general, these comments indicated support for a more stringent standard for visibility impairment, although the commenters did not necessarily specify the alternative standard that would, in their judgment, address the concerns raised. Rather, most of these commenters focused on particular aspects of the visibility metric underlying the current secondary standard, including the form, averaging time, and target level of protection necessary to protect against visibility impairment.

Several commenters argue that the evidence does not support a single level of ''acceptable'' visibility. Commenters expressed the view that the public preference studies present important evidence related to the importance of visibility, but that they do not provide enough information to set a national standard for visibility impairment because the results show that visibility preferences vary regionally and/or locally for a variety of reasons. Commenters additionally state that the EPA failed to explain and analyze the uncertainties associated with the public preference studies, including: (1) The different methods used in the studies and their influence on the responses; (2) the impact of different scenes being viewed on the full range of public preferences; and (3) factors that were not considered in the study methods that could impact judgments in the studies. These commenters suggest that the secondary standards should account for regional variability, although they did not provide specific recommendations regarding how to accomplish this.

The EPA agrees with commenters that the available scientific evidence indicates that public preferences for ''acceptable'' visibility and air quality depends in large part on the characteristics of the scene being viewed. The EPA understands that there is a wide range of urban and rural scenes within the U.S. and included in the public preference studies, including natural vistas such as the Rocky Mountains in Colorado and man-made urban structures such as the Washington Monument. However, the EPA disagrees with commenters that the available evidence cannot support a national standard to protect against PM-related visibility impairment. As at the time of the last review, the EPA believes that the scenes presented in the public preference studies include important types of valued scenic views, and therefore, when considered together, can inform consideration of an acceptable level of visual air quality at the national scale, taking into account variation across the U.S. as evidenced in the studies.

With regard to the comments that these studies do not provide enough information to account for regional variability that is important to consider when setting a national standard for visibility protection, the EPA recognizes that there may be regional variability in the available evidence but believes that these studies provide significant information that is useful for the Administrator to consider in his judgments on the public welfare implications of PM-related visibility effects. While the EPA acknowledges that there may be regional differences in the stated preferences for visibility, the EPA finds there is not enough information available at this time to take such regional differences into account. The commenter did not provide specific recommendations for the EPA's consideration of such information even if such information were available, and the EPA finds the question of how, or if, to account for regional preferences in setting a national standard is a substantial question that should be addressed when it is presented by the available information.

With regard to the commenters' assertion that the current secondary standards are inadequate to protect the public welfare from PM-related visibility impairment, the EPA disagrees that the currently available information is sufficient to suggest that a more stringent standard is warranted. The EPA identified and addressed in great detail the limitations and uncertainties associated with the public preference studies as a part of the last review (78 FR 3210, January 15, 2013). Given that the evidence related to public preferences is the same in this review as it was at the time of the last review, the EPA reiterated the limitations and uncertainties inherent in this evidence as a part of the PA (U.S. EPA, 2020, section 5.5). The PA highlights key uncertainties associated with public perception of visibility impairment and identifies areas for future research to inform future PM NAAQS reviews, including those raised by the commenters (U.S. EPA, 2020, p. 5–41). For example, the PA notes the critical need for information to further our understanding of human perception of visibility impairment in public preference studies in order to address uncertainties and limitations in the evidence, including an expansion of the number and geographic coverage of preference studies in urban, rural, and Class I areas to account for the potential for people to have different preferences based on the conditions that they commonly encounter and potential differences in preferences based on the scene types (U.S. EPA, 2020, p. 5–41).

These same commenters further argue that the EPA omitted recent studies that could further inform our understanding of the public welfare implications of visibility impairment. Commenters specifically point to a recent meta-analysis of available preference studies (Malm et al., 2019) and also cites to several related studies (Malm et al., 2011; Malm, 2013, 2016; Molenar and Malm, 2012). Commenters additionally contend that studies of the economic effects of impaired visibility were omitted from the ISA and PA and were

not considered in the EPA's approach for evaluating visibility.

The EPA disagrees with the commenters that studies related to visibility were inappropriately omitted from the ISA in this review. As an initial matter, the ISA considered and included studies related to PM-related visibility impairment and public preferences that were published prior to the cutoff date for the literature search.[87] As described in the Preamble to the ISA, ''studies and reports that have undergone scientific peer review and have been published (or accepted for publication) are considered for inclusion in the ISA'' (U.S. EPA, 2015, p. 6). The meta-analysis by Malm et al. (2019) was published after the cutoff date for the literature search for the ISA, and therefore, was not included in the ISA. Malm et al. (2019) was provisionally considered, along with other studies published after the cut-off date, and the EPA concluded that these studies did not materially change the broad scientific conclusions of the ISA regarding welfare effects, including visibility impairment. Moreover, the other citations provided by the commenters (Malm et al., 2011; Malm, 2013, 2016; Molenar and Malm, 2012) are not peer-reviewed publications and as such do not meet the criteria for inclusion in the ISA. With regard to studies of economic effects, these studies were not considered to be within the scope of the ISA, and therefore were not included in this review (U.S. EPA, 2019, p. P–16). The studies submitted by the commenters, together with other new evidence, will be assessed consistent with CAA requirements in the next review of the PM NAAQS.

Some commenters contend that the EPA's visibility analyses only focused on locations that met the current standards. These commenters argue that the EPA concluded at the beginning of the analysis that the current standards do not need to be revised and that the EPA's approach ignores information available since the last review, leading to the Administrator to propose no revisions to the standards based on this flawed approach.

We disagree with commenters that the updated analyses of visibility impairment in this review only considered air quality in areas that meet the current standards. As described in detail in the PA, locations included in the analyses were those that met specific data completeness criteria for the monitoring data required as inputs to the IMPROVE equations for estimating light extinction (U.S. EPA, 2020, Appendix D). The data set used for the updated analyses is comprised of sites with data for the 2015–2017 period that supported a valid 24-hour $PM_{2.5}$ design value and met strict criteria for PM species. For $PM_{2.5}$ concentrations, data were screened so that all days either had a valid filter-based 24-hour concentration measurement or at least 18 valid hourly concentration measurements (U.S. EPA, 2020, section D.2.1.2).[88] For coarse PM concentrations, data were included for sites with ≥11 valid days for each quarter of 2015–2017. For $PM_{2.5}$ component concentrations, data were included for days with valid data for all chemical components listed in Table D–1 in the PA and for sites with ≥11 valid days for each quarter of 2015–2017.[89] Of all of the PM monitoring locations in the U.S., 67 monitoring sites met the data completeness criteria and light extinction was calculated without the coarse fraction in the IMPROVE equations. Of these 67 monitoring sites, 20 locations met the data completeness criteria for coarse PM, and as such, light extinction was also estimated with the coarse fraction as an input to the IMPROVE equation at these sites (U.S. EPA, 2020, section 5.2.1.2, Appendix D). For the sites that met the data completeness criteria for inclusion in the analyses, all of the sites met the annual $PM_{2.5}$ and 24-hour PM_{10} standards, and all but one site (located in southern California) met the 24-hour $PM_{2.5}$ standard. Therefore, we disagree with the commenters that the analysis was designed to consider only locations that met the current standards and did not consider locations that did not meet the current secondary PM standards. Moreover, the EPA notes that data from areas exceeding the current standard are generally of limited use in deciding whether to retain the standard, or lower it, because it is not representative or informative of circumstances and effects that would be expected to be seen upon attainment of the standard.

Furthermore, it is unclear what additional information the commenters contend that the EPA omitted from its consideration in this review. All scientific information available in this review has been considered and integrated as a part of the ISA. The Administrator, in considering the adequacy of the current secondary PM standards, considered the available scientific evidence and quantitative information in this review, along with CASAC advice and public comments, and concluded that the current secondary PM standards provide requisite protection against visibility impairment.

Some commenters additionally contend that the EPA's evaluation of public welfare effects of PM in the proposal solely focuses on fine PM and ignores coarse PM. These commenters assert that trends data show that coarse PM is increasing, which they believe to be a concern to public welfare.

We disagree with the commenters that the EPA's proposal failed to consider the public welfare implications of coarse PM. First, we note that there is limited new scientific evidence available in this review on climate- and materials-related effects of coarse PM beyond that of the last review (85 FR 24131, April 30, 2020). With regard to the contribution of coarse PM to visibility impairment, we first note that at the time of the last review, the EPA noted that $PM_{2.5}$ is the size fraction of PM responsible for most of the visibility impairment in urban areas (U.S. EPA, 2020, p. 5–22). Data available for $PM_{10-2.5}$ was very limited in the last review and was not used in quantitative analyses of estimated $PM_{2.5}$ light extinction (U.S. EPA, 2020, Appendix D, section D–1). Since the time of the last review, an expansion of $PM_{10-2.5}$ monitoring efforts has increased the availability of data for use in estimating light extinction with both fine and coarse fractions of PM. As described in the PA, the analyses of visibility impairment were updated in this review to include consideration of the coarse fraction of PM in estimating light extinction in the subset of areas with $PM_{10-2.5}$ monitoring data available for the time period of interest (U.S. EPA, 2020, section 5.2.1.2, Appendix D). The updated analyses in this review included 20 sites that measured both PM_{10} and $PM_{2.5}$ (U.S. EPA, 2020, section 5.2.1.2, Appendix D), all of which meet the current 24-hour $PM_{2.5}$ and PM_{10} standards. All of these sites have 3-year visibility at or below 30 dv regardless of whether light extinction is calculated

[87] As noted earlier in section IV, ''the current ISA identified and evaluated studies and reports that that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3).

[88] A valid filter-based 24-hour concentration measurement is one collected via FRM, and that has undergone laboratory equilibration (at least 24 hours at standardized conditions of 20–23 °C and 30–40% relative humidity) prior to analysis (see Appendix L of 40 CFR part 50 for the 2012 NAAQS for PM).

[89] For coarse PM and $PM_{2.5}$ components, data completeness criteria were selected for the quantitative analyses consistent with those in Appendix N of 40 CFR part 50 for the 2012 NAAQS for PM.

with or without the coarse fraction, and for all three versions of the IMPROVE equation used in this review. Generally, the contribution of the coarse fraction of PM to light extinction in these locations was minimal, contributing less than 1 dv to the 3-year visibility metric (U.S. EPA, 2020, section 5.2.1.2, Appendix D). While there were not monitoring data available to evaluate the impact of coarse PM on estimates of light extinction in locations expected to have higher concentrations of coarse PM, the coarse fraction may be a more important contributor to light extinction and visibility impairment than in those areas included in the PA analyses in this review. As additional information and monitoring data become available to further evaluate the impact of coarse PM on estimates of light extinction in more locations, including geographical locations expected to have high concentrations of coarse PM, such information will be considered in a future PM NAAQS review.

Several commenters in support of revising the secondary PM standards to protect against visibility impairment, generally recommend revisions to elements of the secondary standard and visibility index (indicator, averaging time, form, and level) consistent with those supported by the CASAC and public comments in previous PM reviews. We address comments on the elements of a visibility index and a revised standard for visibility effects below.

With regard to an indicator for the secondary standards to protect against visibility impairment, a number of commenters suggest that the EPA failed to explain why the current indicator is adequate and pointed to recommendations from the CASAC in the PM reviews completed in 2012 and 2006 with regard to alternate indicators. As noted by the commenters, in the 2012 review, the CASAC recommended three alternate indicators for a secondary standard to protect against visibility impairment: (1) Using direct, continuous measurement of PM light extinction to support hourly or multi-hour daylight-only averaging time(s); (2) using PM speciation data to calculate seasonal (or monthly) regional species and relative humidity values to combine with the denser continuous $PM_{2.5}$ monitoring network to calculate hourly PM light extinction; or, (3) using hourly $PM_{2.5}$ as a basis for a sub-daily (hourly or multi-hour) daylight-only indicator, which would intentionally remove the variable influence of water from the regulatory metric. In the 2006 review, as noted by the commenters, the CASAC recommended a $PM_{2.5}$ mass indicator, coupled with revisions to the averaging time, form, and level of the standard, to protect against visibility impairment.

The EPA generally agrees with commenters that an indicator based on directly measured light extinction would provide the most direct link between PM in ambient air and PM-related visibility impairment. However, as noted in the proposal (85 FR 24138, April 30, 2020, sections IV.B.1 and IV.D.1), the Administrator concluded that in the absence of a monitoring network to directly measure light extinction, he judged that estimated light extinction, as calculated using the IMPROVE algorithms, continues to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment in the current review. There has been little progress in development of such a monitoring network since the time of the last review when CASAC concluded that, in the absence of such a monitoring network, relying on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ components and relative humidity represented a reasonable approach and that the inputs for calculating light extinction were readily available through existing monitoring networks and approved monitoring protocols (78 FR 3205, January 15, 2013). Further, in this review, the CASAC generally agreed with the EPA that the available evidence does not call into question the protection afforded by the current secondary PM standards and concurs that they should be retained.

With regard to the elements of the visibility index, in considering the adequacy of the current secondary PM standards to protect against visibility impairment, as described in the proposal (85 FR 24135, April 30, 2020), the Administrator first defined an appropriate target level of protection in terms of a PM visibility index. In defining this target level of protection, the Administrator first considered the indicator of such an index. He noted that, given the lack of availability of methods and an established network for directly measuring light extinction, a visibility index based on estimates of light extinction by $PM_{2.5}$ components derived from an adjusted version of the original IMPROVE algorithm would be most appropriate, consistent with the last review. As described in the proposal and above (section IV.A.2.a.i), the IMPROVE algorithm estimates light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$, along with estimates of relative humidity. The Administrator, while recognizing that some revisions to the IMPROVE algorithm have been made since the time of the last review, noted that the fundamental relationship between ambient PM and light extinction has changed very little and the different versions of the IMPROVE algorithms can appropriately reflect this relationship across the U.S. (85 FR 24138, April 30, 2020). As such, he judged that defining a target level of protection in terms of estimated light extinction continues to be a reasonable approach in the current review.

With regard to averaging time, commenters were critical of the 24-hour averaging time to protect against visibility impairment and argue for a sub-daily averaging time. While some comments clearly focused on the averaging time of the current secondary $PM_{2.5}$ standard, other comments were unclear as to whether they recommended a sub-daily averaging time for the secondary $PM_{2.5}$ standard or for the visibility index used in defining a target level of the protection. Nonetheless, all of these commenters contend that people do not perceive visibility impairment over a 24-hour period, but rather their perception of impairment ranges from minutes to multiday, and that daylight hours are much more important in terms of visibility impairment, particularly in urban areas. As with comments on the indicator of the standard, some commenters also point to previous CASAC advice on the need for a sub-daily standard.

In defining the characteristics of a visibility index, the EPA continues to believe that a 24-hour averaging time is reasonable. This is in part based on analyses conducted in the last review that showed relatively strong correlations between 24-hour and sub-daily (*i.e.,* 4-hour average) $PM_{2.5}$ light extinction from the analyses conducted in the last review (85 FR 24138, April 30, 2020; 78 FR 3226, January 15, 2013), indicating that a 24-hour averaging time is an appropriate surrogate for the sub-daily time periods relevant for visual perception. The EPA believes that these analyses continue to provide support for consideration of a 24-hour averaging time for the visibility index in this review. The EPA also recognizes that the longer averaging time may be less influenced by atypical conditions and/or atypical instrument performance (85 FR 24138, April 30, 2020; 78 FR 3226, January 15, 2013). When taken together, the available scientific information and updated analyses of calculated light extinction available in this review continue to support that a 24-hour averaging time is appropriate when defining a target level of protection

against visibility impairment in terms of a visibility index.

Moreover, the EPA disagrees with commenters that a secondary $PM_{2.5}$ standard with a 24-hour averaging time does not provide requisite protection against the public welfare impacts of visibility impairment. At the time of the last review, the EPA recognized that hourly or sub-daily (*i.e.,* 4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related to the short-term nature of visibility impairment and the relevant viewing periods for segments of the viewing public than a 24-hour averaging time. At that time, the EPA agreed that a sub-daily averaging time would generally be preferable. However, the Agency noted significant data quality uncertainties associated with the instruments that would provide hourly $PM_{2.5}$ mass concentrations necessary to inform a sub-daily averaging time. These uncertainties, as described in the last review, included short-term variability in hourly data from available continuous monitoring methods, which would prohibit establishing a sub-daily averaging time (78 FR 3209, January 15, 2013). For all of these reasons, the EPA continues to believe that a sub-daily averaging time is not supported by the information available in this review.

With regard to the form of the visibility index, many of the commenters contend that the form used in evaluating visibility impairment is not appropriate. First, commenters contend that a 90th percentile form is too low and excludes too many days that could have visibility impairment. These same commenters also suggest that a 3-year average form is not justified and does not protect visibility and public welfare. These commenters also argue that the EPA failed to consider the 98th percentile form for the visibility index as a part of the proposal. Second, some commenters recommend a form for the visibility index within the range of 95th to 98th percentile, coupled with a multi-hour sub-daily averaging time, consistent with the CASAC advice in the 2006 review.

The EPA disagrees with these commenters on both points. With regard to the form of the visibility index, the EPA continues to conclude that a 3-year average of annual 90th percentile values is appropriate. In so doing, the EPA notes that a 3-year average form provides stability from the occasional effect of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year, consistent with the decision in the last review (78 FR 3198, January 15, 2013; U.S. EPA, 2011, p. 4–58). With regard to the annual statistical form to be averaged over 3-years, the EPA considers the evaluation in the 2010 UFVA of three different statistics: 90th, 95th, and 98th percentiles (U.S. EPA, 2010b, chapter 4). In considering the alternative statistical forms, the 2011 PA noted that the Regional Haze Program targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas and that the median of the distribution of these 20 percent worst days would be the 90th percentile. The 2011 PA further noted that strategies that are implemented so that 90 percent of days would have visual air quality that is at or below the level of the standard would reasonably be expected to lead to improvements in visual air quality for the 20 percent most impaired days. Finally, the 2011 PA recognized that the public preference studies available at the time of the last review did not address frequency of occurrence of different levels of visibility and did not identify a basis for a different target for urban areas than for Federal Class I areas (U.S. EPA, 2011, p. 4–59). The analyses and considerations for the form of a visibility index from the 2011 PA continue to provide support for a 90th percentile form, averaged across three years, in defining the characteristics of a visibility index in this review.

Some commenters contend that the EPA's proposal to retain the level of 30 dv for a visibility index is arbitrary, capricious, and not technically sound. These commenters assert that the EPA failed to consider recent research studies that provide a meta-analysis of visibility preference studies that suggest that a level of 30 dv is unacceptable to study participants included in the meta-analysis.

As an initial matter, as described above, the studies cited by the commenters in support of their rationale were either published after the cutoff date for the literature search for the ISA (Malm et al., 2019) or were not peer-reviewed studies that met the inclusion criteria for the ISA (Malm et al., 2011; Malm, 2013, 2016; Molenar and Malm, 2012). The EPA provisionally considered the Malm et al. (2019) study and concludes that this study does not sufficiently alter the conclusions reached in the ISA regarding PM and visibility effects.

With regard to a level of 30 dv for the visibility index, the EPA believes that it is appropriate to establish a target level of protection based on the upper end of the range of levels of visibility impairment judged to be acceptable by at least 50% of study participants in the available visibility preference studies (U.S. EPA, 2020, section 5.2.1.1). The 2011 PA identified a range of levels from 20 to 30 dv based on the responses in the public preference studies available at that time. Given the lack of new preferences studies available in this review, the EPA again relies on the same studies and the range of levels identified in those studies in the current review. As described in detail in the PA (U.S. EPA, 2020, sections 5.2.1.1 and 5.5), there are a number of uncertainties and limitations associated with the public preference studies, including those described in section IV.B.2 above. Recognizing these uncertainties and limitations, the EPA concludes that substantial degrees of variability and uncertainty in the public preference studies should be reflected in a target level of protection at the upper end of the range than if the information was more consistent and certain. Therefore, the EPA believes that 30 dv is an appropriate level for a visibility index in this review.

A number of commenters advocate for a more stringent standard, recommending that the level of the secondary $PM_{2.5}$ standards be lowered. Some commenters reference the recommendations of previous CASAC panels for revisions to the secondary 24-hour $PM_{2.5}$ standard. Additionally, some commenters contend that the secondary $PM_{2.5}$ standards should be set equal to the primary $PM_{2.5}$ standards, with some of the commenters aligning their support for their position with their recommendations for revisions to the primary $PM_{2.5}$ standards in this review.

We disagree with the commenters that the secondary $PM_{2.5}$ standard should be revised to provide additional public welfare protection beyond that achieved under the current standard. Based on the available scientific and quantitative information, and for the reasons discussed above, the EPA concludes that it is appropriate to define a target level of protection in terms of a visibility index based on estimated light extinction with a 24-hour averaging time, a 3-year 90th percentile form, and a level of 30 dv. In having concluded that this visibility index is appropriate, the EPA then considers the degree of protection from visibility impairment afforded by the existing standard. In so doing, we consider results of updated analyses of calculated light extinction that demonstrate that, in areas meeting the current PM mass-based standards, the target level of protection in terms of a visibility index is also achieved (85 FR 24135, April 30, 2020; U.S. EPA, 2020, section 5.2.1.2). The results of these analyses (as described in detail in

section IV.A.3.a above and in section 5.2.1.2 of the PA) demonstrate that the 3-year visibility metric is at or below about 30 dv in all areas meeting the current $PM_{2.5}$ standard, and below 25 dv in most areas. For those areas with available $PM_{10-2.5}$ monitoring data, which met both the current 24-hour $PM_{2.5}$ and PM_{10} standards, 3-year visibility metrics were at or below 30 dv regardless of if the coarse fraction was included in the calculation (U.S. EPA, 2020, section 5.2.1.2). Given the results of these analyses, the Administrator concluded at the time of proposal that the updated scientific evidence and quantitative information support the adequacy of the current secondary $PM_{2.5}$ and PM_{10} standards to protect against PM-related visibility impairment (85 FR 24138–24139, April 30, 2020).

With regard to comments recommending to set the secondary $PM_{2.5}$ standards equal to the current primary $PM_{2.5}$ standards, these commenters do not provide a basis for their recommendation, nor do they provide a rationale for revising the secondary $PM_{2.5}$ standards to their recommended revised levels of the primary $PM_{2.5}$ standards. However, we note that the primary annual $PM_{2.5}$ standard, with its lower level, would be the controlling standard. The EPA disagrees that such revisions would be appropriate, for all of the reasons discussed above.

4. Administrator's Conclusions

In considering the adequacy of the current secondary PM standards in this review, the Administrator has carefully considered the: (1) Policy-relevant evidence and conclusions contained in the ISA; (2) the quantitative information presented and assessed in the PA; (3) the evaluation of this evidence, the quantitative information, and the rationale and conclusions presented in the PA; (4) the advice and recommendations from the CASAC; and (5) public comments, as addressed in section IV.B.3 above. In the discussion below, the Administrator gives weight to the PA conclusions, with which the CASAC concurred, as summarized in section IV.D of the proposal, and takes note of key aspects of the rationale for those conclusions that contribute to his decision in this review. After giving careful consideration to all of this information, the Administrator believes that the conclusions and policy judgments supporting his proposed decision remain valid and the secondary PM standards should be retained.

In considering the PA evaluations and conclusions, the Administrator specifically takes note of the overall conclusions that the welfare effects evidence and quantitative information are generally consistent with what was considered in the last review (U.S. EPA, 2020, section 5.4). In so doing, he additionally notes that the CASAC supports retaining the current standard agreeing with the EPA ''that the available evidence does not call into question the protection afforded by the current secondary PM standards'' (Cox, 2019a, p. 3 of letter). As noted below, the newly available welfare effects evidence, critically assessed in the ISA as part of the full body of current evidence, reaffirms conclusions on the visibility, climate, and materials effects recognized in the last review, including key conclusions on which the current standard is based. Further, as discussed in more detail above, the updated quantitative analyses of visibility impairment for areas meeting the current standards support the adequacy of the current secondary $PM_{2.5}$ and PM_{10} standards to protect against PM-related visibility impairment. The Administrator also recognizes limitations and uncertainties continue to be associated with the available information.

With regard to the current evidence on visibility effects, as summarized in the PA and discussed in detail in the ISA, the Administrator takes note of the long-standing body of evidence for PM-related visibility impairment. This evidence, which is based on the fundamental relationship between light extinction and PM mass, demonstrates that ambient PM can impair visibility in both urban and remote areas, and has changed very little since the last review (U.S. EPA, 2019, section 13.1; U.S. EPA, 2009a, section 9.2.5). The evidence related to public perception of visibility impairment comes from studies from four areas in North America. These studies provide information to inform our understanding of levels of visibility impairment that the public judged to be ''acceptable'' (U.S. EPA, 2010b; 85 FR 24131, April 30, 2020). In considering these public preference studies, the Administrator notes that, as described in the ISA, no new visibility studies have been conducted in the U.S. and there is little newly available information with regard to acceptable levels of visibility impairment in the U.S. The Administrator recognizes that visibility impairment can have implications for people's enjoyment of daily activities and their overall well-being, and therefore, considers the degree to which the current secondary standards protect against PM-related visibility impairment.

Based on the considerations discussed above in sections IV.B.2 and IV.B.3, the Administrator first concludes, consistent with the last review, that a target level of protection for a secondary PM standard is most appropriately defined in terms of a visibility index that directly takes into account the factors (*i.e.,* species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in ambient air and PM-related visibility impairment. In defining a target level of protection, the Administrator has considered the specific aspects of such an index, including the appropriate indicator, averaging time, form, and level.

First, with regard to indicator, the Administrator notes that in the last review, the EPA used an index based on estimates of light extinction by $PM_{2.5}$ components calculated using an adjusted version of the IMPROVE algorithm. As described above (section IV.A.3), this algorithm allows the estimation of light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$, along with estimates of relative humidity. The Administrator recognizes that, while there have been some revisions to the IMPROVE algorithm since the time of the last review, our fundamental understanding of the relationship between PM in ambient air and light extinction has changed little and the various IMPROVE algorithms can appropriately reflect this relationship across the U.S. In the absence of a monitoring network for direct measurement of light extinction (section IV.A.3), he concludes that calculated light extinction indicator that utilizes the IMPROVE algorithms continues to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment in the current review.

In further defining the characteristics of a visibility index, the Administrator next considers the appropriate averaging time, form, and level of the index. Given the available scientific information in this review, and in considering the CASAC's advice and public comments, the Administrator concludes that, consistent with the decision in the last review, a visibility index with a 24-hour averaging time and a form based on the 3-year average of annual 90th percentile values remains reasonable in this review. With regard to the averaging time and form of such an index, the Administrator takes note of analyses conducted in the last review that demonstrated relatively strong correlations between 24-hour and sub-daily (*i.e.,* 4-hour average) $PM_{2.5}$ light extinction (78 FR 3226, January 15,

2013), indicating that a 24-hour averaging time is an appropriate surrogate for the sub-daily time periods of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. This decision also recognized that a 24-hour averaging time may be less influenced by atypical conditions and/or atypical instrument performance (78 FR 3226, January 15, 2013). The Administrator recognizes that there is no new information in the current review to support updated analyses of this nature, and therefore, he believes these analyses continue to provide support for consideration of a 24-hour averaging time for a visibility index in this review. With regard to the statistical form of the index, the Administrator notes that, consistent with the last review: (1) A multi-year percentile form offers greater stability from the occasional effect of inter-annual meteorological variability (78 FR 3198, January 15, 2013; U.S. EPA, 2011, p. 4–58); (2) a 90th percentile represents the median of the distribution of the 20 percent worst visibility days, which are targeted in Federal Class I areas by the Regional Haze Program; and (3) public preference studies did not provide information to identify a different target than that identified for Federal Class I areas (U.S. EPA, 2011, p. 4–59). Therefore, the Administrator judges that a visibility index based on estimates of light extinction, with a 24-hour averaging time and a 90th percentile form, averaged over three years, remains appropriate.

With regard to the level of a visibility index, the Administrator judges that it is appropriate to establish a target level of protection of 30 dv, reflecting the upper end of the range of visibility impairment judged to be acceptable by at least 50% of study participants in the available public preference studies (78 FR 3226, January 15, 2013). The 2011 PA identified a range of levels from 20 to 30 dv based on the responses in the public preference studies available at that time. At the time of the last review, the Administrator noted a number of uncertainties and limitations in public preference studies, including the small number of stated preference studies available, the relatively small number of study participants and the extent to which the study participants may not be representative of the broader study area population in some of the studies, and the variations in the specific materials and methods used in each study. In considering the available preference studies, with their inherent uncertainties and limitations, the prior Administrator concluded that the substantial degree of variability and uncertainty in the public preference studies should be reflected in a target level of protection based on the upper end of the range of CPLs.

Given that there are no new preference studies available in this review, the Administrator notes that his judgments are based on the same studies, with the same range of levels, available in the last review. The Administrator recognizes a number of limitations and uncertainties associated with these studies, as identified in the PA (U.S. EPA, 2020, section 5.5), including the following: (1) Available studies may not represent the full range of preferences for visibility in the U.S. population, particularly given the potential variability in preferences based on the conditions commonly encountered and the scenes being viewed; (2) available preference studies were conducted 15 to 30 years ago and may not accurately represent the current day preferences of people in the U.S.; (3) the variety of methods used in the preference studies may potentially influence the responses as to what level of impairment is deemed acceptable; and (4) factors that are not captured in the methods of the preference studies, such as the time of day when light extinction is the greatest or the frequency of impairment episodes, may influence people's judgment on acceptable visibility (U.S. EPA, 2020, section 5.2.1.1). Therefore, in considering the scientific information, with its uncertainties and limitations, as well as public comments on the level of the target level of protection against visibility impairment, the Administrator concludes that it is appropriate to again use a level of 30 dv for the visibility index.

Having concluded that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index, with a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv, is requisite to protect public welfare with regard to visual air quality, the Administrator next considers the degree of protection from visibility impairment afforded by the existing secondary PM standards. This determination requires considering such protection not in isolation but in the context of the full suite of secondary standards.

In this context, the Administrator has considered the degree of protection from visibility afforded by the existing secondary $PM_{2.5}$ standards. The Administrator has considered both whether the existing 24-hour $PM_{2.5}$ standard of 35 μg/m³ is sufficient (*i.e.,* not under-protective) and whether it is not more stringent than necessary (*i.e.,* not over-protective).

As discussed in section IV.A.3 above, the Administrator considers the updated analyses of visibility impairment presented in the PA (U.S. EPA, 2020, section 5.2.1.2), which reflect a number of improvements since the last review. Specifically, the updated analyses examine multiple versions of the IMPROVE equation, including the version incorporating revisions since the time of the last review (section IV.A.3.a above). These updated analyses provide a further understanding of how variation in the inputs to the algorithms impact the estimates of light extinction (U.S. EPA, 2020, Appendix D). Additionally, for a subset of monitoring sites with available $PM_{10-2.5}$ data, the updated analyses better characterize the influence of coarse PM on light extinction than in the last review (U.S. EPA, 2020, section 5.2.1.2).

As discussed above in section IV.A.3.a, the results of the updated analyses are consistent with those from the last review. Regardless of which version of the IMPROVE equation is used, the analyses demonstrate that, based on 2015–2017 data, the 3-year visibility metric is at or below about 30 dv in all areas meeting the current 24-hour $PM_{2.5}$ standard, and below 25 dv in most of those areas. In locations with available $PM_{10-2.5}$ monitoring, which met both the current 24-hour secondary $PM_{2.5}$ and PM_{10} standards, 3-year visibility index metrics were at or below 30 dv regardless of whether the coarse fraction was included as an input to the algorithm for estimating light extinction (U.S. EPA, 2020, section 5.2.1.2). While the inclusion of the coarse fraction had a relatively modest impact on the estimates of light extinction, as noted in responding to comments in section IV.B.3 above, the Administrator recognizes the continued importance of the PM_{10} standard given the potential for larger impacts on light extinction in areas with higher coarse particle concentrations, which were not included in the PA's analyses due to a lack of available data (U.S. EPA, 2019, section 13.2.4.1; U.S. EPA, 2020, section 5.2.1.2). He notes that the air quality analyses showed that all areas meeting the existing 24-hour $PM_{2.5}$ standard, with its level of 35 μg/m³, had visual air quality at least as good as 30 dv, based on the visibility index. Thus, the secondary 24-hour $PM_{2.5}$ standard would likely be controlling relative to a 24-hour visibility index set at a level of 30 dv. Additionally, areas would be unlikely to exceed the target level of protection for visibility of 30 dv without

also exceeding the existing secondary 24-hour standard. Thus, the Administrator judges that the 24-hour $PM_{2.5}$ standard provides sufficient protection in all areas against the effects of visibility impairment—*i.e.,* that the existing 24-hour $PM_{2.5}$ standard would provide at least the target level of protection for visual air quality of 30 dv which he judges appropriate.

With respect to the non-visibility welfare effects of PM in ambient air, the Administrator concludes that it is generally appropriate to retain the existing standards and that there is insufficient information to establish any distinct secondary PM standards to address climate and materials effects of PM. With regard to climate, he recognizes that there have been a number of improvements and refinements to climate models since the last review. However, as discussed in sections IV.A.3.b and IV.B.3 above, while the evidence continues to support a causal relationship between PM and climate effects (U.S. EPA, 2019, section 13.3.9), the Administrator notes that significant limitations continue to exist related to quantifying the contributions of direct and indirect effects of PM and PM components on climate forcing (U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). He also recognizes that that models continue to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (*e.g.,* ~100 km) as compared to simulations at global scales. Therefore, the resulting uncertainty leads the Administrator to conclude that the available scientific information in this review remains insufficient to quantify climate impacts associated with particular concentrations of PM in ambient air (U.S. EPA, 2020, section 5.2.2.2.1) or to evaluate or consider a level of PM air quality in the U.S. to protect against climate effects and that there is insufficient information available at this time to base a national ambient standard on climate impacts.

With regard to materials effects, the Administrator notes that the evidence available in this review continues to support a causal relationship between materials effects and PM deposition (U.S. EPA, 2019, section 13.4). He recognizes that the deposition of fine and coarse particles to materials can lead to physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the natural weathering processes and by promoting the corrosion of metals, the degradation of painted surfaces, the deterioration of building materials, and the weakening of material components. While some new information is available in this review, as discussed in sections IV.A.3.b and IV.B.3 above, this information is primarily conducted outside the U.S. in areas where PM concentrations in ambient air are typically higher than those observed in the U.S. (U.S. EPA, 2020, section 13.4). Additionally, the newly available information in this review does not support quantitative analyses of PM-related materials effects in this review (U.S. EPA, 2020, section 5.2.2.2.2). Given the limited amount of information available and its inherent uncertainties and limitations, the Administrator concludes that he is unable to relate soiling or damage to specific levels of PM in ambient air or to evaluate or consider a level of air quality to protect against such materials effects, and that there is insufficient information available in this review to support a distinct national ambient standard based on materials effects.

With regard to the secondary PM standards, the Administrator concludes that it is appropriate to retain the existing secondary PM standards, without revision. This conclusion is based on the considerations discussed above in sections IV.A.3.b and IV.B.2, including the latest scientific information and the advice of the CASAC, and the public comments received on the proposal, as discussed above in section IV.B.3. For visibility effects, this decision also reflects his consideration of the evidence for PM-related light extinction, together with his consideration of the updated analyses of the protection provided against visibility impairment by the current secondary $PM_{2.5}$ and PM_{10} standards. For climate and materials effects, this conclusion reflects his judgment that, although it remains important to maintain secondary $PM_{2.5}$ and PM_{10} standards to provide some degree of control over long- and short-term concentrations of both fine and coarse particles, there is insufficient information to establish distinct secondary PM standards to address non-visibility PM-related welfare effects. The Administrator concurs with the advice of the CASAC, which agrees ''that the available evidence does not call into question the protection afforded by the current secondary PM standards'' and recommends that the secondary standards ''should be retained'' (Cox, 2019a, p. 3 of letter). This is also consistent with the conclusions at the time of the proposal (IV.B.2) and with the majority of public comments received on the proposed decision (section IV.B.3).

In addition, the Administrator judges that, based on his review of the science and his judgment that air quality should be maintained to provide the target level of protection for visual air quality of 30 dv (as discussed in more detail above), the degree of public welfare protection provided by the current secondary standards is not greater than warranted. This judgment, together with the fact that no CASAC member expressed support for a less stringent standard, leads the Administrator to conclude that standards less stringent than the current secondary standards (*e.g.,* with higher levels) are also not supported.

Thus, based on his consideration of the evidence and analyses for welfare effects, his consideration of the CASAC's advice and public comments on the secondary standards, and in the absence of information that would support establishment of any different standards, the Administrator concludes that it is appropriate to retain the current 24-hour and annual $PM_{2.5}$ standards and the 24-hour PM_{10} standard, without revision.

D. Decision on the Secondary PM Standards

For the reasons discussed above and taking into account information and assessments presented in the ISA and PA, advice from the CASAC, and consideration of public comments, the Administrator concludes that the current secondary PM standards are requisite to protect public welfare from known or anticipated adverse effects and is retaining the standards, without revision.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The Office of Management and Budget (OMB) determined that this action is a significant regulatory action and it was submitted to OMB for review. Changes made during Executive Order 12866 review have been documented in the docket. Because this action does not change the existing PM NAAQS, it does not impose costs or benefits relative to the baseline of continuing with the current NAAQS in effect. Thus, the EPA has not prepared a Regulatory Impact Analysis for this action.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action. There are no costs or cost savings compared to the current baseline for this action because EPA is retaining the current standards.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. There are no information collection requirements directly associated with a decision to retain a NAAQS without any revision under section 109 of the CAA and this action retains the current PM NAAQS without any revisions.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Rather, this action retains, without revision, existing national standards for allowable concentrations of PM in ambient air as required by section 109 of the CAA. See also *American Trucking Associations* v. *EPA,* 175 F.3d 1027, 1044–45 (D.C. Cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities), reviewed in part on other grounds, *Whitman* v. *American Trucking Associations,* 531 U.S. 457 (2001).

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in the UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes. This action does not change existing regulations; it retains the existing PM NAAQS, without revision. Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. The health effects evidence for this action, which includes evidence for effects in children, is summarized in section II.B above and is described in the ISA and PA, copies of which are in the public docket for this action.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' as defined by Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs (OIRA).

J. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The action described in this document is to retain without revision the existing PM NAAQS based on the Administrator's conclusions that the existing primary standards protect public health, including the health of sensitive groups, with an adequate margin of safety, and the existing secondary standards protect public welfare from known or anticipated adverse effects. As discussed in section II, the EPA expressly considered the available information regarding health effects among at-risk populations in reaching the decision that the existing standard is requisite.

L. Determination Under Section 307(d)

Section 307(d)(1)(V) of the CAA provides that the provisions of section 307(d) apply to ''such other actions as the Administrator may determine.'' Pursuant to section 307(d)(1)(V), the Administrator determines that this action is subject to the provisions of section 307(d).

M. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The Administrator of OIRA has not determined that this action is a ''major rule'' as defined by 5 U.S.C. 804(2).

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List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: December 4, 2020.

Andrew Wheeler,

Administrator.

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Part IV

Department of Justice

Executive Office for Immigration Review
8 CFR Parts 1003, 1103, 1208, et al.

Executive Office for Immigration Review; Fee Review; Final Rule

DEPARTMENT OF JUSTICE

Executive Office for Immigration Review

8 CFR Parts 1003, 1103, 1208, 1216, 1240, 1244, and 1245

[EOIR Docket No. 18–0101; A.G. Order No. 4929–2020]

RIN 1125–AA90

Executive Office for Immigration Review; Fee Review

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: Final rule.

SUMMARY: On February 28, 2020, the Department of Justice (''the Department'' or ''DOJ'') published a notice of proposed rulemaking (''NPRM'' or ''proposed rule'') that would increase the fees for those Executive Office for Immigration Review (''EOIR'') applications, appeals, and motions that are subject to an EOIR-determined fee, based on a fee review conducted by EOIR. The proposed rule would not affect fees established by the Department of Homeland Security (''DHS'') with respect to DHS forms for applications that are filed or submitted in EOIR proceedings. The proposal would not affect the ability of aliens to submit fee waiver requests, nor would it add new fees. The proposed rule would also update cross-references to DHS regulations regarding fees and make a technical change regarding requests under the Freedom of Information Act (''FOIA''). This final rule responds to comments received in response to the NPRM and adopts the fee amounts proposed in the NPRM without change.

DATES: This rule is effective on January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Falls Church, VA 22041, telephone (703) 305–0289 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

I. Summary of the Proposed Rule

On February 28, 2020, the Department published an NPRM that would increase the fees for those EOIR applications, appeals, and motions that are subject to an EOIR-determined fee, based on a fee review conducted by EOIR. Executive Office for Immigration Review; Fee Review, 85 FR 11866 (Feb. 28, 2020). The proposed rule would not affect fees established by DHS with respect to DHS forms for applications that are also filed or submitted in EOIR proceedings. The proposal would not affect the ability of aliens to submit fee waiver requests, nor would it add fees for any EOIR forms or applications other than those which currently have a fee imposed. The proposed rule would also update cross-references to DHS regulations regarding fees to match changes to the organization and structure of DHS's regulations regarding fees for applications and make a non-substantive correction to the regulatory cross-reference for requests under the FOIA.

A. Authority and Legal Framework

The Department published the proposed rule pursuant to its authority to charge fees, also referred to as user charges. 85 FR at 11866–67.

Pursuant to section 286(m) of the Immigration and Nationality Act (the ''Act'' or ''INA'') (8 U.S.C. 1356(m)), the Attorney General and the Secretary of Homeland Security may charge fees for adjudication and naturalization services at a rate that would ensure recovery of both the full cost of providing all such services, including similar services that may be provided without charge to certain categories of aliens, and any additional administrative costs associated with the fees collected.[1] 85 FR at 11867. Accordingly, adjudication fees, as designated in the regulations, are deposited into the Immigration Examinations Fee Account (''IEFA'') in the Treasury of the United States and ''remain available until expended to the Attorney General [or the Secretary] to reimburse any appropriation the amount paid out of such appropriation for expenses in providing immigration adjudication and naturalization services and the collection, safeguarding and accounting for fees deposited in and funds reimbursed from the [IEFA].'' INA 286(n), 8 U.S.C. 1356(n); *see also* 85 FR at 11867.[2] The Act authorizes the Attorney General and Secretary of Homeland Security to promulgate regulations to carry out this authority. INA 286(j), 8 U.S.C. 1356(j).

In addition, the Department notes that this rule is also authorized by title V of the Independent Offices Appropriations Act of 1952 (''IOAA''), Public Law 82–137, 65 Stat. 268, 290 (1951) (codified at 31 U.S.C. 9701). The IOAA provides government-wide authority to charge fees to individuals who receive special services from an agency. 31 U.S.C. 9701(a)–(b).[3] Those fees must be ''fair'' and based on government costs, value provided to the recipient, the public policy or interest served, and other relevant factors. *Id.*

The proposed rule is likewise consistent with Circular No. A–25 Revised,[4] which has been determined to be a ''proper construction'' of the IOAA,[5] and provides guidance to executive branch agencies regarding the scope and types of activities that may be covered by user fees and how to set such fees. Covering all Federal activities, including agency programs, that convey special benefits to recipients beyond those that the general public receives, it instructs agencies to review user charges for such activities biennially. *See* Circular No. A–25 Revised at sec. 8(e); *see also* 31 U.S.C. 902(a)(8) (directing an ''agency Chief Financial Officer'' to ''review, on a biennial basis, the fees, royalties, rents, and other charges imposed by the agency for services and things of value it provides, and make recommendations on revising those charges to reflect costs incurred by it in providing those services and things of value'').

B. Purpose of the Proposed Rule

Before the proposed rule's publication, the Department had fallen out of compliance with Circular No. A–25 Revised and 31 U.S.C. 902(a)(8) regarding the review of EOIR's fees on a biennial basis. For over 30 years the Department did not either review or update the fees charged for applications, appeals, and motions for which EOIR levies a fee. *See* 85 FR at 11869.

[1] Following the Homeland Security Act of 2002 (''HSA''), the Attorney General retained the same authority and functions related to immigration and naturalization of aliens exercised by EOIR or the Attorney General prior to the HSA's effective date. Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135; *see* INA 103(g)(1) (8 U.S.C. 1103(g)(1)). Further, the Attorney General retained the authority to perform actions as necessary, including promulgating regulations, in order to carry out authority under the immigration laws. *See* INA 103(g)(2), 8 U.S.C. 1103(g)(2).

[2] All other payments received for fees and administrative fines and penalties are deposited into the Treasury as miscellaneous receipts, not including some exceptions that are irrelevant for the purposes of this final rule. *See* INA 286(c), 8 U.S.C. 1356(c); 85 FR at 11867.

[3] Title V of the IOAA was first codified at 31 U.S.C. 841. In 1982, the language from title V of the IOAA was subsequently codified, with minor changes and the addition of paragraphing, at 31 U.S.C. 9701. Act of Sept. 13, 1982, Public Law 97–258, 96 Stat. 877, 1051 (revising, codifying, and enacting without substantive change certain general and permanent laws, related to money and finance, as title 31, United States Code, ''Money and Finance'').

[4] Circular No. A–25 was published in 1959. Circular No. A–25 Revised rescinded and replaced Circular No. A–25 and its accompanying Transmittal Memoranda 1 and 2. *See* Office of Management and Budget (''OMB'') Circular A–25, 58 FR 38142, 38144 (July 15, 1993).

[5] *See Fed. Power Comm'n* v. *New England Power Co.,* 415 U.S. 345, 349–51 (1974).

Accordingly, in order to ensure compliance with the IOAA (31 U.S.C. 9701), section 286(m) of the Act (8 U.S.C. 1356(m)), 31 U.S.C. 902(a)(8), and Circular No. A–25 Revised, ''EOIR conducted a comprehensive study using activity-based costing to determine the cost to EOIR for each type of application, appeal, and motion for which EOIR levies a fee under 8 CFR 1103.7(b).'' *Id.*

Through the 3-phase study, EOIR determined the cost for each form and motion by allocating average direct salary costs to each step in an average process map for how the fee, application, or motion works through the adjudicatory process. *See* 85 FR at 11869. In other words, EOIR totaled the total salary costs for the different EOIR staff involved in the processing and adjudication for each form and motion, based on the average time each type of official spends on that processing and adjudication, to determine an average processing cost. *See id.* Despite EOIR's authority to recover the full cost of providing adjudication services, EOIR's study did not include costs aside from the direct salary costs for the involved staff. Specifically, the study did not include: (1) Overhead costs, which the Department determined would occur regardless of how many applications, appeals, or motions to which a fee applies are filed; (2) non-salary benefits, which may vary greatly from person to person depending on which benefits, if any, are selected; or (3) costs associated with filing related documents that may be submitted with the application, appeal, or motion to which a fee applies. *Id.*

Despite including only the direct salary costs in this cost study, the results clearly demonstrated that the processing costs for the applications, appeals, and motions to which a fee applies under 8 CFR 1103.7(b) significantly exceed the fees imposed in 1986. 85 FR at 11870. Accordingly, the Department issued the NPRM to begin rulemaking to update the fees in accordance with the processing costs identified by the EOIR fee study so that the fee amounts ''more accurately reflect the costs for EOIR's adjudications of these matters.'' *Id.*

Because the proposed rule roughly matched the new fee amounts with the processing costs that were identified by a study that did not consider the complete cost to the agency, as explained above, the proposed rule inherently subsidized the costs of adjudicating these applications, appeals, and motions. In other words, the updated fee amounts balance ''the public interest in ensuring that U.S. taxpayers do not bear a disproportionate burden in funding the immigration system'' with the fact that ''these applications for relief, appeals, and motions represent statutorily provided relief and important procedural tools that serve the public interest and provide value to those who are parties to the proceedings by ensuring accurate administrative proceedings.'' *Id.* Put more simply, the proposed rule intentionally put forth fee amounts that were less than the cost to the agency in order to effectively serve the public interest.

C. Provisions of the Proposed Rule

In determining the fees to charge, the agency considered the various public policy interests involved, including ensuring that immigration courts continue to be accessible for aliens seeking relief and that U.S. taxpayers do not bear a disproportionate burden in funding the immigration system. *See id.* Based on the cost study and these considerations, the NPRM proposed the following changes to EOIR's fees:

1. Increase the fee for Form EOIR–26 from $110 to $975.
2. Increase the fee for Form EOIR–29 from $110 to $705.
3. Increase the fee for Form EOIR–40 from $100 to $305.
4. Increase the fee for Form EOIR–42A from $100 to $305.
5. Increase the fee for Form EOIR–42B from $100 to $360.
6. Increase the fee for Form EOIR–45 from $110 to $675.
7. Increase the fee for filing a motion to reopen or reconsider from $110 before both the immigration courts within the Office of the Chief Immigration Judge (''OCIJ'') and the Board of Immigration Appeals (''BIA'' or ''Board'') to $145 if either motion is filed before the OCIJ, and $895 if either motion is filed before the BIA.

The NPRM also proposed numerous technical corrections to fee-related citations to both DHS's regulations in chapter I and EOIR's regulations in chapter V of title 8 of the Code of Federal Regulations following DHS's publication of an NPRM regarding DHS-imposed fees. U.S. Citizenship and Immigration Services Fee Schedule and Changes to Certain Other Immigration Benefit Request Requirements, 84 FR 62280 (Nov. 14, 2019). The Department's NPRM included proposed changes to cross-references to those DHS regulations as used in EOIR's regulations to ensure that all cross-references were accurate in accordance with DHS's proposed rule. *See* 85 FR at 11871–72.

Finally, the proposed rule made additional technical corrections to EOIR's regulations to correct cross-references, both to a provision regarding requests pursuant to FOIA and to EOIR's own fee-related regulations. 85 FR at 11872.

More specifically, the NPRM proposed the following changes to EOIR's regulations.

a. Part 1003—Executive Office for Immigration Review

First, the NPRM proposed to amend 8 CFR part 1003 by updating citations contained in this part. In accordance with DHS's rulemaking, the NPRM proposed to change ''8 CFR 103.7(a)'' to ''§ 1103.7(b)'' in § 1003.8(a)(4)(ii), and it proposed to change ''8 CFR 103.7'' to ''8 CFR 103.7 and 8 CFR part 106'' in § 1003.24(a) and (c).

b. Part 1103—Appeals, Records, and Fees

Also, in accordance with DHS's rulemaking, the NPRM proposed to amend 8 CFR 1103.7 by changing (1) the citation ''8 CFR 103.7(a)(1)'' to ''8 CFR 103.7(a)'' in paragraph (a)(3); (2) the citation ''8 CFR 103.7(a)(2)'' to ''8 CFR 103.7(c) and 8 CFR 106.1'' in paragraph (a)(3); and (3) the citation ''8 CFR 103.7'' to ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (b)(4)(ii). In addition, the NPRM proposed revising paragraph (b)(4)(ii) of § 1103.7 to clarify that despite DHS's proposed assignment of a $50 fee for filing a Form I–589, Application for Asylum and for Withholding of Removal, such fee would not apply for a Form I–589 filed with an immigration judge ''for the sole purpose of seeking withholding of removal under section 241(b)(3) of the Act or protection under the Convention Against Torture regulations.''

Next, the NPRM proposed to revise paragraphs (b)(1), (b)(2), and (b)(4)(i) to reflect the updated fee amounts. Paragraph (b)(1) would contain updated fees for Forms EOIR–26, –29, and –45. Paragraph (b)(2) would contain updated fees for motions to reopen or to reconsider before the immigration court and motions to reopen or to reconsider before the BIA. Paragraph (b)(4)(i) would contain updated fees for Forms EOIR–40, –42A, and –42B.

The NPRM also proposed to revise paragraph (d) to correct a cross-reference to the regulations regarding FOIA. The current regulation incorrectly stated that the FOIA regulation is located at 28 CFR 16.11, and the NPRM corrected that cross-reference to 28 CFR 16.10.

c. Part 1208—Procedures for Asylum and Withholding of Removal

The NPRM proposed to amend 8 CFR 1208.7 to change the citation ''§ 103.7(c)'' to ''8 CFR 106.3'' in paragraph (c), in accordance with DHS's proposed rule.

d. Part 1216—Conditional Basis of Lawful Permanent Residence Status

Also in accordance with DHS's rulemaking, the NPRM proposed to amend 8 CFR part 1216. In § 1216.4, the NPRM proposed to change the citation ''§ 103.7(b)'' to ''§ 106.2'' in paragraph (a)(1). It also proposed to change the citation ''§ 103.7(b)'' to ''§ 106.2'' in paragraph (b). In § 1216.6, the NPRM proposed to change the citation ''§ 103.7(b)(1)'' to ''§ 106.2'' in paragraph (a)(1).

e. Part 1235—Inspection of Persons Applying for Admission

Also in accordance with DHS's rulemaking, the NPRM proposed to amend 8 CFR 1235.1 to change the citation ''§ 103.7(b)(1)'' to ''§ 103.7(d)'' in paragraphs (e)(1)(iii), (e)(2), and (f)(1). This final rule, however, does not adopt that change because an intervening rulemaking, Procedures for Asylum and Withholding of Removal; Credible Fear and Reasonable Fear Review, signed by the Attorney General and the Acting Secretary of Homeland Security on December 2, 2020, removed and reserved 8 CFR 1235.1 altogether.

f. Part 1240—Proceedings to Determine Removability of Aliens in the United States

The NPRM proposed to amend 8 CFR part 1240 to correct cross-references to EOIR's own regulations. In § 1240.11, the NPRM proposed to change the citation ''§ 103.7(b)(1) of 8 CFR chapter I'' to ''§ 1103.7(b)(1) of this chapter'' in paragraph (f). In § 1240.20, the NPRM proposed to change the citation ''§ 103.7(b) of 8 CFR chapter I'' to ''§ 1103.7(b) of this chapter'' in paragraph (a).

g. Part 1244—Temporary Protected Status for Nationals of Designated States

The NPRM proposed to amend 8 CFR part 1244 in accordance with DHS's proposed rulemaking. In § 1244.6, the NPRM proposed to change the citation ''§ 103.7 of this chapter'' to ''8 CFR 106.2''. Further, in § 1244.20, the NPRM proposed to change the citation ''8 CFR 103.7(b)'' to ''8 CFR 106.2'' in paragraph (a).

h. Part 1245—Adjustment of Status to that of Person Admitted for Permanent Residence

The NPRM proposed to amend 8 CFR part 1245 in accordance with DHS's proposed rule.

In § 1245.7, the NPRM proposed to change the citation ''§ 103.7 of this chapter'' to ''8 CFR 103.7 and 8 CFR 103.17'' in paragraph (a).

In § 1245.10, the NPRM proposed to change the citation ''§ 103.7(b)(1) of this chapter'' to ''8 CFR 106.2'' in paragraph (c).

In § 1245.13, the NPRM proposed to change the citation ''§ 103.7(b)(1)'' to ''§ 106.2'' in paragraphs (e)(1), (g), (j)(1), and (k)(1), and it proposed to change the citation ''§ 103.7(b)(1)'' to ''§ 103.7(a)(2)'' in paragraph (e)(2).

In § 1245.15, the NPRM proposed to change the citation ''§ 103.7(b)(1) of this chapter'' to ''8 CFR 106.2'' in paragraph (c)(2)(iv)(A), and it proposed to change the citation ''§ 103.7(c)'' to ''§ 106.3'' in paragraph (c)(2)(iv)(B). Further, in 1245.15, the NPRM proposed to change the citation ''§ 103.7(b)(1)'' to ''§ 106.2'' in paragraph (h)(1), (n)(1), and (t)(1), and it proposed to change the citation ''§ 103.7(b)(1)'' to ''§ 103.2(a)(2)'' in paragraph (h)(2).

In § 1245.20, the NPRM proposed to change the citation ''§ 103.7(b)(1)'' to ''§ 106.2'' in paragraphs (d)(1), (f), and (g).

In § 1245.21, the NPRM proposed to change the citation ''§ 103.7(b)(1) of this chapter'' to ''8 CFR 106.2'' in paragraph (b)(2), and it proposed to change the citation ''8 CFR 103.7(b)(1)'' to ''8 CFR 106.2'' in paragraphs (h) and (i).

II. Public Comments on the Proposed Rule

A. Summary of Public Comments

The comment period for the NPRM closed on March 30, 2020, with 601 comments received.[6] Organizations (including non-governmental organizations, legal advocacy groups, non-profit organizations, and religious organizations), congressional committees, and groups of members of Congress submitted 157 comments, and individual commenters submitted the rest. Most individual comments opposed the NPRM. All organizations but one opposed the NPRM.

[6] The Department reviewed all 601 comments submitted in response to the rule; however, the Department did not post five of the comments to *regulations.gov* for public inspection. Of these comments, three were duplicates of another comment written by the same commenter, one was a blank comment without any attachment, and one was a comment specific to a prior agency rulemaking.

B. Comments Expressing Support for the Proposed Rule

Comment: Some individuals and one organization expressed support for the NPRM. Some supportive commenters noted the length of time since EOIR last reviewed and updated its fees and agreed that the fee amounts should be brought more in line with the modern processing costs to the agency and the costs imposed by United States Citizenship and Immigration Services (''USCIS'') for similar forms or services.

One commenter noted that the criminal and civil court systems also impose fees and fines. Commenters expressed gratitude that the rule would protect taxpayer dollars and stated that taxpayers should not have to be burdened by or pay for immigration-related costs and the immigration court system for non-citizens. Instead, commenters stated that immigrants need to pay for their own immigration-related expenses.

Two commenters characterized the current status quo without the rule as allowing some form of ''free'' immigration, which commenters stated should not be allowed.

Commenters also expressed a belief that the United States cannot afford the current immigration system any longer.

One commenter noted that the commenter's father was an immigrant who paid all his own immigration-related costs.

Response: The Department appreciates the commenters' support for the rule.

Comment: Four commenters who supported the Department's reasoning for increasing EOIR's fees suggested that the Department should consider a more modest fee increase instead of the full amounts proposed. These commenters were concerned that the proposed amounts might be too large and too sudden for people to afford, could render services unattainable, or are simply too high. On the other hand, two commenters suggested that the fees should instead be set at a higher amount.

One commenter suggested that the Department should require supporting documents for any fee-waiver requests. One commenter suggested in the future the Department should propose smaller increases every few years instead of waiting a lengthy period of time to impose such a substantial fee increase.

Response: The Department appreciates the commenters' suggestions and has taken the suggestions under advisement. Regarding suggestions about the proposed changes to the fee amounts, further discussion on the

specific fee amounts to be imposed is contained below in Section II.C.4 of this preamble and further discussion on fee waivers is contained below in Section II.C.5. The Department also acknowledges the comment regarding not waiting thirty years to increase fees again in the future and, going forward, expects to adhere more closely to the biennial fee review timetable established by the Office of Management and Budget (''OMB'') and Congress.

C. Comments Expressing Opposition to the Proposed Rule

1. General opposition

Comment: Numerous commenters expressed general opposition to the NPRM and provided little to no reasoning for their opposition.[7] Many commenters asked the Department to withdraw the NPRM with no supporting rationale. Other commenters expressed opposition to the NPRM based generally upon their belief that it undermines American values. One commenter opposed the NPRM as ''rule by executive decree'' that eroded the separation between Congress and the Executive Branch.

Response: The Department is unable to provide a detailed response to comments that express only general opposition without providing reasoning for such opposition, but the Department reiterates the need to implement this rulemaking in accordance with authority under section 286 of the Act (8 U.S.C. 1356) and the IOAA, especially in light of the length of time since EOIR's fees were last reviewed, notwithstanding Circular No. A–25 Revised and 31 U.S.C. 902(a)(8). In subsequent sections of this final rule, the Department responds to comments that provided specific points of opposition or reasoning underlying their opposition.

Further, the Department disagrees that the rule undermines American values. The rulemaking is promulgated in accordance with the IOAA and section 286(m) of the Act (8 U.S.C. 1356(m)), which statutorily authorize DOJ to charge fees for immigration adjudication and naturalization services. Accordingly, since promulgation of this rule is squarely within the Department's congressionally authorized purview, the Department believes that this rule furthers American values, including the rule of law.

The rule does not constitute ''rule by executive decree.'' Section 286(j) of the Act (8 U.S.C. 1356(j)) authorizes the Attorney General to promulgate regulations to carry out section 286 of the Act. The Administrative Procedure Act (''APA'') establishes rulemaking procedures that agencies must follow when engaging in regulatory activity. *See generally* 5 U.S.C. 553. The Department properly exercised its regulatory authority under section 286(j) of the Act (8 U.S.C. 1356(j)) and followed all relevant APA procedures. Further, the IOAA provides additional authority for this action. See Section II.C.9. of this preamble for further discussion.

2. Opposition to Current United States Immigration System

Comment: Numerous commenters expressed general opposition to the current U.S. immigration system as a whole and included the following perceived concerns: Inefficiencies throughout the system; problems with agency management and personnel; poor treatment of refugees and immigrants in comparison to the United States' wealth and the inscription on the Statue of Liberty; funding for a border wall; politicization of immigration-related issues; and implementation of recent immigration policies, such as the Migrant Protection Protocols (''MPP'') and immigration judge performance measures, which commenters described as ''case completion quotas.''

Many commenters emphasized the positive contributions of immigrants to American society and the economy; relatedly, commenters stated that taxpayers should share some of the cost burden for the forms, applications, or motions affected by this rule because the United States benefits from immigration. These commenters supported simplifying the immigration system so that immigrants may more readily immigrate to the United States and join American communities. Commenters also alleged that, if implemented, the rule would result in a decline in immigration, promote inequality within the immigration system, and overall harm the country.

Response: Commenters' concerns regarding the immigration system as a whole and interest in more sweeping changes to the immigration system are far outside the scope of this rulemaking. The rule amends EOIR regulations specifically in regard to fees for applications, motions, and forms before EOIR. More specifically, and in accordance with EOIR's fee review, the rule increases fees for EOIR applications, appeals, and motions in accordance with the authority discussed in Section I.A of this preamble and EOIR's 2018 fee study; updates cross-references and discussion of DHS regulations regarding fees in response to DHS's rulemaking regarding its immigration fees; and makes technical changes regarding FOIA requests and other internal cross-references. *See generally* 85 FR 11866. Accordingly, comments concerning Federal immigration policy across the Government and the immigration system as a whole are outside the rule's limited scope of EOIR fees.

3. Objections to Fee Increases as a Funding Mechanism for EOIR

Comment: Commenters opposed the NPRM by stating that fees should not serve as a funding mechanism for EOIR's adjudication costs for various reasons: The Department is not statutorily required to recover the full cost of adjudications; the Department lacks authority to recover the full cost; and the Department, as a congressionally appropriated agency (rather than a fee-based agency), should be funded through such appropriations rather than fees. Further, commenters found the Department's determination that it was necessary to update its fees despite being an appropriated agency inadequate and conclusory. Commenters stated that congressional appropriations could adequately support EOIR operations. Some commenters stated that congressional appropriations would have been sufficient, but asserted that the President had diverted EOIR funding toward building a wall on the Southern border with Mexico.

Some commenters explained that fees need not recover the full cost because taxpayers should subsidize the fees in order to keep the relevant forms, applications, or motions ''affordable'' and ''accessible'' for certain people, such as asylum seekers, who would be unable to cover the full proposed fees. One commenter suggested the Department should in fact impose no fees. Another commenter suggested that EOIR should request additional congressional appropriations if the agency is concerned about the budgetary impacts of filing processing.

One commenter alleged that the Department exceeded its statutory authority because section 286(m) of the Act (8 U.S.C. 1356(m)) does not authorize ''[r]aising fees that were previously sufficient, or near sufficient, by seven, eight, and even nine times their current amount.''

[7] Several comments expressed various USCIS-related concerns, such as opposition to USCIS-imposed fees for appeals and waiver requests. As a component of DHS, USCIS is a distinct agency from EOIR, a component of DOJ. This rule does not affect fees established by DHS. *See* 85 FR at 11866. Therefore, such concerns are outside the scope of this rulemaking.

Response: As an initial matter, commenters are correct that the Department, including EOIR, is funded by congressional appropriations. *See, e.g.,* Consolidated Appropriations Act, 2020, Public Law 116–93, 133 Stat. 2317, 2396 (Dec. 20, 2019) (appropriating to EOIR ''$672,966,000, of which $4,000,000 shall be derived by transfer from the Executive Office for Immigration Review fees deposited in the 'Immigration Examinations Fee' account, and of which not less than $18,000,000 shall be available for services and activities provided by the Legal Orientation Program''). It retains authority, however, to charge fees for immigration adjudications to recover up to the full costs expended by the agency in providing such services. INA 286(m), 8 U.S.C. 1356(m); *see also* Circular No. A–25 Revised (available at 58 FR 38142 (July 15, 1993)); 31 U.S.C. 9701(a)–(b) (encouraging agencies to be as self-sustaining as possible). Although the statutory authority requires consideration of various relevant factors, it is not restricted by a strict limit or cap, conditions related to taxpayer contributions or congressional appropriations, or principles of ''affordability'' or ''accessibility''; therefore, the Department's authority to impose fees is not limited in the ways proposed by the commenters. Despite its statutory authority and a rise in caseload and adjudication costs, EOIR's fees have not been updated since 1986—over thirty years ago.

While the Department agrees with commenters that some agency costs are covered by appropriation, this does not obviate the purpose of the rulemaking, which is to lower costs to the taxpayers while still ensuring access to the immigration courts, as appropriated funds reflect costs to taxpayers. Commenters are incorrect that any of EOIR's appropriated funds have been diverted outside the agency to fund construction of a border wall. Moreover, some of EOIR's funding—*e.g.,* the funding for the general Legal Orientation Program (LOP)—cannot be re-purposed to offset costseven though a portion of that funding itself has been found to be financially wasteful. *See* LOP Cohort Analysis (Phase I) (Sept. 5, 2018), *https://www.justice.gov/eoir/file/1091801/download;* LOP Cohort Analysis Addendum (Phase I) (Jan. 29, 2019), and *https://www.justice.gov/eoir/file/1125596/download.*

The sufficiency of EOIR's congressional appropriations is irrelevant for the purpose of this rule, which is to ensure EOIR fees more accurately reflect the costs for EOIR's adjudications, consistent with the Department's authority to impose fees under the IOAA (31 U.S.C. 9701) and section 286(m) of the Act (8 U.S.C. 1356(m)). These authorities demonstrate a congressional intent that, to the extent possible, agencies should levy a fee designed to ensure maximum self-sufficiency, even if the overall budget is supported and funded via congressional appropriations.

The updated fees are based on an assessment that accounted only for direct salary costs required for processing those documents subject to the rule. *See* 85 FR at 11869 (explaining that the survey did not consider overhead costs, costs of non-salary benefits, or costs associated with processing corresponding applications or documents that may be filed with the applications, appeals, and motions subject to the rule). Accordingly, the updated fees are based on a reduced estimate of the processing costs and, thus, inherently do not cover all related costs. The proposed rule did not, and the final rule does not, purport to cover all costs; instead, the rule seeks to update fees so that the fee amounts ''more accurately reflect the costs for EOIR's adjudications of these matters'' while at the same time balancing ''both the public interest in ensuring that the immigration courts are accessible to aliens seeking relief and the public interest in ensuring that U.S. taxpayers do not bear a disproportionate burden in funding the immigration system.'' 85 FR at 11870.

The Department never intended for this rulemaking to update fees in order to recover the entirety of processing costs or to fully fund EOIR's adjudication costs. On the contrary, the Department balanced the public policy interest maintaining accessibility of the immigration courts for aliens while ensuring that U.S. taxpayers do not pay a disproportionate amount to fund the immigration court system. 85 FR at 11870. Indeed, as explained in the NPRM, the Government seeks to ''recoup some of its costs when possible and . . . also protect the public policy interests involved.'' *Id.*

4. Objections to Amount of Fee Increases

Comment: Commenters generally objected to the amount of fee increases, stating that the fee increases were too high.

Commenters asserted that one of the Department's justifications for its proposed adjusted fees was premised on a miscalculation. Specifically, commenters stated that the Department calculated what the estimated increase in fees would have been if the Department had raised its fees on an annual basis since it last adjusted fees in 1986 by calculating the compound annual growth rate (''CAGR''), but asserted that the Department miscalculated the CAGR in some of the filings addressed in the NPRM: The Forms EOIR–40 and –42A and motions to reopen before the immigration court. *See* 85 FR at 11874. Commenters asserted that although these alleged miscalculations were small, they called the Department's computational accuracy into question in arriving at the proposed fees.

Commenters asserted that the Department calculated the CAGR for Form EOIR–40 and Form EOIR–42A as 3.33 percent by inputting the $305 proposed fees, $100 current fees, and the 33-year time period. Commenters asserted that the Department was 0.11 percent too low in its calculation, which should have yielded 3.44 percent CAGR for these forms. Likewise, commenters asserted that the Department miscalculated the CAGR for Form EOIR–42B, at a 3.84 percent CAGR. Commenters asserted that to reach this CAGR, the Department should have input the $360 proposed fee for the Form EOIR–42B, as well as the $100 current fee for the form, and the 33-year time period passing between 1986 and 2019 to get a 3.96 percent CAGR. Instead, DOJ calculated a 3.84 percent CAGR for this form. Commenters also asserted that the Department miscalculated the CAGR for motions to reopen before the immigration court, which it calculated as 0.82 percent. Commenters stated that the Department should have input the proposed $145 fee to file a motion to reopen before the immigration court, the $110 current fee for this motion, and the 33-year timespan to reach a 0.84 percent CAGR.

Commenters similarly criticized the Department's methodology in calculating the costs for each application because the Department did not provide justification or explanation on how the Department determined the estimated costs. Additionally, commenters objected to the fees based on the assertion that the fee increases are unrelated to the cost of inflation.

Commenters further objected to the Department's estimates of the costs associated with processing applications because they were based on current processing methods and failed to account for foreseeable changes in future processing costs. As an example of a consideration the Department failed to include, commenters cited the increased prevalence of affirmances without opinion (''AWO'') on appeals to the BIA following the publication of the

final rule, Board of Immigration Appeals: Affirmance Without Opinion, Referral for Panel Review, and Publication of Decisions as Precedents, 84 FR 31463, on September 3, 2019. Commenters also asserted that the Department failed to consider that the proposed rule would have the effect of reducing the number of case filings, which would result in a decrease to the Department's expenses. Commenters objected to the Department's inclusion of $327.83 of administrative costs in the total costs of appeal, which they stated was one third of the overall calculated cost.

Commenters expressed concern regarding the Department's reliance on a spring 2018 study conducted within the Department. Commenters asserted that the Department failed to provide necessary detail about the survey process and therefore the commenters were concerned because they were unable to verify the validity of the study.

Commenters suggested that, at a minimum, the Department should have addressed whether aliens who are currently making the relevant filings are able to afford the filing fees and should have set fees at a level that most individuals are able to pay.

Commenters also suggested that recently implemented ''case completion quotas'' would affect the EOIR cost analysis, because immigration judges would take less time to make decisions.

Response: The Department notes that some commenters believe that the Department miscalculated the CAGR for Form EOIR–40, Form EOIR–42A, and motions to reopen before the immigration court. Regardless of any miscalculations with respect to the CAGR, as commenters recognized, the Department's calculations differed from the commenters' recommended calculations to a small degree (.11, .12, and .02 percent differentials, respectively) such that they could be attributed to differences in rounding estimates. Even assuming, arguendo, that the commenters' assertions are correct, the Department notes that such calculations need not be exact, so long as the ''fees are no greater than *the rough actual cost* of providing the services.'' *Ayuda, Inc.* v. *Att'y Gen.,* 661 F. Supp. 33, 36 (D.D.C. 1987) (''*Ayuda I*'') (emphasis added), *aff'd,* 848 F.2d 1297 (D.C. Cir. 1988) (''*Ayuda II*''); *see also Nat'l Cable Television Ass'n* v. *FCC,* 554 F.2d 1094, 1108 (D.C. Cir. 1976) (''To be valid, a fee need only bear a *reasonable* relationship to the cost of the services rendered by the agency.'' (emphasis in original)). In addition, these calculations were provided for illustrative purposes only and are unrelated to the underlying calculations of the new fee amounts based on the agency's adjudicatory costs.[8] The Department notes, for example, its decision to round several of its fees to the nearest five-dollar increment and its decision to round the average of actual costs for motions to reopen and reconsider before the immigration courts. 85 FR at 11870. The Department notes that it did not receive any comments objecting to this decision. Accordingly, the Department believes that its calculations are reasonable and fair given the rough actual cost of providing the services and will not make any alterations to the proposed fees on this basis.

The inclusion of administrative costs in EOIR's cost calculations when determining the new fees was appropriate. Administrative costs are essential to the processing and, in turn, the adjudication of these applications, appeals, and motions and are part of a long-standing process necessary to handle the volume of appeals with expediency, appropriate case management, and ensuring that parties before the BIA receive appropriate notice that is essential for due process. *See Board of Immigration Appeals Practice Manual,* Board of Immigration Appeals, *https://www.justice.gov/eoir/page/file/1250701/download* (last updated Oct. 5, 2020) (describing duties of Clerk's Office at 1.3(e)). Further, while the Department agrees with commenters that some costs are covered by appropriations, this does not obviate the purpose of the rulemaking, which is to lower costs to the taxpayers while still ensuring access to the immigration courts, as appropriated funds necessarily reflect costs to taxpayers. Moreover, regardless of appropriations, OMB Circular No. A–25 Revised and 31 U.S.C. 902(a)(8) instruct agencies to review fees biennially and to recommend revisions to fees to reflect costs incurred.

The Department disagrees with commenters' concerns that it did not adequately explain its methodology or justification for increasing costs. The Department has clearly stated that its purpose for the rulemaking is to ensure that U.S. taxpayers do not bear a disproportionate burden in funding the immigration system while also ensuring that immigration courts remain accessible to aliens seeking relief. 85 FR at 11870. Neither OMB Circular No. A–25 Revised nor 31 U.S.C. 9701 indexes or otherwise limits a government agency's ability to increase fees only to the level of inflation. Moreover, the underlying costs that go into EOIR's fee calculations—*e.g.,* salary costs—are not necessarily indexed to inflation, making an inflation percentage a poor metric for calculating appropriate fees. Additionally, the Department has explained its methodology in calculating the CAGR and its consideration of the availability of fee waivers. 85 FR at 11874 (''Taken over the 33-year timespan from 1986 to 2019, the proposed fee increases would represent compound annual growth rates ranging from 0.82 percent to 6.84 percent. As demonstrated in the chart above, these increases are marginal in terms of inflation-adjusted dollars. While EOIR recognizes that the new fees will be more burdensome, fee waivers are still possible for those who seek them.''). However, in light of numerous comment requests, the Department is publishing the data collected in its spring 2018 study, accompanied by an updated dataset that was applied to that study when finalizing this rule, upon which it has based its calculations in the docket of this rulemaking. This data should further illustrate the Department's careful process and data-driven consideration behind setting the new fees. The Department disagrees with commenters' statements that the Department has failed to consider future changes to foreseeable processing costs. Commenters' suggestions that processing costs would change as a result of more AWO decisions, fee waiver adjudications, three-member BIA decisions, and use of video teleconferencing (VTC) are too speculative, illogical, or not supported by evidence. For example, regarding the use of VTC, EOIR must engage in the same adjudicatory steps, which would presumably result in the same processing costs as with in-person hearings. Similarly, EOIR engages in the same adjudicatory steps to determine whether a decision is issued by one Board member or a three-member panel, so the processing costs of those steps would be largely unaltered. *See* 8 CFR 1003.1(e). Moreover, although the number of appeals has increased significantly in the past three years, and is expected to continue increasing, the specific mix of decisions produced by those appeals—*e.g.,* AWO, summary dismissals, single-member decisions, three-member panel decisions—is impossible to predict and depends on the facts of each appeal applied to the relevant regulatory criteria. *See Exec. Office for Immigration Rev. Adjudication Statistics: All Appeals*

[8] Further, the CAGR calculations have been updated below in section IV.D.

Filed, Completed, and Pending, Exec. Office for Immigration Rev., July 14, 2020, *available at https://www.justice.gov/eoir/page/file/1248506/download;* 8 CFR 1003.1(d)(2); 8 CFR 1003.1(e)(4)–(6). Commenters opined that because of the higher fees associated with filings, there might be a possible reduction in case filings; however, neither the projection that a significant number of aliens would be unable to afford filing fees nor the projection that there would be a reduction in filings is supported by evidence. Some commenters stated that the Department did not appropriately consider whether cases decided by the BIA would be precedential or non-precedential; however, the Department fails to see how the precedential impact of a case would affect processing costs for an individual case. Moreover, as the fee charged for an appeal is unrelated to the subject-matter of that appeal, there is no basis to expect that the changes to the appeal fees will cause more or fewer decisions to be designated as precedential.

With respect to comments that the Department should have set the filing fees at a rate that most aliens would be able to pay, the Department notes that it does not generally have an alien's financial records at its disposal for review. In those circumstances in which the agency might have such information available, it is due to the information's submission in support of fee waivers filed under the current fee schedule—submissions made by a group of people who would be in the same circumstance under the new amounts. Moreover, to the extent the Department possesses information that may serve as a proxy for an alien's financial status—*e.g.,* the ability of an alien to retain representation or the ability of an alien to pay application fees set by DHS, which are generally much higher than those set by EOIR—that information suggests that most aliens would be able to afford EOIR's proposed fees.

Comment: Commenters also stated that the Department's calculations are flawed because its calculations are based on the cost to the taxpayer per adjudication, but the Department does not break down the number of appeals filed by the Government as compared with the number of appeals filed by the alien. The commenters asserted that it is fundamentally flawed logic to calculate the cost to the taxpayer of the current number of appeals without specifying how many appeals are filed by DHS, particularly in light of anecdotal evidence that DHS has recently filed appeals in a higher percentage of cases than in the past. Commenters noted that DHS does not have a filing fee associated with its appeals, so there is no incentive for DHS to limit its filings to meritorious appeals. Similarly, commenters averred that if the Department's concern relates to the high pending case load, then DHS should bear some financial responsibility in the process because DHS has control over the number of cases filed and therefore initiated before immigration courts.

Response: Commenters misconstrue the Department's analysis regarding the basis for the new fees. As explained in the NPRM, EOIR conducted a comprehensive study using activity-based costing to determine the cost to EOIR for each form and motion for which EOIR imposes a fee under 8 CFR 1103.7(b). 85 FR at 11869. This study was completed to comply with the IOAA and section 286(m) (8 U.S.C. 1356(m)) of the Act; it was not a response to the high pending case load, though the increased volume in recent years highlights the Department's failure to bring the fees more in line with the current costs. Through the 3-phase study, EOIR determined the cost for each form and motion by allocating average direct salary costs to each step in an average process map for how the fee, application, or motion works through the adjudicatory process. *See id.* In other words, EOIR totaled the total salary costs for the different EOIR staff involved in the processing and adjudication for each form and motion, based on the average time each type of official spends in that processing and adjudication, to determine an average processing cost. *See id.*

The processing costs identified by the fee study, and in turn the new amounts to be charged for these forms and applications, are, as a result, not tied to the volume of the forms or motions filed, either in total or by DHS. Instead, for example, the identified cost for the adjudication of a Form EOIR–26 for an appeal to the BIA from an immigration judge decision, as determined by the study, would be the same if the Department received one appeal as it would be if EOIR received any other number. This is because it would take the same time, considered as an average, for the different BIA staff members to process each individual appeal. Accordingly, the relative volume of appeals (or other forms or motions) DHS files, including trends in those filings, is irrelevant to the Department's determination to update the fee amounts. Nevertheless, in response to the commenters' concerns, the Department has recalculated the receipts reflected in the NPRM to attempt to best account only for those filings by aliens and the resulting costs to the taxpayers.[9]

[9] The Department notes that the numbers do include jointly filed motions, though those types of filings do not incur a fee to the alien. In addition, the Department notes that the fee collection amounts in columns 6, 7, and 8 of this chart are over-inclusive as they do not include fee waivers that were approved. As indicated in the proposed rule, approximately 36 percent of these fees were not received in 2018 due to fee waivers. 85 FR at 11869 n.11.

Form/ Motion	Current Fee	1986 Fee Inflated to 2019 Dollars	Proposed Fee	FY 2018 Receipts	Current Fee Collection	Proposed Fee Collection	Fee Collection Difference
EOIR-26	$110	$252.63	$975	29,123	$3,203,530	$28,394,925	$25,191,395
EOIR-29	$110	$252.63	$705	1,914	$210,540	$1,349,370	$1,138,830
EOIR-40	$100	$229.66	$305	158	$15,800	$48,190	$32,390
EOIR-42A	$100	$229.66	$305	3,426	$342,600	$1,044,930	$702,330
EOIR-42B	$100	$229.66	$360	30,421	$3,042,100	$10,951,560	$7,909,460
MTR OCIJ[10]	$110	$252.63	$145	18,132	$1,994,520	$2,629,140	$634,620
MTR BIA[11]	$110	$252.63	$895	7,414	$815,540	$6,635,530	$5,819,990
EOIR-45	$110	$252.63	$675	0	$0	$0	$0

85 FR at 11870–71.

The Department also disagrees that the lack of a set fee for DHS incentivizes DHS to file non-meritorious forms or motions any more than the relatively low fees currently in place incentivize respondents to file non-meritorious forms or motions. DHS is represented before EOIR by attorneys from U.S. Immigration and Customs Enforcement (''ICE''), Office of the Principal Legal Advisor, in Field Offices around the country. DHS attorneys are bound by the same standards of professional conduct as private attorneys, and the Department expects all EOIR practitioners to behave in a professional manner consistent with such obligations, including by not filing knowingly unmeritorious appeals or other applications or motions. *See, e.g.,* Model Rules of Prof'l Conduct R. 3.1 (2019), *https://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_3_1_meritorious_claims_contentions/* (''A lawyer shall not bring or defend a proceeding, or assert or controvert an issue therein, unless there is a basis in law and fact for doing so that is not frivolous, which includes a good faith argument for an extension, modification or reversal of existing law.'').

Comment: Commenters noted that the fees in the NPRM are higher than fees charged in various Federal courts. Some commenters opined that EOIR's fees should be lower than Federal court fees due to the breadth of issues covered in some Federal courts, as well as their structural complexity. Additionally, commenters stated that the proposed fees are higher than the fees charged by several other agency bodies that perform adjudicative functions. In light of these comparisons, commenters asserted that the fees in the NPRM are unreasonable. One commenter stated that the BIA appeal fee would be the highest appeal fee charged by any court.

Response: The immigration court system is distinct from the Federal court system. Immigration judges are appointed as administrative judges by the Attorney General to conduct specified proceedings under the Act and by regulation, and the BIA is an administrative tribunal that primarily decides appeals from immigration judges. *See* 8 CFR 1003.10(a); 8 CFR 1003.1(b). In contrast, Federal courts are established under Article III of the U.S. Constitution, and Article III judges are appointed by the President and confirmed by the Senate. *See* U.S. Const. art. III, sec. 1.

The Department is authorized to charge fees for immigration adjudication and naturalization services and to set those fees at a level that ensures full recovery of providing such services. INA 286(m), 8 U.S.C. 1356(m); *see also* 31 U.S.C. 9701(a) (explaining that ''each service or thing of value provided by an agency . . . to a person . . . is to be self-sustaining to the extent possible''). In contrast, the Federal court system is not explicitly required by statute to focus on cost recovery and burdens to taxpayers when setting fee schedules. *See generally* 28 U.S.C. ch. 123.

Moreover, Article III courts pass along additional costs to litigants that EOIR does not, making a simple comparison of appeal fees misleading.[12] For example, appellants in civil cases in Article III courts may be required to post an appellate bond to ensure payment of costs on appeal, which is not a requirement for an appeal within EOIR. *See* Fed. R. App. P. 7. Similarly, the appellant in an Article III case is generally required to pay for the cost of the transcript of the proceeding below, whereas the BIA provides a transcript to both parties at no cost. *See* Fed. R. App. P. 10(b)(4). Once these additional costs are factored into the cost of an appeal in Federal court, it is not clear that the cost of a Federal appeal from a district court decision is lower than the cost of an appeal from an immigration judge to the BIA.

Regarding commenters' assertions about Federal courts dealing with more complex and wider-ranging issues, the IOAA sets out a list of factors for consideration when setting fee amounts: Fairness, ''the costs to the Government,'' ''the value of the service or thing to the recipient,'' the ''public policy or interest served,'' and ''other relevant facts.'' 31 U.S.C. 9701(b). Even if the ''breadth of issues'' before a court or the issues' ''structural complexity'' could be considered an ''other relevant fact'' under the IOAA, the Department disputes that either of those factors could even be quantified, as suggested

[10] These numbers include both motions to reopen and motions to reconsider filed at the immigration court level.

[11] These numbers include both motions to reopen and motions to reconsider filed at the BIA level.

[12] Commenters appear to draw a comparison between appeals of immigration judge decisions to the BIA and petitions for review of BIA decisions filed in Federal court, but that comparison mixes appeals from a trial level to an appellate level with petitions for review from a final agency decision filed directly at the appellate level. A more appropriate comparison would be comparing only appeals from a trial level to an appellate level and, thus, comparing appeals from an immigration court to the BIA with appeals from a Federal district court to a circuit court of appeals.

by the commenters. Moreover, courts have determined that fees ''need only bear a reasonable relationship to the cost of services rendered by the agency.'' *Ayuda I,* 661 F. Supp. at 36 (quoting *Nat'l Cable Television Ass'n,* 554 F.2d at 1108).

The Department also disagrees with commenters' comparisons of EOIR's fees with fees charged by other agencies and the conclusion that EOIR's fees are consequently unreasonable. First, the *Ayuda* court succinctly resolved the first argument: ''Plaintiffs' final challenge to the amount of the fees involves the assertion that they are excessive compared with certain court fees and emphasizes that other agencies are not charging for similar services within the purview of the statutes they administer. None of these observations are relevant. Each agency is entitled to set its own fees as it chooses and make its own decisions. Additionally, the missions of other agencies do not exclusively focus on handling matters of those without lawful status in the United States. The acts of one are not controlling on another.'' *Ayuda I,* 661 F. Supp. at 36. Second, as previously explained, the court found that fees must be reasonably related to the cost of the service provided. *See id.* Accordingly, the Department finds comments to the contrary unsupported by case law and retains the updated fee amounts as proposed in the NPRM.[13]

Comment: Commenters opposed the NPRM because they believed that the proposed increases in fees, which would establish fees three to eight times higher than existing fees, would result in many more applications for fee waivers. Commenters asserted that the Department did not account for the fact that this increased number of fee waiver requests would add costs and divert judges' time from substantive claims. Commenters opined that this was particularly true with respect to the costs recouped from the $50 fee for asylum applications, and one commenter noted that EOIR should be making it more efficient to apply for asylum rather than requiring additional hurdles.

Commenters also predicted that because more people would request fee waivers for the increased fees, EOIR would likely lose revenue, rather than make revenue.

Additionally, commenters stated that in DHS's proposed fee schedule, USCIS would exclude asylum seekers from eligibility for a fee waiver, and commenters expressed concern that the Department would similarly do so. Another commenter expressed concerns about the fee waiver process for USCIS.

Commenters asserted that if the Department were to impose a filing fee for asylum applications, the fee waiver process should be clear, reviewable, and robust. One commenter recommended that a one-page fee waiver form specifically for asylum applications be made available in several languages. The commenter explained that it would be comparable to proceeding in forma pauperis, common in the Federal court system.

One commenter noted that Federal courts give a party 21 days to pay the fee or file a renewed fee waiver request following a denied fee waiver request. That commenter noted that while a fee waiver is available for individuals before EOIR, it is not comparable to the policies in the Federal court system.

Second, commenters alleged that the fee waiver process is an insufficient remedy for low-income individuals because determinations are inconsistent. Commenters explained that, in their experience, some immigration courts granted fee waivers as a matter of course, while other immigration courts rarely granted fee waivers at all. Some commenters noted that, while USCIS provides criteria for fee waivers, it was impossible to know the criteria by which EOIR adjudicates fee waiver requests and that the lack of standards could be considered arbitrary and capricious under the APA. 5 U.S.C. 706(2)(A). Commenters suggested that criteria could include specific documentation to file with the request and qualification guidelines, such as income thresholds, for eligibility. Commenters also noted that relevant information about fee waivers is not provided by immigration judge advisals or the Practice Manuals, and, when information is provided (*e.g.,* chapter 3.4(d) of the Immigration Court Practice Manual), such information is inconsistent among various sources. *See Immigration Court Practice Manual,* Exec. Office for Immigration Rev., *https://www.justice.gov/eoir/page/file/1258536/download* (last updated Nov. 18, 2020); *Board of Immigration Appeals Practice Manual,* Exec. Office for Immigration Rev., *https://www.justice.gov/eoir/page/file/1250701/download* (last updated Oct. 5, 2020). Commenters were also concerned that fee waivers, if granted, constitute a negative factor in a public charge determination.

Third, commenters opposed fee waivers as a viable solution because of the discretionary nature of fee waiver determinations. One organization opposed the rule, stating that the ''possibility of a discretionary fee waiver does not serve the same function as a reasonable fee that most individuals subject to EOIR proceedings can afford.'' The organization explained that requesting a fee waiver under the current fee waiver process does not equate to paying the associated fee with an application because paying the fee provides, as a matter of right, an opportunity to have such application adjudicated by the agency while requesting a fee waiver ''simply provides the adjudicator with the option of granting a fee waiver and then considering the merits of the underlying filing. . . . Although immigration judges *may* grant a fee waiver if individuals establish that they are unable to pay, the regulations do not require them to grant fee waivers even to an individual who has provided proof of inability to pay.'' Relatedly, commenters expressed skepticism of such discretion, stating that immigration judges are not independent and are instead subject to the Attorney General's guidance and orders. For aliens who file a Form EOIR–26A and lack work authorization, another commenter suggested that the Department institute a rebuttable presumption that the alien is unable to pay the fee.

Some commenters stated that it was proper for the Department to rely on taxpayers to subsidize adjudication costs, rather than rely on fee increases and fee waivers, stating, for example, ''[t]he burden of correcting for unjust outcomes SHOULD be bourne [sic] by society (*e.g.* the 'taxpayers') not by the affected person alone.''

One commenter was also concerned that the proposed high fees would deter individuals from even considering filing the applications.

One commenter explained that the lack of guaranteed representation in immigration proceedings exacerbated concerns regarding fee waivers, and an organization explained several other aspects about the current fee waiver process that are problematic, including the signature requirement and procurement of income documentation.

Overall, commenters recommended that the Department make fee waivers more ''broadly available.''

Response: While the Department agrees that it is possible—and perhaps even probable—that the increased fees

[13] The Department does note that even if comparisons to other agencies were relevant, the fees charged by other agencies adjudicating immigration-related applications have been substantially higher than fees charged by EOIR for many years. For example, the current fee for an appeal or motion charged by USCIS is $675, which is well above EOIR's current $110 fee and will remain significantly higher than EOIR's new fee for a motion to reopen filed with an immigration court.

may lead more aliens to seek a fee waiver than would without this rule, specific concerns regarding the effects of such fee waivers on adjudications or the ultimate total volume of fee waiver applications that EOIR will receive are speculative. Respondents' financial information submitted in support of fee waiver requests has not been tracked or universally evaluated to provide any indication that an increase in fees, regardless of amount, will necessarily result in an increase in fee waiver applications. Moreover, for most of the proposed fees, respondents' general ability to obtain work authorization while an application is pending, their access to financial resources allowing them to travel to the United States in the first instance, their access to financial resources in the United States for a sufficient period of time necessary to even trigger the need for a filing that requires a fee, their general ability to obtain representation, their general ability to pay existing fees for applications or for ancillary applications, and the ultimate importance of the benefit they seek (*i.e.,* legal status or being able to remain in the United States indefinitely) are all potential countervailing considerations that would not necessarily support the conclusion that the proposed fee increases will inevitably lead to more fee waiver applications. Put more simply, a respondent who could not afford a lesser amount will presumably not be able to afford the new, higher amount, but it is speculative to assert that all who could afford the lower amount will necessarily not be able to pay the higher fee. Rather, a particular subset of those who can afford the current fees currently may not be able to after the increases, but the precise size of that subset, though potentially not as large as commenters suggested for the reasons given above, is not estimated.

EOIR has adjudicated fee waivers for many decades, and both Board members and immigration judges are experienced in adjudicating such requests. Although differences in adjudicatory outcomes are inherent in any system rooted in adjudicator discretion, there is no evidence that Board members or immigration judges would be unable or unwilling to adjudicate fee waiver requests consistent with applicable law and their respective independent judgment and discretion. *See* 8 CFR 1003.1(d)(1)(ii), 1003.10(b). Commenters have not presented any evidence that EOIR would not continue to grant appropriate fee waivers. *See Ayuda II,* 848 F.2d at 1299 n.4 (''Appellants intimate that the waiver provision, 8 CFR 103.7(c)(1) (1986), does not in fact mitigate the deterrent effect of the increased fees because the Attorney General retains discretion to decline to waive the fees even after an applicant has demonstrated his or her inability to pay. We have been directed to no evidence, however, that the Attorney General has in fact exercised his discretion in this manner.''). Any calculations attempted by the Department to ''account for'' the effects of fee waiver adjudications in light of the updated fees would be unreliable because fee waivers are discretionary by nature and the updated fees have not been in force. Accordingly, while the Department acknowledges that it did not include in the NPRM projected costs related to adjudication of fee waivers resulting from the rule, the Department disagrees that inclusion of such costs is necessary or beneficial. Moreover, including such costs would have likely led to a greater fee increase. Further, because concerns regarding lost revenue are ''purely speculative,'' the Department is unable to respond.[14] In addition, the agency is committed to ongoing review and, as necessary, updating of its fees. If the new fees lead to unanticipated results, the agency can evaluate those results upon its next biennial review.

Regarding commenters' concerns with USCIS's proposed fee waiver regulations regarding the Form I–589 application or USCIS's fee waiver process in general, the Department notes that USCIS is a component of DHS, which is a separate agency from DOJ, of which EOIR is a component. *See Operational and Support Components,* Department of Homeland Security, *https://www.dhs.gov/operational-and-support-components* (last updated Nov. 17, 2018). Further, this rulemaking specifically involves EOIR fees, and the USCIS fees and applications referenced by the commenters pertain to a separate USCIS-specific rulemaking. *See* U.S. Citizenship and Immigration Services Fee Schedule and Changes to Certain Other Immigration Benefit Request Requirements, 84 FR 62280 (Nov. 14, 2019) (proposed rule); 85 FR 46788 (Aug. 3, 2020) (final rule).[15]

Further, this rule does not amend the current procedure regarding how DHS forms are treated in immigration court. Accordingly, this rule does not change the practice that neither the BIA nor the immigration judge may grant a fee waiver ''with respect to the fee prescribed for a Department of Homeland Security form or action that is identified as non-waivable in regulations of the Department of Homeland Security.'' 8 CFR 1103.7(c). Accordingly, the waivability of the fee for the Form I–589 filed with USCIS is ultimately determined by DHS's regulations and the waivability of the fee for the Form I–589 filed with EOIR is determined by the DOJ regulation that, in turn, cross-references DHS regulations.[16]

The rule makes no substantive amendments to EOIR's asylum regulations located at 8 CFR part 1208 or DHS's fee schedule. *See* 8 CFR 1103.7(b)(4)(ii). Further, the Department

[14] *Home Box Office, Inc.* v. *FCC,* 567 F.2d 9, 35 n.58 (D.C. Cir. 1977) (per curiam). ''In determining what points are significant, the 'arbitrary and capricious' standard of review must be kept in mind. Thus only comments which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule cast doubt on the reasonableness of a position taken by the agency. Moreover, comments which themselves are purely speculative and do not disclose the factual or policy basis on which they rest require no response. There must be some basis for thinking a position taken in opposition to the agency is true.'' *Id.* The purpose of updating the fees is to better align the fees with the agency's current processing and adjudication costs following an over 30-year period in which the fees were not updated, not to subsidize the Department's, including EOIR's, congressional appropriations. As a result, the number of fee waivers requested does not directly correlate with the Department's total revenue. Accordingly, even if the number of fee waiver requests increased, the Department's conclusions in the rulemaking would still be reasonable: Processing costs would continue to exceed the assessed fees, hence the decision to update the fees to more accurately reflect and recover EOIR's adjudication costs. Further, commenters' concerns on this point provide no factual or policy bases to which the Department may provide a response; thus, the Department finds such concerns to be mere speculation and is unable to provide a response.

[15] The final rule related to fees charged by DHS was preliminarily enjoined by two federal district courts prior to its effective date. *Immigrant Legal Resource Ctr.* v. *Wolf,* No. 20–cv–05883–JSW, 2020 WL 5798269 (N.D. Cal. Sept. 29, 2020); *Nw. Immigrants Rights Proj.* v. *U.S. Citizenship & Immigration Servs.,* No. 19–3283 (RDM), 2020 WL 5995206 (Oct. 8, 2020). Although this final rule updates cross-references in EOIR's regulations to DHS's regulations to account for the DHS rule's amendments of DHS's regulations, the DHS fees remain governed by DHS's previous regulations while the aforementioned injunctions remain in effect. Because the ultimate resolution of the litigation challenging the DHS fee rule is unknown, this final rule amends EOIR's regulations to include cross-references to both the previous DHS regulations and the new regulations to ensure that the cross-references do not become inaccurate regardless of how the litigation is resolved.

[16] The Department notes that DHS's 2019 fee NPRM proposed reorganizing its regulations regarding fee waivers. *Compare* 8 CFR 103.7(c), *with* 84 FR 62363 (proposed 8 CFR 106.3 (Fee waivers and exemptions)). That reorganization was adopted by a final rule, 85 FR at 46920, but that rule was subsequently enjoined before it took effect. *See* note 16, *supra.* To the extent that DHS's regulations allow a fee waiver for a DHS form, the Department would continue to apply that same fee waiver eligibility for the form when it is submitted to EOIR.

continues to apply USCIS fees in accordance with the regulation at 8 CFR 1103.7(b)(4)(ii). For these reasons, comments related to USCIS's asylum application and the corresponding $50 fee are outside the scope of this rulemaking.

Regarding comments referencing USCIS's criteria for fee waivers and the Department's lack of similar, consistent criteria and information dissemination, the Department appreciates this feedback. At present, USCIS adjudicates 22 applications eligible for a fee waiver, 8 CFR 103.7(c)(3)–(4),[17] including many that are not adjudicated by EOIR, such as applications for naturalization. Thus, USCIS receives many more fee waiver requests than EOIR.[18] Further, fee waivers directly impact USCIS's budget and, thus, its operations as a generally fee-funded agency. For example, USCIS recently estimated that it would forgo over $900 million due to fee waivers and exemptions, which is significantly more than EOIR's total budget. *See* 84 FR at 62298. Consequently, it is appropriate for USCIS to have more defined criteria for fee waivers than EOIR because the two agencies are not similarly situated in terms of the impact of such waivers. Nevertheless, the Department may consider the issue further in a future rulemaking should a need for additional clarifications regarding adjudication of fee waivers arise following this rule's implementation. Moreover, the Department also notes that nothing precludes the Board, which receives most fee waiver requests and has extensive experience adjudicating them, from issuing a precedential decision regarding the appropriate criteria for a fee waiver, consistent with its authority to ''provide clear and uniform guidance to [DHS], the immigration judges, and the general public on the proper interpretation and administration of the [INA] and its implementing regulations.'' 8 CFR 1003.1(d)(1).

Despite commenters' allegations that fee waivers are inconsistent around the country, the Department has no evidence or data, and none was provided by commenters, regarding the specific adjudications of fee waivers that would support such statements.

The Department disagrees with commenters that the discretionary nature of fee waivers is problematic. Fee waiver determinations are a matter of discretionary authority and are based upon the unique facts of each case. *See* 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c). When evaluating such requests, EOIR adjudicators, including immigration judges and Board members, exercise independent judgment and discretion. *See* 8 CFR 1003.1(d)(1)(ii), 1003.10(b). The appropriate regulations, 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c), clearly delineate the requirements for fee waivers, and the Department expects its adjudicators to issue fee waiver determinations in a fair manner and consistent with the regulations. The Attorney General does not mandate a specific outcome for fee waiver determinations.

Given this discretionary nature, filing a fee waiver request does not automatically render the request granted. Moreover, the Department has determined, and courts agree, that the fee waiver process is a proper, viable solution for aliens who may be unable to pay updated fees. *See Ayuda II,* 848 F.2d at 1299 & n.4 (holding, in part, that the alleged deterrent effects of increased fees are ''mitigated by the provision for waiver of fees for aliens who certify their inability to pay'').

The Department agrees with commenters that some taxpayer subsidization for the costs of processing and adjudicating these EOIR applications and motions is appropriate; however, the Department disagrees with the extent of the commenters' recommended subsidization. As stated in the NPRM, the updated fees do not cover the full adjudication costs. *See* 85 FR at 11868–69. Some costs—such as overhead costs, cost of non-salary benefits, or costs related to corresponding applications or documents accompanying items for which the Department updated fees—were not included in the Department's calculations and are subsequently covered by congressional appropriation, which is funded, in part, by taxpayer dollars. *See id.* Accordingly, individuals who pay the updated fees will not bear the full adjudication costs, but taxpayers will also not bear a disproportionate share of the costs. *See* 85 FR at 11870.

The Department acknowledges commenters' concerns that fees may affect an individual's decision to file an application, but there is no evidence that filing fees discourage individuals from filing for lawful immigration status to which they believe they are entitled.[19] The Department also emphasizes that an EOIR fee waiver remains available for those individuals who aver that they cannot pay the fee, and individuals should utilize the fee waiver process if they are concerned about the ability to pay fees. *See* 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c).

The remaining concerns likewise exceed the bounds of this rulemaking. The rule does not change the regulations regarding representation, or, as repeatedly mentioned, eligibility for fee waivers, which includes the signature requirement and income documentation. *See* 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c); *see generally* 8 CFR part 1292; 8 CFR 1003.16(b).

5. Concerns With Fee Increases for Filing Appeals With the BIA

Comment: Commenters' primary concerns regarding the proposed fee ($975) for appeals to the BIA were that the fee is too high and too expensive for aliens in proceedings to afford and that, as a result, the fee will foreclose aliens' access to due process via administrative and, in turn, Federal appellate review of the immigration judge's decision(s). Commenters indicated a belief that this concern is exacerbated by the proposal to increase the fee by such a significant amount in the context of the COVID–19 pandemic. Many commenters highlighted that the proposed fee is an 800 percent increase (or a multiple of 8.6) from the $110 fee currently attached to appeals.

Commenters highlighted particular classes of aliens who commenters believe would have a particularly difficult time paying the proposed fee, including individuals in immigration detention, asylum seekers, and ''working class'' respondents.

One commenter argued that the proposed fee is particularly unreasonable due to the number of BIA decisions issued as AWO, which the commenter says are ''little more than a stepping-stone on the way to actual review by a circuit court.'' *See* 8 CFR 1003.1(e)(4).

Commenters compared the fee increase for filing an appeal to the BIA to other government programs that were struck down for conditioning access to services based on an individual's ability to pay and discriminating between indigent and non-indigent individuals. *See, e.g., Boddie* v. *Connecticut,* 401 U.S. 371, 380–82 (1971) (holding that due process of law prohibits a State from denying individuals access to the

[17] If the current injunctions against the DHS fee rule are lifted, DHS's fee waiver provisions will be located in 8 CFR 106.3.

[18] USCIS estimates receipt of approximately 1.5 million applications in FY 2019/2020 without a fee payment, which is significantly higher than EOIR's receipt of all applications and higher than EOIR's total pending caseload. *See* 84 FR at 62288.

[19] To the extent that increased filing fees may discourage individuals without valid claims from pursuing non-meritorious applications for dilatory purposes, the Department does not believe that possible consequence is sufficiently compelling to warrant not changing the fees to the levels proposed in the NPRM.

courts for the purposes of divorce proceedings based solely on an ability to pay); *Burns* v. *Ohio,* 360 U.S. 252, 257–58 (1959) (''There is no rational basis for assuming that indigents' motions for leave to appeal will be less meritorious than those of other defendants. Indigents must, therefore, have the same opportunities to invoke the discretion of the Supreme Court of Ohio.''); *Griffin* v. *Illinois,* 351 U.S. 12, 19 (1956) (holding that a State cannot condition access to a trial transcript on the ability to pay and explaining that ''[t]here can be no equal justice where the kind of trial a man gets depends on the amount of money he has. Destitute defendants must be afforded as adequate appellate review as defendants who have money enough to buy transcripts.'').

Commenters expressed concerns that the proposed rule would effectively render immigration judge decisions as final orders because the proposed fee increases would make it financially impossible for aliens to afford to pursue appeals before the BIA. *See* 8 CFR 1003.39 (''Except when certified to the Board, the decision of the Immigration Judge becomes final upon waiver of appeal or upon expiration of the time to appeal if no appeal is taken whichever occurs first.''). Commenters suggested that it is particularly important for aliens to have access to appeals because immigration judges do not have sufficient time to devote to each case and because ''it is not uncommon for immigration judges to make errors.'' Commenters stated that appellate review was necessary to correct errors that resulted in significant variations in grant rates of applications between immigration courts. Commenters also stated that criticism of EOIR by the circuit courts demonstrated the necessity of BIA appeals for aliens who seek to assert their rights.

Commenters stated that recent administrative changes to immigration procedures make an alien's access to appeals and motions more important than ever. Specifically, commenters cited the following: The implementation of performance metrics for immigration judges; the implementation of a special docket for families who have arrived recently in the United States; docket shuffling; inaccurate court dates in Notices to Appear and Notices of Hearing; recent guidance on administrative closure determinations; recent guidance on continuance determinations; recent case-processing requirements for the BIA; and recent guidance on termination and dismissal determinations. Commenters also asserted that EOIR has become politicized by instituting an Office of Policy and appointing sitting immigration judges with asylum-denial rates of over 90 percent as permanent members of the BIA who could participate in precedential decision making. Commenters asserted that, because of these practices and policies, immigration judges are incentivized to issue removal orders and aliens face an increased likelihood of wanting to file appeals with the BIA. In support of these concerns with the immigration court system, commenters noted that the courts of appeals have at times similarly criticized the immigration courts. *See, e.g., Benslimane* v. *Gonzales,* 430 F.3d 828, 830 (7th Cir. 2005) (''[T]he adjudication of [immigration] cases at the administrative level has fallen below the minimum standards of legal justice.'') Commenters further asserted that it was disingenuous for the Department to argue that increased appeals have become such a burden as to necessitate the promulgation of this rule when the increase in appeals has been a direct result of these Department actions.

Commenters further asserted that the increase in fees would prevent noncitizens from accessing Federal court review because they would be unable to afford the fees to appeal to the BIA, which is required for a decision to be administratively final for judicial review. *See* INA 242(a), 8 U.S.C. 1252(a) (allowing for judicial review of a ''final order of removal''); *see also, e.g., J.E.F.M.* v. *Lynch,* 837 F.3d 1026, 1029 (9th Cir. 2016) (''Despite the gravity of their claims, the minors cannot bypass the immigration courts and proceed directly to district court. Instead, they must exhaust the administrative process before they can access the federal courts.''). Commenters averred that the proposed rule demonstrates the Department's attempt to avoid oversight from the Federal courts by making appeals inaccessible. One commenter noted that the proposed fee for an appeal will increase the total cost for adjudication for aliens who go on to file a petition for review in Federal court to $1,475. Commenters characterized this effect of the rule as allowing ''the administration to both set immigration policy and adjudicate it without meaningful review by an independent judiciary,'' noting that the Seventh Circuit recently criticized the BIA for failing to abide by its instructions. *See Baez-Sanchez* v. *Barr,* 947 F.3d 1033, 1035–36 (7th Cir. 2020) (''In sum, the Board flatly refused to implement our decision. . . . We have never before encountered defiance of a remand order, and we hope never to see it again. Members of the Board must count themselves lucky that Baez-Sanchez has not asked us to hold them in contempt . . . .'').

Commenters indicated a belief that the proposed fee for an appeal is purposefully designed to limit aliens' access to due process or to dissuade aliens from filing an appeal. Commenters characterized the proposal as an intentional barrier to filing an appeal.

Commenters noted that appeals have secondary benefits beyond those which accrue to the appealing party alone. For example, appeals are the vehicle for the BIA to publish precedential decisions, which help the development of case law to properly implement the law in different and evolving circumstances and which help ensure consistency across the country. Commenters explained that this development of case law benefits the Nation generally by ensuring that the immigration laws are accurately and consistently applied.

Commenters noted that the proposed fee will be particularly difficult for aliens to raise in the 30 days allowed for an alien to file an appeal from an immigration judge's final decision.

Commenters explained that the rule is particularly harsh because the Department will not refund fees even when the noncitizen prevails on his or her appeal. Commenters asserted that when the BIA determines that an immigration judge erred it necessarily means that the noncitizen was treated unfairly by the immigration judge. While recognizing that the Equal Access to Justice Act does not directly apply in removal proceedings, commenters asserted that the Department could nonetheless refund appeal fees when noncitizen litigants are successful.

Response: First, the Department rejects commenters' allegations that the proposed rule is purposefully designed to limit access to appeals or impede aliens' due process rights. As explained in the NPRM, the rule is designed to ensure that the Department exercises its authorities under the IOAA, section 286(m) of the Act (8 U.S.C. 1356(m)), and OMB's Circular No. A–25 Revised. *See* 85 FR at 11866–67. Although the rule changes the amount that would be charged for filing an appeal, the Department has been careful through the entire process to ensure that it does not affect the availability of a fee waiver.[20]

As explained in the NPRM, the proposed fee for an appeal was determined following a comprehensive

[20] For further discussion of the availability of fee waivers, see section II.C.4.

activity-based cost study that determined the cost incurred by EOIR to process those applications, appeals, and motions for which EOIR levies a fee. *See* 85 FR at 11868–70. The Department proposed the $975 fee for filing an appeal with the BIA only after (1) determining the appropriate staff levels and time required to process and adjudicate each appeal and the average salary rates for applicable staff levels, based on data from the Office of Personnel Management (''OPM'') and the General Services Administration (''GSA''); (2) developing step-by-step process maps, with assigned times and staff levels, for how the BIA processes each appeal; and (3) allocating the salary costs from the GSA and OPM data to each step in the process, based on the time the step takes, the average salary of the responsible staff, and the percentage of total cases in which the step occurs. 85 FR at 11869. The Department acknowledges that $975 is an increase from the $110 fee that has been levied since 1986, though it amounts to an average annual increase of only slightly more than $25 per year. Nevertheless, that is the amount that in fact represents the agency's best estimate of the current processing costs for appeals, which are complex adjudications that require significant staffing input.

In response to the commenter who argued that the proposed fee is unreasonable due to the BIA's issuance of AWO decisions, the Department notes that $975 is an average processing cost. Some appeals, such as those that raise multiple issues on appeal or that involve a particularly complex set of facts, take more time to adjudicate than others. By regulation, Board members are to issue an AWO for certain less complex cases. 8 CFR 1003.1(e)(4). Because the determination of whether a case is appropriate for an AWO is a matter of legal judgment for the Board member after the initial review of the appeal, it would not be possible to charge one, possibly lower, fee for appeals in which the immigration judge order is ultimately affirmed without an opinion and a different fee for appeals that result in a written BIA decision. Instead, the Department believes it is reasonable to charge a single average processing cost for all appeals.

Fees cannot be based upon the reason for appeal or the result of the appeal. Fees are levied based on averages; this is common practice throughout government. For example, DHS charges a flat filing fee that is based on the average complexity of that filing's adjudications. *See, e.g.,* 84 FR at 62309 (proposing fee changes to H–2A and H–2B visas based on average adjudication times estimated by USCIS). To illustrate, DHS charges the same filing fee for an N–400, Application for Naturalization, regardless of whether the applicant is an 18-year-old who has not traveled outside of the United States since entry or an 80-year-old who has traveled back to his or her country of origin once a year for several decades. Adjudicating eligibility for the latter is likely to be far more complex and time-consuming.

In response to comments suggesting that variations in grant rates and circuit court criticism demonstrate the necessity for appellate review, the Department reiterates that nothing in this rule forecloses appellate review by the Board. Further, discussions of grant rate disparities often do not account for the unique factors of each case or the relevant applicable law, including variations in circuit law. Moreover, they frequently also do not account for ecological inference problems by attempting to draw conclusions about individual adjudicators based solely on aggregate data.

The Department also notes that criticism is to be expected at times for any adjudicatory body, and that the vast majority of cases go without such critique.[21] *See Exec. Office for Immigration Rev. Adjudication Statistics: Circuit Court Remands Filed,* Exec. Office for Immigration Rev., July 14, 2020, *https://www.justice.gov/eoir/page/file/1199211/download* (showing drop in circuit court remands filed from 1,081 in 2010 to 602 in 2019, and 134 in the first quarter of 2020). Moreover, as only the alien can appeal a case to Federal court, assertions based on circuit court decisions present only part of the overall picture of adjudications. Further, the Department states again that it does not believe that this rulemaking will limit an alien's right to seek appellate review.

As stated in the NPRM, this rule does not foreclose or limit the ability of aliens to seek a fee waiver for the appeal fee. *See* 8 CFR 1003.8(a)(3) (''The Board has the discretion to waive a fee for an appeal, motion to reconsider, or motion to reopen upon a showing that the filing party is unable to pay the fee.''); 85 FR at 11871. To the extent that an individual in immigration proceedings is concerned about his or her ability to pay the fee for an appeal, the Department expects that such an alien would file the Form EOIR–26A, Fee Waiver Request, and proceed with his or her case in the same manner as before the change in the fee.

Accordingly, the Department disagrees that the appeal fee is akin to other court fees cited by commenters that have been struck down for conditioning access on the ability to pay. *See, e.g., Boddie,* 401 U.S. 371; *Burns,* 360 U.S. 252; *Griffin,* 351 U.S. 12. In those cases there was no allowance made for individuals who were unable to pay the state-imposed fee. *See, e.g., Griffin,* 351 U.S. at 14 (''Indigent defendants sentenced to death are provided with a free transcript at the expense of the county where convicted. In all other criminal cases defendants needing a transcript, whether indigent or not, must themselves buy it.'' (footnote omitted)). Here, however, the proposed fee does not prevent indigent individuals from accessing the BIA's administrative review, and in turn the Federal courts, because a fee waiver remains available for those who are unable to pay the fee. 8 CFR 1003.8(a)(3).

In addition, because fee waivers remain available and the rule will not prevent aliens from filing an appeal with the BIA, the Department also disagrees with commenters that the increased fee for filing a BIA appeal will render immigration judge decisions final orders or foreclose Federal judicial review of EOIR decisions through alien-initiated petitions for review.[22] To the extent that commenters believe that EOIR policies or procedures have increased the frequency or need for filing an appeal from an immigration judge to the BIA and, in turn, from the BIA to a circuit court, the Department believes that aliens' access to appeals is protected through the fee waiver allowance as explained above.[23]

[21] The Department unequivocally rejects comments impugning the integrity or competence of its adjudicators and the suggestion that they behave incompetently or unethically solely because they do not grant every request for relief that the commenters believe should be granted.

[22] To the extent that commenters argued that the fee for an appeal is too high when considered together with the cost for filing a petition for review at the circuit court, the Department notes that consideration of any possible Federal court costs is unrelated to the expenses incurred by EOIR to process the appeal and outside the scope of this rule. Moreover, this comment presumes that the alien's appeal at the BIA will be unsuccessful, which is not necessarily the case, or that the BIA's decision is somehow legally deficient, which is a presumption the Department declines to make. Nevertheless, EOIR notes that other court systems also provide for fee waivers in recognition of the fact that some parties will be unable to pay fees relevant to their cases. Further discussion of the comparison of this rule's fees with the costs of other court systems is contained at Section II.C.4 of this preamble.

[23] In addition, despite commenters' concerns that recent Department and EOIR policies and procedures have resulted in greater error rates or other problematic decisions, the Department notes that in fact remands from the circuit courts to the BIA have decreased in recent years even as EOIR's total adjudication volume has increased. *See Exec. Office for Immigration Rev. Adjudication Statistics:*

As explained above, commenters argued that BIA appeals have benefits beyond the individual direct benefits related to an alien's particular personal interest in his or her case and that, as a result, the appeal fee is too high. First, the Department believes that the overarching purpose of each individual appeal is the individual benefit for the appealing party who seeks to correct an alleged error of law. At the same time, however, the Department agrees that administrative and appellate review can, at times, provide national benefits for immigration adjudications, such as providing clarity on complex topics that in turn creates efficiencies for immigration judges. *See, e.g., Amicus Invitation No. 20–24–02,* Board of Immigration Appeals, Feb. 24, 2020, *available at https://www.justice.gov/eoir/page/file/1251526/download* (welcoming amicus curiae briefs regarding selected issues involving Notices to Appear). The Department believes that this public interest is balanced against the need to recover EOIR's costs for providing an individual service and benefit for the appealing party by the Department's choice not to set the fees at amounts that would account for full cost recovery by including (1) overhead costs, (2) cost of non-salary benefits, and (3) costs that stem from processing corresponding applications or documents that may be filed in conjunction with those items for which EOIR charges a fee. *See* 85 FR at 11869. Had these items been included in the analysis, the fee required to align with EOIR's processing costs would assumedly have been higher than $975.

Regarding commenters' concerns that the appeal fee will be difficult to raise in the time period allowed for filing an appeal with the BIA, *see* 8 CFR 1003.38(b) (instructing that appeals must be filed with the BIA within 30 calendar days after the immigration judge decision), the Department notes that the public will be on notice about the new fee amount as of this rule's publication. The new fee will be stated in the regulations at 8 CFR 1103.7(b)(1), published in the instructions to the EOIR–26 appeal form, and published on the EOIR website where EOIR forms are made available. Moreover, immigration judges are required in every removal case to ascertain that an alien has received a copy of the alien's appeal rights, which typically includes the appeal form and instructions that will provide information on both the fee and the fee waiver process. 8 CFR 1240.10(a)(3). An alien who is concerned that he or she may wish to appeal the immigration judge's decision should, accordingly, use that time between the initiation of the proceeding and the immigration judge's issuance of a final decision to begin arranging funds for the future payment of the appeal.

Finally, the Department disagrees with commenters that the Department should refund appeal fees when the alien succeeds on the merits. This argument misses the Department's purpose to more accurately reflect the Department's costs in processing and adjudicating the appeal. *See* 85 FR at 11870. EOIR's costs for the adjudication of an appeal are the same regardless of which party prevails on the merits, and the fact that the alien may ultimately demonstrate error by the immigration judge does not lessen the cost incurred by the BIA staff, attorneys, and Board members who were involved in the determination of the alien's success.

6. Concerns With Fee Increases for Cancellation of Removal Forms

Comment: Commenters expressed concern regarding the increased fees for applications for cancellation of removal (Forms EOIR–42A and –42B). Some commenters noted that applicants for these forms of relief have remained in the United States for many years, creating ties between applicants and their communities. Commenters explained that because applicants would likely be unable to afford the NPRM's increased fees for cancellation of removal, these communities would be negatively impacted by the severance of those ties.

Specifically regarding the Form EOIR–42B, Application for Cancellation of Removal and Adjustment of Status for Certain Nonpermanent Residents, commenters noted that successful applicants must demonstrate exceptional and extremely unusual hardship to a qualifying relative who is either a United States citizen or a lawful permanent resident. *See* INA 240A(b)(1)(D), 8 U.S.C. 1229b(b)(1)(D). According to commenters, this level of hardship often additionally results in economic hardship for the applicant. For example, commenters pointed to economic hardship that results from the applicant's qualifying relatives suffering severe medical issues.

Further, some commenters noted that applicants for cancellation of removal are unable to procure employment authorization until after the application is filed. Thus, some commenters opined that some applicants for cancellation of removal would be unable to generate the necessary income to pay the increased fees.

As to those applicants for cancellation of removal under the Violence Against Women Act (''VAWA''), *see* INA 240A(b)(2) (8 U.S.C. 1229b(b)(2)), commenters asserted that the increase in fees would run ''contrary to congressional intent to strengthen protections for victims of intra-familial violence.'' In support of this, some commenters noted that affirmative applications to USCIS for relief under VAWA have no filing fees.

Response: Whether communities in the United States will suffer greater harm due to an increased number of unlawful aliens departing the country rather than filing applications for cancellation of removal is both speculative and beyond the scope of this rulemaking. To the extent that commenters are concerned that eligible aliens will not file applications for cancellation of removal due to the increased cost, the Department notes that both immigration judges and the BIA would continue to entertain requests from aliens for fee waivers and retain the discretionary authority to grant such waivers upon a showing that the alien is unable to pay. *See* 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c). Moreover, the Department does not expect that individuals who have resided in the United States for at least seven or ten years before being placed in immigration proceedings will generally be destitute, and there is no evidence that the filing fee will dissuade an alien with a valid claim—as opposed to one filing an application for dilatory purposes—from pursuing that claim.

As to the comments regarding the economic hardship faced by aliens filing Form EOIR–42B, the Department again notes the availability of requests for fee waivers. Although some aliens may be unable to afford the fee for an application based on the timing of work authorization, the Department notes that this will vary by case, and for those aliens for whom it is true, the Department refers commenters to its prior discussion of fee waivers. Further, the Department disagrees that evidence an alien's removal would cause his or her qualifying family member an exceptional and extremely unusual hardship is related to the alien's hypothetical ability to pay the application fee. Instead, it misplaces the analysis, which focuses on the future harm to the family without the alien's presence rather than a current consideration of the alien's financial

Circuit Court Remands Filed, Exec. Office for Immigration Rev., July 14, 2020, *https://www.justice.gov/eoir/page/file/1199211/download; Exec. Office for Immigration Rev. Adjudication Statistics: New Cases and Total Completions,* Exec. Office for Immigration Rev., Jan. 23, 2020, *https://www.justice.gov/eoir/page/file/1238741/download.*

picture with his or her residence in the United States.

To the extent commenters expressed concern that applicants for cancellation of removal may not be able to afford the new fee because they lack employment authorization documents, the Department first notes that such an assumption is not true for all cancellation applicants. Instead, all applicants who would submit the Form EOIR–42A, Application for Cancellation of Removal for Certain Permanent Residents, are lawful permanent residents who must have had that status for at least five years. INA 240A(a)(1), 8 U.S.C. 1229b(a)(1). All lawful permanent residents are entitled to employment authorization. *See* 8 CFR 274a.12(a)(1). Second, eligibility for cancellation of removal for nonpermanent residents requires the alien to demonstrate certain levels of harm to a qualifying family member, demonstrating that the alien has other individuals from whom they may be able to seek assistance in paying the fee. *See* INA 240A(b)(1)(D), 8 U.S.C. 1229b(b)(1)(D); INA 240A(b)(2)(A)(v), 8 U.S.C. 1229b(b)(2)(A)(v). Further, all such applicants must have resided in the United States for at least ten years prior to being placed in removal proceedings, indicating that they do possess access to available resources to live in the United States and that such resources would presumably assist them in paying the application fee. Finally, the Department again emphasizes that a fee waiver remains available for a cancellation applicant, such as possibly an applicant without employment authorization, who is unable to pay the fee. *See* 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c).

The Department disagrees that an increase in the fee for applications for cancellation of removal runs contrary to congressional intent. Congress's stated intent in enacting VAWA was to combat violence and crimes against women. *See* H.R. Rep. No. 103–395, at 25–27 (1993); S. Rep. No. 103–138, at 37–38, 41 (1993). The original act, and its subsequent reauthorizations, provided various protections for victims of domestic and sexual violence. 159 Cong. Rec. S44–01 (Jan. 22, 2013) (statement of Sen. Reid). One such protection is the unique avenue of cancellation of removal available to certain victims of domestic violence. *See* INA 240A(b)(2)(A), 8 U.S.C. 1229b(b)(2)(A). Congress instructed only that aliens seeking, inter alia, VAWA cancellation of removal must be permitted ''to apply for a waiver of any fees''—not that no fee apply in all cases. William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (''TVPRA''), Public Law 110–457, 122 Stat. 5044, 5054 (adding paragraph (7) to section 245(*l*) of the Act (8 U.S.C. 1255(*l*))). Accordingly, the increased fee, in conjunction with the fee waiver, does not obstruct the availability of such discretionary relief, just as the previous $100 fee did not impede the availability of VAWA cancellation of removal.

7. Concerns With Fee Increases for Motions To Reopen or Reconsider

Comment: Some commenters also expressed concerns specifically with the proposed fee increases that would apply to motions to reopen or motions to reconsider. *See* 85 FR at 11870.[24] As with comments regarding the fees generally, commenters expressed a belief that the proposed fee increase for these motions, particularly for motions before the BIA, is too high. Commenters expressed concern that although the INA provides a statutory right to file a motion to reopen as well as a motion to reconsider, *see* INA 240(c)(6)–(7) (8 U.S.C. 1229a(c)(6)–(7)), the proposed fees will prevent aliens from being able to access these procedural options or discourage aliens from filing available motions.

Commenters stated that recent EOIR procedures and policies have also resulted in increased numbers of in absentia removal orders, necessitating the filing of motions to reopen and rescind such orders. Commenters described motions to reopen and reconsider as essential tools for the protection of due process, noting their usage to, for example, seek redress for ineffective assistance of counsel and demonstrate changed country conditions in the country of removal. Other commenters noted that motions to reopen allow children who are granted Special Immigrant Juvenile (''SIJ'') visas (INA 101(a)(27)(J) (8 U.S.C. 1101(a)(27)(J))), trafficking survivors who are granted T nonimmigrant visas (INA 101(a)(15)(T) (8 U.S.C. 1101(a)(15)(T))), and crime victims who are granted U nonimmigrant visas (INA 101(a)(15)(U) (8 U.S.C. 1101(a)(15)(U))) to reopen their prior proceedings and gain long-term stability for their immigration status. Accordingly, commenters argue that these individuals would remain at risk of removal despite qualifying for special forms of protection. In other words, commenters argued that the proposed fees will prevent individuals from getting a ''second chance.''

Response: The Department disagrees that this rule will prevent aliens from accessing their statutory right to file a motion to reopen or a motion to reconsider[25] or leave aliens without access to these procedural options.

As noted by the commenters, the increase for the fee for a motion to reopen or reconsider when the proceeding is before the BIA is a notable increase, from $110 to $895. However, as explained in the NPRM, the new fees represent EOIR's cost to adjudicate motions to reopen and reconsider, less the overhead costs, cost of non-salary benefits, or costs stemming from processing documents that correspond with those for which a fee applies. *See* 85 FR at 11869–71. This analysis is consistent with the Department's obligations under section 286(m) of the Act (8 U.S.C. 1356(m)) and the IOAA, 31 U.S.C. 9701(a).[26]

Although some aliens will be required to pay a greater amount to file a motion to reopen or reconsider under this rule than without its implementation, the Department disagrees that aliens will be prevented from filing a motion to reopen or reconsider simply due to an inability to pay the higher fee.[27] Consistent with longstanding practice, a fee waiver remains available for motions to reopen and motions to reconsider. *See* 8 CFR 1003.8(a)(3) (''The Board has the discretion to waive a fee for an appeal, motion to reconsider, or motion to reopen upon a showing that the filing party is unable to pay the fee.''); 8 CFR 1003.24(d) (''The immigration judge has the discretion to waive a fee for a motion or application for relief upon a showing that the filing party is unable to pay the fee.''). EOIR adjudicators act with independent discretion when making all legal determinations, and the Department expects adjudicators to adjudicate fee waivers fairly and consistent with the regulations. In

[24] To the extent commenters conflated the fees for motions to reopen with the fees for an appeal, the Department notes that fees for appeals are discussed above in Section II.C.5 of this preamble.

[25] To the extent commenters may have implied that the Department cannot charge a fee for a motion to reopen or reconsider because the INA generally affords aliens the right to file such a motion, the Department disagrees. Other forms of relief for which the Department and DHS charge fees are included in the INA, *see, e.g.,* INA 240B (8 U.S.C. 1229b) (cancellation of removal), but there has never been any indication that a fee is inappropriate simply because the relief is in the INA. In fact, such logic is contradicted by section 286(m) of the Act (8 U.S.C. 1356(m)), which provides rules for the imposition of fees for ''adjudication and naturalization services''—services that are directly guided by the INA's provisions.

[26] Further discussion of the proposed fee amounts in general is contained above in Section II.C.4 of this preamble.

[27] Further discussion of fee waiver availability is contained above in Section II.C.5 of this preamble.

addition, the Department notes that the rule does not change the exceptions to the otherwise applicable fee for a motion to reopen or reconsider. *See* 8 CFR 1003.8(a)(2)(i)–(viii); 8 CFR 1003.24(b)(2)(i)–(viii). Thus, filing a motion to reopen an in absentia order of removal premised on a lack of notice will continue to not require a filing fee. 8 CFR 1003.24(b)(2)(v). Further, the filing fee for a motion to reopen would not apply if, inter alia, the ''motion is agreed upon by all parties and is jointly filed.'' 8 CFR 1003.8(a)(2)(vii); 8 CFR 1003.24(b)(2)(vii). Accordingly, joint motions to reopen following the approval of U or T nonimmigrant visas will also continue to not require a filing fee. 8 CFR 214.14(c)(5)(i); 8 CFR 214.11(d)(9)(ii); 8 CFR 1003.24(b)(2)(vii).[28]

8. Concerns With Imposing $50 Fee for Asylum Applications

Comment: Commenters objected to the NPRM because they claimed that it would result in a $50 filing fee for asylum applications. Commenters asserted that such a fee would be immoral. A commenter stated that the fee would establish a ''pay for play'' system for those fleeing persecution. Commenters stated that a fee for asylum relief was akin to applicants having to pay a price for their survival. Commenters also stated that an asylum-application fee would be unprecedented. Commenters stated that in the past, ''the process of seeking asylum has been subsidized entirely by surcharges on other fee applications.'' Many commenters who are legal service providers stated that a large number of their clients would be negatively impacted by the proposed rule but did not provide specific data to support this assertion. Many commenters suggested that asylum applications should be free while other commenters stated that the Department should provide a better justification for imposing a fee on asylum applications.

Some commenters stated that the NPRM misstated that the proposed rule would not add any new fees because, commenters stated, a $50 filing fee for asylum applications would be new. Commenters stated that the NPRM did not reference an asylum fee in the charts that the Department used to discuss other fee increases.[29] *See* 85 FR at 11871.

Commenters asserted that asylum protection is an internationally guaranteed human right and stated that denying protection for asylum seekers based on their ability to pay the filing fee would violate the United States' treaty obligations, as a signatory to the Protocol Relating to the Status of Refugees (''Protocol'' or ''1967 Protocol''), which incorporates Articles 2 to 34 of the 1951 Convention Relating to the Status of Refugees (''Refugee Convention''); domestic laws, such as the Refugee Act of 1980; international principles of non-refoulement; and regulations. Protocol Relating to the Status of Refugees, Jan. 31, 1967, 19 U.S.T. 6223; Convention Relating to the Status of Refugees, July 28, 1951, 19 U.S.T. 6233, 6259–6276; Refugee Act of 1980, Public Law 96–212, 94 Stat. 102. Commenters cited Article 29(1) of the Refugee Convention, which commenters asserted prohibits any physical charges ''whatsoever'' other than those that may be ''levied on [signatories'] nationals in similar situations,'' for example by requiring asylum seekers in the United States to pay income taxes.

Commenters stated that a large majority of signatories to the Refugee Convention or 1967 Protocol do not charge a fee for asylum applications. A commenter stated that if the United States were to charge a filing fee for asylum applications, it would be joining ''an adversary on which [the United States] imposes sanctions (Iran), a small island nation (Fiji), and one that has been condemned by an independent body of the United Nations Human Rights Council for its mistreatment of asylum seekers (Australia).'' Commenters asserted that, of those three countries, Australia's fee is half of the proposed fee, Fiji offers a fee waiver, and Iran's fee applies only to families of five or more and allows exemptions.

Commenters expressed concern that if the United States began charging filing fees for asylum applications, other countries might follow suit. Commenters stated that such a pattern could have detrimental effects on refugee resettlement at a time when the number of refugees and displaced people ''are at historic highs.'' Commenters stated that charging a fee for asylum applications could render the entire international framework to safeguard humanitarian protections for asylum seekers vulnerable because it would undermine longstanding international agreements that asylum is intended to provide relief and support. Commenters suggested that charging a fee for asylum applications, but not for withholding of removal or Convention Against Torture (''CAT'') applications, suggested that the Department recognized that it would run afoul of international law to deny protection to individuals who could not afford it and indicated an attempt to keep people from accessing ''full protection as they should under our Constitution.''

Commenters expressed concern that the fee would prevent asylum seekers who cannot afford the fee from applying for asylum altogether in the event that their requests for a fee waiver are also denied.

Commenters explained that sometimes it is best practice for each member of a family to file an individual asylum claim because long-standing precedent upon which a lead applicant's claim is based could be overturned. If asylum applicants would be required to pay a filing fee for each member of their family, and possibly all dependents, the actual financial burden would then be much greater than $50. Commenters suggested that the rule, if issued, should clarify that there is no fee for dependents' asylum applications. Commenters stated that to not do so might result in hundreds of dollars of fees for asylum applicants. Commenters offered the example that a family of five—two parents and three children—might have five primary asylum applications, as well as each spouse listed as a dependent on the other spouse's application and each child listed as a dependent on each parent's Form I–589 for a total of 10 separate dependent applications and 15 applications altogether. Commenters expressed concerns that if the Department did not make such an exception, family units of asylum seekers would be forced to choose to only file one asylum application in order to save money.

Commenters stated that the $50 fee would pose an even heavier burden in cases where asylum seekers had to pay for counsel, which, commenters stated, is critical in an asylum case.

Commenters stated that they believe asylum-seekers face unique vulnerabilities that could hinder them from being able to afford a $50 filing fee for asylum applications. For example, commenters stated that asylum seekers often use all of their savings to travel to the United States such that even a $50 additional expense would pose a significant burden. Additionally,

[28] The approval of an SIJ visa, if the priority date is current, may allow an alien to seek reopening in order to apply for adjustment of status. 8 U.S.C. 1255(a), (h). The fee for the Form I–485, Application for Adjustment of Status, is either $750 or $1140, depending on the age of the applicant and whether the applicant is filing the application with a parent. Thus, the Department expects that an individual with an approved, current SIJ visa who is able to pay this underlying application fee would, in many cases, also be able to pay the fee for a motion to reopen.

[29] Commenters did not comment specifically regarding fee increases proposed by DHS for other DHS applications adjudicated by EOIR—*e.g.,* I–485, I–601, I–751, I–821, I–881—which were also not included in the chart of fees for EOIR applications.

commenters stated, asylum applicants often arrive to the United States financially indebted to those who assisted them with their journey. Commenters expressed concerns that establishing filing fees for asylum applications could provide smugglers and traffickers with additional opportunities to exploit asylum seekers. Commenters also noted that, because asylum-seekers must file their applications for asylum within one year of their arrival to the United States, they may not have the time to accrue the resources to pay the filing fee for their applications.

Commenters also stated that asylum seekers must wait until 150 days after they file their applications to apply for an employment authorization document (''EAD'') and that the EAD would not be issued until after the application has been pending for 180 days. *See* 8 CFR 208.7(a)(1). Accordingly, commenters asserted, asylum seekers cannot begin to financially stabilize themselves until six months after their applications have been filed. Commenters noted that proposed DHS rules, if implemented, would eliminate the requirement that USCIS process EAD applications within 30 days of filing and would lengthen the amount of time that asylum seekers would have to wait to file their EAD applications to 365 days after their asylum applications have been filed. *See* Removal of 30-Day Processing Provision for Asylum Applicant-Related Form I–765 Employment Authorization Applications, 84 FR 47148 (Sep. 9, 2019); *see also* Asylum Application, Interview, and Employment Authorization for Applicants, 84 FR 62374, 62377 (Nov. 14, 2019).[30] Commenters suggested that the combined effect of DHS's rules and EOIR's policies would encourage asylum seekers to engage in unauthorized employment. Commenters asserted that it would be unreasonable to require an asylum seeker who is not lawfully permitted to work to pay a fee for filing his or her asylum application.

Commenters also noted that asylum seekers are generally prohibited from receiving public benefits and thus do not have access to a ''safety net.'' Commenters also stated that asylum-seekers often have few, if any, contacts in the United States on whom they can rely. Commenters stated that when asylum-seekers first arrive in the United States, they may not be able to open a bank account, have access to a credit card, or have any prior experience with money orders.

Commenters stated that ''[t]echnical glitches'' regularly lead to rejections of applications to USCIS but did not specify further the sort of glitches to which they were referring.

Commenters also raised concerns that the Department did not properly explain how individuals who are subject to the MPP, and are not actually in the United States, would be required to pay such a fee as they do not have physical access to the immigration courts.

Commenters stated that in the past, the former Immigration and Naturalization Service (''INS'') withdrew a proposed rule that would have required a fee for a Form I–730, Refugee/Asylee Relative Petition, on the basis that ''[u]nlike some benefits sought by asylees, a relative petition may be filed at a time when the asylee has recently arrived in the United States and is most unlikely to be financially self-sufficient.'' Fees for Processing Certain Asylee/Refugee Related Applications, 58 FR 12146, 12147 (Mar. 3, 1993). Commenters asserted that such difficulties would be exacerbated with respect to children, who would be less likely to have the knowledge and capacity to fill out a fee waiver request.

Commenters stated that USCIS had, in its 2019 proposed rule regarding its fees, considered a distinction between affirmative and defensive asylum applications. For example, commenters noted that USCIS declined to impose a filing fee for asylum applications by unaccompanied children whose cases originated in immigration court, noting that it did not wish to create any delays for children in removal proceedings; however, USCIS did propose a $50 fee for unaccompanied minors who filed affirmatively and are not in removal proceedings. *See* 84 FR at 62319. Commenters asserted that the Department could not justify imposing a filing fee for defensive asylum applications solely by relying on USCIS's decision to charge a filing fee for affirmative asylum applications. Commenters stated that the Department did not engage in independent analysis, such as an activity-based analysis, to justify setting such a fee.

Commenters asserted that it was difficult to assume that the Department would be acting in good faith in implementing a fee for asylum applications in light of recent administrative actions that commenters purport were taken to limit asylum seekers from succeeding on their claims. Specifically, commenters referenced ''metering,'' the MPP, Asylum Cooperative Agreements, and DHS's Prompt Asylum Claim Review and Humanitarian Asylum Claim Review Process, among other things.

Commenters expressed concern about the impact that imposing such a fee would have on motions to reopen and appeals based on applications for asylum. Specifically, commenters expressed concerns that the $50 filing fee would trigger other fees related to their asylum claims. Commenters stated that existing regulations only charge fees for motions to reopen if they are based exclusively on an application for relief that in turn requires a fee. Commenters stated that while motions to reopen based on an asylum application would not have previously carried an associated fee, under the NPRM, motions to reopen based on asylum applications could potentially require movants to pay the full, proposed filing fee of $145 for motions to reopen before an immigration judge and $895 for motions to reopen filed before the BIA. Commenters asserted that such fees would be unaffordable and undermine an alien's statutory right to a motion to reopen.

Additionally, commenters stated that an asylum seeker might have to pay up to $975 to file an appeal if his or her application is denied by the immigration judge. Commenters stated that it would be unreasonable to expect asylum seekers to pay such fees. Commenters noted the Supreme Court's statement that that ''there is a public interest in preventing aliens from being wrongfully removed, particularly to countries where they are likely to face substantial harm.'' *Nken* v. *Holder,* 556 U.S. 418, 436 (2009). Commenters stated that the Department did not adequately consider the cumulative effect of these fees on asylum applications. Commenters expressed concern that DHS's proposed rules, which could increase the amount of time that it would take for asylum seekers to obtain work authorization, in conjunction with EOIR's policies to expedite asylum adjudications before the court, could result in asylum seekers being required to pay the proposed $975 filing fee to appeal their asylum decision to the BIA before having received employment authorization that would allow them to do so.

Commenters stated that detained individuals would be particularly impacted by the NPRM because of their limitations on earning money while in detention. Commenters recommended that detained individuals be exempted from paying the $50 asylum filing fee.

[30] DHS has subsequently published both of these rules as final. Removal of 30-Day Processing Provision for Asylum Applicant-Related Form I–765 Employment Authorization Applications, 85 FR 37502 (June 22, 2020); *see also* Asylum Application, Interview, and Employment Authorization for Applicants, 85 FR 38532 (June 26, 2020).

Commenters stated that imposing a fee on asylum seekers would place an undue burden on nonprofit organizations and faith-based organizations that serve asylum seekers because in situations where asylum seekers could not afford the proposed filing fee or have their fee waiver rejected, such organizations might feel compelled to pay the fee themselves. Commenters stated that if this becomes common practice, legal service providers would have fewer resources to expend on their core missions of providing legal representation, which would ultimately lead to decreased representation rates. Commenters stated that pro se applicants, children, LGBTQ individuals (who commenters stated are often ostracized and isolated by their families), and detained individuals would be disproportionately impacted by the rule. Commenters noted that there is no right to appointed counsel in asylum proceedings.

A commenter asserted that the Department did not properly consider ''extraordinary public comments against charging for asylum.'' For example, commenters stated, Congress had previously admonished USCIS to refrain from charging a fee for humanitarian applications, such as asylum, directed that it should consult with the USCIS Ombudsman's office before imposing such fees, and required it to brief Congress on the possible impact that such fees might have. *See* 165 Cong. Rec. H11021 (2019).

Commenters stated that the NRPM would not comply with international law and that the continued availability of statutory withholding of removal or protection under the CAT regulations for those who are deemed ineligible for failure to pay the filing fee or be granted a fee waiver would not be a sufficient alternative. Specifically, commenters asserted that statutory withholding of removal or protection under the CAT regulations are lesser forms of relief, as they still result in a final order of removal that can be executed at a later date, do not provide a path to lawful permanent residence or citizenship, do not allow for derivative relief for family members, and do not confer a form of relief that would permit recipients to petition for family members to join them in the United States or to travel to visit family members abroad. Additionally, commenters stated that it is more difficult to demonstrate eligibility for statutory withholding of removal or protection under the CAT regulations. Commenters stated that the NPRM would lead to at least some individuals who could meet the lower threshold for asylum having to forgo protection because they could not afford the filing fee, would not receive a fee waiver, and would not be able to meet the higher threshold of statutory withholding of removal or protection under the CAT regulations.

Commenters further asserted that the Department did not adequately explain why it imposed a filing fee for asylum applications but not for the adjudication of statutory withholding of removal or protection under the CAT regulations. Commenters opined that to do so would be irrational and appeared to be punitive. Commenters stated that, in particular, the Department did not adequately justify why it should charge a fee for one application for relief where the immigration judge would be required to consider identical evidence regardless of whether the alien's application is for asylum or for statutory withholding of removal. Commenters also noted that when an individual applies for asylum, statutory withholding of removal, and protection under the CAT regulations, the immigration judge considers the claims simultaneously. Commenters further asserted that, while immigration judges would not have to adjudicate filing-deadline issues in statutory withholding of removal claims, asylum and statutory withholding of removal require consideration of otherwise identical evidence of persecution on account of a protected ground. Other commenters stated that very few applicants would apply statutory withholding of removal or protection under the CAT regulations to the exclusion of asylum.

Some commenters suggested that EOIR create its own form to be used for asylum applications, statutory withholding of removal applications, and applications for protection under the CAT regulations, and not use DHS's form. Commenters also recommended that, if the Department does not rescind the NPRM, it should clarify that an asylum seeker need only pay the fee one time, and not upon filing a new Form I–589 that might correct erroneous information or more fully explain the basis for their claim.

Response: The Department notes that USCIS is a component of DHS, which is a separate agency from the Department, of which EOIR is a component. *See Operational and Support Components,* Department of Homeland Security, *https://www.dhs.gov/operational-and-support-components* (last updated Nov. 17, 2018). Further, this rulemaking specifically involves EOIR fees, and the USCIS fees and applications referenced by the commenters pertain to a separate USCIS-specific rulemaking. *See* 85 FR at 11866; 84 FR at 62280.

Because DHS determines the fee for DHS applications, including those that are also adjudicated by the Department, and because Form I–589 is a DHS application, most of the comments regarding DHS's $50 fee for an asylum application are beyond the scope of this rulemaking. The Department's NPRM did not purport to propose changes to the well-established regulatory provisions distinguishing between fees for DHS forms and fees for EOIR forms, and fees for DHS forms adjudicated by EOIR, including the Form I–589, continue to be set by DHS.[31] *See* 8 CFR 1103.7(b)(4)(ii); *see also* Exec. Office for Immigration Rev.; Definitions; Fees; Powers and Authority of DHS Officers and Employees in Removal Proceedings, 69 FR 44903, 44904 (July 28, 2004) (stating that provisions related to charging the same fees as DHS for DHS-managed forms ''reflect current practice and reduce that practice to regulatory form.'').

DHS collects the fees for all forms submitted in EOIR proceedings, *see* 8 CFR 1003.24(a) (''All fees for the filing of motions and applications in connection with proceedings before the immigration judges are paid to the Department of Homeland Security.''), and the Department believes that creating a new system that would require different fees for the Form I–589 application depending on the agency that will adjudicate the application would create unnecessary confusion for parties.[32] Further, the bases highlighted

[31] The Department notes that DHS proposed a fee for the Form I–589 asylum application for such applications filed with DHS. *See* 84 FR at 62318. DHS noted that whether such fee would apply to asylum applications filed with the Department would be ''subject to the laws and regulations governing the fees charged in EOIR immigration proceedings.'' *Id.* As indicated in the NPRM, the regulation governing fees in EOIR proceedings for application forms published by DHS, 8 CFR 1103.7(b)(4)(ii), relies on the fees established by DHS for those applications. Consequently, because the Form I–589 is a DHS form, the DHS regulation setting the fee for that form determines the fee charged for it in EOIR immigration proceedings, and neither the NPRM nor the final rule purports to change that structure.

[32] The Department acknowledges that the Form I–881 has had a separate fee depending on where the form is filed for over 20 years. *See* Suspension of Deportation and Special Rule Cancellation of Removal for Certain Nationals of Guatemala, El Salvador, and Former Soviet Bloc Countries, 64 FR 27856, 27867–68 (May 21, 1999) (establishing a fee of up to $430 if the application was filed with the INS or $100 if filed before EOIR). Current DHS regulations set the fee differently for a Form I–881 filed by an individual with DHS than for one filed with EOIR; if DHS refers the Form I–881, there is no additional fee. 8 CFR 106.2(a)(41) (replacing 8 CFR 103.7(b)(1)(i)(QQ) if the injunctions against the DHS fee rule are lifted). Given both the anomalous nature of the Form I–881 as the only application, out of several, jointly adjudicated by the

Continued

by DHS as the reason to impose a fee for Form I–589 applications, including increased volume of applications that represent a significant increase in their adjudicatory caseload, apply similarly to EOIR's adjudications. *See* 84 FR at 62318; *Exec. Office for Immigration Rev. Adjudication Statistics: Total Asylum Applications,* Exec. Office for Immigration Rev., July 14, 2020, *available at https://www.justice.gov/eoir/page/file/1106366/download* (showing a significant increase in asylum applications filed with EOIR in recent fiscal years, from a low of 32,888 in Fiscal Year 2010 to a record high of 211,794 in Fiscal Year 2019). Moreover, section 208(d)(3) of the Act (8 U.S.C. 1158(d)(3)) authorizes the imposition of a fee on applications for asylum. In addition, because DHS sets the fee for the Form I–589, as a DHS form, DHS's regulations would control whether or not the fee applies if an alien submits a new or updated Form I–589 for some reason.

For the same reasons, the Department declines to implement commenters' recommendations for EOIR to create its own form for asylum, statutory withholding of removal, and protection under the CAT regulations.[33] DHS's and EOIR's adjudications of such claims are so intertwined that the current one-form system is the most efficient procedure, and the joint form is also easier for applicants as it reduces the number of forms that an applicant would have to complete and submit for the same asylum claim.[34] The same asylum claim may be considered and adjudicated before both USCIS and EOIR. *See, e.g.,* 8 CFR 208.14(c)(1) (directing asylum officers to refer applications to EOIR if the asylum officer does not grant the affirmative application of an inadmissible or deportable alien). With respect to unaccompanied alien children (''UACs''), following the TVPRA, USCIS asylum officers have original jurisdiction over an asylum application submitted by individuals who are otherwise in removal proceedings before EOIR. *See* INA 208(b)(3)(C), 8 U.S.C. 1158(b)(3)(C) (''An asylum officer . . . shall have initial jurisdiction over any asylum application filed by an unaccompanied alien child . . . .''). If the asylum officer does not grant the UAC's asylum application, the UAC may raise the same claim again during removal proceedings before EOIR. *See* INA 208(b)(3)(C), 8 U.S.C. 1158(b)(3)(C) (establishing ''*initial* jurisdiction'' with USCIS (emphasis added)); *see also* 8 CFR 208.14.

The Department notes that the filing fees associated with DHS-issued applications are set by DHS and will continue to be set by DHS, as neither the NPRM nor this final rule purports to change that longstanding practice. Thus, the Department disagrees with comments stating that the NPRM misstated that the rule would not add any new fees. *See* 85 FR at 11866. Although the NPRM did not reference the $50 asylum fee in charts illustrating changes to EOIR-controlled fees—or any other proposed fee increases by DHS for DHS-issued forms, *e.g.,* Form I–485, Form I–601, Form I–751, Form I–821, or Form I–881, that are adjudicated by both DHS and the Department—the Department explicitly discussed DHS's proposed rule to implement a $50 fee for asylum applications on the Form I–589, as well as the Department's reasoning for charging the DHS-set fee for DHS-issued forms. *See* 85 FR at 11871. Thus, the NPRM provided notice about any potential fee increases occasioned by DHS's proposed rulemaking, including for asylum applications.[35]

The Department disagrees with commenters' concerns that a $50 filing fee would be unaffordable, thus discouraging or preventing individuals from filing meritorious asylum claims. *Cf. Ayuda I,* 661 F. Supp. at 35 (rejecting concern that increased fees would limit access to courts). The Department agrees with DHS's position that $50 is a fee that could be paid in one payment, would not take an unreasonable amount of time to save, and would not be so high as to be unaffordable, even to indigent aliens. 84 FR at 62320. The Department notes that generalized statements and anecdotal reports about asylum seekers' financial status do not provide information about actual hardship. To the extent that commenters are concerned that an asylum fee could lead to additional, higher fees for appeals or motions to reopen associated with an asylum claim, the Department notes that fee waivers will continue to be available for EOIR-prescribed fees pursuant to 8 CFR 1103.7(c), which remains unchanged by the rule. *See* 8 CFR 1103.7(c) (''For provisions relating to the authority of the Board or the immigration judges to waive any of the fees prescribed in paragraph (b) of this section, see 8 CFR 1003.8 and 1003.24.''); *Ayuda I,* 661 F. Supp. at 35 (''Moreover, these concerns [about deterrent effect of increased fees] are wholly overstated inasmuch as INS regulations excuse the requirement to pay in the event the alien certifies inability to pay.''). This includes a motion to reopen based on an asylum application and appeals to the BIA.

The Department recognizes commenters' concerns that asylum seekers may face unique challenges that would make raising a substantial sum of money difficult, including, for example, the costs expended on travel to the United States, the one-year filing deadline, indigent status, and waiting periods for employment authorization.[36] The Department also acknowledges that those seeking services from non-profit providers, by the nature of the very services they provide, would have clients with incomes that would make any fee challenging. The Department, however, believes that such challenges have been properly considered in DHS's proposal to establish a $50 fee, which falls well below an amount that would recuperate the full cost of consideration of asylum applications, as permitted by section 208(d)(3) of the Act (8 U.S.C. 1158(d)(3)). *See* 84 FR at 62319–20. The Department disagrees that a $50 filing fee would provide traffickers and smugglers with additional opportunities to exploit asylum seekers and commenters have not presented evidence to support their position.

The Department disagrees with comments that a $50 fee for asylum applications would violate human rights or U.S. treaty obligations. The USCIS rule is consistent with the United States' obligations as a signatory to the 1967

Department and DHS with separate fees and the declining frequency with which it is filed due to the declining pool of eligible applicants—each of whom must have taken some relevant action in the United States in either 1990 or 1991, *see* 8 CFR 1240.61(a)—the Department does not believe that a system of two separate fees for the Form I–589 could similarly be accomplished without increased confusion. Moreover, the separate fee structure for the Form I–881 is contained within regulations pertaining to DHS, not EOIR, and DHS has not chosen to alter that structure.

[33] In addition, the Department notes that even if the Department creates a DOJ version of the Form I–589, such an application could have a fee imposed in the same manner as DHS has proposed. *See, e.g.,* 8 CFR 1103.7(b)(4)(i) (setting fees for DOJ-controlled forms for applications for relief).

[34] The Department notes that there are multiple forms adjudicated by both it and DHS, in addition to the Form I–589—*e.g.,* Form I–485, Form I–601, Form I–751, Form I–821, and Form I–881. The current one-form system for all of these applications has served both agencies well, and the Department sees no reason to create a carve-out solely for the Form I–589. Moreover, creating separate forms for some applications adjudicated by both agencies but not for all such forms would increase the likelihood of confusion by aliens regarding the appropriate form to file.

[35] The Department further notes that DHS has not assessed a $50 fee for asylum applications filed by a UAC in removal proceedings. 85 FR at 46809.

[36] The Department notes that some of these factors, including an alien's ability to pay hundreds or thousands of dollars for travel to the United States, actually undermine the commenters' concerns that aliens with valid asylum claims will be unable to pay the proposed fee.

Protocol, which incorporates Articles 2 through 34 of the Refugee Convention.[37] The rule is also consistent with U.S. obligations under Article 3 of the CAT, as codified in the regulations. *See* 8 CFR 1208.16–18.

Specifically, to the extent that the asylum application fee is considered a ''fiscal charge'' for purposes of Article 29(1) of the Refugee Convention—as incorporated by reference in the 1967 Protocol—the proposed $50 fee would be in accord with that provision, which limits fiscal charges charged to refugees to an amount not higher than those charged by the United States to U.S. nationals in similar situations. And Congress, as evidenced by the express authority conferred in section 208(d)(3) of the Act (8 U.S.C. 1158(d)(3)), has clearly indicated that charging a fee for asylum applications would not run contrary to U.S. obligations. *See* INA 208(d)(3), 8 U.S.C. 1158(d)(3) (''The Attorney General may impose fees for the consideration of an application for asylum'').

Because the USCIS rule does not impose a fee for statutory withholding of removal or protection under the CAT regulations, the rule would still be consistent with the 1951 Refugee Convention's, 1967 Protocol's, and the CAT's non-refoulement provisions. *See R–S–C–* v *Sessions,* 869 F.3d 1176, 1188 n.11 (10th Cir. 2017) (explaining that ''the Refugee Convention's nonrefoulement principle—which prohibits the deportation of aliens to countries where the alien will experience persecution—is given full effect by the Attorney General's withholding-only rule''); *Cazun* v. *Att'y Gen. U.S.,* 856 F.3d 249, 257 & n.16 (3d Cir. 2017); *Ramirez-Mejia* v. *Lynch,* 813 F.3d 240, 241 (5th Cir. 2016); *Maldonado* v. *Lynch,* 786 F.3d 1155, 1162 (9th Cir. 2015) (en banc) (explaining that Article 3 of the CAT, which sets out the non-refoulement obligations of signatories, was implemented in the United States by the Foreign Affairs Reform and Restructuring Act of 1998, Public Law 105–277, sec. 2242(b), 112 Stat. 2681, 2631–822) and its implementing regulations); *see also INS* v. *Cardoza-Fonseca,* 480 U.S. 421, 429, 441 (1987) (''[Withholding of removal] corresponds to Article 33.1 of the Convention . . . . [Asylum], by contrast, is a discretionary mechanism which gives the Attorney General the *authority* to grant the broader relief of asylum to refugees. As such, it does not correspond to Article 33 of the Convention, but instead corresponds to Article 34.'' (emphasis in original)).

Commenters' assertions that statutory withholding of removal and protection under the CAT regulations essentially trap individuals in the United States are beyond the scope of this rulemaking, as nothing in the NPRM purported to propose changes to the regulations governing eligibility for those forms of protection or the restrictions attendant to them. Similarly, the NPRM did not purport to overrule *Matter of I–S– & C–S–,* 24 I&N Dec. 432 (BIA 2008), which requires the entry of an order of removal for aliens granted statutory withholding of removal or protection under the CAT regulations. Thus, although an individual who has been granted these forms of protection is not guaranteed return to the United States if he or she leaves the country, these forms of protection do not prevent individuals from traveling outside the United States. *See Cazun,* 856 F.3d at 257 n.16. To the extent commenters raised concerns that recipients of statutory withholding or CAT protection must apply annually for work authorization, the Department does not adjudicate applications for employment authorization, and such concerns are far beyond the scope of this rule.

In response to comments regarding previous rulemakings by the former INS, which decided not to implement a fee requirement for the Form I–730, Refugee/Asylee Relative Petition because aliens generally filed such petitions shortly after their arrival to the United States, the Department notes that the cited rulemaking was published in the **Federal Register** on March 3, 1993, 58 FR 12146, several years prior to Congress's express grant of authority to the Department to charge fees for asylum applications, employment authorizations, and asylum-related adjustment of status. Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Public Law 104–208, div. C, tit. V, 110 Stat. 3009, 3009–693 (Sep. 30, 1996); INA 208(d)(3), 8 U.S.C. 1158(d)(3). The Department further notes that adjudication of the Form I–730 is not comparable to the significantly lengthier and more in-depth adjudication required for a Form I–589. At the same time, the increased volume of applications for asylum represents a significant increase in the Department's adjudicatory workload. *See Exec. Office for Immigration Rev. Adjudication Statistics: Total Asylum Applications,* Exec. Office for Immigration Rev., July 14, 2020, *https://www.justice.gov/eoir/page/file/1106366/download* (showing a significant increase in asylum applications filed with EOIR in recent fiscal years, from a low of 32,888 in Fiscal Year 2010 to a record high of 211,794 in Fiscal Year 2019). Thus, the Department does not believe that the former INS's articulated reasons for not implementing a fee are persuasive when applied to current considerations regarding the Form I–589. Regardless, whether to charge a fee for a Form I–730 does not necessarily dictate whether a fee for the Form I–589 is warranted, and although DHS has promulgated a $50 fee for the latter, it maintains no fee—nor even a proposed fee—for the former.

The Department disagrees with comments that it would be irrational to charge a filing fee for an asylum claim filed on a Form I–589, but not for statutory withholding of removal or CAT claims filed on the same form. The Department reiterates that DHS is acting within its express statutory authority to implement such fees for asylum claims for the reasons articulated above. *See* INA 208(d)(3), 8 U.S.C. 1158(d)(3).

The Department also disagrees with commenters' assertions that asylum and withholding of removal demand identical considerations. As discussed above, asylum is a discretionary form of relief, while statutory withholding of removal is not. Accordingly, for asylum claims, adjudicators must consider additional evidence with respect to whether an alien merits a favorable exercise of discretion in granting asylum relief. As a discretionary form of relief, asylum is also subject to numerous additional statutory and regulatory requirements that statutory withholding of removal is not. For example, asylum seekers are subject to filing deadline requirements, limitations on multiple applications for relief, numerous criminal exceptions to eligibility, the firm-resettlement bar, and the safe-third country bar. *See* INA 208(a)(2), 8 U.S.C. 1158(a)(2); INA 208(b)(2), 8 U.S.C. 1158(b)(2). Additionally, the Attorney General has the express authority to impose additional limitations and conditions on asylum eligibility. INA 208(b)(2)(C), 8 U.S.C. 1158(b)(2)(C).

[37] The Department also notes that neither of these treaties is self-executing and therefore they are not directly enforceable in U.S. law unless implemented under domestic law. *INS* v. *Stevic,* 467 U.S. 407, 428 n.22 (1984) (''Article 34 merely called on nations to facilitate the admission of refugees to the extent possible; the language of Article 34 was precatory and not self-executing.''); *Al-Fara* v. *Gonzales,* 404 F.3d 733, 743 (3d Cir. 2005) (''The 1967 Protocol is not self-executing, nor does it confer any rights beyond those granted by implementing domestic legislation.''); *Auguste* v. *Ridge,* 395 F.3d 123, 132 (3d Cir. 2005) (CAT ''was not self-executing''); *see also INS* v. *Stevic,* 467 U.S. 407, 428 n.22 (1984) (describing provisions of the Convention and Protocol as ''precatory and not self-executing'').

9. Violates the Administrative Procedure Act

Comment: Commenters stated generally that the Department should withdraw the NPRM for procedural deficiencies, including that the Department did not adequately justify the rule, the rule was arbitrary and capricious, and the rule was outside of the scope of the Department's delegated authority. Specifically, commenters stated that the Department did not give adequate time for comments. Commenters objected to the Department's choice to allow for a 30-day comment period in lieu of a 60-day comment period and stated that the Department did not explain the basis for this decision. Commenters stated that the Department acknowledged that the proposed rule was a ''significant regulatory action'' pursuant to Executive Order 12866, but it failed to discuss or provide a rational basis for departing from the mandated 60-day comment period for such actions. Some commenters suggested that a 30-day comment period deviated from the Department's ''usual'' comment period of 60 days.

Commenters expressed confusion over the urgency of having a shorter comment period after the Department waited over thirty years to adjust fees. Commenters noted that, because EOIR had not changed its fees in over three decades, it was even more important for the public to have sufficient notice and, before commenting, time to understand EOIR's reasons and methodology behind the proposed increases, as well as how EOIR plans to ensure that vulnerable, low-income individuals will have access to proceedings. Commenters suggested that, on this basis, the Department should withdraw the NPRM and suggested that, if it were to reissue the rule in the future, the Department should allow for a longer comment period.

Commenters stated that they did not have sufficient notice because the NPRM did not adequately explain a DHS proposed rule that is cross-referenced in the regulatory language and that proposed rule's potential impact on an asylum applicant's ability to apply for fee waivers for appeals. Commenters asserted that the NPRM's stated purpose of balancing accessibility of the EOIR applications and motions for which the Department imposes a fee against saving taxpayer money was inadequate because EOIR has not taken other less expensive, burdensome, or prejudicial procedural improvements that would speed up the resolution of cases and potentially reduce costs associated with adjudications. Commenters stated that the Department did not present sufficient facts showing that it fully considered the public policy interest in accessibility to EOIR proceedings and that the Department instead relies on conclusory statements. Commenters stated that, rather than reducing the costs of adjudications, the proposed rule limited access to adjudications.

Commenters noted that numerous immigration and legal service providers requested an extension of the 30-day comment period. The commenters noted that USCIS had previously complied with a similar request in response to its own proposed rule to raise USCIS application fees, *see* 84 FR 67243 (Dec. 9, 2019), but the Department neither extended the comment deadline nor responded to the request. Commenters also stated that the Department should withdraw the NPRM or extend the comment period due to the novel coronavirus (''COVID–19'') pandemic. Specifically, commenters stated that it was unreasonable to expect the public to submit comments by March 30 on the changes proposed as they adjusted to new challenges, such as learning to perform their jobs remotely, not having access to hard copies of resources and background materials, and having to provide childcare. A commenter also stated that, in response to the pandemic, ''immigration procedures have been changing on a daily basis, forcing immigration practitioners to keep up and inform clients of this ever-changing landscape.''

Commenters asserted that numerous organizations submitted a letter requesting that the comment period be delayed due to the disruptions caused by the COVID–19 pandemic, and the Department has not responded to this request. Commenters stated that an additional 30-day comment period would ensure that individuals who are sick or caring for somebody who is sick would still have the opportunity to submit a public comment.

Commenters also expressed a belief that the Department should not implement the proposed fee increases at this time due to the economic effects of the COVID–19 pandemic. At least one commenter acknowledged that while the Department could implement the rule despite public comments, it would need to read all comments received and show that they were considered, and that such consideration might slow down efforts for the Department to move forward with the rulemaking process. Commenters also objected to the NPRM because it did not include any of the underlying data that the public would need to assess whether the Department's fee calculation was accurate or reasonable. Commenters acknowledged that the Department explained the process that it employed when polling its staff about work flow concerning particular types of applications, but stated that the Department only provided the conclusions, and not the underlying data, as part of the rulemaking record. Commenters stated that they had requested this data and the underlying study from OMB but that they had not received the information by the date of their comment submission. Commenters also stated that the Department did not state the amount of time expended by each person involved in an application for relief. Commenters asserted that this lack of information rendered it impossible for the public to assess whether the proposed fee structure is arbitrary and that the Department should withdraw the NPRM because it did not make this data, including the 2018 study, publicly available. Commenters also stated that they had submitted FOIA requests to the Department, seeking data on the number of fee waivers that had been filed, granted, and denied and additional information regarding the underlying cost study that was the basis for the NPRM. Commenters explained that if the Department raises EOIR fees, it would be crucial to make fee waivers broadly available and that such information was important to providing comprehensive responses to the NPRM.

Commenters stated that, as of the date of their comment submission, they had not received a response to the FOIA request, and that DOJ should withdraw the NPRM based on its failure to provide this information. Several commenters qualified their comment responses, stating that their responses were as complete as possible given the lack of data provided by the Department but that their responses could not be complete without such data. Commenters stated that the Department had not given an explanation for why it had not increased EOIR fees for 33 years. Due to the lack of an explanation, commenters presumed that it was a policy choice designed to keep fees affordable to allow access to justice in the immigration system. Commenters stated that the Department erroneously interpreted the statutory term ''fair'' as it related to the fee determinations. Commenters stated that it was irrational for the Department to suggest that the proposed fees were intended to significantly increase revenue for the Federal Government but was also not an

economically significant rule under Executive Order 12866, *i.e.,* a rule that would increase revenue by $100 million or more. Other commenters noted that the proposed rule would not comply with Executive Orders 12866 and 13563 because the Department did not accurately assess the costs and benefits, determine that the benefits outweigh the costs, maximize the net benefits, or tailor the proposed rule to impose the least burden on society. Commenters stated that the Department failed to consider the costs that deterring individuals from pursuing meritorious claims would have on individuals, families, employers, State and local governments, the economy, and society as a whole.

Response: The Department disagrees with comments suggesting that the NPRM, rule, or rulemaking process violates the APA. The fees are based on a cost study, and the Department is acting within its statutory authority to reflect the costs associated with present-day costs after more than 30 years without adjusting fees. As stated above, the Department is releasing the underlying data from its 2018 fee study in response to multiple requests for it. The Department is also including its updated dataset for full transparency.

Regarding commenters' further statements that the Department has not responded to commenters' FOIA request(s), the Department will continue to respond to any FOIA requests in accordance with FOIA and the relevant regulations. Specific concerns regarding EOIR's FOIA responses should be directed to the EOIR Office of General Counsel: U.S. Department of Justice, Executive Office for Immigration Review, Office of General Counsel—FOIA Service Center, 5107 Leesburg Pike, Suite 2150, Falls Church, VA 22041, Email address: *EOIR.FOIARequests@usdoj.gov*, FOIA Public Liaison: Crystal Souza, Telephone: 703–605–1297.

The Department believes the 30-day comment period was sufficient to allow for a meaningful public input, as evidenced by the significant number of public comments received, including 157 detailed comments from interested organizations. Further, commenters did not suggest or indicate what additional issues the comment period precluded them from addressing; to the contrary, the comments received reflect both a breadth and a level of detail that suggest that the period was more than sufficient. Additionally, to the extent that commenters referred to other proposed rulemakings as a basis for asserting the comment period should have been longer, their comparisons are inapposite. No other proposed rulemaking cited by commenters addressed a small, discrete number of applications that are well established and with which aliens and practitioners have been quite familiar with for decades. In short, the Department acknowledges and has reviewed commenters' concerns about the 30-day comment period, but those comments are unavailing for all of the reasons given herein.

The APA does not require a specific comment period length. *See generally* 5 U.S.C. 553(b)–(c). Similarly, although Executive Orders 12866 and 13563 provide that the comment period should generally be at least 60 days, it is not required. Federal courts have presumed 30 days to be a reasonable comment period length. For example, the D.C. Circuit recently stated that ''[w]hen substantial rule changes are proposed, a 30-day comment period is generally the shortest time period sufficient for interested persons to meaningfully review a proposed rule and provide informed comment,'' even when ''substantial rule changes'' are proposed. *Nat'l Lifeline Ass'n* v. *FCC,* 921 F.3d 1102, 1117 (D.C. Cir. 2019) (citing *Petry* v. *Block,* 737 F.2d 1193, 1201 (D.C. Cir. 1984)). Litigation has mainly focused on the reasonableness of comment periods shorter than 30 days, often in the face of exigent circumstances. *See, e.g., N.C. Growers' Ass'n, Inc.* v. *United Farm Workers,* 702 F.3d 755, 770 (4th Cir. 2012) (analyzing the sufficiency of a 10-day comment period); *Omnipoint Corp.* v. *FCC,* 78 F.3d 620, 629–30 (D.C. Cir. 1996) (7-day comment period); *Nw. Airlines, Inc.* v. *Goldschmidt,* 645 F.2d 1309, 1321 (8th Cir. 1981) (7-day comment period).

The Department is not obligated to extend the notice and comment period at the public's request. Regarding DHS's extension of the comment period for its fee rule, the Department notes that, at the time DHS extended the comment period, DHS provided supplemental information that changed some of the calculations underlying the proposed rule. 84 FR at 67243. The Department finds the circumstances of DHS's extension distinguishable from the Department's proposed rule, which does not involve any relevant changed information . The Department believes that the COVID–19 pandemic has no effect on the sufficiency of the 30-day comment period. Employers around the country have adopted telework flexibilities to the greatest extent possible, and the Department believes that interested parties can use the available technological tools to prepare their comments and submit them electronically. Indeed, nearly every comment was received in this manner. Further, some of the issues identified by commenters—*e.g.,* childcare—would apply regardless of the length of the comment period and would effectively preclude rulemaking by the Department for the duration of the COVID–19 pandemic. The Department finds no basis to suspend all rulemaking while the COVID–19 pandemic is ongoing. Overall, the Department believes that the COVID–19 pandemic has not limited the public's ability to meaningfully engage in the notice and comment period.

In addition, regarding commenters' concerns that the Department should delay implementation of this rule due to the economic effects of the COVID–19 pandemic, the Department again emphasizes that an alien who is unable to pay the fee may, consistent with current practice, apply for a fee waiver.

The Department gave the public sufficient notice of the rule's impact as it cross-references DHS's proposed rule. *See* 84 FR at 62280. The Department notes that this rulemaking does not alter EOIR's long-standing procedures with respect to how DHS-issued forms are treated in EOIR proceedings, and thus the public has had adequate notice that any changes that DHS makes to its fees through its own rulemaking would affect fees for DHS-issued forms filed with EOIR. *See* 8 CFR 1103.7(b)(4)(ii). While this rule updates cross-references to match DHS's proposed changes to DHS's regulations, the practices remain the same. To the extent that commenters believe they should have additional time for notice and comment to understand the Department's plans to ensure that low-income individuals will continue to have access to proceedings, the Department notes that its procedures with respect to fee waivers remain the same, including fee waivers associated with DHS-issued forms. 8 CFR 1103.7(c).

In response to commenters' concerns that this rulemaking does not fully accomplish balancing costs to the taxpayer against accessibility to the immigration courts, the Department notes, as discussed in part I.B, *supra,* that it fully considered the public interest, including access to the immigration courts, balanced against the cost to taxpayers in electing to not recoup the full costs of adjudications in assessing fees. The Department's policy has not changed since the last time it assessed fees. As when the Department last updated EOIR's fees, the proposed changes in the NPRM ''are necessary to place the financial burden of providing special services and benefits, which do

not accrue to the public at large, on the recipients.'' Powers and Duties of Service Offices; Availability of Service Records, 51 FR 39993, 39993 (Nov. 4, 1986). Thus, fees ''have been adjusted to more nearly reflect the current cost of providing the benefits and services, taking into account public policy and other pertinent facts.'' *Id.* In short, as it did previously, the Department fully considered public interest when reviewing and updating its fees for the first time in over 30 years.

Moreover, as the Department discussed in the NPRM, it intentionally did not include a variety of costs in its fee analysis to more fully ensure the fees remained at a level reflected by the public interest. 85 FR at 11869 (''EOIR's decision not to include overhead and non-salary benefits in the calculation of actual costs also accounts for the public interest in having non-parties bear some of the cost burden for filing documents associated with proper application of the law as it pertains to the statutory right to appeal or apply for certain forms of relief.''). Factoring in additional costs would almost inevitably have led to even higher proposed fees, which is a result commenters would have opposed even though, paradoxically, some of those same commenters criticized the Department for not conducting further analyses that would have likely required including such costs. In short, the Department recognizes that most commenters, as a matter of policy preference, oppose any fee increase at all because fees have remained artificially and inappropriately low for over three decades. Nevetheless, commenters did not persuasively explain why the Department should maintain that posture, especially when it conflicts with longstanding law and policy, nor identify shortcomings in the Department's analysis that, if remedied, would not have actually increased fees to a greater degree.

The Department disagrees with comments suggesting that this rule would deter individuals from pursuing meritorious claims, though it acknowledges that it may have some deterrent effect on individuals pursuing non-meritorious or otherwise dilatory claims. Nevertheless, such speculative deterrent effects are not supported by any evidence presented to the Department.

In response to commenters' statements that the Department had not adequately explained why it has not increased fees for 33 years, the Department notes that such a lack of action was a shortcoming by the agency that it is currently remedying, as stated in the NPRM. *See* 85 FR at 11869 (''EOIR is now proposing this rule to remedy the failure to update the fees in past years.''). Regardless of the reason for this lapse in reassessment, the Department is presently acting within its authority to charge fees, as discussed in the NPRM. 85 FR at 11872; *see* 31 U.S.C. 9701(a)–(b); Circular No. A–25 Revised at sec. 8(e); INA 286(m), 8 U.S.C. 1356(m).

The Department believes that the newly established fees are fair. The Department has set the new fees based upon data gathered from an activity-based cost analysis. As stated in the NPRM, EOIR's calculation of fees has factored in both ''the public interest in ensuring that the immigration courts are accessible to aliens seeking relief and the public interest in ensuring that U.S. taxpayers do not bear a disproportionate burden in funding the immigration system.'' 85 FR 11870; *see Ayuda I,* 661 F. Supp. at 36 (dismissing position that fees were ''arbitrarily and capriciously unreasonable'' where former INS-implemented fees that were ''no greater than the rough actual cost of providing the services'').

Regarding commenters' allegations that the Department's analysis under Executive Order 12866 is inadequate, the Department disagrees. The Department has properly considered the rule's economic effects and determined, in coordination with OMB, that the rule is not likely to have a significant economic effect. Moreover, as the difference in fee collections illustrates, the impact on the economy is clearly less than $100 million.

10. Violates Due Process

Comment: Commenters argued that immigration proceedings must not infringe on aliens' due process rights, citing *Salgado-Diaz* v. *Gonzales,* 395 F.3d 1158, 1162 (9th Cir. 2005) (as amended) (''Immigration proceedings, although not subject to the full range of constitutional protections, must conform to the Fifth Amendment's requirement of due process.''), and *Gutierrez* v. *Holder,* 662 F.3d 1083, 1091 (9th Cir. 2011) (''A full and fair hearing is one of the due process rights afforded to aliens in deportation proceedings.''). Similarly, relying on *Zadvydas* v. *Davis,* 533 U.S. 678, 690 (2001), commenters asserted that the increased fees act as barriers to appeal orders of removal, thus violating immigrants' constitutionally protected due process rights.

Commenters asserted that the proposed fee increases would make it impossible for many noncitizens to pursue their statutory rights to seek many of the specific applications, appeals, and motions at issue in the NPRM. *See, e.g.,* INA 240A, 8 U.S.C. 1229b (cancellation of removal); INA 240(c)(5), 8 U.S.C. 1229a(c)(5) (appeals of immigration judge decisions); INA 101(a)(47)(B), 8 U.S.C. 1101(a)(47)(B) (same); INA 240(c)(6), 8 U.S.C. 1229a(c)(6) (motions to reconsider); INA 240(c)(7), 8 U.S.C. 1229a(c)(7) (motions to reopen); INA 244(a), 8 U.S.C. 1254(a) (1995) (suspension of deportation). Commenters stated that the rule even appears to have been designed in order to yield such outcomes and that ''[w]here fees have an impact on individuals' ability to exercise their statutory and regulatory rights, agencies necessarily must consider ability to pay to avoid infringing upon those rights.''

Relatedly, commenters stated that the cost of pursuing relief could violate due process if it forecloses a party's opportunity to be heard, citing *Boddie,* 401 U.S. at 380 (''Just as a generally valid notice procedure may fail to satisfy due process because of the circumstances of the defendant, so too a cost requirement, valid on its face, may offend due process because it operates to foreclose a particular party's opportunity to be heard.''). Commenters disagreed with the NPRM's reasoning that unmet costs justified fee increases, explaining that the U.S. Supreme Court rejected that reasoning as a sufficient basis for denying indigent individuals access to the courts. *See id.* at 381 (rejecting justification of fees based on allocating scarce resources and deterring frivolous litigation and finding that ''none of these considerations is sufficient to override the interest of these plaintiff-appellants in having access to the only avenue open for dissolving their allegedly untenable marriages.'').

Commenters expressed concerns that the proposed rule continues administrative trends to speed up removals without providing noncitizens with fair opportunities to present their cases in court. Commenters opined that the current administration was taking steps to emphasize deporting aliens over due process in EOIR proceedings and stated that it had taken similar steps to turn USCIS, a benefits-granting agency, into an enforcement agency.

Commenters alleged that EOIR must ensure that fees remain ''accessible'' and ''affordable'' in order to ensure due process is extended to all individuals, regardless of income. The proposed fees, commenters alleged, are neither accessible nor affordable, especially in the context of appeals, given that aliens would have only 30 days from the immigration judge decision to file an appeal and pay the increased fee.

Response: The rule does not infringe upon due process rights. Aliens continue to receive a ''full and fair hearing,'' *see Gutierrez,* 662 F.3d at 1091, before an immigration judge to present their case. *Gutierrez* further explained that the hearing must not be ''so fundamentally unfair that the alien was prevented from reasonably presenting his case.'' *Id.* at 1091 (quoting *Ibarra-Flores* v. *Gonzales,* 439 F.3d 614, 620 (9th Cir. 2006)). ''Where an alien is given a full and fair opportunity to be represented by counsel, prepare an application for . . . relief, and to present testimony and other evidence in support of the application, he or she has been provided with due process.'' *Vargas-Hernandez* v. *Gonzales,* 497 F.3d 919, 926–27 (9th Cir. 2007). The rule does not alter proceedings before an immigration judge; further, statutory provisions cited by commenters remain unchanged. Appeals, motions, and other forms of relief remain available; the rule only updates the fees to file applications for such relief while at the same time keeping fee waivers as an available option for aliens who cannot pay the fee. Accordingly, allegations that the rule proposed to change proceedings in a way that deprives aliens of due process is unfounded.[38]

Likewise, the rule is distinct from *Zadvydas,* 533 U.S. 678, which was relied upon by commenters. *Zadvydas* examined liberty interests in the context of detention that was indefinite and possibly permanent. *Id.* at 696. In fact, the Court explicitly provided that ''the issue we address is whether aliens that the Government finds itself unable to remove are to be condemned to an indefinite term of imprisonment within the United States.'' *Id.* at 695. The rule at hand, however, involves updating fees in accordance with section 286(m) of the Act (8 U.S.C. 1356(m)) and the agency's authorities for certain appeals, applications, and motions filed with EOIR. *See generally* 85 FR 11866. Updating fees to recover costs for providing services, in accordance with statutory authority, does not mandate or implicate detention in a way that *Zadvydas* would directly apply, and not all processes provided by law and regulation are constitutionally required. Nevertheless, the rule comports with foundational principles of due process, outlined in *Zadvydas* and numerous cases preceding and subsequent to that decision, because it does not alter regulations providing notice to aliens (8 CFR 1003.18(a), (b)), the alien's opportunity to present his or her case (8 CFR 1240.10), the option to be represented by counsel (8 CFR 1003.16(b), 1240.3), the ability to file an application for relief (8 CFR 1240.1(a), 1240.11), or the opportunity to provide evidence or testimony in support of the application (8 CFR 1240.7).

As Section II.C.4 of this preamble extensively explains, the rule preserves the ability to submit fee waiver requests. Contrary to commenters' assertions, the Department considered aliens' ability to pay in updating the fees and subsequently retaining the fee waiver process, as reflected in the NPRM. The Department explained that ''[w]hile EOIR recognizes that the new fees will be more burdensome, fee waivers are still possible for those who seek them'' and, accordingly, that EOIR would continue to ''entertain requests for fee waivers . . . and waive a fee for an application or motion upon a showing that the filing party is unable to pay.'' 85 FR at 11871, 11874.

The Department disagrees with commenters' assertions that Supreme Court precedent undermines the NPRM's reasoning that because EOIR's processing costs ''consistently exceed the assessed fees,'' updating fees is necessary to ''recoup some of [the Government's] costs when possible.'' 85 FR at 11870. In *Boddie,* 401 U.S. 371, one case cited by the commenters, the Court considered a state's required $60 fee to file for divorce. Because payment of the fee determined ''access to the judicial process in the first instance'' and the appellants had proven their inability to afford such fee, the Court found that the fee barred individuals ''from the only forum effectively empowered to settle their disputes,'' thus depriving them of their due process rights. *Id.* at 375–76. However, *Boddie's* holding was based on the fact that plaintiffs were prevented *altogether* from accessing the judicial process required to end their marriages unless they paid the $60 fee. In contrast, separate and apart from this rule, aliens are provided an opportunity, at no charge, to present their case in a hearing before an immigration judge, and a fee waiver remains available to aliens who are unable to pay for the application or motion, including an appeal, they wish to pursue. Further, the updated fees apply to certain applications for discretionary forms of relief, in which aliens have no due process rights,[39] and applications for appeals and motions, which are filed after an immigration judge issues a final decision. Accordingly, the rule does not wholly preclude aliens from their opportunity to be heard, and so the holding in *Boddie* is distinguishable.

The cases cited by commenters are also distinguishable because they involve, as commenters note, discrimination based on poverty, but the rule does not discriminate on any basis. Fees apply equally to all applicants regardless of financial status, and fees may be waived upon a showing of the filing party's inability to pay. *See* 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c). The rule does not discriminate on its face or in its application—it does not act as a blanket prohibition on people without financial means from submitting the applications, appeals, and motions at issue. Rather, the fees apply equally to all aliens unless an alien's fee waiver request is granted by an immigration judge or the BIA, based upon a showing of the alien's inability to pay. *See* 85 FR at 11871.

The Department disagrees that the rule acts to ''speed up removals'' without providing opportunities for aliens to present their cases. The rule only increases fees for certain applications, appeals, and motions due to the rising adjudication costs that greatly exceed current fees. The rule does not alter proceedings in any way. Contrary to commenters' claims, the Department does not emphasize deporting aliens over due process: Immigration judges and the BIA continue to exercise independent judgment and discretion in applying the immigration laws to each unique case before them. 8 CFR 1003.1(d)(1)(ii), 1003.10(b). Further, commenters' claims alleging USCIS's enforcement-related activities impeding due process are unrelated to EOIR's rule. As part of DOJ, EOIR is a separate agency from USCIS, which is part of DHS. *See Operational and Support Components,* Department of Homeland Security, *https://*

[38] Due process does not require a right to appeal at all, even in the criminal context. *Halbert* v. *Michigan,* 545 U.S. 605, 610 (2005) (''The Federal Constitution imposes on the States no obligation to provide appellate review of criminal convictions.'' (citing *McKane* v. *Durston,* 153 U.S. 684, 687 (1894)); *accord Guentchev* v. *INS,* 77 F.3d 1036, 1037–38 (7th Cir. 1996) (''The Constitution does not entitle aliens to administrative appeals. Even litigants in the federal courts are not constitutionally entitled to multiple layers of review. The Attorney General could dispense with the Board and delegate her powers to the immigration judges, or could give the Board discretion to choose which cases to review (a la the Appeals Council of the Social Security Administration, or the Supreme Court exercising its certiorari power).'').

[39] ''[B]ecause discretionary relief is necessarily a matter of grace rather than of right, aliens do not have a due process liberty interest in consideration for such relief.'' *United States* v. *Torres,* 383 F.3d 92, 104 (3d Cir. 2004); *see also Ticoalu* v. *Gonzales,* 472 F.3d 8, 11 (1st Cir. 2006); *Smith* v. *Ashcroft,* 295 F.3d 425, 429–30 (4th Cir. 2002); *United States* v. *Lopez-Ortiz,* 313 F.3d 225, 231 (5th Cir. 2002); *Oguejiofor* v. *Att'y Gen.,* 277 F.3d 1305, 1309 (11th Cir. 2002).

www.dhs.gov/operational-and-support-components (last updated Nov. 17, 2018).

By retaining the current fee waiver process, the Department ensures that aliens who aver that they are unable to pay have an avenue to request consideration of an appropriate application, appeal, or motion. The Board has possessed explicit, discretionary authority to waive an appeal or motion fee since 1953, 18 FR 3526, 3527 (Jun. 11, 1953), and there is no evidence that the Department's longstanding fee waiver process is inadequate or ineffective to address situations in which an alien is genuinely unable to pay a relevant fee. Regarding the commenters' concerns with the 30-day period from an immigration judge decision to file an appeal and pay the fee, the Department again notes that the public will be on notice about the new fee amount as of this rule's publication. An alien who is concerned that he or she may wish to appeal the immigration judge's decision should, accordingly, use that time between the initiation of the proceeding and the immigration judge's issuance of a final decision to begin arranging funds for the future payment of the appeal.

11. Fee Increases Will Have Negative Effects on EOIR/Immigration System

Comment: Commenters indicated a wide range of disparate concerns that the NPRM will have potential negative effects on the functioning of EOIR and the U.S. immigration system.

Commenters stated that it would exacerbate the ''already strenuous situation on our southern border,'' the ''dismal . . . asylum system,'' and aliens' access to courts. Relatedly, commenters stated there was no reason to believe that updated fees would improve the BIA's case completion rate, which they noted has continuously decreased. Another commenter explained that the NPRM would discourage even those with meritorious claims from pursuing them in EOIR proceedings.

Commenters explained that the rule diminished the institutional integrity of EOIR and would have cumulative negative, and in some cases irreversible, effects on aliens who would be unable to afford the fees, those aliens' families, and their communities. One commenter anticipated increased crime in these communities because aliens would lack options for relief. One commenter expressed concern that the NPRM would cause predatory lenders to prey on aliens.

Several commenters opined that the increased fees would incentivize unlawful immigration, which would also lead to more undocumented workers in the United States. Another commenter further explained that unlawful immigration would lead to a shift in costs from adjudication (EOIR) to enforcement (ICE). One commenter stated that no evidence exists to demonstrate that possible difficulties with processing upon entry has any deterrent effect on aliens' decisions to enter the United States.

Many commenters opposed the NPRM because they alleged that it would negatively affect representation rates. Some commenters expressed concern that the increased fees would place aliens in a position of choosing between paying the fee or obtaining counsel. Commenters explained that aliens who choose to pay the fee and have nothing left to obtain counsel would then appear pro se for their hearings. One commenter stated that this would ''interfere with the statutorily granted right to counsel for alien respondents,'' while another commenter stated that this violated the ''American principle of legal representation for all.'' One commenter stated that ''substantial evidence [shows] that having counsel makes a critical difference in the outcome of one's case.''

Numerous commenters expressed concerns that the rule would negatively affect legal service providers. For example, commenters emphasized that legal aid organizations, small firms, and attorneys providing pro bono services would be unable to routinely pay the fees for their clients. According to commenters, they would be forced to assist fewer aliens, especially indigent aliens and children, which would also preclude law students from gaining valuable experience and reduce the availability of pro bono counsel generally. Commenters further suggested that, overall, this would cause the courts additional costs and delays. Other commenters expressed concerns that the funds used to pay their clients' fees would come at the expense of other programmatic elements of their budget; thus, they would be less able to provide comprehensive services to aliens. Some commenters stated that the higher fees and resulting fee waivers would increase the time that an attorney spends on a case, which would compound the burden on both legal aid organizations and firms, such that they would be more hesitant to take these cases. Several commenters noted that attorneys would be forced to spend more time on fee waiver applications rather than substantive issues, which could relatedly cause them to turn away clients for lack of time and resources to represent them. Further, one commenter expressed concern that the increased fees would make aliens susceptible to fraud by notarios because aliens would be forced to seek the services of fraudulent notarios in place of licensed counsel.[40]

Some commenters expressed concern that an increase in fee waivers would further ''backlog'' the immigration courts. A commenter explained that immigration judges make ''bad decisions'' when under such pressure. Other commenters explained that more aliens would file fee waiver requests, thereby increasing the caseload in immigration courts and at the BIA and diverting resources from substantive claims to fee waiver adjudication. Commenters alleged that the NPRM failed to consider this inevitable burden. One commenter explained that increasing the caseload would further extend proceedings, forcing derivative family members to file separate applications that would also increase the caseload.

Commenters stated that the burden on immigration judges to implement the $50 asylum fee would exceed the monetary gain from charging the fee. One commenter stated that increased fees on H–1B visas and temporary guest worker visas would hurt American businesses. Another commenter explained that USCIS almost always issues Requests for Evidence (USCIS Form I–797), requiring additional filing fees, to support USCIS fee waiver requests (USCIS Form I–912).

Response: Overall, the Department finds these general concerns about possible negative effects too speculative to warrant changes to the NPRM, and the Department disagrees with commenters' concerns about the rule's extensive negative impact. Nevertheless, the Department responds to the different concerns below.

[40] ''The term 'notario publico' is particularly problematic in that it creates a unique opportunity for deception. The literal translation of 'notario publico' is 'notary public.' While a notary public in the United States is authorized only to witness the signature of forms, a notary public in many Latin American (and European) countries refers to an individual who has received the equivalent of a law license and who is authorized to represent others before the government. The problem arises when individuals obtain a notary public license in the United States, and use that license to substantiate representations that they are a 'notario publico' to immigrant populations that ascribe a vastly different meaning to the term,'' and may not realize that, in the United States, a notary public is not authorized to provide representation or legal assistance to individuals in immigration proceedings. *About Notario Fraud,* American Bar Association, July 19, 2018, *https://www.americanbar.org/groups/public_interest/immigration/projects_initiatives/fight-notario-fraud/about_notario_fraud/* (last visited Oct. 30, 2020).

The Department disagrees with allegations that the rule would have a definitive impact at the border because the rule makes no amendments to various policies related to the border or border enforcement, only to applications and motions submitted during immigration proceedings before EOIR. Similarly, because the rule makes no substantive amendments to EOIR's asylum regulations in 8 CFR part 1208, the Department disagrees it would have an impact on the ''dismal . . . asylum system,'' as characterized by commenters.

Commenters are correct that the BIA's case completions have decreased or remained stagnant in recent years. *See* Exec. Office for Immigration Rev. Adjudication Statistics: Case Appeals Filed, Completed, and Pending, Exec. Office for Immigration Rev., July 14, 2020, *https://www.justice.gov/eoir/page/file/1248501/download.* However, this rule is not designed to improve BIA completion rates. Instead, the purpose is to better align the fees charged for EOIR applications and motions with the costs of the agency to provide immigration adjudication and naturalization services. *See generally* 85 FR 11866.

Further, the Department disagrees with allegations of the widespread effects on families, communities, crime rates, and predatory lending tactics. The Department continues to offer the same options for relief, including fee waivers for aliens who cannot pay a fee imposed by EOIR, and such concerns are extremely attenuated.

The Department declines to respond to commenters' speculative concerns regarding an increase in unlawful immigration and aliens' ability to obtain counsel, including effects on legal service providers. As previously explained, the rule updates EOIR fees to recover costs of the agency in providing particular services. Unlawful immigration and access to counsel are affected by a number of factors beyond the cost of applications and appeals, and commenters provided no factual or policy bases for the Department to consider. Further, the rule was not proposed to curb unlawful immigration, deter aliens from entry, or increase aliens' access to counsel. Accordingly, the Department finds such concerns to be mere speculation and is thus unable to provide a response. *See Home Box Office,* 567 F.2d at 35 n.58.[41] Additionally, the Department reiterates the continued availability of fee waivers available to aliens who are unable to afford the cost of an application or appeal. The Department also notes that, contrary to some commenters' assertions, aliens have a right to representation at their own expense, but the Government is not required to provide such representation. Accordingly, the Government is also not required to subsidize representation through artificially low fees or by ignoring OMB and statutory directives for over three decades.

The Department disagrees that the burden placed on aliens due to the increased fees is excessive or undue. When calculating the fee increase pursuant to its statutory authority, the Department carefully balanced the public policy interest of maintaining accessibility of the immigration courts for aliens and the public interest in ensuring that U.S. taxpayers do not bear a disproportionate burden in funding the immigration system. 85 FR at 11870.

Additionally, commenters' assertions concerning the burden of increased fees on organizations and the private bar falls outside the limited scope of this rulemaking.

While the Department is likewise concerned about notario fraud, *see, e.g.,* Exec. Office for Immigration Rev., Notario Notice (July 22, 2009), *https://www.justice.gov/eoir/notarionotice national072209,* the commenter's statement is both speculative and outside of the scope of this rulemaking.

As to the various comments regarding the increasing pending caseload, the Department recognizes that an increase in fee waiver requests is possible; yet, it is the Department's view that the increase alone will not substantially increase the burden on either the immigration courts or the BIA. Moreover, immigration judges and Board members have extensive experience dealing with fee waivers and would not be expected to have any difficulty adjusting to any increase in fee waiver requests.

Commenters' concerns related to H–1B visas, temporary guest worker visas, and the Form I–797 are outside the scope of this rulemaking. EOIR is a separate agency from USCIS, which is part of DHS. Relatedly, the rule makes no substantive amendments to DHS's fees schedule, and the Department continues to apply USCIS fees in accordance with the regulation at 8 CFR 1103.7(b)(4)(ii).

Comment: Commenters also asserted that the proposed fees will result in an imbalance between DHS and aliens because DHS is exempted from paying a fee and that this imbalance may influence the future development of the law by further exacerbating an ''asymmetry of resources and skew outcomes in favor of removal.'' Commenters stated that such inequity would be contrary to both Supreme Court and agency precedent, both of which caution against allowing one party to unilaterally control adversarial proceedings. Commenters cited *Boumediene* v. *Bush,* 553 U.S. 723, 765 (2008), in which the Supreme Court rejected an argument that would allow ''the political branches to govern without legal constraint.'' Commenters also cited BIA precedent in *Matter of Diaz-Garcia,* 25 I&N Dec. 794, 796 (BIA 2012), in which the BIA held that the unlawful removal of an alien during the pendency of a direct appeal does not deprive the BIA of jurisdiction over the case. Specifically, the BIA rejected DHS's interpretation because it would allow DHS ''to unilaterally deprive the [BIA] of further jurisdiction'' over a case. *Id.*

Commenters suggested that ICE should also be required to pay for its appeals to the BIA, asserting that EOIR could collect a substantial amount of fees without overburdening aliens who are defending their rights before the courts. Commenters also suggested that DHS be required to pay a filing fee for each Notice to Appear (''NTA'') in addition to each Notice of Appeal. Commenters remarked that, under the NPRM, DHS unfairly bears no costs for initiating proceedings while aliens must pay the updated fees to appeal. Commenters relatedly explained that if EOIR was concerned about the increased caseload, it should charge DHS—the entity responsible for the growing caseload due to its changed enforcement priorities—for filing NTAs and Notices of Appeal, rather than charge aliens defending themselves with applications they are statutorily entitled to file. Similarly, one organization suggested that, in accordance with the IOAA's mandated consideration of fairness in charging fees, EOIR charge an ''intergovernmental user fee on federal agency filings that is equivalent to fees imposed on noncitizen users.'' The organization explained that such fees were ''not uncommon or rare.''

Response: Commenters' concerns that the fees will create an imbalance between DHS and aliens and that such imbalance will in turn affect the development of case law are entirely speculative. As discussed above, to the extent that an alien is unable to pay the new fees, a fee waiver remains available. 8 CFR 1003.8(a)(3), 1003.24(d). Accordingly, aliens who are unable to pay the fee may continue to file appeals of unfavorable immigration judge decisions should they so choose.

[41] *See also* footnote 18 *supra* for further discussion.

In no way is the decision to better align the fees for these EOIR applications and motions with the Government's adjudication costs akin to the argument in *Boumediene* that the aliens in Guantanamo Bay, Cuba did not have described rights because the Suspension Clause of the U.S. Constitution does not apply to an area where the United States does not claim sovereignty. *Boumediene,* 553 U.S. at 753–71. Here, for example, even where DHS files the appeal with the BIA, the BIA reviews all questions of law, discretion, and judgment de novo. *See* 8 CFR 1003.1(d)(3)(ii).

The Department declines to adopt commenters' suggestions to charge new intra-governmental fees for DHS-initiated filings, such as for NTAs. The NTA is the initial document that initiates most immigration court proceedings. *See* INA 239(a), 8 U.S.C. 1229(a). Such a suggestion is beyond the scope of the NPRM and would require contemplation and analysis of filing fees for other government case-initiation documents for cases adjudicated by EOIR, such as the amount of a fee for a complaint filed with the Office of the Chief Administrative Hearing Officer pursuant to INA 274A, 8 U.S.C. 1324a; INA 274B, 8 U.S.C. 1324b; and INA 274C, 8 U.S.C. 1324c. Moreover, the Department declines to impose a fee for the receipt and processing of NTAs at this time. The Department finds that NTAs serve the purpose of ensuring that aliens in removal proceedings are provided with written notice of important information regarding their removal proceedings. *See* INA 239(a), 8 U.S.C. 1229(a). The Department similarly does not collect fees for other notices that DHS serves upon parties for the purpose of ensuring that parties are provided with important information that may affect their proceedings, even where service of such notice also incurs responsibilities on the immigration court. *See, e.g.,* 8 CFR 1003.47(d) (''DHS . . . shall provide a biometrics notice and instructions to the respondent for such procedures. The immigration judge shall specify for the record when the respondent receives the biometrics notice and instructions and the consequences for failing to comply with the requirements of this section.''). Moreover, no provision of the INA or any other statute authorizes the Department to impose a fee for the issuance of an NTA, and the Department is unaware of any authority it possesses to do so. *See Authority of the Nuclear Regulatory Commission to Collect Annual Charges from Federal Agencies,* 15 Op. O.L.C. 74, 75 (1991) (''It is settled law that federal agencies may not charge other federal agencies user fees under [title 31] section 9701[.]'').

12. Discussion of How Funds Raised Will Be Used

Comment: Other commenters stated that the cost calculations improperly included costs that EOIR incurred for actions that only helped DHS, and commenters disagreed that fee proceeds resulting from a fee increase in accordance with such calculations should fund those actions. For example, commenters suggested that the Department should not consider the following costs to the agency: Wired network access for ICE in immigration court; spending additional time scrutinizing respondent filings; maintaining databases that immediately notify ICE, but not respondents, of EOIR rulings; establishing and maintaining VTC; new immigration judge training; EOIR trainings; and cases that circuit courts have found to be improper. Some commenters suggested that EOIR was seeking to profit off of aliens who appear before the court. Commenters stated that the Department's reliance on the IOAA, section 286(m) of the Act (8 U.S.C. 1356(m)), and *Ayuda II,* 848 F.2d at 1301, as current sources of authority was misguided because those sources of authority predate the Homeland Security Act of 2002 (''HSA''), Public Law 107–296, 116 Stat. 2135. Commenters also generally disagreed with the Department's discussion of *Ayuda I, Ayuda II,* and *National Cable Television Ass'n,* 554 F.2d 1094, in the NPRM.

One commenter stated that despite the Department's position that it is permitted to charge ''user fees'' to recipients who receive ''special benefits,'' 85 FR at 11866–67, aliens in removal proceedings are not voluntarily accessing a benefit system, unlike aliens affirmatively seeking benefits from USCIS. Instead, they are being '''prosecuted' '' by DHS for immigration violations. Commenters acknowledged that immigration court proceedings are civil, but nonetheless asserted that aspects of the system are more akin to criminal proceedings, and equated charging cost-prohibitive fees for cancellation of removal, suspension of deportation, or asylum to charging criminal defendants for making affirmative defenses in cases in which they face prosecution.

One commenter also expressed concerns that the proposed fees that would be collected might be transferred to ICE, ''the very agency prosecuting and appealing these cases, and in some instances holding the noncitizens in detention,'' and would not be used for immigration adjudications. Specifically, commenters stated that the rulemaking did not make clear that the proposed fees, if collected, would be used to fund the immigration court system, citing the Board of Immigration Appeals Practice Manual and the Immigration Court Practice Manual, which state that EOIR fees for immigration court applications are paid to DHS, not the Department. *See Board of Immigration Appeals Practice Manual* ch. 3.4(i), Board of Immigration Appeals, *https://www.justice.gov/eoir/page/file/1250701/download* (last updated Feb. 20, 2020); *Immigration Court Practice Manual* ch. 3.4(a), Office of the Chief Immigration Judge, *https://www.justice.gov/eoir/page/file/1258536/download* (last updated July 2, 2020). Commenters also asserted that the NPRM did not state that the Department needed the fees collected to meet its costs or that it had a funding shortfall.

Commenters opposed funding numerous immigration-related measures, including funding for private prisons, maintaining ICE detention facilities, hiring Border Patrol Agents, building a border wall, and developing immigrant detention policies. Commenters suggested that cutting costs by reducing such activities could prevent the need for increasing fees.

Response: Commenters observed that the IOAA, section 286(m) of the Act (8 U.S.C. 1356(m)), and the *Ayuda* decision predate the HSA. However, contrary to the commenters' statements, this does not undermine the Department's reliance on such sources of authority and judicial guidance. Following the creation of DHS by the HSA, Congress explicitly affirmed that ''[t]he Attorney General [retained the same] authorities and functions under [the INA] and all other laws relating to the immigration and naturalization of aliens as were exercised by [EOIR], or by the Attorney General with respect to [EOIR],'' prior to the effective date of the HSA. INA 103(g)(1), 8 U.S.C. 1103(g)(1). These authorities and functions include the authority to promulgate regulations; prescribe bonds, reports, entries, and other papers; issue instructions; review administrative determinations in immigration proceedings; delegate authority; and perform other acts as the Attorney General determines are necessary to carry out the Attorney General's authorities under the immigration laws. INA 103(g)(2), 8 U.S.C. 1103(g)(2). In sum, the Attorney General retained the same authority to implement fees after passage of the HSA as before passage of the HSA, just as the Attorney General may continue to take

actions related to other INA provisions that predate the HSA, such as asylum under section 208 of the Act (8 U.S.C. 1158). The Attorney General continues to operate under his express statutory authority to carry out the provisions of section 286 of the Act (8 U.S.C. 1356). INA 286(j), 8 U.S.C. 1356(j) (''The Attorney General may prescribe such rules and regulations as may be necessary to carry out the provisions of this section.''). Commenters have not pointed to any language in the HSA that would suggest otherwise.

Commenters are incorrect that the Department included costs that EOIR incurs for actions that only help DHS when determining the new fee. As stated in the NPRM, EOIR conducted a cost study that considered the direct salary costs required for each step in the processing and adjudications of those applications, appeals, and motions for which EOIR levies a fee. 85 FR at 11869. The Department did not include any other costs, such as the cost of network access, maintenance of EOIR databases, EOIR adjudicator training, or other non-direct salary costs, although those costs could have been included in accordance with the law. *Id.*

In response to commenters' assertions that fees associated with ''adjudication and naturalization services'' do not include adjudications before EOIR, the Department notes that no such limitation is included in the statutory language. INA 286(m), 8 U.S.C. 1356(m). At the time that Congress enacted section 286(m) of the Act (8 U.S.C. 1356(m)), the Department adjudicated both benefits applications (through the former INS) that would now be adjudicated before USCIS as well as applications submitted for purposes of removal defense. Therefore, the term ''adjudication,'' as used in section 286(m) of the Act (8 U.S.C. 1356(m)), can be reasonably read to include EOIR adjudications. Further, prior to the enactment of section 286(m), the Department had implemented a number of fees pertaining to adjudications before EOIR, such as filing an application for a stay of deportation, filing an application for suspension of deportation, filing an appeal before the BIA, and filing a motion to reopen or reconsider. *See* 51 FR at 39993–94; *Ayuda II,* 848 F.2d at 1298 n.2. Nothing in the language of section 286(m) of the Act (8 U.S.C. 1356(m)) suggests that Congress intended to limit or deviate from the Department's existing practice to charge fees for adjudications associated with EOIR, and this rule builds on this history of charging EOIR fees.

Additionally, the Department believes that both *National Cable Television Ass'n* and *Ayuda* highlight that existing case law supports the Department's position that the IOAA gives the Attorney General broad authority to set fees. The Department notes that the commenters have not cited any case law that would limit the Department's authority to set or increase existing fees for applications and motions filed before EOIR, so long as the fee amounts do not exceed the cost of providing the required service, including similar services that may be provided without charge to certain categories of aliens, and any additional administrative costs associated with the fees collected, and otherwise comply with the IOAA (31 U.S.C. 9701). Accordingly, the Department disagrees with commenters' suggestions that its citations to these cases are misguided.

The Department notes that even assuming arguendo, as commenters asserted, that the fees described in *National Cable Television Ass'n* are distinguishable from those in this rulemaking, the IOAA confers broad authority upon agency heads, including the Attorney General, to establish fees, as is ''unmistakably'' supported by case law. *Ayuda II,* 848 F.2d at 1300 (citing *Nat'l Cable Television Ass'n,* 554 F.2d at 1101). Accordingly, the Department has properly relied on *National Cable Television Ass'n* as a source of interpretive guidance.

The Department also believes that commenters' objections to the Department's reliance on *Ayuda II* as interpretive authority are unfounded. Specifically, commenters attempted to distinguish between *Ayuda II* and the proposed rule because *Ayuda II* was filed prior to the enactment of section 286(m) of the Act (8 U.S.C. 1356(m)). *Compare Ayuda II,* 848 F.2d 1297 (decided June 10, 1988), *with* Public Law 100–459, sec. 209(a), 102 Stat. 2609 (Oct. 1, 1988) (adding subsections (m)–(p) to section 286 of the Act (8 U.S.C. 1356)). The commenters did not specify how a subsequent express grant of the authority that *Ayuda II* determined that EOIR had, to charge fees associated with proceedings, would undermine *Ayuda II's* reasoning, rather than strengthening it. *See Ayuda II,* 848 F.2d at 1301 (''In light of settled law, we are constrained to conclude that the INS fees at issue are for a 'service or thing of value' which provides the recipients with a special benefit.''); INA 286(m), 8 U.S.C. 1356(m) (authorizing DOJ to charge fees for immigration adjudication and naturalization services at a level to ''ensure recovery of the full costs of providing all such services, including the costs of similar services provided without charge to asylum applicants or other immigrants''). Accordingly, the Department believes that this rulemaking is well supported by *Ayuda II,* 848 F.2d at 1301, as well as the statutory sources of authority. *See* 31 U.S.C. 9701; INA 286(m), 8 U.S.C. 1356(m).

With respect to commenters' concerns that fees associated with EOIR proceedings are not charges for ''special benefits'' pursuant to the IOAA and Circular No. A–25 Revised, the Department notes that the term ''special benefits'' has been interpreted broadly to include fees associated with applications and motions included in the rulemaking. *See Ayuda II,* 848 F.2d at 1301 (determining that ''the breadth of the [IOAA's] language and the courts' generous reading of the provision in question'' require a finding that ''the INS fees at issue are for a 'service or thing of value' which provides the recipients with a special benefit'').[42] The Department also notes that it is not adding any new fees for EOIR-issued forms, and that it has been charging fees for these applications and motions since at least 1986. *See* 85 FR at 11866; 51 FR at 39993. To date, no authority has directed that these fees are not ''special benefits'' pursuant to the IOAA.

Additionally, as commenters acknowledged, immigration proceedings are civil in nature, not criminal. *See INS* v. *Lopez-Mendoza,* 468 U.S. 1032, 1038–39 (1984); *Guti* v. *INS,* 908 F.2d 495, 496 (9th Cir. 1992) (per curiam) (holding Bail Reform Act inapplicable to immigration proceedings). Thus, applications and motions in immigration proceedings are not precisely analogous to affirmative defenses raised in criminal proceedings. Moreover, even if they were akin to affirmative defenses, Congress has not directed courts to recoup adjudication costs the way it has administrative agencies through the IOAA.

In response to commenters' concerns that they are unsure about how the fees collected would be allocated, the

[42] The fees at issue included: (1) A decrease from $50 to $35 in the fee for filing a petition to classify preference status of an alien on the basis of profession or occupation; (2) an increase from $70 to $125 in the fee for filing an application for a stay of deportation; (3) an increase from $75 to $100 in the fee for filing an application for suspension of deportation; (4) an increase from $50 to $110 in the fee for filing an appeal from any decision under the immigration laws in any proceeding (except a bond decision) over which the BIA has appellate jurisdiction; (5) an increase from $50 to $110 in the fee for filing a motion to reopen or reconsider any decision under the immigration laws, with certain exceptions; and (6) elimination of the $50 fee for filing a request for temporary withholding of deportation. *See Ayuda II,* 848 F.2d at 1298 n.2.

Department reiterates that the fees will be deposited into the IEFA pursuant to section 286(m) of the Act (8 U.S.C. 1356(m)). 85 FR at 11867. The Department rejects any allegations that it would profit off of any fees that it would collect pursuant to this rulemaking. All adjudication fees that are designated in regulations are deposited in the IEFA in the Treasury of the United States. *Id.* Although the fees for EOIR applications and motions are paid to DHS, as noted by commenters, DHS does not retain the fee amounts as an addition to DHS's budget. Deposits into the IEFA ''remain available until expended to the Attorney General [or the Secretary] to reimburse any appropriation the amount paid out of such appropriation for expenses in providing immigration adjudication and naturalization services and the collection, safeguarding and accounting for fees deposited in and funds reimbursed from the [IEFA].'' INA 286(n), 8 U.S.C. 1356(n).

Except as noted in consideration of the public interest, the Department included all operational costs in evaluating fee levels as described in the NPRM. 85 FR at 11869. The Department notes that such costs are associated with maintaining well-functioning immigration proceedings that balance due process and efficiency interests, which is of interest to both DHS and respondents, as well as the general public, and that the Attorney General may charge fees for adjudication and naturalization services at a rate that would ensure recovery of both the full cost of providing all such services, including similar services that may be provided without charge to certain categories of aliens, and any additional administrative costs. INA 286(m), 8 U.S.C. 1356(m).

Commenters' suggestions regarding immigration detention and non-EOIR programs are outside the scope of this rulemaking and, more generally, outside the purview of the Department. ICE, which is responsible in part for immigrant detention policies and facilities, and U.S. Customs and Border Protection, of which Border Patrol agents are a part, are components within DHS. *See Operational and Support Components,* Department of Homeland Security, *https://www.dhs.gov/operational-and-support-components* (last updated Nov. 17, 2018). The Department does not have authority over how DHS implements its authority on these topics, and the budgetary choices made by DHS could not in turn be altered to support EOIR's adjudications without congressional action.

13. Policy Disagreements and Concerns

Comment: Commenters expressed multiple objections to the NPRM related to policy decisions surrounding family separation and harm to discrete populations.

Commenters opposed the NPRM, stating that it would separate families.[43] Commenters explained that aliens would be unable to afford the proposed increased application fees for all family members. Further, commenters were concerned that aliens unable to afford to appeal immigration judge decisions would face deportations, thus separating families of mixed legal status. Commenters feared that such separation would subsequently result in children raised without both parents, removal to countries where aliens have little to no ties, family members burdened to assist separated family members, aliens remaining in the United States needing and seeking public assistance, furthered emotional and mental harm, and numerous other hardships related to financial and physical wellbeing. For these reasons, commenters asserted that the rule would destroy family unity, which they alleged is a bedrock principle of immigration law.

Commenters were also concerned that the rule would harm discrete groups of aliens, specifically UACs, detainees, women, and victims of trafficking and domestic violence, thereby inflicting or furthering mental health consequences. One commenter explained that ''[a]ll immigrants, by virtue of being away from their home country, are considered vulnerable. For those who do not have the financial resources to support themselves in a new country, poverty creates additional vulnerability.'' Accordingly, commenters were concerned that the rule would have significant consequences, in addition to its effects on mental health, for specific populations.

For UACs, commenters emphasized they are by definition in an already vulnerable state and typically lack financial resources, which results in a significant need for pro bono counsel. Commenters stated that because UACs would be unable to afford increased fees, the new fees would be passed on to organizations and counsel and ultimately result in fewer pro bono organizations and attorneys who will be both willing and able to provide pro bono services to UACs. Further, commenters alleged that, in their experience, fee waivers for UACs have been consistently denied by DHS and are, therefore, an insufficient remedy for this population. In this way, commenters opposed the NPRM as a violation of UAC rights to access to the legal system and protection from deportation, which commenters asserted are protected by domestic and international law. Relatedly, one commenter opposed the rule based on its effect on applicants for SIJ classification. Stating that those children need ''unfettered access to BIA appellate review and motions to reopen or reconsider,'' the commenter asserted that the NPRM's increased fees will place an unnecessary burden on applicants for SIJ classification to demonstrate financial inability in requesting a fee waiver, which they have already demonstrated because ''SIJ[ ] petitioners and recipients, by definition, have already lost the financial and emotional support of one parent, if not both.''

With regard to detainees, commenters expressed the same concerns regarding their vulnerability, financial hardship, and difficulty securing representation. Commenters were concerned that detainees would either lack the necessary money to pay fees, encounter difficulty securing representation who could pay the increased fees, or be unable to navigate the fee waiver process on their own based on lacking resources in detention facilities.

Commenters also explained that the rule would negatively impact women and girls because they typically earn less than their male counterparts and are therefore less likely to be able to pay increased fees. Further, commenters explained that women and girls are more likely to have experienced gender-based domestic violence and related harms, upon which their applications for relief are based.

Commenters alleged that victims of domestic violence and transgender individuals are also significantly impacted by the rule because they lack adequate finances, have increased vulnerabilities, and may have suffered specific previous trauma.

Several commenters emphasized the consequences to trafficking victims imposed by the rule. Commenters stated that trafficking victims were especially vulnerable, given the harm imposed by their traffickers. Commenters explained that because trafficking victims are financially dependent on their traffickers, the increased fees will likely preclude them from pursuing review before the BIA and the Federal courts. In addition, commenters explained that trafficking victims lack both the funds to

[43] This section responds to comments regarding family separation, except in the context of statutory withholding of removal and protection under the CAT. For comments concerning family separation in that context, see Section II.C.8 of this preamble.

pay the increased fees and the documentation required to apply for a fee waiver, and, further, that immigration judges oftentimes lack understanding of the issues involved in human trafficking. Without access to courts, commenters stated, trafficking victims would be deprived of congressionally authorized forms of relief and may be subject to further exploitation and abuse.

Response: The Department disagrees that the rule will separate families and harm discrete populations.

First, with regard to family separation, the commenters' concerns are entirely speculative and neglect the availability of a fee waiver. The rule does not require removal of particular family members or parents, nor does it preclude family members or parents from applying for such forms of relief. Rather, the rule simply increases fees for various applications for relief. *See generally* 85 FR 11866. The Department disagrees with the commenters' reasoning because multiple intervening factors must subsequently occur before family separation would result, and commenters' assertions that each intervening event will necessarily occur as alleged are speculative. Moreover, the merits of a case determine whether a removal order is entered, and the rule has no bearing on the relative merits of any applications filed in immigration proceedings.

Nevertheless, the Department reiterates the availability of a fee waiver for any alien, including children, parents, and family members, who is unable to pay the assigned fee for the applications or motions implicated by the rule. *See* 85 FR at 11868. Aliens may apply for a fee waiver, upon which the immigration judge or the BIA may exercise discretionary authority to waive the fee for the application. *See* 8 CFR 1003.8(a)(3), 1003.24(d), and 1103.7(c). The fee waiver process was established to assist aliens who are unable to pay.

As noted in the NPRM, EOIR estimated that 36 percent of fee-related filings did not result in a collection of fees due to fee waivers. Out of 19,874 completed case appeals or motions decided by the Board in FY 2019, it granted, either tacitly or explicitly, approximately 5,499 fee waivers and recorded no fee waiver requested for approximately 14,322 cases. Although the Board does not track fee waiver denials separately, the data suggest that, at most, the Board denied 53 fee waiver requests in FY 2019.[44] Consequently, concerns about the inability of respondents to obtain fee waivers are unfounded.[45]

In addition, the Department reiterates that respondents may access the List of Pro Bono Legal Service Providers, maintained by the Department's Office of Legal Access Programs. *See* 8 CFR 1003.61. This list contains contact information for pro bono legal service providers and referral services that refer aliens to pro bono counsel. *See List of Pro Bono Legal Service Providers,* Exec. Office for Immigration Rev., *https://www.justice.gov/eoir/list-pro-bono-legal-service-providers* (last updated Apr. 14, 2020).

Second, the Department disagrees that the rule harms the specified populations—UACs, detainees, women, transgender individuals, and victims of trafficking and domestic violence.[46] With the continued availability of fee waivers, in addition to the List of Pro Bono Legal Service Providers previously described, the rule provides a mechanism for aliens who are unable to pay to seek a waiver of the fees. Moreover, many of these populations have paid EOIR filing fees for years—*e.g.,* for motions to reopen or Forms EOIR–42A or EOIR–42B—with no indication that the fees affect those populations any differently than the alien population as a whole.

The Department disagrees that fee waivers are not a viable option. Fee waiver determinations are based upon an immigration judge's exercise of discretionary authority following a case-by-case analysis. *See* 8 CFR 1003.8(a)(3), 1003.24(d), and 1103.7(c). Despite commenters' anecdotal and unsubstantiated allegations that fee waivers for any particular population are consistently denied, the Department has no data to indicate such a practice.[47] In regard to the effects cited by commenters that the rule would have on various populations, such effects are wholly speculative and depend most significantly on the merits of the particular case.

14. Bad Motives

Comment: Some commenters who opposed the NPRM alleged that it was based on anti-immigrant sentiment to discourage appeals, reduce immigration judge authority, and curb access to courts by ''pricing out'' certain aliens. Numerous commenters expressed different versions of the sentiment that the NPRM was ''cruel,'' such as stating that the rule was ''downright cruel,'' ''evidence[d] the agency's lack of compassion,'' or constituted a ''cruelly excessive extra burden on those already burdened by the bureaucratic processes involved in immigration review.''

Other commenters opposed the NPRM for discriminating against non-white, low-income people. One commenter described it as a ''race-based wealth test.'' Some commenters alleged that the rule targets the poor because it makes immigration available only to the wealthy who can afford the increased fees. Commenters explained that low-income aliens would be without redress, ''simply because they are poor.'' Commenters tried to illustrate their position by citing a Federal Reserve report stating that 40 percent of all Americans would struggle to pay an unexpected $400 bill. *See Report on the Economic Well-Being of U.S. Households in 2018—May 2019,* Federal Reserve, *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm* (last visited Sept. 14, 2020). Commenters also asserted that many aliens' struggle to retain representation in removal proceedings provided further evidence that aliens would likely struggle to pay the higher fees, but did not offer any evidence that aliens are unable to obtain counsel due to prohibitive cost.

Response: The Department disagrees that the rule is cruel or discriminatory, or that it targets the poor. The rule was not based on ill-conceived or anti-immigrant motives, and the NPRM was not meant to discourage appeals, reduce immigration judge authority, or curb access to courts.

[44] Depending on the nature of the denial of the fee waiver request (*e.g.,* a denial based on the submission of an unsigned or incomplete Fee Waiver Request Form, Form EOIR–26A), some fee waiver requests that are initially denied may subsequently be granted if the request is corrected.

[45] Information on fee waiver grants and denials at the immigration court level is not tracked by the Department. Nevertheless, the denial of a fee waiver would lead to the immigration judge denying an application or motion, which is then appealable to the Board, including with a potential fee waiver request for the appeal. Consequently, a respondent whose fee waiver request is denied by an immigration judge has recourse to review that decision as part of an appeal to the Board.

[46] The Department reiterates that DHS has not assessed a $50 fee for asylum applications filed by a UAC in removal proceedings. 84 FR at 62319.

[47] Indeed, because there was until recently no fee for an asylum application and because most other relevant applications for the populations identified—*e.g.,* nonimmigrant visas for victims of human trafficking, special immigrant visas for certain categories of juveniles, or immigrant visas for certain victims of domestic violence—are adjudicated by DHS, it is implausible that EOIR has ''consistently denied'' fee waivers for these populations. Moreover, to the extent that some commenters allege that all aliens are ''vulnerable,'' EOIR's fee waiver statistics noted above and previously, 85 FR at 11869, do not indicate that it consistently denies such waivers to all aliens.

Generally, the NPRM proposed to amend EOIR regulations involving fees. More specifically, and in accordance with EOIR's fee review, it proposed to increase fees for EOIR applications, appeals, and motions; update cross-references to DHS regulations regarding fees; and make a technical change regarding FOIA requests. *See generally* 85 FR 11866. The rule does not amend EOIR's regulations regarding fees established by DHS for DHS forms filed or submitted in EOIR proceedings, nor does the rule add new fees or affect an alien's ability to apply for a fee waiver request. *See id.*

The changes in this final rule apply to any alien who files a relevant form under the rule, unless the alien applies for and receives a fee waiver. In this way, the rule does not discriminate, and it targets no particular group. The rule applies equally to all aliens, and fees charged are based on the application filed, contrary to commenters' assertions that the rule is discriminatory.

Further, the rule does not target the ''poor'' or low-income individuals in proceedings. As explained above, a fee waiver remains available for individuals who are unable to pay the fee. 8 CFR 1003.8(a)(3), 1003.24(d). Accordingly, the Department disagrees that an alien's access to the EOIR applications or motions for which EOIR imposes a fee is conditioned in any way on a wealth test or other financial status. With respect to the Federal Reserve report that was cited by commenters regarding Americans' ability to pay unexpected fees, the Department notes that publication of this rule provides notice to the public such that individuals who have a valid claim for relief will have time to prepare for filing any associated applications or motions, including filing fees. Accordingly, such fees are not necessarily unexpected. Additionally, the Department notes that the above-cited report by the Federal Reserve states that 39 percent of adults would have ''more difficulty'' paying an unexpected fee, with ''more difficulty'' defined as an individual being unable to pay with cash or a cash equivalent at the time of the bill. Only 12 percent of Americans would be unable to pay. Those aliens who fall into a similar category of the 12 percent of Americans who would be unable to pay at all might be eligible for a fee waiver pursuant to § 1103.7(c).

The Department also disagrees with commenters' assertions that the rule is ''cruel.'' As explained in the NPRM, EOIR's processing costs currently exceed the assessed fees for EOIR applications for relief, appeals, and motions, which have not changed since 1986. 85 FR at 11870. Accordingly, the rule updates EOIR's fees to more accurately reflect the processing costs incurred by the agency in providing such services. *See id.* The updated fees do not recover the full costs of the services; rather, the updates more accurately reflect the costs for the Department to provide such services. The Department recognizes that its services are significant procedural tools that serve the public interest and facilitate accurate administrative proceedings. *Id.* (citing *Ayuda II,* 848 F.2d at 1301). In this way, the Department preserves access to courts and the appeal process. Given this value, the Department was also careful to update its fees in accordance with the known, quantifiable costs of direct salaries, rather than variable costs such as overhead and non-salary benefits, thereby balancing the need to update fees with public policy interests. *See generally* 85 FR 11869. Consequently, the Department disagrees that the rulemaking updating the fees is ''cruel.''

15. Other Suggestions

Comment: Commenters suggested that, rather than raising fees as proposed by the NPRM, EOIR could transfer $8 million of unclaimed bond money to EOIR pursuant to section 286(r) of the Act (8 U.S.C. 1356(r)).

Response: Given the limitations of section 286(r)(3) of the Act (8 U.S.C. 1356(r)(3)) identified by the commenters, the Department reiterates its decision in the NPRM to raise fees in accordance with the authority in section 286(m) of the Act (8 U.S.C. 1356(m)). *See* 85 FR at 11866, 11870. Subsection (r)(3) limits refunds to the agency in the following scenarios: (1) Expenses incurred to collect breached bonds and (2) expenses associated with the detention of aliens. INA 286(r), 8 U.S.C. 1356(r). Therefore, recovery of processing costs through updating fees is proper and consistent with the agency's statutory authority in section 286(m) of the Act (8 U.S.C. 1356(m)) rather than section 286(r) of the Act (8 U.S.C. 1356(r)).

Comment: Commenters suggested that the Department should clarify that if an asylum seeker properly submits a fee waiver application that is rejected by the immigration judge, the asylum seeker's application would qualify for an extraordinary circumstances exception and the asylum seeker would not be denied asylum based on the one-year filing deadline. Commenters further explained that this clarification should be made notwithstanding the language of the Immigration Court Practice Manual, which states that ''[i]f a filing is submitted without a required fee and the request for a fee waiver is denied, the filing will be deemed defectively filed and may be rejected or excluded from evidence.'' Immigration Court Practice Manual ch. 3.4(d), Office of the Chief Immigration Judge, *https://www.justice.gov/file/1250706/download* (last updated July 2, 2020).

Commenters urged the Department to adopt relaxed fee waiver rules for particular individuals including but not limited to those who are: Detained, UACs, deemed mentally incompetent, or subject to the MPP. Commenters also recommended that such individuals be considered presumptively eligible for a fee waiver.

Response: The Department declines to adopt suggestions regarding fee waivers for asylum applications and the extraordinary circumstances exception. EOIR did not propose altering its longstanding fee waiver structure in the NPRM, and there is no supporting evidence that any such revisions are necessary. The NPRM addressed neither EOIR's longstanding regulations regarding fee waivers, 8 CFR 1103.7(c), nor the provisions relating to extraordinary circumstance determinations, 8 CFR 1208.4(a)(5).[48] The Department also declines to adopt relaxed fee waiver rules for certain individuals, including commenters' suggestion regarding presumptive eligibility. Fee waiver determinations are based on an alien's financial situation, and an alien's presence or absence in any asserted group says little about that particular alien's financial status. For example, 87 percent of aliens who have an asylum application pending before EOIR have representation, suggesting that such aliens may possess financial resources—or the access to such resources—that would not support providing presumptive fee waiver eligibility for all such aliens. Similarly, many detained aliens are lawful permanent residents who possess employment authorization and may have significant financial resources, making a presumption that they are entitled to a fee waiver inappropriate. Finally, these groups have existed for years, and there is no evidence that the existing fee waiver procedure, which is unchanged, is inadequate to address individual circumstances in individual cases.

Comment: One commenter complained about the EOIR process for accepting fees, which requires filers to pay through USCIS. The filer

[48] The Department also notes that the one-year filing deadline for asylum applications does not apply to UACs. 8 U.S.C. 1158(a)(2)(E).

recommended that EOIR accept fees electronically for all filings, whether at the immigration courts or the BIA. Another commenter argued that, rather than significantly increasing the fees, EOIR should focus on making filing processing more efficient, thereby reducing the costs needed to process filings requiring fees.

Response: The Department does not believe that any revisions to 8 CFR 1103.7(a) that would change the payment process are needed at this time; subsequently, payments must continue to be made in accordance with the regulation. Nevertheless, while electronic payment methods are not currently available for EOIR fees, the Department continues to modernize its technological capabilities. *See Welcome to the EOIR Courts & Appeals System (ECAS) Information Page,* Exec. Office for Immigration Rev., *https://www.justice.gov/eoir/ECAS* (last updated Sept. 8, 2020); *see also* EOIR Electronic Filing Pilot Program, 83 FR 29575 (June 25, 2018) (establishing a pilot electronic system for filing and case management). As EOIR continues to move toward further electronic system developments, the Department expects EOIR to also move toward additional electronic payment capabilities, including reducing the need to use DHS as a payment intermediary for the immigration courts.

Further, the Department continues to evaluate ways in which it may increase the ''productivity and timeliness of case processing by setting appropriate standards, streamlining procedures, and implementing staff-generated recommendations.'' *See About the Office: Goals,* Exec. Office for Immigration Rev., *https://www.justice.gov/eoir/about-office* (last updated Aug. 14, 2018). To that end, the Department has already made various changes to improve efficiency at EOIR,[49] and the Department appreciates commenters' suggestions on improving efficiency. Nevertheless, under statutory authority in section 286(m) of the Act (8 U.S.C. 1356(m)), the Department finds that updating fees properly allows the agency to recoup some of its processing costs, and thus declines to change the regulatory language of the NPRM with the publication of this final rule. *See* 85 FR at 11866, 11870.

Comment: One organization argued that the main driver of increased EOIR case receipts, which EOIR relies on as justification for these fee increases, are the actions of DHS and EOIR itself. For example, the organization explained that DHS has significantly increased its removal operations, which results in more relief applications being filed once aliens are placed into removal proceedings. Similarly, the organization stated that DHS and EOIR policies designed to limit asylum eligibility necessarily result in increases in applications for other forms of potential relief. The organization argued that these limitations, coupled with EOIR's case completion goals for immigration judges, result in increased denials of relief applications and lead to the increased filing of appeals and motions to reopen or reconsider.

Response: Although the Department acknowledges that new case filings reached record levels in FY 2019, Executive Office for Immigration Review Workload and Adjudication Statistics, *New Cases and Total Completions-Historical* (Oct. 13, 2020), *https://www.justice.gov/eoir/page/file/1139176/download* (showing 545,729 new cases filed in FY 2019, the highest single-year total since EOIR was established in 1983), that number supports the Department's need to review and update its fee structure regardless of the cause. Moreover, the Department finds unpersuasive the commenter's tacit suggestion that if DHS declined to enforce the laws against illegal immigration, then it would file fewer cases with EOIR, which would, in turn, have fewer cases to adjudicate and, thus, not need to raise fees. The Department recognizes the commenter's policy disagreement with DHS's immigration enforcement priorities, but that disagreement is beyond the scope of this rulemaking. Moreover, DHS, not EOIR, is statutorily tasked by Congress with ''[e]stablishing national immigration enforcement policies and priorities,'' Homeland Security Act of 2002, Public Law 107–296, sec. 402(5), 116 Stat. 2135, 2178 (codified at 6 U.S.C. 202(5)), and it is not appropriate for EOIR to review DHS's decision to initiate proceedings to remove an alien from the United States. *See, e.g.,* Matter of Quintero, 18 I&N Dec. 348, 350 (BIA 1982) (''Once deportation proceedings have been initiated by the District Director, the immigration judge may not review the wisdom of the District Director's action''); *see also* Lopez-Telles v. INS, 564 F.2d 1302, 1304 (9th Cir. 1977) (per curiam) (''The immigration judge is not empowered to review the wisdom of the [now DHS] in instituting the proceedings.'').

The Department disagrees with commenters' allegations that Government policies necessarily result in increases in applications for other forms of potential relief. Individuals choose to file motions, appeals, and applications for relief or protection based on their own individual circumstances, none of which affect the Department's authority under section 286(m) of the Act (8 U.S.C. 1356(m)) to charge fees. Moreover, all types of relief from removal have their own eligibility criteria—*e.g.,* cancellation of removal for certain nonpermanent residents, INA 240A(b) (8 U.S.C. 1229b(b))—and there is no statutory link between eligibility for asylum and eligibility for some other form of relief. To the contrary, eligibility for most other forms of relief from removal require either some significant period of residence in the United States, *e.g.,* INA 240A(b)(1)(A) (8 U.S.C. 1229b(b)(1)(A)) (requiring ten years of continuous physical presence in the United States), or some established connection to an employer or a relative who could petition on behalf of the alien, *e.g.,* INA 203(a), (b) (8 U.S.C. 1153(a), (b)) (preference allocation system for immigrant visas based on familial relationships or employment). Consequently, rules restricting asylum eligibility for recent or future arrivals to the United States have little expected impact on applications for other types of relief. In short, there is no basis for the commenters' alleged link between Government asylum policies and increased applications for other types of relief from removal.

Commenters also did not substantiate their assertions that Government policies have led to increased appeals or motions to reopen or reconsider, and their allegations rest on the implicit premise that either immigration judges are unethical or incompetent—and, thus deny otherwise meritorious claims that then require appeals or motions to reopen—or aliens without meritorious claims should not be charged

[49] The Department has recently undertaken several initiatives to improve efficiency. The Department has prioritized immigration judge hiring, increasing the number of immigration judges from 245 in 2010 to 446 in the first quarter of 2020. *See Exec. Office for Immigration Rev. Adjudication Statistics: Immigration Judge (IJ) Hiring,* Oct. 2020, *https://www.justice.gov/eoir/page/file/1242156/download.* Further, the Department increased the number of appellate immigration judges authorized to serve on the BIA from 17 to 21 in 2018. Expanding the Size of the Board of Immigration Appeals, 83 FR 8321 (Feb. 27, 2018). Recently, the Department announced that it has further increased this number to 23. Expanding the Size of the Board of Immigration Appeals, 85 FR 18105 (Apr. 1, 2020); EOIR Announces Three New Appellate Immigration Judges, Exec. Office for Immigration Rev., Aug. 7, 2020, *https://www.justice.gov/eoir/page/file/1302796/download.* EOIR has also taken steps to ensure that courtrooms are utilized to the maximum extent during business hours. James R. McHenry III, *Policy Memorandum 19–11: No Dark Courtrooms,* Exec. Office for Immigration Rev., Mar. 29, 2019, *https://www.justice.gov/eoir/file/1149286/download* (memorializing policies to reduce and minimize the impact of unused courtrooms and docket time).

appropriate fees for filing appeals or motions to reopen. Neither assertion, however, is a persuasive reason for forgoing the fee review and increases proposed by the Department. Again, the appropriateness of filing a motion or appeal rests on the individual circumstances of the alien, not on any particular policy of the Government.[50]

16. Miscellaneous

Comment: Commenters stated that the proposed fees in the NPRM were unfair because of the disparity between EOIR's adjudications budget and the DHS's enforcement budget. Specifically, commenters asserted that it was unfair for the Department to pass the costs of adjudications on to aliens where the United States was willing to ''pay billions of dollars'' in enforcement operations.

Response: The Department disagrees that the fees are ''unfair.'' While the Department submits an annual budget request, Congress ultimately determines agency budget allocations through the appropriations process, and the Department does not have any control over the funds appropriated to DHS, a separate agency, for enforcement operations. At the same time, and independent of the appropriations process, Congress has authorized the Department to charge fees for immigration adjudication, and expressed its general sense that agencies should impose fees in order to be as self-sustaining as possible, 31 U.S.C. 9701(a). INA 286(m), 8 U.S.C. 1356(m). The Department exercises such statutory authority in updating the fees to more accurately reflect EOIR's processing costs, and the Department finds that proper exercise of statutory authority is not ''unfair.''

Comment: Regarding the Petition Clause of the First Amendment, which protects the right of individuals to appeal to courts for dispute resolution, *see Borough of Duryea* v. *Guarnieri,* 564 U.S. 379, 387 (2011), commenters explained that ''absent a uniform, accessible, rational fee-waiver process that allows indigent individuals to consistently have fees waived—and . . . there is no evidence that EOIR has such a process—the proposed changes violate that constitutional right.''

Response: The rule does not violate the Petition Clause of the First Amendment, which secures the right ''to petition the Government for a redress of grievances.'' U.S. Const. amdt. I. Commenters cited *Borough of Duryea,* 564 U.S. 379, which states that ''the Petition Clause protects the right of individuals to appeal to courts and other forums established by the government for resolution of legal disputes.'' *Id.* at 387. The contours of the Petition Clause have not definitely been extended to include aliens[51] implicated by the rule at hand; however, even assuming that aliens possess rights under the Petition Clause, the rule does not alter the longstanding ability of aliens to access the immigration courts and to appeal a decision by an immigration judge. INA 240(c)(5), 8 U.S.C. 1229a(c)(5); *see also* 8 CFR 1240.13(d). The rule only proposed changes to the fee that must be submitted with such application. Further, although the Department disagrees that the Petition Clause mandates a particular fee waiver process, the rule does not disturb the longstanding regulatory allowance for a fee waiver for aliens unable to afford the new fees. This process applies uniformly to all aliens in proceedings, and determinations whether to grant a fee waiver request are discretionary. *See* 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c). The Department believes this process is rational and accessible and allows for individuals to have fees waived upon a discretionary determination of inability to pay.

Comment: Commenters objected to the NPRM's justification that raising fees would save taxpayer money. Specifically, commenters asserted that only a small portion of money collected from income taxes went toward EOIR's operations. Specifically, the commenters stated that out of the average amount of money that each of the 143.3 million taxpayers paid in 2017, which amounted to approximately $11,165, only $2.79 went to fund EOIR, as compared with $108.86 per taxpayer to CBP and $69.08 per taxpayer to ICE.

Response: The Department presented a number of factors underlying the updated fees, including taxpayer subsidization. Based on recalculations to exclude DHS-only motions, the chart provided in the NPRM is updated below.

[50] The commenter provided no empirical substantiation for the assertion that performance measures implemented for immigration judges lead to increased denials of applications, nor is there any logical basis to support such an assertion. The immigration judge performance measure cited by commenters is based on completions, not outcomes, and whether an immigration judge grants or denies relief is wholly irrelevant to the measure. Rather, the commenter again appears to be asserting that immigration judges are either unethical or incompetent—and, thus, deny applications based on factors other than the record and applicable law—but that assertion is unfounded and not well taken by the Department. *See United States* v. *Chem. Found., Inc.,* 272 U.S. 1, 14–15 (1926) (''The presumption of regularity supports the official acts of public officers, and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties.'').

[51] Constitutional protections do not necessarily apply equally to U.S. residents and non-residents alike. For example, the Court has suggested that '' 'the people' protected by the Fourth Amendment, and by the First and Second Amendments, and to whom rights and powers are reserved in the Ninth and Tenth Amendments, refers to a class of persons who are part of a national community or who have otherwise developed sufficient connection with this country to be considered part of that community.'' *United States* v. *Verdugo-Urquidez,* 494 U.S. 259, 265 (1990). Courts, however, have not definitively determined the extent and application to aliens of the Petition Clause of the First Amendment.

Form	Receipts FY 2009	Receipts FY 2018	FY 2018 Cost to Agency	FY 2018 Fees Charged[52]	FY 2018 U.S. Taxpayer Subsidization
EOIR-26	16,839	29,123	$28,396,381	$3,203,530	$25,192,851
EOIR-29	4,314	1,914	$1,349,006	$210,540	$1,138,466
EOIR-40	206	158	$48,566	$15,800	$32,766
EOIR-42A	5,272	3,426	$1,053,084	$342,600	$710,484
EOIR-42B	16,327	30,421	$10,954,602	$3,042,100	$7,912,502
Motion to Reconsider (OCIJ)	566	1,043	$145,937	$114,730	$31,207
Motion to Reopen (OCIJ)	10,402	17,089	$2,610,687	$1,879,790	$730,897
MTRs (BIA)[53]	10,071	7,414	$6,636,420	$815,540	$5,820,880
Total	**63,997**	**90,588**	**$51,194,683**	**$9,624,630**	**$41,570,053**

85 FR at 11869.

To reiterate, in 2018 alone, U.S. taxpayers subsidized fee-based forms and motions by at least $41.5 million. 85 FR at 11869. As previously mentioned, the congressional appropriations process determines the amount of funding each agency receives. Commenters may disagree with the amount of money EOIR receives in comparison to other agencies, but beyond submitting a budget request, EOIR plays no role in determining the amount of funding it ultimately receives or the overall allocation of funding among agencies. Moreover, the Department maintains that consideration of taxpayer subsidization is one of many significant factors underlying its decision to update fees. Even if the cost per taxpayer were minimal, $41,570,053 in total is not an insignificant amount, and the Department disagrees with subsidizing fee-based forms to that extent using taxpayer dollars.

Comment: Commenters objected to the Department's description of its interests as purportedly being identical to those of DHS. Commenters explained that ''EOIR itself should be representing the equally important 'Federal interest' of fairness and justice for all parties who appear before the immigration court and BIA.'' Further, commenters asserted that the Department did not conduct an independent analysis of its obligations in setting fees but instead simply adopted the analysis from USCIS.

Response: The Department disagrees with commenters that it ever purported to have identical interests to DHS when DHS is a party before the agency in immigration proceedings. At issue is the following statement from the NPRM: ''As DHS is the party opposite the alien in these proceedings, EOIR's hearings provide value to both aliens seeking relief and the Federal interests that DHS represents.'' 85 FR at 11870. Through that statement, the Department sought to explain that revenue from updated fees would advance the public interest of ensuring accurate administrative proceedings, which in turn benefits both the alien and DHS. EOIR's interests are not identical to DHS's interests in immigration proceedings. EOIR administers the Nation's immigration laws through adjudication of removal cases and claims to defend against such removal, while DHS represents the Government's interest in enforcing such laws. In this way, EOIR provides fair and just proceedings for all parties before the agency, and the updated fees ensure that EOIR continues to provide such services. *See* 85 FR at 11870.

The Department also disagrees with commenters' allegations that the agency failed to conduct an independent analysis from USCIS. Both agencies exercise authority to set fees pursuant to section 286(m) of the Act (8 U.S.C. 1356(m)). Further, both agencies follow non-statutory guidance from OMB in exercising such authority. Accordingly, the analysis contained in EOIR's NPRM (85 FR 11866) is reasonably similar to the analysis contained in USCIS's NPRM (84 FR 62280). Notwithstanding this same statutory conferral of authority, the Department reiterates that it conducts its own independent analyses throughout its rulemaking

[52] Approximately 36 percent of these fees were not received due to fee waiver approvals. The impact of the waivers themselves is to provide a Government subsidy because the Government absorbs required costs on behalf of an individual who is subject to the fee. The taxpayer subsidization, therefore, is greater than the number provided in this chart.

[53] These numbers include both motions to reopen and motions to reconsider filed at the Board level.

activities as a separate agency from DHS.[54]

Comment: Commenters compared the NPRM to policies under prior administrations that established a streamlined appeal system whereby the BIA could affirm immigration judge decisions without opinion. Commenters asserted that under such procedures, litigants did not receive justice at the BIA and the number of Federal appeals increased. By contrast, commenters stated, when the BIA rescinded a number of the streamlining policies, Federal appeals dropped. The commenters opined that the NPRM would similarly burden the Federal courts by creating a new source of appeals: Denial of the fee waiver and subsequent dismissal of the appeal for lack of timely filing. The commenters opined that such appeals would likely be remanded to the BIA, increasing the backlog there. The commenters asserted that any money taken in by the fees paid under the NPRM would likely be expended by the Federal courts and Department attorneys ''in processing and likely remanding hundreds or thousands of cases in which fee waiver requests have been wrongly denied.''

Response: The Department disagrees with commenters' assertions that the increase in fees would result in an undue burden on Federal courts. As stated in the NPRM, this rule does not foreclose or limit the ability of aliens to seek a fee waiver for the appeal fee before the BIA. *See* 8 CFR 1003.8(a)(3); 85 FR at 11871. An alien who is unable to pay for the increased fee of an appeal would file the EOIR–26A, Fee Waiver Request. The availability of the fee waiver ensures aliens' continued access to the BIA, and in turn the Federal courts.

Moreover, the Department is unable to respond to commenters' assertions that there will be an increase in appeals of denied fee waivers because these concerns are merely speculative and beyond the scope of this rulemaking. Nothing in this rule affects the adjudication process of fee waiver applications and therefore does not implicate the need for additional appeals of fee waiver denials.

Comment: Commenters also asserted that the proposed rule will operate as an unlawful tax for individuals who rely on the immigration court system for relief. Commenters cited Article 29 of the Refugee Convention, which bars imposing on refugees ''duties, charges or taxes, of any description whatsoever, other or higher than those which are or may be levied on [signatories'] nationals in similar situations.'' One commenter asserted that the proposed rule violated Article 25 of the Convention because although ''fees may be charged for the services mentioned [t]herein,'' those ''fees shall be moderate and commensurate with those charged to nationals for similar services.''

Response: As previously explained in Section II.C.8 of this preamble, the rule does not violate Article 29 of the Refugee Convention. That reasoning also applies to Article 25's requirement that certain fees charged to refugees must be ''moderate and commensurate with those charged to nationals for similar services.'' Examples of such services are the Form I–130, Petition for Alien Relative, $560, and Form I–360, Petition for Amerasian, Widow(er), or Special Immigrant, $450. *See* 8 CFR 106.2(a)(6), (16). Accordingly, the Department finds that fees charged to refugees under the rule are reasonably commensurate with fees charged to nationals, such that the rule upholds United States treaty obligations.

III. Provisions of the Final Rule

The Department has considered and responded to the comments received in response to the proposed rule. In accordance with the authorities discussed above in Section I.A of this preamble, the Department is now issuing this final rule to finalize the NPRM. The final rule adopts the fee amounts set out in the proposed rule as final for the reasons discussed above in Section II of this preamble in responses to the comments received. As a result, the fees for those forms, motions, and applications for which EOIR charges a fee will be as follows:

Form/ Motion	Old Fee	New Fee
EOIR-26	$110	$975
EOIR-29	$110	$705
EOIR-40	$100	$305
EOIR-42A	$100	$305
EOIR-42B	$100	$360
MTR OCIJ	$110	$145
MTR BIA	$110	$895
EOIR-45	$110	$675

Applying the same 36 percent fee waiver rate[55] that EOIR previously estimated, see 85 FR at 11869 n.11,[56] these new fees would be expected to result in the fee revenues for Fiscal Year 2021 that are reflected in the table below.[57] The table also presents the incremental fee revenue that would be

[54] However, as stated elsewhere, the Department's analysis and fee-setting decisions only apply to those applications, appeals, or motions controlled by the Department and not to forms that are maintained by DHS, such as the Form I–589. Accordingly, the Department does not conduct analyses for fees set by DHS for DHS forms.

[55] The fee waiver rate was not applied to the EOIR–29 or the EOIR–45 due to the low number of filings projected. For the other forms, the impact of the waivers themselves is to provide a Government subsidy because the Government absorbs required costs on behalf of an individual who is subject to the fee. The taxpayer subsidization, therefore, is greater than contemplated by the incremental fee revenue alone.

[56] The Department notes that this rate may be low as more aliens may file for fee waivers and, thus, more waivers may be granted following the implementation of this rule. However, EOIR is unable to more specifically predict future fee waiver grant rates because each fee waiver request is an individual adjudication and because EOIR does not have data on the average income of aliens who file these forms and motions today or other data that would be required to increase this prediction's accuracy.

[57] The Department notes that FY 2021 began prior to the publication of this final rule. The projections for FY 2021 presumed that the new fees would be in effect for the entire fiscal year.

paid [58] by applicants or by others assisting the applicants, including family, friends, or social agencies. Aggregating this incremental fee revenue across fee types gives an estimate of the transfer effects of the rule, which are estimated to be about $45.2 million in FY 2021. This incremental fee revenue is estimated based on an assumption that the fee increases will not lead to a reduction in applications. The incremental fee revenue also represents an estimate of the expected transfer effects of the rule from applicants, and individuals or groups assisting those applicants, to the Federal Government. The table also provides the actual cost to the Government of providing the covered services based on the Government's activity-based costing study for these services.

Form/ Motion	FY 2021 Cost to Government[59]	New Fee	FY 2021 Projected[60] Fee Revenue (undiscounted)	FY 2021 Projected Fee Revenue (3% discount)	FY 2021 Projected Fee Revenue (7% discount)	FY 2021 Incremental Fee Revenue
EOIR-26	$59,315,217	$975	$37,959,792	$36,820,998	$35,302,607	$33,677,149
EOIR-29	$0[61]	$705	$0	$0	$0	$0
EOIR-40	$71,927	$305	$45,677	$44,306	$42,479	$30,701
EOIR-42A	$830,233	$305	$527,235	$511,418	$490,329	$354,371
EOIR-42B	$16,148,160	$360	$10,334,822	$10,024,778	$9,611,385	$7,464,038
MTR OCIJ	$2,968,200	$145	$1,893,120	$1,836,326	$1,760,602	$456,960
MTR BIA	$5,531,842	$895	$3,636,134	$3,527,050	$3,381,605	$3,189,235
EOIR-45	$677.11	$675	$675	$655	$628	$565
TOTAL	$84,866.26	--	$52,397,455	$52,765,531	$50,589,635	$45,173,019

In addition, this final rule, like the NPRM, includes regulatory cross-reference changes and corrections for the reasons discussed above in Section II. However, because the USCIS final rule is currently enjoined as noted above, this final rule revises EOIR's cross-references to direct the reader to both 8 CFR 103.7 and 8 CFR part 106 in order to prevent confusion and ensure consistency regardless of how the litigation over that rule is resolved. In addition, this final rule includes an additional correction to the cross-reference to 8 CFR 103.7(c) in 8 CFR 1245.13(g) that was inadvertently not included in the similar changes set out in the NPRM.

IV. Regulatory Requirements

A. Regulatory Flexibility Act

The Department has reviewed this regulation in accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612) (''RFA''), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, tit. II, 110 Stat. 847, and has determined that this rule would not have a significant economic impact on a substantial number of small entities. The rule would not regulate ''small entities'' as that term is defined in 5 U.S.C. 601(6). Only individuals, rather than entities, are responsible for paying the fees affected by this proposed rule. This position reflects the Department's consistent view for decades regarding fees in EOIR proceedings. *See, e.g.,* Powers and Duties of Service Officers; Availability of Service Records, 51 FR 2895 (Jan. 22, 1986) (proposed rule for changes to EOIR's fee schedule for appeals and motions) (''In accordance with 5 U.S.C. 605(b), the Attorney General certifies that the rule will not have a significant economic impact on a substantial number of small entities.''); 51 FR at 39994 (final rule adopting in pertinent part the proposed changes to the fee schedule) (maintaining the position that changes to the fee schedule will not have a significant impact on a substantial number of small entities). The Department is unaware of any challenge to this position and finds no reason to depart from that well-established position. The rule applies to aliens in immigration proceedings, who are individuals, not entities. *See* 5 U.S.C. 601(6). The rule does not limit in any way the ability of practitioners to accept cases, manage dockets, or assess fees. Indeed, nothing in the rule in any fashion regulates the legal representatives of such individuals or the organizations by which those representatives are employed, and the Department is unaware of cases in which the RFA's requirements have been applied to legal representatives of entities subject to its provisions, in addition to or in lieu of the entities themselves. *See* 5 U.S.C. 603(b)(3) (requiring that an RFA analysis include a description of and, if feasible, an estimate of the number of ''small entities'' to which the rule ''will apply''). To the contrary, case law indicates that indirect effects on entities not regulated by a proposed rule are not subject to an RFA analysis. *See, e.g., Mid-Tex Elec. Coop., Inc.* v. *FERC,* 773 F.2d 327, 342–43 (D.C. Cir. 1985) (''[W]e conclude that an agency may properly certify that no regulatory flexibility analysis is necessary when it determines that the rule will not have a significant

[58] Incremental fee revenue was calculated by applying the FY 2021 projected filings to former and new fee amounts, including the 36% of forms with approved fee waivers.

[59] The cost to the Government is the product of the projected number of filings and the cost calculated in the activity-based costing study.

[60] FY 2021 projections were calculated applying the average percent change over ten fiscal years to FY 2020 estimated receipts. EOIR calculated the FY 2020 estmated receipts as follows. First, EOIR added the first three quarters of FY 2020 receipts and divided by three to get an estimate for the last quarter of FY 2020. Second, EOIR added together the first three quarters along with the estimated last quarter to get the total. Next, the agency calculated the percent increase or decrease between each fiscal year and the average percent change.

[61] Projections result in zero filings of Form EOIR–29. Each filing would cost the Government $704.81 based on the activity-based costing study.

economic impact on a substantial number of small entities that are subject to the requirements of the rule. . . . Congress did not intend to require that every agency consider every indirect effect that any regulation might have on small businesses in any stratum of the national economy. That is a very broad and ambitious agenda, and we think that Congress is unlikely to have embarked on such a course without airing the matter.''); *Cement Kiln Recycling Coal.* v. *EPA,* 255 F.3d 855, 869 (D.C. Cir. 2001) (per curiam) (''Contrary to what [petitioner] supposes, application of the RFA does turn on whether particular entities are the 'targets' of a given rule. The statute requires that the agency conduct the relevant analysis or certify 'no impact' for those small businesses that are 'subject to' the regulation, that is, those to which the regulation 'will apply.' . . . The rule will doubtless have economic impacts in many ectors of the economy. But to require an agency to assess the impact on all of the nation's small businesses possibly affected by a rule would be to convert every rulemaking process into a massive exercise in economic modeling, an approach we have already rejected.'' (citing *Mid-Tex,* 773 F.2d at 343)); *see also White Eagle Coop. Ass'n* v. *Conner,* 553 F.3d 467, 480 (7th Cir. 2009) (''The rule that emerges from this line of cases is that small entities directly regulated by the proposed [rulemaking]—whose conduct is circumscribed or mandated—may bring a challenge to the RFA analysis or certification of an agency. . . . However, when the regulation reaches small entities only indirectly, they do not have standing to bring an RFA challenge.'').

Further, the Department has consistently maintained this position regarding immigration regulations aimed at aliens, rather than practitioners who represent aliens, including much broader and more sweeping rulemakings. *See, e.g.,* Inspection and Expedited Removal of Aliens; Detention and Removal of Aliens; Conduct of Removal Proceedings; Asylum Procedures, 62 FR 444, 453 (Jan. 3, 1997) (certifying that the rule would not have a significant impact on a substantial number of small entities because it ''affects only Federal government operations'' by revising the procedures for the ''examination, detention, and removal of aliens''). That conclusion was reiterated in the interim rule, 62 FR 10312, 10328 (Mar. 6, 1997), which was adopted with no noted challenge or dispute. This final rule is similar, in that it, too, affects only the operations of the Federal Government by amending certain discrete categories of fees related to immigration forms filed by aliens. The Department thus believes that the experience of implementing the prior rules cited above supports its conclusion that there is no evidence that this final rule will have a significant impact on small entities as contemplated by the RFA.

B. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

C. Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act. 5 U.S.C. 804(2). This rule would not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. Executive Orders 12866, 13563, and 13771

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). Executive Order 13563 emphasizes the importance of using the best available methods to quantify costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 13771 directs agencies to reduce regulation and control regulatory costs and, for all qualifying regulations, to identify at least two existing regulations for elimination.

This rule has been drafted in accordance with the principles of Executive Order 12866, section 1(b), and Executive Order 13563. The Department considers this rule to be a ''significant regulatory action'' under section 3(f)(3) of Executive Order 12866 because it materially alters user fees, but it is not an economically significant action because the annual effect on the economy is less than $100 million annually. Accordingly, this rule has been submitted to OMB for review. This rule imposes transfer payments between the public and the Government and does not impose any new cost burdens that will need to be offset under Executive Order 13771. Thus, this rule is not subject to the requirements of Executive Order 13771.

In the spring of 2018, EOIR conducted a comprehensive study using activity-based costing to determine the cost to EOIR for each type of application, appeal, and motion for which EOIR levies a fee under 8 CFR 1103.7(b). EOIR's methodology for conducting this comprehensive study was as follows:

First, in the survey-data phase, EOIR gathered survey data and consulted with OCIJ and BIA experts to determine the appropriate staff positions involved and the average time required to process and adjudicate each fee-based form or motion. EOIR also researched data from OPM and the GSA to determine the average salary rates for the applicable staff positions, including both Federal employees and EOIR contractors.

Second, in the process-mapping phase, EOIR developed step-by-step process maps, with assigned times and staff positions, for each fee-based form or motion processed in the OCIJ and the BIA. OCIJ and BIA experts validated any assumptions made during the process-mapping phase.

Third, in the activity-based-costing phase, EOIR allocated the salary costs from the GSA and OPM data to each step in the process, based on the amount of time the step takes, the average salary of the responsible staff, and the percentage of total cases in which the step occurs. As discussed above, EOIR did not include other costs, such as the overhead costs for EOIR space that is used for processing applications, fringe benefits received by EOIR staff and contractors, interpreter costs, Federal Records Center costs, non-EOIR government agency costs, or the costs and time to process any non-fee-based application that is submitted in conjunction with a motion to reopen or reconsider. *See* 8 CFR 1003.23(b)(3) (''Any motion to reopen for the purpose of acting on an application for relief must be accompanied by the appropriate application for relief and all supporting documents.''). These costs were not included in the analysis because they represent costs that are incurred regardless of processing fee-based motions or forms or because they

are not applicable in every adjudication of a fee-based motion or form, and DOJ did not employ a methodology to assign such costs equitably to various motion or form types.

EOIR used this methodology to calculate an estimated cost for processing each form or motion for which EOIR levies a fee. The results of the activity-based-costing analysis are as follows:

1. EOIR-40, Application for Suspension of Deportation

Staff Level	Total Cost, by Staff Level
Immigration Judge	$277.51
Judicial Law Clerk	$17.78
Legal Assistant	$12.08
Interpreter	$0.00
TOTAL	**$307.38**

Process Category	Total Cost, by Process Category
Administrative	$12.08
IJ Prep Time	$77.66
In-Court Time	$149.58
Written Decisions	$68.06
TOTAL	**$307.38**

2. EOIR-42A, Application for Cancellation of Removal for Certain Permanent Residents

Staff Level	Total Cost, by Staff Level
Immigration Judge	$277.51
Judicial Law Clerk	$17.78
Legal Assistant	$12.07
Interpreter	$0.00
TOTAL	**$307.38**

Process Category	Total Cost, by Process Category
Administrative	$12.08
IJ Prep Time	$77.66
In-Court Time	$149.58
Written Decisions	$68.06
TOTAL	**$307.38**

3. EOIR-42B, Application for Cancellation of Removal and Adjustment of Status for Certain Nonpermanent Residents

Staff Level	Total Cost, by Staff Level
Immigration Judge	$315.74
Judicial Law Clerk	$32.27
Legal Assistant	$12.08
Interpreter	$0.00
TOTAL	**$360.10**

Process Category	Total Cost, by Process Category
Administrative	$12.08
IJ Prep Time	$74.91
In-Court Time	$149.58
Written Decisions	$123.52
TOTAL	**$360.10**

4. Motion to Reopen (OCIJ)

Staff Level	Total Cost, by Staff Level
Immigration Judge	$103.61
Judicial Law Clerk	$41.17
Legal Assistant	$7.99
TOTAL	**$152.77**

Process Category	Total Cost, by Process Category
Administrative	$7.99
IJ Prep Time	$38.95
Written Decisions	$105.83
TOTAL	**$152.77**

5. Motion to Reconsider (OCIJ)

Staff Level	Total Cost, by Staff Level
Immigration Judge	$90.76
Judicial Law Clerk	$41.17
Legal Assistant	$7.99
TOTAL	**$139.92**

Process Category	Total Cost, by Process Category
Administrative	$7.99
IJ Prep Time	$38.95
In-Court Time	$0.00
Written Decisions	$93.97
TOTAL	**$139.92**

6. EOIR-26, Notice of Appeal from a Decision of an Immigration Judge

Staff Level	Total Cost, by Staff Level
Legal Assistant (GS-05/06/07)	$5.42
Legal Assistant (GS-08/09)	$66.64
Admin Staff (GS-08/09)	$198.23
Paralegal	$83.12
Attorney	$537.52
Board Member	$76.38
Digital Image Processor	$7.75
TOTAL	**$975.05**

Process Category	Total Cost, by Process Category
Initial Processing	$140.68
Case Screening/Preparation	$116.44
Decision and Adjudication	$647.22
Final Processing	$70.71
TOTAL	**$975.05**

7. EOIR-29, Notice of Appeal to the Board of Immigration Appeals from a Decision of a DHS Officer

Staff Level	Total Cost, by Staff Level
Legal Assistant (GS-05/06/07)	$5.42
Legal Assistant (GS-08/09)	$66.64
Admin Staff (GS-08/09)	$121.49
Paralegal	$83.12
Attorney	$344.01
Board Member	$76.38
Digital Image Processor	$7.75
TOTAL	**$704.81**

Process Category	Total Cost, by Process Category
Initial Processing	$63.94
Case Screening/Preparation	$116.44
Decision and Adjudication	$453.71
Final Processing	$70.71
TOTAL	**$704.81**

8. EOIR-45, Notice of Appeal from a Decision of an Adjudicating Official in a Practitioner Disciplinary Case

Staff Level	Total Cost, by Staff Level
Legal Assistant (GS-08/09)	$33.32
Admin Staff (LIE, LA, or SA; GS-08/09)	$172.65
Attorney	$387.02
Board Member	$76.38
Digital Image Processor	$7.75
TOTAL	**$677.11**

Process Category	Total Cost, by Process Category
Initial Processing	$115.10
Decision and Adjudication	$496.72
Final Processing	$65.30
TOTAL	**$677.11**

9. Motion to Reopen/Reconsider (BIA)

Staff Level	Total Cost, by Staff Level
Legal Assistant (GS-05/06/07)	$5.42
Legal Assistant (GS-08/09)	$66.64
Admin Staff (LIE, LA, or SA; GS-08/09)	$118.30
Paralegal	$83.12
Attorney	$537.52
Board Member	$76.38
Digital Image Processor	$7.75
TOTAL	**$895.12**

Process Category	Total Cost, by Process Category
Initial Processing	$60.75
Case Screening/Preparation	$116.44
Decision and Adjudication	$647.22
Final Processing	$70.71
TOTAL	**$895.12**

As discussed above, these estimated costs calculated from the study demonstrate that EOIR's processing costs exceed the currently assessed fees for every fee-based form or motion processed byy EOIR. Accordingly, this rule raises the fees for these filiings.

Form/ Motion	New Fee	Total Cost
EOIR-26	$975	$975
EOIR-29	$705	$705
EOIR-40	$305	$307
EOIR-42A	$305	$307
EOIR-42B	$360	$360
MTReconsider (OCIJ)	$145	$140
MTReopen (OCIJ)	$145	$153
Motion to Reopen/Reconsider (BIA)	$895	$895
EOIR-45	$675	$677

To determine the economic impact of this rule, EOIR compared current fee collection levels and the fee collections that would have been generated by the proposed fees, as applied to filings from FY 2018.[62] In FY 2018, EOIR received more than 90,000 applications, appeals, and motions for which EOIR levies a fee. If fees had been collected for each of those filings at the current fee levels, EOIR would have collected $9.6 million in revenue. If, instead, the aforementioned FY 2018 filings had been charged the fees established by this rule, fee revenue for that fiscal year would have been approximately $51.1 million. In sum, the rule will cause applicants to pay approximately $41.4 million in fee revenue beyond that which would be expected if the filing fees were not changed. Comparing current fee collection levels with fee collections that would have been generated by the new fees in inflation-

[62] Data documenting the FY 2018 filings were obtained from the EOIR Database on July 16, 2020, applying a dataset from Aug. 7, 2019.

adjusted dollars[63] shows that the total revenue would have been approximately $22 million, or a difference of approximately $12.4 million. EOIR, however, does not require a fee in every circumstance when a party files one of the affected forms or motions. Instead, there are certain circumstances when the normal filing fee does not apply, and this rule does not impact immigration judges' and the BIA's discretionary authority to waive a fee upon a showing that the filing party is unable to pay. *See* 8 CFR 1003.8(a)(2)–(3), 1003.24(b)(2), (d), 1103.7(c). Therefore, the actual fee collection that results from this rule may in fact be lower than stated above, which would result in a lower cost to applicants than the collection projections outlined in this cost analysis.

Given the continued availability of fee waivers, the Department does not believe that these fees will have a material impact on the volume of filings received annually. Indeed, because these forms and applications are connected with immigration benefits and applications and must be filed as a precursor to an alien obtaining the desired relief or processes—which may determine whether the alien is able to remain lawfully in the United States or is removed to a country to which he or she has repeatedly demonstrated a desire not to return—the Department expects the demand for filing these forms and motions to be relatively inelastic, particularly due to the relatively modest nature of the increases (*i.e.* less than $1000), their comparative similarity with fees imposed by USCIS, and the ability of many aliens to obtain access to financial resources which may be used to pay for them. Thus, the Department expects that aliens will continue to file the forms at roughly the same or similar rates as today following this rule's implementation.

Ultimately, EOIR estimates the following filing numbers for these forms and motions in FY 2021:[64]

Form/ Motion	FY 2018 Receipts	FY 2021 Receipts (projected)
EOIR-26	29,123	60,833
EOIR-29	1,914	0
EOIR-40	158	234
EOIR-42A	3,426	2,701
EOIR-42B	30,421	44,856
MTR OCIJ[65]	18,132	20,400
MTR BIA[66]	7,414	6,180
EOIR-45	0	1

Transfers to EOIR from the actual revenues flow from the individual applicants to the IEFA administered by DHS and then to EOIR in a fixed amount regardless of the decreased subsidy to filing aliens.[67] Though the fees may seem high as compared to the current fees, the agency has not increased its fees since 1986. Taken over the 33-year timespan from 1986 to 2019, the fee increases represent compound annual growth rates ranging from 0.84 percent to 6.84 percent. While EOIR recognizes that the new fees will be more burdensome, individuals may still apply for a fee waiver for these fees pursuant to 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c).

Form/Motion	Old Fee	New Fee	Percent Increase	Compound Annual Growth Rate Since 1986
EOIR-40	$100	$305	205%	3.44%
EOIR-42A	$100	$305	205%	3.44%
EOIR-42B	$100	$360	260%	3.96%
MTR OCIJ	$110	$145	32%	0.84%
EOIR-26	$110	$975	786%	6.84%
EOIR-29	$110	$705	541%	5.79%
EOIR-45	$110	$675	514%	5.65%
MTR BIA	$110	$895	714%	6.56%

[63] This calculation was made by applying the consumer price index from January 1986 (109.6) to the real dollars calculation as compared to January 2019 (251.7). *Historical Consumer Price Index for All Urban Consumers,* Bureau of Labor Statistics, *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202009.pdf* (last accessed Nov. 12, 2020).

[64] FY 2021 projections were calculated applying the average percent change over ten fiscal years to FY2020 estimated receipts. EOIR first calculated the FY 2020 estimated receipts by adding the first three quarters of FY2020 receipts, divided by three, to itself. Next, the agency calculated the percent increase or decrease between each fiscal year and the average percent change.

[65] These numbers include both motions to reopen and motions to reconsider filed at the immigration court level.

[66] These numbers include both motions to reopen and motions to reconsider filed at the BIA level.

[67] As also discussed above, the Department did not include in the NPRM projected costs related to adjudication of fee waivers resulting from the rule, nor did it include overhead costs, non-salary benefits, and costs associated with filing corollary documents that may be submitted with the application, appeal, or motion to which a fee applies. The inclusion of such costs would have likely led to greater fee increases and, thus, imposed greater costs on aliens.

The Department determined that it is appropriate to move forward with full implementation of these new fees with one effective date. The Department considered commenters' suggestions, discussed above, that the Department should phase in the new fees. However, the Department again notes the significant length of time since the Department has updated the fees for these forms, applications, and motions. In addition, members of the public, including aliens in immigration proceedings who would be required to pay the new fee amounts if they do not seek or are not granted a fee waiver, have been on notice of the possible new fee amounts since the proposed rule's publication in February 2020. And as stated above, the Department does not believe a phased implementation is needed to provide individuals additional time to prepare for the new fees as fee waivers remain available by regulation for individuals who are unable to afford the new fee amount. *See* 8 CFR 1003.8(a)(3), 1003.24(d), 1103.7(c). Further, the Department notes that the closest comparable agency, USCIS, generally does not phase in fee increases even when they may be perceived as significant, and the Department is unaware of any difficulties that practice has created.

Finally, as the Department discussed, the increase in fees may constitute an additional cost to an individual alien in the amount of the relevant increase, depending on the particular circumstances of each individual alien.[68] It is also possible—and perhaps even probable—that the increased fees may lead additional aliens to seek a fee waiver than would without this rule, though the precise size of that group of aliens, though likely small for the reasons given, *supra,* is not estimated. Otherwise, the rule will impose minimal additional costs to the Government, as the Department has adjudicated fee waivers for many decades, and both Board members and immigration judges are experienced in adjudicating such requests.

E. Executive Order 13132: Federalism

This rule will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule would not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988: Criminal Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. Paperwork Reduction Act

This rule does not propose new ''collection[s] of information'' as that term is defined under the Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (codified at 44 U.S.C. 3501–3521) (''PRA''), and its implementing regulations, 5 CFR part 1320. There are no substantive changes to the forms as a result of this rulemaking; the only changes being proposed are revisions to the fee amounts for the existing forms for which EOIR sets the fees. The Department will be coordinating separately regarding updates to the existing forms under the PRA.

List of Subjects

8 CFR Part 1003

Administrative practice and procedure, Aliens, Immigration, Legal Services, Organization and functions (Government agencies).

8 CFR Part 1103

Administrative practice and procedure, Aliens, Immigration.

8 CFR Part 1208

Administrative practice and procedure, Aliens, Immigration, Reporting and recordkeeping requirements.

8 CFR Part 1216

Administrative practice and procedure, Aliens.

8 CFR Part 1240

Administrative practice and procedure, Aliens.

8 CFR Part 1244

Administrative practice and procedure, Immigration.

8 CFR Part 1245

Aliens, Immigration, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, the Attorney General amends title 8, chapter V of the Code of Federal Regulations as follows:

PART 1003—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

■ 1. The authority for part 1003 continues to read as follows:

Authority: 5 U.S.C. 301; 6 U.S.C. 521; 8 U.S.C. 1101, 1103, 1154, 1155, 1158, 1182, 1226, 1229, 1229a, 1229b, 1229c, 1231, 1254a, 1255, 1324d, 1330, 1361, 1362; 28 U.S.C. 509, 510, 1746; sec. 2 Reorg. Plan No. 2 of 1950; 3 CFR, 1949–1953 Comp., p. 1002; section 203 of Pub. L. 105–100, 111 Stat. 2196–200; sections 1506 and 1510 of Pub. L. 106–386, 114 Stat. 1527–29, 1531–32; section 1505 of Pub. L. 106–554, 114 Stat. 2763A–326 to –328.

§ 1003.8 [Amended]

■ 2. Section 1003.8 is amended by removing the citation ''8 CFR 103.7(a)'' and adding, in its place, the citation ''§ 1103.7(b)'' in paragraph (a)(4)(ii).

§ 1003.24 [Amended]

■ 3. Section 1003.24 is amended by removing the citation ''8 CFR 103.7'' and adding, in its place, the words ''8 CFR 103.7 and 8 CFR part 106'' in paragraphs (a) and (c)(1).

PART 1103—APPEALS, RECORDS, AND FEES

■ 4. The authority for part 1103 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1304, 1356; 31 U.S.C. 9701; 28 U.S.C. 509, 510.

■ 5. Section 1103.7 is amended by:
■ a. Removing the citation ''8 CFR 103.7(a)(1)'' and adding, in its place, the citation ''8 CFR 103.7'' in paragraph (a)(3);
■ b. Removing the citation ''8 CFR 103.7(a)(2)'' and adding, in its place, the words ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (a)(3);
■ c. Removing the citation ''8 CFR 103.7'' and adding, in its place, the words ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (b)(4)(ii); and
■ d. Revising paragraphs (b)(1) and (2), (b)(4), and (d).

The revisions read as follows:

§ 1103.7 Fees.

* * * * *

(b) *Amounts of Fees*—(1) *Appeals.* For filing an appeal to the Board of Immigration Appeals, when a fee is required pursuant to 8 CFR 1003.8, as follows:

Form EOIR–26. For filing an appeal from a decision of an immigration judge—$975.

Form EOIR–29. For filing an appeal from a decision of an officer of the Department of Homeland Security—$705.

[68] As also discussed above, the Department did not include in the NPRM projected costs related to adjudication of fee waivers resulting from the rule, nor did it include overhead costs, non-salary benefits, and costs associated with filing corollary documents that may be submitted with the application, appeal, or motion to which a fee applies. The inclusion of such costs would have likely led to greater fee increases and, thus, imposed a greater costs on aliens.

Form EOIR–45. For filing an appeal from a decision of an adjudicating official in a practitioner disciplinary case—$675.

(2) *Motions.* For filing a motion to reopen or a motion to reconsider, when a fee is required pursuant to 8 CFR 1003.8 or 1003.24, as follows:

Motion to reopen or motion to reconsider before the immigration court—$145.

Motion to reopen or motion to reconsider before the Board of Immigration Appeals—$895.

* * * * *

(4) *Applications for Relief*—(i) *Forms published by the Executive Office for Immigration Review.* Fees for applications for relief shall be paid in accordance with 8 CFR 1003.8(b) and 1003.24(c) as follows:

Form EOIR–40. Application for Suspension of Deportation—$305.

Form EOIR–42A. Application for Cancellation of Removal for Certain Permanent Residents—$305.

Form EOIR–42B. Application for Cancellation of Removal and Adjustment of Status for Certain Nonpermanent Residents—$360.

(ii) *Forms published by the Department of Homeland Security.* The fees for applications published by the Department of Homeland Security and used in immigration proceedings are governed by 8 CFR 103.7 and 8 CFR part 106. Consistent with 8 CFR 106.2, no fee shall apply to a Form I–589 filed with an immigration judge for the sole purpose of seeking withholding of removal under section 241(b)(3) of the Act or protection under the Convention Against Torture regulations.

* * * * *

(d) *Requests for records under the Freedom of Information Act.* Fees for production or disclosure of records under 5 U.S.C. 552 may be waived or reduced in accordance with 28 CFR 16.10.

PART 1208—PROCEDURES FOR ASYLUM AND WITHHOLDING OF REMOVAL

■ 6. The authority for part 1208 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1158, 1226, 1252, 1282; Title VII of Public Law 110–229.

§ 1208.7 [Amended]

■ 7. Section 1208.7 is amended by removing the words ''§ 103.7(c) of this chapter'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (c) introductory text.

PART 1216—CONDITIONAL BASIS OF LAWFUL PERMANENT RESIDENCE STATUS

■ 8. The authority for part 1216 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1154, 1184, 1186a, 1186b, and 8 CFR part 2.

§ 1216.4 [Amended]

■ 9. Section 1216.4 is amended by removing the words ''§ 103.7(b) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (a)(1).

§ 1216.5 [Amended]

■ 10. Section 1216.5 is amended by removing the words ''§ 103.7(b) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (b).

§ 1216.6 [Amended]

■ 11. Section 1216.6 is amended by removing the words ''§ 103.7(b)(1) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (a)(1).

PART 1240—PROCEEDINGS TO DETERMINE REMOVABILITY OF ALIENS IN THE UNITED STATES

■ 12. The authority for part 1240 continues to read as follows:

Authority: 8 U.S.C. 1103, 1158, 1182, 1186a, 1186b, 1225, 1226, 1227, 1228, 1229a, 1229b, 1229c, 1252 note, 1361, 1362; secs. 202 and 203, Pub. L. 105–100 (111 Stat. 2160, 2193); sec. 902, Pub. L. 105–277 (112 Stat. 2681).

§ 1240.11 [Amended]

■ 13. Section 1240.11 is amended by:

■ a. Removing the words ''§ 103.7(b)(1) of 8 CFR chapter I'' and adding, in their place, the words ''§ 1103.7(b)(1) of this chapter'' in paragraph (f); and

■ b. Removing the citation ''8 CFR 103.7(b)(1)'' and adding, in its place, the words ''§ 1103.7(b)(4) of this chapter'' in paragraph (f).

§ 1240.20 [Amended]

■ 14. Section 1240.20 is amended by removing the words ''§ 103.7(b) of 8 CFR chapter I'' and adding, in their place, the words ''§ 1103.7(b) of this chapter'' in paragraph (a).

PART 1244—TEMPORARY PROTECTED STATUS FOR NATIONALS OF DESIGNATED STATES

■ 15. The authority for part 1244 continues to read as follows:

Authority: 8 U.S.C. 1103, 1254, 1254a note, 8 CFR part 2.

§ 1244.6 [Amended]

■ 16. Section 1244.6 is amended by removing the words ''§ 103.7 of this chapter'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106''.

§ 1244.20 [Amended]

■ 17. Section 1244.20 is amended by removing the citation ''8 CFR 103.7(b)'' and adding, in its place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (a).

PART 1245—ADJUSTMENT OF STATUS TO THAT OF PERSON ADMITTED FOR PERMANENT RESIDENCE

■ 18. The authority for part 1245 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1182, 1255; section 202, Public Law 105–100, 111 Stat. 2160, 2193; section 902, Public Law 105–277, 112 Stat. 2681; Title VII of Public Law 110–229.

§ 1245.7 [Amended]

■ 19. Section 1245.7 is amended by removing the words ''§ 103.7 of this chapter'' and adding, in their place, the words ''8 CFR 103.7 and 8 CFR 103.17'' in paragraph (a).

§ 1245.10 [Amended]

■ 20. Section 1245.10 is amended by removing the words ''§ 103.7(b)(1) of this chapter'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (c) introductory text.

§ 1245.13 [Amended]

■ 21. Section 1245.13 is amended by:

■ a. Removing the words ''§ 103.7(b)(1) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraphs (e)(1), (g), (j)(1), and (k)(1);

■ b. Removing the words ''§ 103.7(b)(1) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7'' in paragraph (e)(2); and

■ c. Removing the words ''§ 103.7(c) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (g).

§ 1245.15 [Amended]

■ 22. Section 1245.15 is amended by:

■ a. Removing the words ''§ 103.7(b)(1) of this chapter'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (c)(2)(iv)(A);

■ b. Removing words ''§ 103.7(c) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (c)(2)(iv)(B); and

■ c. Removing the words ''§ 103.7(b)(1) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraphs (h)(1) and (2), (n)(1), and (t)(1).

§ 1245.20 [Amended]

■ 23. Section 1245.20 is amended by removing the words ''§ 103.7(b)(1) of 8 CFR chapter I'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraphs (d)(1), (f), and (g).

§ 1245.21 [Amended]

■ 24. Section 1245.21 is amended by:

■ a. Removing the words ''§ 103.7(b)(1) of this chapter'' and adding, in their place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraph (b)(2); and

■ b. Removing the citation ''8 CFR 103.7(b)(1)'' and adding, in its place, the citation ''8 CFR 103.7 and 8 CFR part 106'' in paragraphs (h) and (i).

Dated: December 9, 2020.

William P. Barr,

Attorney General.

[FR Doc. 2020–27506 Filed 12–15–20; 11:15 am]

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Part V

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2550

Prohibited Transaction Exemption 2020–02, Improving Investment Advice for Workers & Retirees; Rule

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

[Application No. D–12011]

ZRIN 1210–ZA29

Prohibited Transaction Exemption 2020–02, Improving Investment Advice for Workers & Retirees

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor.

ACTION: Adoption of class exemption and interpretation.

SUMMARY: This document contains a class exemption from certain prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974, as amended (the Act). Title I of the Act codified a prohibited transaction provision in title 29 of the U.S. Code (referred to in this document as Title I). Title II of the Act codified a parallel provision now found in the Internal Revenue Code of 1986, as amended (the Code). These prohibited transaction provisions of Title I and the Code generally prohibit fiduciaries with respect to ''plans,'' including workplace retirement plans (Plans) and individual retirement accounts and annuities (IRAs), from engaging in self-dealing and receiving compensation from third parties in connection with transactions involving the Plans and IRAs. The provisions also prohibit purchasing and selling investments with the Plans and IRAs when the fiduciaries are acting on behalf of their own accounts (principal transactions). This exemption allows investment advice fiduciaries to plans under both Title I and the Code to receive compensation, including as a result of advice to roll over assets from a Plan to an IRA, and to engage in principal transactions, that would otherwise violate the prohibited transaction provisions of Title I and the Code. The exemption applies to Securities and Exchange Commission—and state-registered investment advisers, broker-dealers, banks, insurance companies, and their employees, agents, and representatives that are investment advice fiduciaries. The exemption includes protective conditions designed to safeguard the interests of Plans, participants and beneficiaries, and IRA owners. The class exemption affects participants and beneficiaries of Plans, IRA owners, and fiduciaries with respect to such Plans and IRAs. This notice also sets forth the Department's final interpretation of when advice to roll over Plan assets to an IRA will be considered fiduciary investment advice under Title I and the Code.

DATES: The exemption is effective as of: February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Susan Wilker, telephone (202) 693–8557, or Erin Hesse, telephone (202) 693–8546, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The Employee Retirement Income Security Act of 1974 (the Act) provides, in relevant part, that a person is a fiduciary with respect to a ''plan'' to the extent he or she renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of such plan, or has any authority or responsibility to do so. Title I of the Act (referred to herein as Title I), which generally applies to employer-sponsored Plans (Title I Plans), includes this provision in section 3(21)(A)(ii).[1] The Act's Title II (referred to herein as the Code), includes a parallel provision in section 4975(e)(3)(B), which defines a fiduciary of a tax-qualified plan, including IRAs.[2]

In 1975, the Department issued a regulation establishing a five-part test for fiduciary status under this provision of Title I.[3] The 1975 regulation also applies to the definition of fiduciary in the Code, which is identical in its wording.[4] Under the 1975 regulation, for advice to constitute ''investment advice,'' a financial institution or investment professional who is not a fiduciary under another provision of the statute must—(1) render advice as to the value of securities or other property, or make recommendations as to the advisability of investing in, purchasing, or selling securities or other property (2) on a regular basis (3) pursuant to a mutual agreement, arrangement, or understanding with the Plan, Plan fiduciary or IRA owner, that (4) the advice will serve as a primary basis for investment decisions with respect to Plan or IRA assets, and that (5) the advice will be individualized based on the particular needs of the Plan or IRA. A financial institution or investment professional that meets this five-part test, and receives a fee or other compensation, direct or indirect, is an investment advice fiduciary under Title I and under the Code.

Investment advice fiduciaries, like other fiduciaries to Plans and IRAs, are subject to duties and liabilities established in Title I and the Code. Fiduciaries to Title I Plans must act prudently and with undivided loyalty to the plans and their participants and beneficiaries. Although these statutory fiduciary duties are not in the Code, both Title I and the Code contain provisions forbidding fiduciaries from engaging in certain specified ''prohibited transactions,'' involving Plans and IRAs, including conflict of interest transactions.[5] Under these prohibited transaction provisions, a fiduciary may not deal with the income or assets of a Plan or an IRA in his or her own interest or for his or her own account, and a fiduciary may not receive payments from any party dealing with the Plan or IRA in connection with a transaction involving assets of the Plan or IRA. The Department has authority in ERISA section 408(a) and Code section 4975(c)(2) to grant administrative exemptions from the prohibited transaction provisions in Title I and the Code.[6]

In 2016, the Department finalized a new regulation that would have replaced the 1975 regulation, and granted new associated prohibited transaction exemptions.[7] After the U.S. Court of Appeals for the Fifth Circuit vacated that rulemaking, including the new exemptions, in *Chamber of Commerce of the United States* v. *U.S. Department of Labor* in 2018 (the *Chamber* opinion),[8] the Department issued Field Assistance Bulletin (FAB) 2018–02, a temporary enforcement policy providing prohibited transaction relief to investment advice fiduciaries.[9]

[1] Section 3(21)(A)(ii) of the Act is codified at 29 U.S.C. 1002(3)(21)(A)(ii). As noted above, Title I of the Act was codified in Title 29 of the U.S. Code. As a matter of practice, this preamble refers to the codified provisions in Title I by reference to the sections of ERISA, as amended, and not by its numbering in the U.S. Code.

[2] As noted above, Title II of the Act was codified in the Internal Revenue Code.

[3] 29 CFR 2510.3–21(c)(1), 40 FR 50842 (October 31, 1975).

[4] 26 CFR 54.4975–9(c), 40 FR 50840 (October 31, 1975).

[5] ERISA section 406 and Code section 4975. *Cf.* Code section 4975(f)(5), which defines ''correction'' with respect to prohibited transactions as placing a Plan or an IRA in a financial position not worse than it would have been in if the person had acted ''under the highest fiduciary standards.''

[6] Reorganization Plan No. 4 of 1978 (5 U.S.C. App. 1 (2018)) generally transferred the authority of the Secretary of the Treasury to grant administrative exemptions under Code section 4975 to the Secretary of Labor.

[7] *See* Definition of the Term ''Fiduciary''; Conflict of Interest Rule—Retirement Investment Advice, 81 FR 20945 (Apr. 8, 2016).

[8] 885 F.3d 360 (5th Cir. 2018).

[9] *Available at www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-*

In the FAB, the Department stated it would not pursue prohibited transaction claims against investment advice fiduciaries who worked diligently and in good faith to comply with ''Impartial Conduct Standards'' for transactions that would have been exempted in the new exemptions, or treat the fiduciaries as violating the applicable prohibited transaction rules. The Impartial Conduct Standards have three components: A best interest standard; a reasonable compensation standard; and a requirement to make no misleading statements about investment transactions and other relevant matters.

On July 7, 2020, the Department proposed this class exemption, which took into consideration the public correspondence and comments received by the Department since February 2017 and responded to informal industry feedback seeking an administrative class exemption based on FAB 2018–02.[10] On the same day, the Department issued a technical amendment to 29 CFR 2510–3.21, instructing the Office of the Federal Register to remove language that was added in 2016 and reinsert the text of the 1975 regulation.[11] This ministerial action reflected the Fifth Circuit's vacatur of the 2016 fiduciary rule.[12] The technical amendment also reinserted into the CFR Interpretive Bulletin 96–1 relating to participant investment education, which had been removed and largely incorporated into the text of the 2016 fiduciary rule.[13] The Department received 106 written comments on the proposed exemption, and on September 3, 2020, held a public hearing at which the commenters were permitted to give additional testimony.[14]

After careful consideration of the comments and testimony on the proposed exemption, the Department is granting the exemption. While the final exemption makes a number of significant changes in response to comments, it retains the proposal's broad protective framework, including the Impartial Conduct Standards; disclosures, including a written acknowledgment of fiduciary status; policies and procedures prudently designed to ensure compliance with the Impartial Conduct Standards and that mitigate conflicts of interest; and a retrospective compliance review. The exemption, like the proposal, also specifies the circumstances in which Financial Institutions and Investment Professionals are ineligible to rely upon its terms.

In response to commenters, the Department made a number of important changes. First, the final exemption's recordkeeping requirements have been narrowed to allow only the Department and the Department of the Treasury to obtain access to a Financial Institution's records as opposed to plan fiduciaries and other Retirement Investors. Second, the final exemption's disclosure requirements have been revised to include written disclosure to Retirement Investors of the reasons that a rollover recommendation was in their best interest. Third, the final exemption's retrospective review provision has been revised to provide that certification can be made by any Senior Executive Officer, as defined in the exemption, rather than requiring certification by the chief executive officer (or equivalent officer) as proposed. Fourth, a self-correction provision has also been added to the final exemption.

This document also sets forth the Department's final interpretation of the five-part test of investment advice fiduciary status for purposes of this exemption, and provides the Department's views on when advice to roll over Title I Plan assets to an IRA will be considered fiduciary investment advice under Title I and the Code.[15] Comments on the interpretation, which was proposed in the notice of proposed exemption, are discussed below.

The Department has also provided explanation in the preamble to respond to issues raised during the comment period. Additionally, to the extent public comments were based on concerns about compliance and interpretive issues with the final exemption or the Act, the Department intends to support Financial Institutions, Investment Professionals, plan sponsors and fiduciaries, and other affected parties, with compliance assistance following publication of the final exemption.

The Department further announces that FAB 2018–02 will remain in effect until December 20, 2021. This will provide a transition period for parties to develop mechanisms to comply with the provisions in the new exemption.

The Department grants this exemption, which was proposed on its own motion, pursuant to its authority under ERISA section 408(a) and Code section 4975(c)(2) and in accordance with procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637 (October 27, 2011)). The Department finds that the exemption is administratively feasible, in the interests of Plans and their participants and beneficiaries and of IRA owners, and protective of the rights of participants and beneficiaries of Plans and IRA owners. The Department has determined that the exemption is an Executive Order (E.O.) 13771 deregulatory action because it provides broader and more flexible exemptions that allow investment advice fiduciaries with respect to Plans and IRAs to receive compensation and engage in certain principal transactions that would otherwise be prohibited under Title I and the Code.

Overview of the Final Exemption and Discussion of Comments Received

This exemption is available to registered investment advisers, broker-dealers, banks, and insurance companies (Financial Institutions) and their individual employees, agents, and representatives (Investment Professionals) that provide fiduciary investment advice to Retirement Investors.[16] The exemption defines Retirement Investors as Plan participants and beneficiaries, IRA owners, and Plan and IRA fiduciaries.[17] Under the exemption, Financial Institutions and Investment Professionals can receive a wide variety of payments that would otherwise violate the prohibited transaction rules, including, but not limited to, commissions, 12b–1 fees, trailing commissions, sales loads, mark-ups and mark-downs, and revenue sharing payments from investment providers or third parties. The exemption's relief extends to prohibited transactions arising as a result of investment advice to roll over assets from a Plan to an IRA, as detailed later in this exemption. The

bulletins/2018-02. The Impartial Conduct Standards incorporated in the FAB were conditions of the new exemptions granted in 2016. *See* Best Interest Contract Exemption, 81 FR 21002 (Apr. 8, 2016), as corrected at 81 FR 44773 (July 11, 2016).

[10] 85 FR 40834 (July 7, 2020).

[11] 85 FR 40589 (July 7, 2020).

[12] The amendment also corrected a typographical error in the original text of the 1975 regulation, at 29 CFR 2510–3.21(e)(1)(ii).

[13] 29 CFR 2509.96–1.

[14] Hearing on Improving Investment Advice for Workers & Retirees, 85 FR 52292 (August 25, 2020).

[15] For purposes of any rollover of assets from a Title I Plan to an IRA described in this preamble, the term ''Plan'' only includes an employee pension benefit plan described in ERISA section 3(2) or a plan described in Code section 4975(e)(1)(A), and the term ''IRA'' only includes an account or annuity described in Code section 4975(e)(1)(B) or (C).

[16] References in the preamble to registered investment advisers include both SEC- and state-registered investment advisers.

[17] As defined in Section V(i) of the exemption, the term ''Plan'' means any employee benefit plan described in ERISA section 3(3) and any plan described in Code section 4975(e)(1)(A). In Section V(g), the term ''Individual Retirement Account'' or ''IRA'' is defined as any account or annuity described in Code section 4975(e)(1)(B) through (F), including an Archer medical savings account, a health savings account, and a Coverdell education savings account.

exemption also allows Financial Institutions to engage in principal transactions with Plans and IRAs in which the Financial Institution purchases or sells certain investments from its own account.

As noted above, Title I and the Code include broad prohibitions on self-dealing. Absent an exemption, a fiduciary may not deal with the income or assets of a Plan or an IRA in his or her own interest or for his or her own account, and a fiduciary may not receive payments from any party dealing with the Plan or IRA in connection with a transaction involving assets of the Plan or IRA. As a result, fiduciaries who use their authority to cause themselves or their affiliates [18] or related entities [19] to receive additional compensation violate the prohibited transaction provisions unless an exemption applies.[20]

This exemption conditions relief on the Investment Professional and Financial Institution investment advice fiduciaries providing advice in accordance with the Impartial Conduct Standards. In addition, the exemption requires Financial Institutions to acknowledge in writing their and their Investment Professionals' fiduciary status under Title I and the Code, as applicable, when providing investment advice to the Retirement Investor, and to describe in writing the services to be provided and the Financial Institutions' and Investment Professionals' material conflicts of interest. Financial Institutions must document the reasons that a rollover recommendation is in the best interest of the Retirement Investor and provide that documentation to the Retirement Investor. Financial Institutions are required to adopt policies and procedures prudently designed to ensure compliance with the Impartial Conduct Standards and conduct a retrospective review of compliance. The exemption also provides, subject to additional safeguards, relief for Financial Institutions to enter into principal transactions with Retirement Investors, in which they purchase or sell certain investments from their own accounts.

In order to ensure that Financial Institutions provide reasonable oversight of Investment Professionals and adopt a culture of compliance, the exemption provides that Financial Institutions and Investment Professionals will be ineligible to rely on the exemption if, within the previous 10 years, they were convicted of certain crimes arising out of their provision of investment advice to Retirement Investors. They will also be ineligible if they engaged in systematic or intentional violation of the exemption's conditions or provided materially misleading information to the Department in relation to their conduct under the exemption. Ineligible parties are permitted to rely on an otherwise available statutory exemption or administrative class exemption, or they can apply for an individual prohibited transaction exemption from the Department. This targeted approach of allowing the Department to give special attention to parties with certain criminal convictions or with a history of egregious conduct with respect to compliance with the exemption will provide meaningful protections for Retirement Investors.

While the exemption's eligibility provision provides an incentive to maintain an appropriate focus on compliance with legal requirements and with the exemption, it does not represent the only available enforcement mechanism. The Department has investigative and enforcement authority with respect to transactions involving Plans under Title I of ERISA, and it has interpretive authority as to whether exemption conditions have been satisfied. Further, ERISA section 3003(c) provides that the Department will transmit information to the Secretary of the Treasury regarding a party's violation of the prohibited transaction provisions of ERISA section 406. In addition, participants, beneficiaries, and fiduciaries with respect to Plans covered under Title I have a statutory cause of action under ERISA section 502(a) for fiduciary breaches and prohibited transactions under Title I. The exemption, however, does not expand Retirement Investors' ability to enforce their rights in court or create any new legal claims above and beyond those expressly authorized in Title I or the Code, such as by requiring contracts and/or warranty provisions.

Exemption Approach and Alignment With Other Regulators' Conduct Standards

This exemption provides relief that is broader and more flexible than the other prohibited transaction exemptions currently available for investment advice fiduciaries. Those exemptions generally provide relief to specific types of financial services providers, for discrete, specifically identified transactions, and often do not extend to compensation arrangements that developed after the Department first granted the exemptions.[21] In comparison, this new exemption provides relief for multiple categories of Financial Institutions and Investment Professionals, and extends broadly to their receipt of reasonable compensation as a result of the provision of fiduciary investment advice. The conditions are principles-based rather than prescriptive, so as to apply across different financial services sectors and business models. The exemption provides additional certainty regarding covered compensation arrangements and avoids the complexity associated with requiring a Financial Institution to rely upon a patchwork of different exemptions when providing investment advice.

The exemption's principles-based approach is rooted in the Impartial Conduct Standards for fiduciaries providing investment advice. The Impartial Conduct Standards include a best interest standard, a reasonable compensation standard, and a requirement to make no misleading statements about investment transactions and other relevant matters.

[18] As defined in Section V(a) of the exemption, an ''affiliate'' includes: (1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the Investment Professional or Financial Institution. (For this purpose, ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual); (2) any officer, director, partner, employee, or relative (as defined in ERISA section 3(15)), of the Investment Professional or Financial Institution; and (3) any corporation or partnership of which the Investment Professional or Financial Institution is an officer, director, or partner.

[19] As defined in Section V(j) of the exemption, a ''related entity'' is an entity that is not an affiliate, but in which the Investment Professional or Financial Institution has an interest that may affect the exercise of its best judgment as a fiduciary.

[20] As articulated in the Department's regulations, ''a fiduciary may not use the authority, control, or responsibility which makes such a person a fiduciary to cause a plan to pay an additional fee to such fiduciary (or to a person in which such fiduciary has an interest which may affect the exercise of such fiduciary's best judgment as a fiduciary) to provide a service.'' 29 CFR 2550.408b–2(e)(1).

[21] *See e.g.,* PTE 86–128, Class Exemption for Securities Transactions involving Employee Benefit Plans and Broker-Dealers, 51 FR 41686 (Nov. 18, 1986), as amended, 67 FR 64137 (Oct. 17, 2002) (providing relief for a fiduciary's use of its authority to cause a Plan or an IRA to pay a fee for effecting or executing securities transactions to the fiduciary, as agent for the Plan or IRA, and for a fiduciary to act as an agent in an agency cross transaction for a Plan or an IRA and another party to the transaction and receive reasonable compensation for effecting or executing the transaction from the other party to the transaction); PTE 84–24, Class Exemption for Certain Transactions Involving Insurance Agents and Brokers, Pension Consultants, Insurance Companies, Investment Companies and Investment Company Principal Underwriters, 49 FR 13208 (Apr. 3, 1984), as corrected, 49 FR 24819 (June 15, 1984), as amended, 71 FR 5887 (Feb. 3, 2006) (providing relief for the receipt of a sales commission by an insurance agent or broker from an insurance company in connection with the purchase, with plan assets, of an insurance or annuity contract).

In the proposed exemption, the Department noted that the best interest standard was based on concepts of law and equity ''developed in significant part to deal with the issues that arise when agents and persons in a position of trust have conflicting interests,'' and accordingly, the standard is well-suited to the problems posed by conflicted investment advice.[22] The Department believes that conditioning the exemption on satisfaction of the Impartial Conduct Standards protects the interests of Retirement Investors in connection with this broader grant of exemptive relief.

The best interest standard in the exemption is broadly aligned with recent rulemaking by the Securities and Exchange Commission (SEC), in particular. On June 5, 2019, the SEC finalized a regulatory package relating to conduct standards for broker-dealers and investment advisers. The package included Regulation Best Interest which establishes a best interest standard applicable to broker-dealers when making a recommendation of any securities transaction or investment strategy involving securities to retail customers.[23] The SEC also issued an interpretation of the fiduciary conduct standards applicable to investment advisers under the Investment Advisers Act of 1940 (SEC Fiduciary Interpretation).[24] In addition, as part of the package, the SEC adopted new Form CRS, which requires broker-dealers and SEC-registered investment advisers to provide retail investors with a short relationship summary with specified information (SEC Form CRS).[25]

The exemption's best interest standard is also aligned with the standard included in the National Association of Insurance Commissioners (NAIC)'s Suitability in Annuity Transactions Model Regulation (NAIC Model Regulation) which was updated in Spring 2020.[26] The model regulation provides that all recommendations by agents and insurers must be in the best interest of the consumer and that agents and carriers may not place their financial interest ahead of the consumer's interest. Both Iowa and Arizona have adopted updated rules following the update of the NAIC Model Regulation.[27]

Some commenters expressed general support for the approach taken in the proposed exemption, although they opposed certain specific conditions as discussed in greater detail below. Commenters cited the flexible, principles-based approach rather than a prescriptive approach to exemptive relief, and they also praised the proposed exemptive relief for a broad range of otherwise prohibited compensation types which they said did not favor certain market segments or arrangements. Many of these commenters supported what they viewed as the proposed exemption's alignment with regulatory conduct standards under the securities laws, particularly Regulation Best Interest. The commenters said this approach would reduce compliance costs and burdens, which will ultimately benefit Retirement Investors through reduced fees. Commenters also stated that they believed the exemption's approach would facilitate providing investment advice to Retirement Investors through a wide variety of methods.

Some commenters urged the Department to more closely mirror Regulation Best Interest or offer an explicit safe harbor for compliance with Regulation Best Interest, or with any ''primary financial regulator'' of the Financial Institution, rather than including additional conditions in the exemption. They argued that otherwise Financial Institutions would have to comply with two differing yet mostly redundant regimes, with their attendant additional costs and liability exposure, and that the Department had failed to show that Retirement Investors would be insufficiently protected by other regulators' standards. Some commenters focused on conduct standards, disclosures, and policies and procedures as areas for increased alignment, which they said would further reduce compliance burdens. These comments, as they pertain to these particular aspects of the exemption, are discussed in greater detail below in their respective parts of the preamble.

Commenters made similar points with respect to alignment with the NAIC Model Regulation. Some commenters asked the Department to go further in aligning the exemption's terms to the NAIC Model Regulation, or even offer a safe harbor based on compliance with it. Commenters asserted that increased alignment is particularly important to allow for distribution of insurance products by independent insurance agents. Specifically, commenters expressed the view that the exemption establishes a structure of Financial Institution oversight for Investment Professionals that is incompatible with the independent agent distribution model, because independent insurance agents sell the products of more than one insurance company. They suggested that the NAIC Model Regulation better accommodated that business model.

In contrast, many commenters opposed the approach taken in the proposed exemption as insufficiently protective of Retirement Investors, and urged the Department to withdraw the proposal. Some of these commenters expressed the view that the exemption would not satisfy the statutory criteria under ERISA section 408(a) for the granting of an exemption or, more generally, that the conditions would not protect Plans and IRAs and their participants and beneficiaries from the dangers of conflicts of interest and self-dealing.

These commenters focused much of their opposition on the exemption's alignment with Regulation Best Interest and the NAIC Model Regulation, which the commenters said do not encompass a ''true'' fiduciary standard. Commenters stated that the provisions of Regulation Best Interest and the NAIC Model Regulation restricting conflicts of interest do not sufficiently protect investors from conflicted investment advice. Furthermore, commenters stated that the Act was enacted to provide *additional* protections to individuals saving for retirement, above and beyond existing laws. Some commenters noted that at the time the Act was enacted, Congress was aware of other federal and state regulatory schemes and that there was no suggestion of congressional purpose to base compliance on federal securities laws or other regulatory schemes.

Some commenters took the position that the alignment with the conduct

[22] 85 FR 40842.

[23] Regulation Best Interest: The Broker-Dealer Standard of Conduct, 84 FR 33318 (July 12, 2019) (Regulation Best Interest Release).

[24] Commission Interpretation Regarding Standard of Conduct for Investment Advisers, 84 FR 33669 (July 12, 2019).

[25] Form CRS Relationship Summary; Amendments to Form ADV, 84 FR 33492 (July 12, 2019) (Form CRS Relationship Summary Release). In addition to the SEC's rulemaking, the Massachusetts Securities Division amended its regulations for broker-dealers to apply a fiduciary conduct standard, under which broker-dealers and their agents must ''[m]ake recommendations and provide investment advice without regard to the financial or any other interest of any party other than the customer.'' 950 Mass. Code Regs. 12.204 & 12.207 as amended effective March 6, 2020.

[26] NAIC Suitability in Annuity Transactions Model Regulation, Spring 2020, *available at www.naic.org/store/free/MDL-275.pdf* (NAIC Model Regulation).

[27] Iowa Code § 507B.48 (2020), *available at https://iid.iowa.gov/sites/default/files/bi_af.pdf;* Arizona Senate Bill 1557 (2020), *available at www.azleg.gov/legtext/54Leg/2R/laws/0090.pdf.* The New York State Department of Financial Services also amended its insurance regulations to establish a best interest standard in connection with life insurance and annuity transactions. New York State Department of Financial Services Insurance Regulation 187, 11 NYCRR 224, First Amendment, effective August 1, 2019 for annuity transactions.

standards in Regulation Best Interest rendered many of the exemption's other conditions, which are designed to support investment advice that meets the standards, too lax. Some commenters also opposed the breadth of the exemption. These commenters suggested that the exemption should not allow receipt of payments from third parties. Some commenters also opposed the exemption's application to recommendations of proprietary products. Further, commenters also stated that the failure to provide a mechanism for IRA owners to enforce the Impartial Conduct Standards was a significant flaw in the exemption's approach. Some of these commenters noted that the Department also lacks the authority to enforce the exemption with respect to these investors.

The Department has carefully considered these comments on the exemption's approach, its alignment with other regulators' conduct standards, as well as the comments on specific provisions of the exemption discussed below. The Department has proceeded with granting the final exemption based on the view that the exemption will provide important protections to Retirement Investors in the context of a principles-based exemption that permits a broad range of otherwise prohibited compensation, including compensation from third parties and from proprietary products.

In this regard, the Impartial Conduct Standards are strong fiduciary standards based on longstanding concepts in the Act and the common law of trusts. The exemption includes additional supporting conditions including a written acknowledgment of fiduciary status to ensure that the nature of the relationship is clear to Financial Institutions, Investment Professionals, and Retirement Investors; policies and procedures that require mitigation of conflicts of interest to the extent that a reasonable person reviewing the policies and procedures and incentive practices as a whole would conclude that they do not create an incentive for a Financial Institution or Investment Professional to place their interests ahead of the interest of the Retirement Investor; and documentation and disclosure to Retirement Investors of the reasons that a rollover recommendation is in the Retirement Investor's best interest.

The exemption does not include a provision permitting IRA owners to enforce the Impartial Conduct Standards. In developing the exemption, the Department was mindful of the Fifth Circuit's *Chamber* opinion holding that the Department did not have authority to include certain contract requirements in the new exemptions enforceable by IRA owners as granted by the 2016 fiduciary rulemaking. In addition, the Department intends to avoid any potential for disruption in the market for investment advice that may occur related to a contract requirement. Instead, the exemption includes many protective measures and targeted opportunities for the Department to review compliance within its existing oversight and enforcement authority under the Act. For example, Financial Institutions' reports regarding their retrospective review are required to be certified by a Senior Executive Officer [28] of the Financial Institution and provided to the Department within 10 business days of request. The exemption also includes eligibility provisions, discussed below, which the Department believes will encourage Financial Institutions and Investment Professionals to maintain an appropriate focus on compliance with legal requirements and with the exemption.

The Department believes that general alignment with the other regulators' conduct standards is beneficial in allowing for the development of compliance structures that lack complexity and unnecessary burden. The Department has not, however, offered a safe harbor based solely on compliance with regulatory conduct standards under federal or state securities laws. The Department disagrees with commenters' arguments that the failure to do so will create a redundant, cost-ineffective regime, or one that could create unexpected liabilities at the edges. This exemption is offered as a deregulatory option for interested parties; it does not unilaterally impose any obligations. The additional conditions of the exemption provide important protections to Retirement Investors, who are investing through tax advantaged accounts and are the subject of unique protections under Title I and the Code.[29] The approach in the final exemption exemplifies the Department's important role in protecting Retirement Investors through promulgating only those exemptions that meet the requirements of ERISA section 408(a) and Code section 4975(c)(2).

For the same reasons, the Department likewise declines to provide a safe harbor based on the NAIC Model Regulation. A uniform approach to safeguards for Retirement Investors receiving fiduciary investment advice in the insurance marketplace is particularly important given the potential for variation across state insurance laws. Moreover, although commenters expressed concern about the scope of an insurance company's supervisory oversight responsibilities as a Financial Institution, the Department believes that the exemption is workable for the insurance industry, as discussed in greater detail below.

Some commenters raised questions as to whether the Department intends to defer to the SEC or other regulators on enforcement and how the Department will treat violations under other regulatory regimes. The Department has worked with other regulatory agencies, including the SEC, in numerous cases that implicate violations under different laws. The interaction of findings or settlements in parallel suits or investigations is decidedly a case-by-case determination. The Department confirms that it will coordinate with other regulators, including the SEC, on enforcement strategies and will harmonize regimes to the extent possible, but will not defer to other regulators on enforcement under the Act. Retirement Investors who have concerns about whether they have received investment advice that is not in accordance with the Impartial Conduct Standards or other conditions of the exemption are encouraged to contact the Department.[30]

Interpretation of Fiduciary Investment Advice in Connection With Rollover Recommendations

As stated in the proposed exemption, amounts accrued in a Title I Plan can represent a lifetime of savings, and often comprise the largest sum of money a worker has at retirement. Therefore, the decision to roll over assets from a Title I Plan to an IRA is potentially a very consequential financial decision for a Retirement Investor.[31] A sound decision on the rollover will typically turn on numerous factors, including the relative costs associated with the new investment options, the range of available investment options under the

[28] Senior Executive Officer is defined in Section V(l) as any of the following: The chief compliance officer, the chief executive officer, president, chief financial officer, or one of the three most senior officers of the Financial Institution.

[29] *See* ERISA section 2(a).

[30] Contact information for regional offices of the Department's Employee Benefits Security Administration is available at *www.dol.gov/agencies/ebsa/about-ebsa/about-us/regional-offices.*

[31] For simplicity, this preamble interpretation uses the term *Retirement Investor,* which is a defined term in the exemption. This is not intended to suggest that the interpretation is limited to Retirement Investors impacted by the class exemption. In this preamble interpretation, the term *Retirement Investor* is intended to refer more generally to Plan participants and beneficiaries and IRA owners.

plan and the IRA, and the individual circumstances of the particular investor.

Rollovers from Title I Plans to IRAs are expected to approach $2.4 trillion cumulatively from 2016 through 2020.[32] These large sums of money eligible for rollover represent a significant revenue source for investment advice providers. A firm that recommends a rollover to a Retirement Investor can generally expect to earn transaction-based compensation such as commissions, or an ongoing advisory fee, from the IRA, but may or may not earn compensation if the assets remain in the Title I Plan.

In light of potential conflicts of interest related to rollovers from Title I Plans to IRAs, Title I and the Code prohibit an investment advice fiduciary from receiving fees resulting from investment advice to Title I Plan participants to roll over assets from the plan to an IRA, unless an exemption applies. The exemption provides relief, as needed, for this prohibited transaction, if the Financial Institution and Investment Professional provide investment advice that satisfies the Impartial Conduct Standards and comply with the other applicable conditions discussed below.[33] In particular, the Financial Institution is required to document the reasons that the advice to roll over was in the Retirement Investor's best interest, and provide the documentation to the Retirement Investor.

The preamble to the proposed exemption provided the Department's proposed views on when advice to roll over Plan assets to an IRA should be considered fiduciary investment advice under the Department's regulation defining fiduciary investment advice,[34] and requested comment on all aspects of the interpretation. The proposed interpretation addressed both Advisory Opinion 2005–23A (the Deseret Letter) as well as the facts and circumstances analysis of rollover recommendations under the five-part test. The discussion also touched on the statutory definitional prerequisite that advice be provided ''for a fee or other compensation, direct or indirect.''

Comments on the proposed interpretation are discussed below. The Department has carefully considered these comments and has adopted the final interpretation, as follows.

Deseret Letter

The proposed exemption announced that, in determining the fiduciary status of an investment advice provider in the context of advice to roll over Title I Plan assets to an IRA, the Department does not intend to apply the analysis in the Deseret Letter stating that advice to roll assets out of a Title I Plan, even when combined with a recommendation as to how the distribution should be invested, did not constitute investment advice with respect to the Title I Plan. The Department believes that the analysis in the Deseret Letter was incorrect when it stated that advice to take a distribution of assets from a Title I Plan is not advice to sell, withdraw, or transfer investment assets currently held in the plan. A recommendation to roll assets out of a Title I Plan is necessarily a recommendation to liquidate or transfer the plan's property interest in the affected assets and the participant's associated property interest in plan investments.[35] Typically the assets, fees, asset management structure, investment options, and investment service options all change with the decision to roll money out of a Title I Plan. Moreover, a distribution recommendation commonly involves either advice to change specific investments in the Title I Plan or to change fees and services directly affecting the return on those investments. Accordingly, the better view is that a recommendation to roll assets out of a Title I Plan is advice with respect to moneys or other property of the plan. An investment advice fiduciary making a rollover recommendation would be required to avoid prohibited transactions under Title I and the Code unless an exemption, including this one, applies.

Some commenters supported the Department's announcement that it would not apply the reasoning of the Deseret Letter but would rather approach the analysis of rollovers based on all the facts and circumstances under the five-part test. These commenters generally supported the possibility that rollover recommendations could be considered fiduciary investment advice if the five-part test is satisfied, particularly given the consequence of the decision to roll over large sums typically accumulated in a Retirement Investor's workplace Plan.

Some commenters stated the Department's proposed interpretation did not go far enough in protecting Retirement Investors, and that all rollover recommendations should be deemed fiduciary investment advice regardless of whether the five-part test is satisfied. Commenters noted that financial professionals have adopted titles such as financial consultant, financial planner, and wealth manager. These commenters stated that reinsertion of the five-part test makes it all too easy for financial services providers to hold themselves out as acting in positions of trust and confidence, even as they effectively avoided fiduciary status by relying on the ''regular basis,'' ''mutual agreement, arrangement, or understanding'' and ''primary basis'' prongs of the test.[36] One commenter argued that a rollover recommendation should be viewed as always satisfying the ''regular basis'' prong because, in its view, there are two distinct steps—the decision to do a rollover, and the decision to invest its proceeds.

Other commenters asserted that the facts-and-circumstances analysis would lead to uncertainty as to fiduciary status and that a consequence of that uncertainty is a potential reduction in access to advice. One commenter argued that would lead to more leakage, missing participants, and abandoned accounts. Commenters disagreed with the conclusion that rollover recommendations typically include investment recommendations. Many commenters expressed concern that the Department intended to apply the facts and circumstances analysis to transactions occurring in the past. They said the Department's statement that it would no longer apply the reasoning in the Deseret Letter would expose financial services providers to liability for transactions entered into in the past. Some commenters asked for additional guidance on other types of interactions, including recommendations to increase contributions to a Plan.

After careful consideration of these comments, the Department has determined that, consistent with the position taken in the proposal, the facts and circumstances analysis required by the five-part test applies to rollover recommendations. A recommendation

[32] Cerulli Associates, ''U.S. Retirement Markets 2019.''

[33] The exemption would also provide relief for investment advice fiduciaries under either Title I or the Code to receive compensation for advice to roll Plan assets to another Plan, to roll IRA assets to another IRA or to a Plan, and to transfer assets from one type of account to another, all limited to the extent such rollovers are permitted under applicable law. The analysis set forth in this section will apply as relevant to those transactions as well. For purposes of any rollover of assets between a Title I Plan and an IRA described in this preamble, the term ''IRA'' includes only an account or annuity described in Code section 4975(e)(1)(B) or (C).

[34] 29 CFR 2510–3.21.

[35] Similarly, the SEC and FINRA have each recognized that recommendations to roll over Plan assets to an IRA will almost always involve a securities transaction. *See* Regulation Best Interest Release, 84 FR 33339; FINRA Regulatory Notice 13–45 Rollovers to Individual Retirement Accounts (December 2013), *available at www.finra.org/sites/default/files/NoticeDocument/p418695.pdf.*

[36] Comments on the reinsertion of the five-part test are discussed in greater detail below in the section ''Reinsertion of the Five-Part Test.''

to roll assets out of a Title I Plan *is* advice with respect to moneys or other property of the plan and, if provided by a person who satisfies all of the requirements of the five-part test, constitutes fiduciary investment advice. This outcome is more aligned with both the facts and circumstances approach taken by Congress in drafting the Act's statutory functional fiduciary test, and with an approach centered on whether the parties have entered into a relationship of trust and confidence.[37] This outcome is also consistent with the Act's goal of protecting the interests of Retirement Investors given the central importance to investors' retirement security consequences of a decision to roll over Title I Plan assets.

The Department agrees that not all rollover recommendations can be considered fiduciary investment advice under the five-part test set forth in the Department's regulation. Parties can and do, for example, enter into one-time sales transactions in which there is no ongoing investment advice relationship, or expectation of such a relationship. If, for example, a participant purchases an annuity based upon a recommendation from an insurance agent without receiving subsequent, ongoing advice, the advice does not meet the ''regular basis'' prong as specifically required by the regulation.[38] Nor is the Department persuaded by the commenter who suggested that a rollover transaction should always satisfy the regular basis prong on the grounds that it can be viewed as involving two separate steps—the rollover and a subsequent investment decision. These two steps do not, in and of themselves, establish a regular basis.

The Department does not believe that its interpretation will lead to loss of access to investment advice due to uncertainty of financial services providers as to their fiduciary status. Taken together, the five-part test as interpreted here and Interpretive Bulletin 96–1, regarding participant investment education, provide Financial Institutions and Investment Professionals a clear roadmap for when they are, and are not, Title I and Code fiduciaries. Since the exemption provides prohibited transaction relief for rollover recommendations that do constitute fiduciary investment advice, Financial Institutions and Investment Professionals would be free to provide fiduciary investment advice and comply with the exemption to avoid a prohibited transaction. In this regard, some commenters specifically supported the proposed exemption as facilitating investment advice and options for consumers. Alternatively, financial services providers can choose not to provide fiduciary investment advice and have no need of this exemption. And, of course, the Department acknowledges some commenters' observations that Retirement Investors may choose on their own to withdraw assets from a Title I Plan and roll over funds to an IRA; however, this exemption focuses on the interests of those Retirement Investors who do receive fiduciary investment advice. The Department further addresses concerns regarding purported uncertainty over whether certain relationships meet the prongs of the five-part test, including the ''regular basis'' and ''mutual agreement'' prongs, later in this preamble.

Some commenters stated that the Department should have engaged in notice and comment prior to announcing that it would no longer apply the analysis in the Deseret Letter. Commenters said that the position in the Deseret Letter contributed to a longstanding understanding of the five-part test which should be reversed only through the regulatory process. A commenter noted that, in 2016, the Department characterized the 2016 fiduciary rule as ''superseding'' the Deseret Letter, and asserted that characterization as evidence that the Department's procedure in this exemption proceeding is inadequate.

The Department does not believe these comments have merit. Advisory opinions, such as the Deseret Letter, are interpretive statements that were not subject to the notice and comment process. As such, the Department need not go through notice and comment to offer a new interpretation of the regulation based on a better reading of governing statutory and regulatory authority, as here.[39] Moreover, in this instance, the statements made in the preamble to the now-vacated 2016 fiduciary rule are also unpersuasive as to the effect of the Deseret Letter for the same reasons. Rather than take the 2016 fiduciary rule's approach of removing the five-part test through an amendment to the Code of Federal Regulations and, thus, ''superseding'' the Deseret Letter, the Department now is only changing its view on the Deseret Letter (and specifically, one aspect of it). The five-part test still applies without the Deseret Letter, as it did for decades before the letter. The 2016 fiduciary rule is not in effect, and statements made in the preamble to the vacated rule bear no weight. And, in this instance, the Department solicited and has had the benefit of public comment on its interpretation through the notice and comment process for the exemption. Comments regarding the Department's compliance with Executive Order 13891 are addressed later in this preamble.

Nevertheless, in response to commenters expressing concern about the possibility of being held liable for past transactions that would not have been treated as fiduciary under the Deseret analysis, the Department will not pursue claims for breach of fiduciary duty or prohibited transactions against any party, or treat any party as violating the applicable prohibited transaction rules, for the period between 2005, when the Deseret Letter was issued, and February 16, 2021, based on a rollover recommendation that would have been considered non-fiduciary conduct under the reasoning in the Deseret Letter. The Department recognizes that advisory opinions issued under ERISA Procedure 76–1, while directly applicable only to their requester, *see* ERISA Procedure 76–1 section 10, can also constitute ''a body of experience and informed judgment to which the courts and litigants may properly resort for guidance.'' *Raymond B. Yates, M.D., P.C. Profit Sharing Plan* v. *Hendon,* 541 U.S. 1, 18 (2004) (quoting *Skidmore* v. *Swift & Co.,* 323 U.S. 134, 140 (1944)). For this reason, and because the Department does not wish to disturb the reliance interests of those who looked to the Deseret Letter for guidance, the Department also does not expect or intend a private right of action to be viable for a transaction conducted in reliance on the Deseret Letter prior to that date. Further, the extension of the temporary enforcement policy in FAB 2018–02 until its expiration on December 20, 2021 will allow parties a transition period during which the Department will not pursue prohibited transaction claims against investment advice fiduciaries who work diligently and in good faith to comply with the Impartial Conduct Standards for rollover recommendations or treat such fiduciaries as violating the applicable prohibited transaction rules.[40]

[37] For example, ERISA section 3(21) discusses a fiduciary relationship surrounding the ''disposition of [plan] assets.''

[38] Where a broker-dealer or investment adviser makes a recommendation or provides advice that does not meet the five-part test, the recommendation or advice could still be subject to Regulation Best Interest or the investment adviser's fiduciary duty under securities laws, as applicable.

[39] *See Perez* v. *Mortgage Bankers Assoc.,* 575 U.S. 92, 100–01 (2015).

[40] On March 28, 2017, the Treasury Department and the IRS issued IRS Announcement 2017–4 stating that the IRS will not apply § 4975 (which

Additionally, although the Department declines to set broad guidelines in this preamble for what is necessarily a facts-and-circumstances determination about particular business practices, to the extent public comments were based on concerns about compliance and interpretive issues with the final exemption or the Act, the Department intends to support Financial Institutions, Investment Professionals, plan sponsors and fiduciaries, and other affected parties with compliance assistance following publication of the final exemption.

Facts and Circumstances Analysis

All the elements of the five-part test must be satisfied for the investment advice provider to be a fiduciary within the meaning of the regulatory definition, including the ''regular basis'' prong as well as requirements that the advice be provided pursuant to a ''mutual'' agreement, arrangement, or understanding that the advice will serve as ''a primary basis'' for investment decisions. In addition to satisfying the five-part test, a person must also receive a fee or other compensation to be an investment advice fiduciary under the provisions of Title I and the Code.

If, under this facts and circumstances analysis, advice to roll Title I Plan assets over to an IRA is fiduciary investment advice under Title I, the fiduciary duties of prudence and loyalty under ERISA section 404 would apply to the initial instance of advice to take the distribution and to roll over the assets. Fiduciary investment advice concerning investment of the rollover assets and ongoing management of the assets, once distributed from the Title I Plan into the IRA, would be subject to obligations in the Code. For example, a broker-dealer who satisfies the five-part test with respect to a Retirement Investor in advising on assets in a Title I Plan, advises the Retirement Investor to move his or her assets from the plan to an IRA, and receives any fees or compensation incident to distributing those assets, will be a fiduciary subject to Title I, including section 404, with respect to the advice regarding the rollover. Following the rollover, the broker-dealer will be a fiduciary under the Code subject to the prohibited transaction provisions in Code section 4975.

Final Interpretation

The Department acknowledges that a single instance of advice to take a distribution from a Title I Plan and roll over the assets would fail to meet the regular basis prong. Likewise, sporadic interactions between a financial services professional and a Retirement Investor do not meet the regular basis prong. For example, if a Retirement Investor who is assisted with a rollover expresses the intent to direct his or her own investments in a brokerage account, without any expectation of entering into an ongoing advisory relationship and without receiving repeated investment recommendations from the investment professional, the Department would not view the regular basis prong as being satisfied merely because the investor subsequently sought the professional's advice in connection with another transaction long after receiving the rollover assistance.

However, advice to roll over plan assets can also occur as part of an ongoing relationship or an intended ongoing relationship that an individual enjoys with his or her investment advice provider. In circumstances in which the investment advice provider has been giving advice to the individual about investing in, purchasing, or selling securities or other financial instruments through tax-advantaged retirement vehicles subject to Title I or the Code, the advice to roll assets out of a Title I Plan is part of an ongoing advice relationship that satisfies the regular basis prong. Similarly, advice to roll assets out of a Title I Plan into an IRA where the investment advice provider has not previously provided advice but will be regularly giving advice regarding the IRA in the course of a more lengthy financial relationship would be the start of an advice relationship that satisfies the regular basis prong. It is clear under Title I and the Code that advice to a Title I Plan includes advice to participants and beneficiaries in participant-directed individual account pension plans, so in these scenarios, there is advice to the Title I Plan—meaning the Plan participant or beneficiary—on a regular basis.[41]

This interpretation is consistent with the approach of other regulators and protects Plan participants and beneficiaries under today's market practices, including the increasing prevalence of 401(k) Plans and self-directed accounts. Numerous sources acknowledge that an outcome of advice given to a Retirement Investor to roll over Title I Plan assets is the compensation an advice provider receives from the investments made in an IRA. For example, in a 2013 notice reminding firms of their responsibilities regarding IRA rollovers, FINRA stated that ''a financial adviser has an economic incentive to encourage an investor to roll plan assets into an IRA that he will represent as either a broker-dealer or an investment adviser representative.''[42] Similarly, in 2011, the U.S. Government Accountability Office (GAO) discussed the practice of cross-selling, in which 401(k) service providers sell Plan participants products and services outside of their Title I Plans, including IRA rollovers. GAO reported that industry professionals said ''cross-selling IRA rollovers to participants, in particular, is an important source of income for service providers.''[43] These types of transactions can initiate a future, ongoing relationship.[44]

In applying the regular basis prong of the five-part test, however, the Department intends to preserve the ability of financial services professionals to engage in one-time sales transactions without becoming fiduciaries under the Act, including by assisting with a rollover.[45] For example, such parties can make clear in their communications that they do not intend to enter into an ongoing relationship to provide investment advice and act in conformity with that communication. In the event that assistance with a rollover does in fact mark the beginning of an ongoing relationship, however, the functional fiduciary test under Title I and the Code appropriately covers the entire fiduciary relationship, including the first instance of advice.

With respect to determining whether there is ''a mutual agreement, arrangement, or understanding'' that the investment advice will serve as ''a primary basis for investment decisions,''

provides excise taxes relating to prohibited transactions) and related reporting obligations with respect to any transaction or agreement to which the Labor Department's temporary enforcement policy described in FAB 2017–01, or other subsequent related enforcement guidance, would apply. The Treasury Department and the IRS have confirmed that, for purposes of applying IRS Announcement 2017–4, this preamble discussion and FAB 2018–02 constitute ''other subsequent related enforcement guidance.''

[41] *See* ERISA section 408(b)(14) (providing a statutory exemption for transactions in connection with the provision of investment advice described in ERISA section 3(21)(A)(ii) to a participant or beneficiary of an individual account plan that permits such participant or beneficiary to direct the investment of assets in their individual account); Code section 4975(d)(17) (same); *see also* Interpretive Bulletin 96–1, 29 CFR 2509.96–1.

[42] FINRA Regulatory Notice 13–45.

[43] U.S. General Accountability Office, 401(k) Plans: Improved Regulation Could Better Protect Participants from Conflicts of Interest, GAO 11–119 (Washington, DC 2011), *available at www.gao.gov/assets/320/315363.pdf.*

[44] It is by no means uncommon to interpret regulatory or statutory terms phrased in the present to incorporate the future tense. *See, e.g.,* 1 U.S.C. 1.

[45] Merely executing a sales transaction at the customer's request also does not confer fiduciary status.

the Department intends to consider the *reasonable* understanding of each of the parties, if no mutual agreement or arrangement is demonstrated. Written statements disclaiming a mutual understanding or forbidding reliance on the advice as a primary basis for investment decisions will not be determinative, although such statements will be appropriately considered in determining whether a mutual understanding exists. Similarly, after consideration of the comments, the Department also intends to consider marketing materials in which Financial Institutions and Investment Professionals hold themselves out as trusted advisers, in evaluating the parties' reasonable understandings with respect to the relationship.

The Department believes that Financial Institutions and Investment Professionals who meet the five-part test and are investment advice fiduciaries relying on this exemption should clearly disclose their fiduciary status to their Retirement Investor customers. By making this disclosure, they provide important clarity to the Retirement Investor and put themselves in the best possible position to meet their fiduciary obligations and comply with the exemption. By setting clear expectations and acting accordingly, the mutual understanding prong of the five-part test should seldom be an issue for parties relying on the exemption. Similarly, if a Financial Institution or Investment Professional does not want to assume a fiduciary relationship or create misimpressions about the nature of its undertaking, it can clearly disclose that fact to its customers up-front, clearly disclaim any fiduciary relationship, and avoid holding itself out to its Retirement Investor customer as acting in a position of trust and confidence.

The Department does not intend to apply the five-part test to determine whether the advice serves as ''the'' primary basis of investment decisions, as advocated by some commenters, but whether it serves as ''a'' primary basis, as the regulatory text provides.

Comments on the Regular Basis Analysis

Some commenters on the Department's proposed interpretation of the regular basis prong asserted that the regular basis prong would always be satisfied under the interpretation, and, therefore, the prong was effectively being eliminated from the five-part test. In this regard, one commenter stated that every financial professional wants to develop an ongoing relationship with her customers. Commenters opposed the statement that a rollover recommendation could be the first step in an ongoing advice relationship that would satisfy the regular basis prong. Some commenters characterized this statement as allowing for the ''retroactive'' imposition of fiduciary status on financial services providers in the event an ongoing relationship develops. Some commenters additionally opined that to be ''regular,'' the interactions would have to be more than discrete or episodic. Some commenters stated that the advice to a Retirement Investor in a Title I Plan should be viewed as distinct from the advice to the same Retirement Investor whose assets have been transferred to an IRA, for purposes of the analysis of the regular basis prong. Commenters also cautioned that the preamble statement about rollover advice following a pre-existing advice relationship appeared to be overbroad with respect to the types of pre-existing advice relationships to which it would apply.

Commenters in the insurance industry asked the Department to confirm that insurance transactions generally would not be considered fiduciary investment advice, because commenters said they occur infrequently and that ongoing interactions may occur but they are related to servicing the insurance or annuity contract. Some commenters objected to the Department's statement in the preamble that agents who receive trailing commissions on annuity transactions may continue to provide ongoing recommendations or service with respect to the annuity. Commenters asserted that this method of compensation is paid for a variety of reasons and does not indicate an ongoing advice relationship.[46]

The Department has carefully considered these comments in clarifying its interpretation of the ''regular basis'' prong of the five-part test. The Department does not believe that the regular basis prong has effectively been eliminated by stating that this prong may be satisfied, in some cases, with the occurrence of first-time advice on rollovers that is intended to be the beginning of a long-term relationship. The regulation still requires, in all cases, that advice will be provided on a regular basis. The Department's interpretation merely recognizes that the rollover recommendation can be the beginning of an ongoing advice relationship. It is important that fiduciary status extend to the entire advisory relationship.

In this regard, when the parties reasonably expect an ongoing advice relationship at the time of the rollover recommendation, the regular basis prong is satisfied. This expectation can be shown by various kinds of objective evidence, of which some examples are discussed below, such as the parties agreeing to check-in periodically on the performance of the customer's post-rollover financial products. In such cases, the parties' expectation at the time of the rollover recommendation appropriately demonstrates that the regular basis prong has been satisfied, and, if the other prongs of the test are satisfied, the financial service providers making the recommendation are appropriately treated as investment advice fiduciaries under Title I and the Code. Likewise, to the extent that financial service providers hold themselves out to the customer as providing such ongoing services, and meet the other elements of the five-part test, they are fiduciaries.

In the Department's view, the updated conduct standards adopted by the SEC and the NAIC reflect an acknowledgment of the fact that broker-dealers and insurance agents commonly provide investment and annuity recommendations to their customers.[47] To the extent these professionals engage in an ongoing advice relationship, they will likely satisfy the regular basis prong. Moreover, the Department does not intend to interpret ''regular basis'' to be limited to relationships in which advice is provided at fixed intervals, as suggested by a commenter, but, instead, believes the term ''regular basis'' broadly describes a relationship where advice is recurring, non-sporadic, and expected to continue. When insurance agents or broker-dealers frequently or periodically make recommendations to their clients on annuity or investment products or features, or on the

[46] A few commenters in the insurance industry and the brokerage industry cited statements in the Fifth Circuit's *Chamber* opinion for the proposition that brokers-dealers and insurance agents would ordinarily not develop a relationship of trust and confidence with prospective customers so as to properly be considered fiduciaries under Title I and the Code. These comments related to the Fifth Circuit's *Chamber* opinion are discussed later in this preamble.

[47] *See Regulation Best Interest,* 17 CFR 240.15l–1(a) (''A broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer.'') and NAIC Model Regulation Section 6.A. (''A producer, when making a recommendation of an annuity, shall act in the best interest of the consumer under the circumstances known at the time the recommendation is made, without placing the producer's or the insurer's financial interest ahead of the consumer's interest.'').

investment of additional assets in existing products, they may meet the ''regular basis'' prong of the five-part test, and are appropriately treated as fiduciaries, assuming that they meet the remaining elements of the fiduciary definition.

The Department's interpretation of the regular basis prong does not result in retroactive imposition of fiduciary status, as suggested by some commenters. As noted above, fiduciary status is determined by the facts as they exist at the time of the recommendation, including whether the parties, at that time, mutually intend an ongoing advisory relationship. Every relationship has a beginning, and the five-part test does not provide that the first instance of advice in an ongoing relationship is automatically free from fiduciary obligations. The fact that the relationship of trust and confidence starts with a recommendation to roll the investor's retirement savings out of a Title I Plan is not an argument for treating the recommendation as non-fiduciary. Rather, fiduciary status extends to the entire advisory relationship, including the first—and often most important—advice on rolling the investor's retirement savings out of the Title I Plan in the first place. A financial services provider that recommends that Retirement Investors roll potential life savings out of a Title I Plan with the expectation of offering ongoing advice to the same Retirement Investor whose retirement assets will now be held in an IRA should reasonably understand that the provider will be held to fiduciary standards.

This does not mean that fiduciary status applies to a prior isolated interaction, if the facts and circumstances surrounding the interaction do not reflect that the interaction marked the beginning of an ongoing fiduciary advice relationship. The Department recognizes that relationships, and the parties' understandings of their relationships, can change over time. The Department emphasizes that parties who do not wish to enter into an ongoing relationship can make that fact consistently clear in their communications and act accordingly.

The Department disagrees with commenters who suggested that the ''regular basis'' requirement must first be met with respect to the Title I Plan, and then again with respect to the IRA. Under the logic of this position, even if the investment advice provider specifically recommended the rollover to the IRA as part of a planned ongoing investment advice relationship, the ''regular basis'' requirement would not be satisfied with respect to the rollover advice because there was only one instance of advice under the Title I Plan, notwithstanding the expectation of a continued advisory relationship with the same customer with respect to the same assets that were rolled out of the plan. Similarly, the argument asserts that even if the investment advice provider regularly advised the Plan participant on how to invest plan assets, recommended the rollover to an IRA, and then continued to give advice on the IRA account, the first instance of advice post-rollover did not count because the ''regular basis'' requirement had only been satisfied with respect to the Title I Plan, but not the IRA.

In response, the Department notes that under Title I and the Code, advice to a Title I Plan includes advice to participants and beneficiaries in participant-directed individual account pension plans.[48] Given that the identical five-part test definition appears in the regulatory definition under both Title I and the Code, the advice is rendered to the exact same Retirement Investor (first as a Plan participant and then as IRA owner), and the IRA assets are derived, in the first place, from that Retirement Investor's Title I Plan account, it is appropriate to conclude that an ongoing advisory relationship spanning both the Title I Plan and the IRA satisfies the regular basis prong. It is enough, in the scenarios outlined above, that the same financial services provider is giving advice to the same person with respect to the same assets (or proceeds of those assets), pursuant to identical five-part tests. A different outcome could all too easily defeat legitimate investor expectations of trust and confidence by arbitrarily dividing an ongoing relationship of ongoing advice and uniquely carving out rollover advice from fiduciary protection.

Further, the Department believes an approach that coordinates the five-part test under Title I with the identical test under the Code is consistent with the transfer of authority to the Department under Reorganization Plan No. 4 of 1978.[49] Pursuant to the Reorganization Plan, the Secretary of Labor has authority to issue regulations, rulings, opinions, and exemptions under Code section 4975, with some limited exceptions not relevant here. The message of the President that accompanied the Reorganization Plan indicated an intent to streamline administration of the Act, and to entrust the Department of Labor with responsibility to oversee fiduciary conduct.[50]

For similar reasons, the Department's interpretation of the regular basis prong does not artificially distinguish between advice to a Retirement Investor in a Title I Plan and advice to the same Retirement Investor in an IRA, when evaluating a rollover recommendation made in the context of a pre-existing advice relationship. Likewise, the Department does not arbitrarily subdivide advice rendered to a plan sponsor on multiple Title I Plans. It is enough, in that case, that the parties have an ongoing advisory relationship with respect to Title I Plans. If, on the other hand, the investment professional only made recommendations to the investor on non-''plan'' assets held outside a Plan or an IRA, he or she would not meet the ''regular basis'' test based solely on additional one-time advice with respect to the Plan or IRA. To meet the regular basis prong in that circumstance, there must be ongoing advice to a ''plan'' (including Plans and IRAs).

As indicated by the discussion above, whether insurance transactions will fall within or outside the scope of the fiduciary definition in Title I and the Code depends on the related facts and circumstances. Like other transactions involving Retirement Investors, insurance and annuity transactions must be evaluated based on application of the five-part test to the particular scenario. Some commenters raised concerns that trailing annuity commissions could be seen as indicating ongoing service that the Department would view as fiduciary investment advice. Other commenters asserted that the Department's view on this point fails to recognize that insurance agents may receive trailing commissions for reasons wholly unrelated to their relationship with a Retirement Investor, and that how an agent is compensated does not impact whether the regular basis prong of the five-part test is satisfied. The Department clarifies that payment of a trailing commission will not, in and of itself, result in the Department taking the position that the regular basis prong of the five-part test is satisfied with respect to a transaction. On the other hand, if the trailing commission is intended to compensate a financial professional for providing advice to the

[48] *See supra,* n. 41.

[49] 5 U.S.C. App. (2018).

[50] Presidential Statement of October 14, 1978 on Congressional Action on Reorganization Plan No. 4, 1978, Weekly Compilation of Presidential Documents, Vol. 14, No. 42 (Aug. 10, 1978) (accompanying the Reorganization Plan No. 4 of 1978, 5 U.S.C.A. App. 1, 43 FR 47713–16 (Oct. 17, 1978)).

Retirement Investor on an ongoing basis, the conclusion could be different, depending on the full facts and circumstances of the advice arrangement.

Mutual Agreement, Arrangement, or Understanding That the Investment Advice Will Serve as a Primary Basis for Investment Decisions

Similar to the comments discussed above, some commenters also asserted that the Department's interpretation of the ''mutual agreement, arrangement, or understanding'' and the ''primary basis'' requirements is so broad as to render them meaningless. Some of these commenters objected to the statement that recommendations by financial professionals, particularly pursuant to a best interest standard or another requirement to provide advice based on the individualized needs of the Retirement Investor, will typically involve a reasonable understanding by both parties that the advice will serve as at least a primary basis for the decision. The commenters asserted that the statement is inconsistent with the fact that the broker-dealer and insurance regulatory regimes do not incorporate a fiduciary standard. A few commenters sought confirmation that compliance with Regulation Best Interest would not automatically result in satisfaction of the primary basis prong of the five-part test. Some commenters stated that investors may consult multiple financial professionals and, therefore, the response by any one professional should not be considered a primary basis for the investment decision.

Some commenters opposed the Department's interpretive statement that written disclaimers of fiduciary status or elements of the five-part test will not be determinative. They stated that this interpretation ignores the requirement of ''mutuality.'' Some commenters also criticized the statement that the five-part test focuses on ''a'' primary basis, not ''the'' primary basis, although some acknowledged that ''a'' is, in fact, the word used in the regulation. Commenters said the interpretation is at odds with the common understanding of the word ''primary'' and will result in an unwarranted expansion of the five-part test. Commenters also asserted that the statement in the Department's interpretation conflated the primary basis requirement with a separate requirement for individualized advice. On the other hand, another commenter advocated that a Retirement Investor's position as to whether there is an understanding for the advice to provide a primary basis for the investment decision should be provided a presumption of correctness, which can only be overcome with significant evidence.

The Department is not persuaded by these comments to revise its interpretation. As stated above, the Department's interpretation has not rendered these requirements of the five-part test meaningless. Rather, the Department is appropriately applying the five-part test to current marketplace conduct and realities. The fact that a financial services professional is not considered a fiduciary under other laws, such as securities law or insurance law, is not a determinative factor under the five-part test. The focus is on the facts and circumstances surrounding the recommendation and the relationship, including whether those facts and circumstances give rise to a mutual agreement, arrangement, or understanding that the advice will serve as a primary basis for an investment decision. While satisfying the other laws may implicate parts of the test, fiduciary status applies only if all five prongs are satisfied.

The Department does not interpret the ''primary basis'' requirement as requiring proof that the advice was the single most important determinative factor in the Retirement Investor's investment decision. This is consistent with the regulation's reference to the advice as ''a'' primary basis rather than ''the'' primary basis. Similarly, the fact that a Retirement Investor may consult multiple financial professionals about a particular investment does not indicate that the Department's analysis is incorrect. If, in each instance, the parties reasonably understand that the advice is important to the Retirement Investor and could determine the outcome of the investor's decision, that is enough to satisfy the ''primary basis'' requirement. Even so, all elements of the five-part test must be satisfied for a particular recommendation to be considered fiduciary investment advice, and if a Retirement Investor does not act on a recommendation made by a financial professional, the financial professional would not have any liability for that recommendation.

The Department also recognizes that the requirement for ''individualized'' advice is separate from the ''primary basis'' requirement, but this does not mean that the individualized nature of a particular advice recommendation is irrelevant to whether the parties understood that the advice could serve as a ''primary basis'' for investment decisions.

The Department also is not persuaded by commenters to change its position on the role of written disclaimers of fiduciary status or of elements of the five-part test. In the context of the rendering of investment advice by a financial services professional, written statements disclaiming a mutual understanding or forbidding reliance on the advice as a primary basis for investment decisions will not be determinative, although such statements can be appropriately considered in determining whether a mutual understanding exists. This interpretation will not deprive parties of the ability to define the nature of their relationship, but recognizes that there needs to be consistency in that respect. A financial services provider should not, for example, expect to avoid fiduciary status through a boilerplate disclaimer buried in the fine print, while in all other communications holding itself out as rendering best interest advice that can be relied upon by the customer in making investment decisions. While financial services professionals may contractually disclaim engaging in activities that trigger elements of the five-part test, such as rendering advice that can be relied upon as a primary basis for the Retirement Investor's investment decisions, they must do so clearly and act accordingly to demonstrate that there is in fact no mutual agreement, arrangement, or understanding to the contrary.

One commenter similarly requested that the Department confirm that broker-dealers can disclaim a mutual agreement, arrangement or understanding in cases in which they provide investment recommendations that comply with Regulation Best Interest. The Department declines to do so expressly. As discussed above, the Department has not provided a safe harbor in this exemption for compliance with other regulators' conduct standards. The Department also declines in this exemption to set forth evidentiary burdens applied to establish a mutual understanding, including any presumptions as one commenter suggested. That question is better left to development by the courts or, if necessary, future guidance or rulemaking. The Department reiterates, however, that all prongs of the five-part test, including the regular basis prong, must be satisfied for a person or entity to be a fiduciary. Further, as noted above, a broker-dealer who does not wish to establish a fiduciary relationship in connection with a rollover may make clear in its communications that it does not intend to enter into an ongoing relationship to

provide investment advice and act in conformity with that communication.

''Hire Me'' Communications

Some commenters asked the Department to confirm that so-called ''hire me'' communications, in which financial services professionals engage in introductory conversations to promote their advisory services to Retirement Investors, will not be treated as fiduciary communications under Title I and the Code. Commenters indicated that these types of communications are an important part of the process for a Retirement Investor to select an investment advice provider. A commenter pointed to statements in the Department's 2016 fiduciary rulemaking about the ability of a person or firm to ''tout the quality of his, her, or its own advisory or investment management services'' without being considered an investment advice fiduciary.[51] The commenter also pointed to an FAQ issued by the SEC staff in the context of Regulation Best Interest, which confirmed that, absent other factors, the SEC staff would not view this type of communication as a recommendation:

> I have been working with our mutual friend, Bob, for fifteen years, helping him to invest for his kids' college tuition and for retirement. I would love to talk with you about the types of services my firm offers, and how I could help you meet your goals. Here is my business card. Please give me a call on Monday so that we can discuss.[52]

In the context of the present exemption proceeding, the Department does not believe that there should be significant concerns about introductory ''hire me'' conversations. This is because all prongs of the five-part test must be satisfied for a financial services provider to be considered a fiduciary. Nevertheless, the Department confirms that the interpretive statements in this preamble are not intended to suggest that marketing activity of the type described above would be treated as investment advice covered under the five-part test. To the extent, however, that the marketing of advisory services is accompanied by an investment recommendation, such as a recommendation to invest in a particular fund or security, the investment recommendation would be covered if all five parts of the test were satisfied.

For a Fee or Other Compensation, Direct or Indirect

The Department's preamble interpretation in the proposal noted that in addition to satisfying the five-part test, a person must receive a ''fee or other compensation, direct or indirect'' to be an investment advice fiduciary.[53] The Department has long interpreted this requirement broadly to cover ''all fees or other compensation incident to the transaction in which the investment advice to the plan has been rendered or will be rendered.'' [54] The Department previously noted that ''this may include, for example, brokerage commissions, mutual fund sales commissions, and insurance sales commissions.'' [55] In the rollover context, fees and compensation received from transactions involving rollover assets would be incident to the advice to take a distribution from the Plan and to roll over the assets to an IRA.

While commenters acknowledged this discussion is consistent with the Department's longstanding interpretive position, they asserted that it is inconsistent with views expressed by the Fifth Circuit in the *Chamber* opinion and with the definition of a fiduciary in Title I and the Code. Responses to arguments about the fee requirement and the *Chamber* opinion follow in the next section.

Procedural and Legal Arguments

Many commenters asserted that the Department failed to comply with the Administrative Procedure Act because the interpretation of the five-part test set forth in the proposal, in their view, effectively amended the five-part test without appropriate procedures. As discussed above, the commenters expressed the view that the Department's preamble interpretation effectively eliminated the ''regular basis'' and ''mutual agreement, arrangement or understanding'' prongs of the five-part test. A few commenters additionally suggested that providing the interpretation in the preamble of a proposed class exemption did not provide sufficient notice and opportunity for comment.

The Department's interpretation does not amend the five-part test, but only provides interpretive guidance, in the context of the relief provided in the new exemption, as to how that test applies to current practices in providing investment advice. The regulatory five-part test has long been understood to provide a functional fiduciary test, and the Department's interpretation is based on this understanding. The Department's interpretation does not effectively eliminate any of the elements of the five-part test, but rather applies them to current marketplace conduct and harmonizes with the current regulatory environment.[56]

Some commenters opined that the Department's proposed interpretation of the five-part test would result in parties being considered fiduciaries under Title I and the Code under circumstances that would be inconsistent with pronouncements and holdings by the Fifth Circuit in the *Chamber* opinion. In particular, commenters invoked statements by the court that fiduciary status is based on the existence of a relationship of trust and confidence. Commenters stated that at the time of the first instance of advice in an ongoing relationship, a financial services professional may not have developed a relationship of trust and confidence with its customer.

In response, the Department notes that the Fifth Circuit's *Chamber* opinion discussed approvingly the Department's 1975 regulation, which established the five-part test. The court did not indicate that, in an ongoing relationship, there should be any initial instances of advice free of fiduciary status until some later period in which a relationship of trust and confidence has been demonstrated repeatedly. To the contrary, the court expressed agreement that investment advisers registered under the Investment Advisers Act may appropriately be considered fiduciaries without indicating that fiduciary status would only apply after a period of time. Of particular importance, in the Department's view, is the court's approving discussion that the SEC has ''repeatedly held'' that ''[t]he very function of furnishing [investment advice for compensation]—learning the personal and intimate details of the financial affairs of clients and making recommendations as to purchases and

[51] Definition of the Term ''Fiduciary''; Conflict of Interest Rule—Retirement Investment Advice, 81 FR 20946, 20968 (April 8, 2016).

[52] *See* Frequently Asked Questions on Regulation Best Interest, *available at www.sec.gov/tm/faq-regulation-best-interest.*

[53] ERISA section 3(21)(A)(ii); Code section 4975(e)(3)(B).

[54] Preamble to the Department's 1975 Regulation, 40 FR 50842 (October 31, 1975).

[55] *Id.*

[56] One commenter asserted that the Department's interpretation was in substance a ''legislative rule'' which required notice and comment rulemaking, citing *Am. Min. Cong.* v. *Mine Safety & Health Admin.,* 995 F.2d 1106, 1112 (D.C. Cir. 1993), and *Chao* v. *Rothermel,* 327 F.3d 223, 227 (3d Cir. 2003). The Department disagrees that the factors cited in these cases are satisfied. In this regard, there would be an adequate legislative basis for enforcement in the absence of the interpretation; the preamble interpretation will not be published in the CFR; the Department has not invoked its general legislative authority; and for the reasons stated above, the interpretation does not effectively amend the five-part test. The Department further notes that the interpretation was subject to notice and comment as part of the proposal.

sales of securities—cultivates a confidential and intimate relationship.'' [57]

The proposed exemption preamble included a discussion of some Financial Institutions paying unrelated parties to solicit clients for them in accordance with Rule 206(4)–3 under the Investment Advisers Act.[58] The Department noted that advice by a paid solicitor to take a distribution from a Title I Plan and to roll over assets to an IRA could be part of ongoing advice to a Retirement Investor, if the Financial Institution that pays the solicitor provides ongoing fiduciary advice to the IRA owner. A commenter asserted that the interpretation appeared to confer fiduciary status on the solicitor in the absence of a relationship of trust or confidence, which would be impermissible under the Fifth Circuit's opinion. The commenter further asked the Department to clarify whether the mere fact of an affiliation, such as between a broker-dealer and a registered investment adviser, would result in a recommendation by a broker-dealer being considered fiduciary investment advice if an ongoing relationship later developed with an affiliated registered investment adviser.

The Department's statement regarding paid solicitors was intended to ensure that Financial Institutions do not take the position that the actions of a party paid to solicit business for them would be considered distinct from any ongoing relationship that resulted. Although the Fifth Circuit's *Chamber* opinion expressed agreement that investment advisers registered under the Investment Advisers Act may appropriately be considered fiduciaries under Title I and the Code, the opinion did not address the practice of paid solicitors. The Department confirms, however, that its statement about paid solicitors was not intended to suggest that a broker-dealer that makes an isolated recommendation would be considered a fiduciary if, entirely unrelated to the recommendation, an ongoing relationship developed with an affiliated investment adviser.

Commenters likewise pointed to statements made in the proposed exemption preamble regarding the statutory requirement that, for fiduciary status to attach, advice must be provided ''for a fee or other compensation, direct or indirect.'' The preamble stated, ''[i]n the rollover context, fees and compensation received from transactions involving rollover assets would be incident to the advice to take a distribution from the Plan and to roll over the assets to an IRA.'' [59] This is consistent with the Department's longstanding position that the statutory language covers ''all fees or other compensation incident to the transaction in which the investment advice to the plan has been rendered or will be rendered.'' [60]

Commenters stated that the preamble interpretation is inconsistent with the statute because, in their view, the fee would be for completed sales, rather than for advice. Some commenters asserted that their view was supported by the Fifth Circuit's *Chamber* opinion. The Fifth Circuit's *Chamber* opinion, however, did not criticize the Department's longstanding interpretation of this statutory requirement. The Fifth Circuit, in fact, indicated the interpretation is appropriate as applied to a party that has met the elements of the five-part test.[61] The Department's interpretation of the requirement of a ''fee or compensation, direct or indirect'' is consistent with the statutory language defining a fiduciary under Title I and the Code. Of course, this does not suggest that the Department intends to take the position that transactional compensation to an investment professional who does not meet the elements of the five-part test is a fee for advice. Rather, the Department recognizes that investment professionals may engage in non-fiduciary sales activity in which, as in many sales activities, recommendations are made to a customer. The Department's interpretation respects the legitimate sales function of such a non-fiduciary investment professional.

A few commenters additionally asserted that the Department's preamble interpretation is inconsistent with Executive Orders 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents, and 13892, Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication, which they described as requiring transparency and fairness, and as imposing notice and comment requirements, or new restrictions, on agencies when issuing guidance documents.[62] Even assuming the preamble interpretation is guidance regulated by the Executive Orders, the proposed preamble statement provided notice of the interpretation and solicited public comments on it.[63] Accordingly, the Department complied with the Executive Orders.

A few commenters contended that the Department's preamble interpretation is inconsistent with the characterization of the regulatory package as deregulatory. In the Department's view, the exemption as a whole is deregulatory because it provides a broader and more flexible means under which investment advice fiduciaries to Plans and IRAs may receive compensation and engage in certain principal transactions that would otherwise be prohibited under Title I and the Code. Some commenters stated that the exemption effectively reinstates the 2016 fiduciary rule, and one asserted that the Department did so without addressing the President's related concerns in his Memorandum on Fiduciary Duty Rule.[64] As discussed above, the proposed exemption did not amend the 1975 regulation as the 2016 fiduciary rule sought to undertake. In addition, unlike the 2016 fiduciary rulemaking, this project did not amend other, previously granted, prohibited transaction exemptions.

Description of the Final Exemption

Scope of Relief—Section I

Financial Institutions

The exemption is available to entities that satisfy the exemption's definition of a ''Financial Institution.'' The exemption limits the types of entities that qualify as a Financial Institution to SEC- and state-registered investment advisers, broker-dealers, insurance companies, and banks.[65] The definition is based on the entities identified in the statutory exemption for investment advice under ERISA section 408(b)(14)

[57] 885 F.3d 360, 374 (5th Cir. 2018) (citing Hughes, Exchange Act Release No. 4048, 1948 WL 29537, at *4, *7 (Feb. 18, 1948), aff'd sub nom., *Hughes* v. *SEC,* 174 F.2d 969 (D.C. Cir. 1949) and Mason, Moran & Co., Exchange Act Release No. 4832, 1953 WL 44092, at *4 (Apr. 23, 1953)).

[58] 85 FR 40840 at n.40.

[59] *Id.* at 40840.

[60] *Id.*

[61] 885 F.3d at 374 (discussing approvingly the Department's Advisory Opinion 83–60 (Nov. 21 1983) which provided that, ''if, under the particular facts and circumstances, the services provided by the broker-dealer include the provision of 'investment advice', as defined in regulation 2510.3–21(c), it may be reasonably expected that, even in the absence of a distinct and identifiable fee for such advice, a portion of the commissions paid to the broker-dealer would represent compensation for the provision of such investment advice'').

[62] Executive Order 13891, 84 FR 55235 (Oct. 15, 2019); Executive Order 13892, 84 FR 55238 (Oct. 15, 2019).

[63] *See* 85 FR 40840 (''The Department requests comment on all aspects of this part of its proposal.'').

[64] *See Presidential Memorandum on Fiduciary Duty Rule* (Feb. 3, 2017), *www.whitehouse.gov/presidential-actions/presidential-memorandum-fiduciary-duty-rule/.*

[65] The exemption includes a ''bank or similar financial institution supervised by the United States or a state, or a savings association (as defined in section 3(b)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1813(b)(1)).'' The Department interprets this definition to extend to credit unions.

and Code section 4975(d)(17), which are subject to well-established regulatory conditions and oversight [66] and have been deemed able to prudently mitigate certain conflicts of interest in their investment advice through adherence to tailored principles under the statutory exemption. The Department takes a similar approach here, and, therefore, is including the same group of entities. To fit within the definition of *Financial Institution,* the firm must not have been disqualified or barred from making investment recommendations by any insurance, banking, or securities law or regulatory authority (including any self-regulatory organization).

The Department recognized in the proposed exemption that different types of Financial Institutions have different business models, and the exemption is drafted to apply flexibly to these institutions.[67] Following is a discussion of the different types of Financial Institutions and comments received in connection with the definition.

Broker-Dealers

Broker-dealers provide a range of services to Retirement Investors, ranging from executing one-time transactions to providing personalized investment recommendations, and they may be compensated on a transactional basis such as through commissions.[68] If broker-dealers that are investment advice fiduciaries with respect to Retirement Investors provide investment advice that affects the amount of their compensation, they must rely on an exemption.

One commenter argued that broker-dealers should not be able to rely on the exemption because they are not fiduciaries under the securities laws. The fiduciary definition in Title I and the Code does not turn, however, on whether parties are characterized as fiduciaries under the securities laws, but rather on whether the persons rendering advice meet the conditions of the functional test of fiduciary status as set forth in the Department's regulation. Moreover, the best interest standard applicable to broker-dealers under Regulation Best Interest is rooted in fiduciary principles.[69]

As discussed by the SEC, under the securities laws, a key difference between broker-dealers and investment advisers is that investment advisers typically have a duty to monitor their customers' investments, whereas broker-dealers may more readily limit the scope of their obligations to the specific transactions recommended.[70] Under Title I and the Code, investment advice fiduciaries are not necessarily obligated to assume a duty to monitor, absent an agreement, arrangement or understanding with their investor client to the contrary. The Department's exemption places the transaction-based advice model on an even playing field with the investment adviser model, and applies fiduciary standards in both contexts that are generally consistent with the standards imposed by the SEC. In this manner, the exemption avoids undue expense and generally aligns its requirements with SEC requirements. Moreover, Congress included broker-dealers and registered investment advisers in the statutory advice exemption in ERISA section 408(b)(14) and Code section 4975(d)(17), according to the same set of conditions.

Registered Investment Advisers

Registered investment advisers generally provide ongoing investment advice and services and are commonly paid either an assets under management fee or a fixed fee.[71] If a registered investment adviser is an investment advice fiduciary that charges only a level fee that does not vary on the basis of the investment advice provided, the registered investment adviser may not violate the prohibited transaction rules.[72] However, if the registered investment adviser provides investment advice that causes itself to receive the level fee, such as through advice to roll over Plan assets to an IRA, the fee (including an ongoing management fee paid with respect to the IRA) is prohibited under Title I and the Code.[73] Additionally, if a registered investment adviser that is an investment advice fiduciary is dually-registered as a broker-dealer, the registered investment adviser may engage in a prohibited transaction if it recommends a transaction that increases the firm's compensation, such as for execution of securities transactions in its brokerage capacity. Of course, as discussed above, rollover recommendations or assistance with a rollover do not constitute fiduciary investment advice if the five-part test, including the regular basis prong, is not satisfied.

Commenters sought clarification of the exemption's coverage of certain transactions particularly relevant to registered investment advisers. The commenters inquired about reliance on the exemption solely for a rollover recommendation, under circumstances in which the advice arrangement after the rollover does not involve prohibited transactions (*e.g.,* the compensation arrangement involves only a level fee that does not vary on the basis of the investment transactions) or is not eligible for relief because it is discretionary. The Department confirms that the exemption is available for fiduciary investment advice regarding rollover transactions, even in situations where the exemption is not available (or needed) either before or after the rollover transaction. The commenter also inquired as to whether a financial services provider that serves as a discretionary investment manager to a Plan pursuant to ERISA section 3(38), a transaction that is not covered by the exemption, can rely on the exemption to provide fiduciary investment advice to the Plan's participants and beneficiaries on distribution options. The Department confirms that the exemption is available in that circumstance as well.

Insurance Companies

Insurance companies commonly compensate insurance agents on a commission basis, which generally creates prohibited transactions when insurance agents are investment advice fiduciaries that provide investment advice to Retirement Investors in connection with the sales. The Department is aware that insurance companies often sell insurance products and fixed (including indexed) annuities through different distribution channels

[66] ERISA section 408(g)(11)(A) and Code section 4975(f)(8)(J)(i).

[67] Some of the Department's existing prohibited transaction exemptions would also apply to the transactions described in the next few paragraphs.

[68] Regulation Best Interest Release, 84 FR 33319.

[69] The SEC explained ''key elements of the standard of conduct that applies to broker-dealers, at the time a recommendation is made, under Regulation Best Interest will be substantially similar to key elements of the standard of conduct that applies to investment advisers pursuant to their fiduciary duty under the Advisers Act.'' Regulation Best Interest Release, 84 FR 33461.

[70] The SEC explained that ''[t]here are also key differences between Regulation Best Interest and the Advisers Act fiduciary standard that reflect the distinction between the services and relationships typically offered under the two business models. For example, an investment adviser's fiduciary duty generally includes a duty to provide ongoing advice and monitoring, while Regulation Best Interest imposes no such duty and, instead, requires that a broker-dealer act in the retail customer's best interest *at the time* a recommendation is made.'' Regulation Best Interest Release, 84 FR 33321 (emphasis in the original).

[71] 84 FR 33319.

[72] As noted above, fiduciaries who use their authority to cause themselves or their affiliates or related entities to receive additional compensation violate the prohibited transaction provisions unless an exemption applies. 29 CFR 2550.408b–2(e)(1).

[73] As discussed above, the Department has long interpreted the requirement of a fee to cover ''all fees or other compensation incident to the transaction in which the investment advice to the plan has been rendered or will be rendered.'' Preamble to the Department's 1975 Regulation, 40 FR 50842 (October 31, 1975).

than broker-dealers and registered investment advisers. While some insurance agents are employees of an insurance company, other insurance agents are independent, and work with multiple insurance companies. The final exemption applies to all of these business models.

In the proposal, the Department suggested insurance companies would have several options for compliance. The proposal stated that insurance companies could comply with the new exemption by overseeing independent insurance agents; they could comply with the new exemption by creating oversight and compliance systems through contracts with insurance intermediaries such as independent marketing organizations (IMOs), field marketing organizations (FMOs) or brokerage general agencies (BGAs); or they could rely on the existing class exemption for insurance transactions, PTE 84–24,[74] as an alternative. Further, the Department sought comment on whether the exemption should include insurance intermediaries as Financial Institutions for the recommendation of fixed (including indexed) annuity contracts, and if so, how the insurance intermediaries should be defined and whether additional protective conditions might be necessary with respect to the intermediaries. Discussion of comments on these aspects of the proposal follow.

Direct Oversight

In the proposal, the Department stated that insurance companies could supervise independent insurance agent Investment Professionals who provide investment advice on their products. To comply with the exemption, the Department stated that an insurance company could adopt and implement supervisory and review mechanisms and avoid improper incentives that preferentially push the products, riders, and annuity features that might incentivize Investment Professionals to provide investment advice to Retirement Investors that does not meet the Impartial Conduct Standards. Insurance companies could implement procedures to review annuity sales to Retirement Investors to ensure that they were made in satisfaction of the Impartial Conduct Standards, much as they may already be required to review annuity sales to ensure compliance with state-law suitability requirements.[75] The Department stated in the proposal that insurance company Financial Institutions would be responsible only for an Investment Professional's recommendation and sale of products offered to Retirement Investors by the insurance company in conjunction with fiduciary investment advice, and not unrelated and unaffiliated insurers.[76]

A few commenters took the position in response to the proposal that insurance companies are not set up in such a manner as to be able to act as Financial Institutions with respect to independent insurance agents, which they said would ultimately put insurance companies and insurance products at a competitive disadvantage. Commenters asserted that insurance companies do not have insight into or control over independent agents' business and/or behavior and do not consent to or authorize their activities. While several commenters acknowledged that the proposal was consistent with the NAIC Model Regulation in providing that an insurance company Financial Institution would be responsible only for recommendations with respect to its own products, they argued that the proposed exemption deviated from the NAIC's approach in failing to also state that insurers do not have to include in their supervisory systems ''consideration of or comparison to options available to the producer or compensation relating to those options other than annuities or other products offered by the insurer.'' [77]

In response, the Department notes that the NAIC Model Regulation contemplates that insurance companies will maintain a system of oversight with respect to insurance agents. Section I provides that the purpose of the Model Regulation is to ''require producers, as defined in this regulation, to act in the best interest of the consumer when making a recommendation of an annuity and to require insurers to establish and maintain a system to supervise recommendations so that the insurance needs and financial objectives of consumers at the time of the transaction are effectively addressed.'' [78] Accordingly, the Department believes that a system of oversight by insurance companies over independent insurance agents is achievable.

In terms of the specific oversight requirements, the Department reiterates the statement in the proposal that the exemption requires insurance company Financial Institutions to be responsible only for an Investment Professional's recommendation and sale of products offered to Retirement Investors by the insurance company in conjunction with fiduciary investment advice, and not an unrelated and unaffiliated insurer. The Department also clarifies, in response to commenters, that the exemption does not require consideration of or comparison to specific options available to an independent insurance agent or compensation relating to those options, other than annuities or other products offered by the insurer. The Department's approach is consistent with the approach of the NAIC Model Regulation in this regard as well. However, the Department does not intend to suggest that insurance company Financial Institutions have no obligation to evaluate the financial inducements they offer to independent agents to ensure that the exemption's standards are

[74] Class Exemption for Certain Transactions Involving Insurance Agents and Brokers, Pension Consultants, Insurance Companies, Investment Companies and Investment Company Principal Underwriters, 49 FR 13208 (Apr. 3, 1984), as corrected, 49 FR 24819 (June 15, 1984), as amended, 71 FR 5887 (Feb. 3, 2006).

[75] *Cf.* NAIC Model Regulation Section 6.C.(2)(d) (''The insurer shall establish and maintain procedures for the review of each recommendation prior to issuance of an annuity that are designed to ensure that there is a reasonable basis to determine that the recommended annuity would effectively address the particular consumer's financial situation, insurance needs and financial objectives. Such review procedures may apply a screening system for the purpose of identifying selected transactions for additional review and may be accomplished electronically or through other means including, but not limited to, physical review. Such an electronic or other system may be designed to require additional review only of those transactions identified for additional review by the selection criteria''); and (e) (''The insurer shall establish and maintain reasonable procedures to detect recommendations that are not in compliance with subsections A, B, D and E. This may include, but is not limited to, confirmation of the consumer's consumer profile information, systematic customer surveys, producer and consumer interviews, confirmation letters, producer statements or attestations and programs of internal monitoring. Nothing in this subparagraph prevents an insurer from complying with this subparagraph by applying sampling procedures, or by confirming the consumer profile information or other required information under this section after issuance or delivery of the annuity''),. The prior version of the model regulation, which was adopted in some form by a number of states, also included similar provisions requiring systems to supervise recommendations. *See* Annuity Suitability (A) Working Group Exposure Draft, Adopted by the Committee Dec. 30, 2019, *available at www.naic.org/documents/committees_mo275.pdf.* (comparing 2020 version with prior version).

[76] *Cf. id.,* Section 6.C.(4) (''An insurer is not required to include in its system of supervision: (a) A producer's recommendations to consumers of products other than the annuities offered by the insurer'').

[77] NAIC Model Regulation Section 6.C.(4)(B).

[78] *Id.,* Section 1.A. The Department also notes that the prior version of the Model Regulation, which was adopted in some form by a number of states, contains a similar statement. (''The purpose of this regulation is to require insurers to establish a system to supervise recommendations and to set forth standards and procedures for recommendations to consumers that result in transactions involving annuity products so that the insurance needs and financial objectives of consumers at the time of the transaction are appropriately addressed.'')

satisfied. As discussed above, Financial Institutions can implement procedures to review annuity sales to Retirement Investors under fiduciary investment advice arrangements to ensure that they were made in satisfaction of the Impartial Conduct Standards, much as they may already be required to review annuity sales to ensure compliance with state-law suitability requirements.[79]

Insurance Intermediaries

In the proposal, the Department stated that insurance companies could create a system of oversight and compliance by contracting with an insurance intermediary or other entity to implement policies and procedures designed to ensure that all of the agents associated with the intermediary adhere to the conditions of this exemption. Thus, for example, as one possible approach, the preamble stated that an insurance intermediary could eliminate compensation incentives across all the insurance companies that work with the insurance intermediary, assisting each of the insurance companies with their independent obligations under the exemption. This might involve the insurance intermediary's review of documentation prepared by insurance agents to comply with the exemption, as may be required by the insurance company, or the use of third-party industry comparisons available in the marketplace to help independent insurance agents recommend products that are prudent for the Retirement Investors they advise.

This type of arrangement is also contemplated by the NAIC Model Regulation, which provides that an insurer is not restricted from contracting for performance of supervisory review functions.[80] Also, insurance intermediaries can receive payment for these services; to the extent they are ''affiliates'' or ''related entities'' of the Financial Institution or Investment Professional, the exemption extends to their receipt of compensation so long as the conditions of the exemption are satisfied.

One commenter that is an IMO supported the suggestion in the preamble that insurance intermediaries could serve this function. The commenter stated that it currently works with insurance companies to ensure that their policies and procedures are carried out by independent agents. The commenter took the position that it is positioned to work directly with insurance companies to ensure that the proper oversight and compliance systems are in place to comply with the exemption.

PTE 84–24

To the extent that insurance companies determine that the supervisory requirements of this exemption are not well-suited to their business models, it is important to note that insurance and annuity products can also continue to be recommended and sold under the existing exemption for insurance transactions, PTE 84–24. Unlike in the Department's 2016 fiduciary rulemaking, PTE 84–24 is not being amended in connection with the current proposed exemption.

PTE 84–24 provides prohibited transaction relief for the ''receipt, directly or indirectly, by an insurance agent or broker . . . of a sales commission from an insurance company in connection with the purchase, with plan assets, of an insurance or annuity contract.'' The agent or broker must generally disclose its sales commission and receive written approval of the transaction from an independent fiduciary.

A commenter expressed concern that the Department's disavowal of the Deseret Letter would result in a requirement to provide the disclosures required by PTE 84–24 to a plan fiduciary, rather than the IRA owner, in the case of a rollover recommendation. The Department confirms that when a transaction under PTE 84–24 involves an IRA, the disclosure can be provided to the IRA owner. Further, to avoid uncertainty, the Department also confirms that an insurance intermediary can receive a part of the commission payment that is permitted under PTE 84–24, provided the conditions of the exemption are satisfied.

Insurance Intermediaries as Financial Institutions

The Department also sought comment in the proposal as to whether the exemption's definition of Financial Institution should be expanded to include insurance intermediaries. Under that approach, the insurance intermediary would implement the conditions of the exemption applicable to Financial Institutions, and insurance companies would not have to do so.

Several commenters supported the addition of insurance intermediaries as Financial Institutions, in connection with their contention that insurance companies are not in a position to exert oversight over independent insurance agents because the independent agents sell products of other insurance companies as well. A few commenters stated that the insurance intermediaries are in a position to do so because of their proximity to and expertise working with independent insurance agents. The commenters stated that insurance intermediaries have greater insight into and control over the actions of independent insurance agents than insurance companies. Further, the commenters emphasized that insurance intermediaries are regulated by the states as insurance agencies, and they have sufficient resources and staff to act as Financial Institutions. These commenters also asserted insurance intermediaries' similarity to the registered investment adviser business model and stated that a failure to include insurance intermediaries as Financial Institutions would result in a competitive disadvantage for insurance intermediaries and potentially less choice for Retirement Investors.

Other commenters, however, indicated that insurance intermediaries are not in a position to oversee independent insurance agents because it is common for independent insurance agents to work with multiple intermediaries, raising issues as to whether multiple intermediaries would have to oversee the same independent agent. One commenter also indicated that independent agents have contracts or arrangements directly with the insurance company; by contrast, there is no contract or implied contract between insurance intermediaries and independent insurance agents, and insurance intermediaries do not direct the independent insurance agents' recommendations to Retirement Investors. A few commenters asserted that unlike the other entities included in the definition of a Financial Institution, insurance intermediaries do not have a regulator that sets standards regarding oversight and supervisory policies and procedures. One commenter asserted that the exemption would need to include conditions addressing the Department's oversight of insurance intermediaries if they were included in the definition of a Financial Institution. Another commenter urged the Department to work closely with insurance intermediaries before including them as Financial Institutions, so as to avoid imposing conditions that are impractical or burdensome.

Based on the record before it, the Department has concluded that it should not expand the scope of the definition of Financial Institution to insurance intermediaries, such as IMOs, FMOs, or BGAs. These entities do not have supervisory obligations over independent insurance agents under state or federal law that are comparable

[79] *See supra* n. 75.

[80] NAIC Model Regulation, Section 6.C.(3)(a).

to those of the other entities, such as insurance companies, banks, and broker-dealers, or a history of exercising such supervision in practice. They are generally described as wholesaling and marketing and support organizations, but not tasked with ensuring compliance with regulatory standards. In addition, they are not subject to the sort of capital and solvency requirements imposed on state-regulated insurance companies and banks.

Commenters also did not provide specific suggestions for how to define the insurance intermediaries that could be Financial Institutions. One commenter suggested that Financial Institution status and its attendant compliance responsibilities should be placed on the intermediary that is closest to the Retirement Investor and the Investment Professional advising that investor. However, this suggestion does not alleviate the operational issues that would exist when an independent agent works with or through more than one intermediary. Commenters also did not offer suggestions as to substantive conditions that should be included to make up for the lack of regulatory oversight. The considerations above may not be insuperable obstacles to treating insurance intermediaries as Financial Institutions under the terms of a future exemption that is based on an appropriate record focused on such support organizations. The Department anticipates that any such exemption would specifically focus on the unique attributes, strengths, and weaknesses of these entities, and on any special conditions that would be necessary to ensure they are able to act in the necessary supervisory capacity as Financial Institutions.

The Department also has maintained the provision in this exemption under which the definition of a Financial Institution can expand based upon subsequently granting individual exemptions to additional entities that are investment advice fiduciaries that meet the five-part test and are seeking to be treated as covered Financial Institutions. Thus, additional types of entities, such as IMOs, FMOs, or BGAs may separately apply for prohibited transaction relief to receive compensation in connection with the provision of investment advice, according to the same conditions that apply to the Financial Institutions covered by this exemption. If the Department grants to such an entity an individual exemption under ERISA section 408(a) and Code section 4975(c)(2) after the date this exemption is granted, the expanded definition of Financial Institution in the individual exemption would be added to this class exemption so other entities that satisfy the definition could similarly use this class exemption.

The Department acknowledges that some commenters felt this approach would put insurance intermediaries at a disadvantage as compared to other Financial Institutions. As discussed above, however, there is cause for concern about including insurance intermediaries in the final exemption on the same footing as the types of entities included in the Financial Institution definition. On the record before it, the Department has concluded that the better course of action is to invite any insurance intermediaries to apply for a separate exemption as part of a public notice and comment process that can specifically focus on their unique attributes, so that the Department can determine whether and how to grant exemptive relief, subject to appropriate definitional and protective conditions.

Banks

Banks and similar institutions are permitted to act as Financial Institutions under the exemption if they or their employees are investment advice fiduciaries with respect to Retirement Investors. The Department sought comment on whether banks and their employees provide investment advice to Retirement Investors, and if so, whether the proposal needed adjustment to address any unique aspects of their business models.

A trade association representing banks submitted a comment that described a wide variety of interactions with banking customers, including IRA investment programs and bank networking arrangements and referral programs. The commenter stated that banks that render investment advice are fully subject to applicable federal and state banking laws governing fiduciary status and activities.[81] The commenter expressed support for the exemption, so long as certain suggested changes were adopted to conform to banks' distinct business model, particularly with respect to the retrospective review and the recordkeeping provision. The Department's responses to these comments on the exemption are discussed below in the sections on the retrospective review and recordkeeping provision.

Affiliates and Related Entities

One commenter stated that the exemption text should include a definition of ''affiliate'' and ''related entity.'' The Department has added the definitions that previously appeared in the preamble of the proposed exemption, in Section V(a) and (j), respectively, of the final exemption text.

An affiliate is defined as (1) any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the Investment Professional or Financial Institution (for this purpose, ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual); (2) any officer, director, partner, employee, or relative (as defined in ERISA section 3(15)), of the Investment Professional or Financial Institution; and (3) any corporation or partnership of which the Investment Professional or Financial Institution is an officer, director, or partner. A related entity is defined as an entity that is not an affiliate, but in which the Investment Professional or Financial Institution has an interest that may affect the exercise of its best judgment as a fiduciary.

Another commenter stated that the Department should add foreign affiliates of banks, broker-dealers, insurance companies, and registered investment advisers to the entities covered by the exemption, given the increasingly global nature of retirement services. The proposed exemption indicated that relief would be available to affiliates and related entities of a Financial Institution and Investment Professional, if the Financial Institution and Investment Professional satisfied the exemption's conditions. The Department did not exclude foreign affiliates in the proposal, and confirms that they are not excluded in the exemption, as finalized.

Other Entities—Recordkeepers and HSA Providers

One commenter requested that recordkeepers be included as Financial Institutions. To the extent that an entity hired to act as a recordkeeper to a Plan or an IRA falls within the list of defined Financial Institutions, it may rely upon the exemption. However, the Department declines to add a general category for recordkeepers to the definition. The Department does not believe a recordkeeper that is not also a bank, broker-dealer, insurance company, or registered investment adviser would have the requisite regulatory oversight to necessarily act as a Financial Institution. However, such parties can seek an individual exemption from the Department, as

[81] Citing 12 CFR part 9 (fiduciary activities of banks).

provided in the definition of a Financial Institution in Section V(e).

One commenter addressed health savings accounts (HSAs), indicating that the exemption should apply to advice to individuals with HSAs. The commenter did not indicate whether the definition of Financial Institution needed to be expanded to facilitate advice regarding HSAs. The exemption, as proposed and finalized, defines an IRA as ''any account or annuity described in Code section 4975(e)(1)(B) through (F)'' which includes a ''health savings account described in [Code] section 223(d).'' Therefore, advice may be provided to individuals with HSAs, subject to the conditions of the exemption.

Investment Professionals

As defined in the proposal, an *Investment Professional* is an individual who is a fiduciary of a Plan or an IRA by reason of the provision of investment advice, who is an employee, independent contractor, agent, or representative of a Financial Institution, and who satisfies the federal and state regulatory and licensing requirements of insurance, banking, and securities laws (including self-regulatory organizations) with respect to the covered transaction, as applicable. Similar to the definition of *Financial Institution,* this definition also includes a requirement that the Investment Professional has not been disqualified from making investment recommendations by any insurance, banking, or securities law or regulatory authority (including any self-regulatory organization).

One commenter suggested that the exemption should require investment professionals to be certified by an accredited organization or state agency in financial planning issues. The Department has not adopted this suggestion because it does not have sufficient information in the record on this type of certification to incorporate it as a condition.

Another commenter asked the Department to confirm that insurance agents unaffiliated with a broker-dealer or registered investment adviser are investment advice fiduciaries when providing investment advice to Retirement Investors through the sale of insurance products and fixed (including indexed) annuities, and are subject to the requirements under the exemption. The Department confirms that an insurance agent that meets the elements of the five-part test and receives a fee or other compensation, direct or indirect, with respect to a particular transaction, is a fiduciary with respect to that transaction. Under those circumstances, the insurance agent must avoid prohibited transactions or comply with a prohibited transaction exemption.

Retirement Investors and Plans

The exemption provides relief for specified Covered Transactions when Financial Institutions and Investment Professionals provide investment advice to *Retirement Investors.* A Retirement Investor is defined as (1) a participant or beneficiary of a Plan with authority to direct the investment of assets in his or her account or to take a distribution, (2) the beneficial owner of an IRA acting on behalf of the IRA, or (3) a fiduciary of a Plan or an IRA. A *Plan* for purposes of the exemption is defined as any employee benefit plan described in ERISA section 3(3) and any plan described in Code section 4975(e)(1)(A). An *IRA* is defined as any plan that is an account or annuity described in the other parts of section 4975(e)(1): Paragraphs 4975(e)(1)(B) through (F).

A few commenters questioned the meaning of Retirement Investor with respect to the definition's use of the word *Plan.* One commenter requested clarification that the use of the term *Plan* with respect to a Retirement Investor, in fact, included Title I welfare benefit plans despite the use of the word ''retirement.'' Two other commenters requested that the definition of Plan specifically exclude Title I welfare benefit plans that do not include an investment component, such as health insurance plans, disability insurance plans, and term life insurance plans.

While the exemption uses the term Retirement Investor throughout the exemption, the use of the term was not intended to exclude investment advice provided to Title I welfare benefit plans. In fact, the exemption's definition of Plan states that it is defined, in part, by reference to ERISA section 3(3), which explicitly includes Title I welfare benefit plans.

With respect to the request to exclude Plans that do not contain an investment component, the Department responds that the exemption is only necessary and available to fiduciaries who provide investment advice as described in the five-part test. If there is no fiduciary investment advice, the exemption would not be applicable or needed. In light of this limitation, the Department does not believe any further amendment to the definition of a Plan is necessary.

Covered Transactions

The exemption permits Financial Institutions and Investment Professionals, and their affiliates and related entities, to receive reasonable compensation as a result of providing fiduciary investment advice. The exemption specifically covers compensation received as a result of investment advice to roll over assets from a Plan to an IRA. The exemption also provides relief for a Financial Institution to engage in the purchase or sale of an asset in a riskless principal transaction or a Covered Principal Transaction, and receive a mark-up, mark-down, or other payment. The exemption provides relief from ERISA section 406(a)(1)(A) and (D) and 406(b) and Code section 4975(c)(1)(A), (D), (E), and (F).[82]

Section I(b)(1) of the exemption provides broad relief for Financial Institutions and Investment Professionals that are investment advice fiduciaries to receive all types of compensation as a result of their investment advice to Retirement Investors, so long as the compensation is reasonable. For example, it covers compensation received as a result of investment advice to acquire, hold, dispose of, or exchange securities and other investments. It also covers compensation received as a result of investment advice to take a distribution from a Plan or to roll over the assets to an IRA, or from investment advice regarding other similar transactions including (but not limited to) rollovers from one Plan to another Plan, one IRA to another IRA, or from one type of account to another account (*e.g.,* from a commission-based account to a fee-based account), all limited to the extent such rollovers are permitted under applicable law.

Section I(b)(2) addresses the circumstance in which the Financial Institution may, in addition to providing investment advice, engage in a purchase or sale of an investment with a Retirement Investor and receive a mark-up or a mark-down or similar payment on the transaction. The exemption extends to both riskless principal transactions and Covered Principal Transactions. A riskless principal transaction is a transaction in which a Financial Institution, after having received an order from a Retirement Investor to buy or sell an investment product, purchases or sells the same investment product for the Financial Institution's own account to offset the contemporaneous transaction with the Retirement Investor. Covered Principal

[82] The exemption does not include relief from ERISA section 406(a)(1)(C) and Code section 4975(c)(1)(C) for the furnishing of goods, services, or facilities between a Plan/IRA and a party in interest/disqualified person. The statutory exemptions in ERISA section 408(b)(2) and Code section 4975(d)(2) provide this necessary relief for Plan or IRA service providers, subject to the applicable conditions and accompanying regulations.

Transactions are defined in the exemption as principal transactions involving certain specified types of investments, discussed in more detail below. Principal transactions that are not riskless and that do not fall within the definition of Covered Principal Transaction are not covered by the exemption.

General Comments on the Covered Transactions

Several commenters expressed concern about the scope of the exemption extending to the receipt of payments from third parties, such as 12b–1 fees and revenue sharing. One commenter also objected to relief for sales loads. The commenter opined that the market itself is moving away from these types of fees and expenses and numerous court decisions indicate that a Plan's payment of such fees may be a violation of the duty of prudence. Another commenter likened this type of payment as akin to doctors taking kickbacks from pharmaceutical companies. Another commenter stated that the exemption should not provide relief for principal transactions and proprietary products.

The Department believes that the flexibility provided under the exemption ensures that the various business models used by different Financial Institutions are accommodated under the exemption to ensure Retirement Investors have full access to their preferred advice provider and method of paying for advice. The conditions of the exemption are designed to ensure that Financial Institutions assess all sources of fees and revenue to identify and mitigate conflicts of interest that they create, and ultimately receive no more than reasonable compensation in connection with investment advice transactions. These conditions are designed to ensure that Financial Institutions and Investment Professionals act in the best interest of Retirement Investors, even if some sources of compensation come from 12b–1 fees, revenue sharing, sales loads, principal transactions, or proprietary products. The Department continues to believe that this principles-based approach provides flexibility to Financial Institutions while ensuring all advice is in the best interest of Retirement Investors, compensation is limited to reasonable compensation, and Investment Professionals do not subordinate the Retirement Investors' interest to their own.

Another commenter asked the Department to expand the scope of relief in the exemption to ERISA section 406(a)(1)(B) and Code section 4975(c)(1)(B) for extensions of credit, in order to cover items such as overdraft protection, receipt of float, error corrections, settlement accommodations, short sales and other margin transactions, and paying fees in advance.

The Department has not expanded the exemption as requested by the commenter. The commenter did not provide information on these transactions and how the exemption conditions would protect the interests of Retirement Investors engaging in the transactions. An existing exemption, PTE 75–1, Part V, provides relief for an extension of credit by a broker-dealer in connection with the purchase or sale of securities; however, the exemption does not extend to the receipt of compensation for the extension of credit if the broker-dealer renders fiduciary investment advice with respect to the transaction. This does not foreclose the Department, however, from considering expanding the relief in PTE 75–1, Part V, based upon a separate request for exemptive relief.

Principal Transactions

Principal transactions involve the purchase from, or sale to, a Plan or an IRA, of an investment, on behalf of the Financial Institution's own account or the account of a person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with the Financial Institution. Because an investment advice fiduciary engaging in a principal transaction is on both sides of the transaction, the firm has a clear and direct conflict of interest. In addition, the securities typically traded in principal transactions often lack pre-trade price transparency and Retirement Investors may, therefore, have difficulty in prospectively evaluating the fairness of a particular principal transaction. These investments also can be associated with low liquidity, low transparency, and the possible incentive to sell unwanted investments held by the Financial Institution.

Consistent with the Department's historical approach to prohibited transaction exemptions for fiduciaries, this exemption includes relief for principal transactions that is limited in scope and subject to additional conditions, as set forth in the definition of Covered Principal Transaction, described below. Importantly, certain transactions are not considered principal transactions for purposes of the exemption, and so can occur under the more general conditions. This includes the sale of an insurance or annuity contract, or a mutual fund transaction.

Principal transactions that are ''riskless principal transactions'' are covered under the exemption as well, subject to the general conditions. A riskless principal transaction is a transaction in which a Financial Institution, after having received an order from a Retirement Investor to buy or sell an investment product, purchases or sells the same investment product in a contemporaneous transaction for the Financial Institution's own account to offset the transaction with the Retirement Investor.

Limited Definition of ''Covered Principal Transaction''

The exemption uses the defined term *Covered Principal Transaction* to describe the types of non-riskless principal transactions that are covered under the exemption. For *purchases* from a Plan or an IRA, the term is broadly defined to include any security or other investment property. This is to reflect the possibility that a principal transaction will be needed to provide liquidity to a Retirement Investor. However, for *sales* to a Plan or an IRA, the exemption provides more limited relief. For sales, the definition of Covered Principal Transaction is limited to transactions involving: U.S. dollar denominated corporate debt securities offered pursuant to a registration statement under the Securities Act of 1933, U.S. Treasury securities, debt securities issued or guaranteed by a U.S. federal government agency other than the U.S. Department of Treasury, debt securities issued or guaranteed by a government-sponsored enterprise (GSE), municipal securities, certificates of deposit, and interests in Unit Investment Trusts. In response to one commenter's specific question as to whether the term ''certificates of deposit'' includes brokered certificates of deposit, the Department clarifies that the use of the term ''certificates of deposit'' includes brokered certificates of deposit that are sold in principal transactions.

With respect to the definition of Covered Principal Transaction, some commenters wrote that there should not be a limit on the types of investments that can be sold by Financial Institutions to Retirement Investors, including one commenter who stated that the Department should eliminate or adjust exemption conditions that would limit Retirement Investors' access to full service brokerage accounts, including access to principal markets. They argued that some products would generally only be available through a

principal transaction, and that the Department should not substitute its judgment for a fiduciary acting in accordance with the Act's standards. Further, they stated that the existing limit is inconsistent with Regulation Best Interest which does not include any limitations on principal transactions, and that there were sufficient existing protections under securities laws. Commenters identified a variety of potential investments that they would like to see incorporated as Covered Principal Transactions, including foreign debt, structured notes, corporate debt in the secondary market, equity securities (including initial public offerings and national market system securities), new issues, issuers other than corporations, foreign currency, foreign securities, and closed end funds.

The Department has considered these comments but has not expanded the exemption's definition of a Covered Principal Transaction, including its enumerated list of investments. The definition of Covered Principal Transaction is intentionally narrow, based on the potentially acute conflicts of interest created by principal transactions. While commenters argued that the Department is substituting its own judgment for that of Financial Institutions and Investment Professionals, the Department believes that the risks created by principal transactions' unique conflicts are great enough to only justify allowing otherwise prohibited transactions if those transactions are set within prescribed conditions specifically designed to address those conflicts of interest. Further, because the exemption is addressing transactions prohibited solely under Title I and the Code, whether the definition of a Covered Principal Transaction is consistent with Regulation Best Interest, or subject to other securities law protections, is not determinative. The Department is required to make findings as to whether the exemption is in the interests of, and protective of the rights of, Plan participants and beneficiaries and IRA owners.[83] The Department stresses its obligation to exercise great care in authorizing transactions that Congress prohibited based upon their potential for abuse and resulting injury to Plan participants and IRA owners. Given the unique starting point—that Congress statutorily prohibited these transactions in Title I and the Code—the Department does not agree that the approach suggested by the commenters is appropriate. To the extent parties have interpretive questions regarding the scope of the exemption in this regard, the Department intends to support Financial Institutions, Investment Professionals, plan sponsors and fiduciaries, and other affected parties, with compliance assistance following publication of the final exemption.

The Department believes the best way to address commenters' concerns regarding additional investments is to include the provision allowing the definition of Covered Principal Transaction to expand upon the Department's grant of an individual exemption covering a particular type of principal transaction. An individual exemption request would provide the Department with the opportunity to gain the additional information it would need to determine whether an investment should be included in this exemption. Further, individual exemptions are required to be published in the **Federal Register** and allow for public comment before they are finalized. These procedural requirements are protective of Retirement Investors.

One commenter disagreed with the addition of investments through the individual prohibited transaction exemption process. The commenter argued that the addition of investments should be accomplished through a formal amendment to the exemption. The Department believes that the procedural requirements described in the preceding paragraph provide protections to Retirement Investors, and the ability to incorporate additional investments by adopting an individual exemption provides an appropriately streamlined approach to address discrete areas of scope within the class exemption.

Credit Quality and Liquidity

For sales of a debt security to a Plan or an IRA, the definition of Covered Principal Transaction requires the Financial Institution to adopt written policies and procedures related to credit quality and liquidity. Specifically, the policies and procedures must be reasonably designed to ensure that the debt security, at the time of the recommendation, has no greater than moderate credit risk and has sufficient liquidity that it could be sold at or near its carrying value within a reasonably short period of time. This standard is included to prevent the exemption from being available to Financial Institutions that recommend speculative or illiquid debt securities from their own accounts.

A few commenters opposed the proposed condition requiring adoption of policies and procedures related to credit quality and liquidity. The commenters argued that this condition substitutes the Department's judgment for that of the Retirement Investor. Further, they stated that the standards would be difficult to apply, requiring firms to look into the future to know whether a bond would be actively traded. One commenter stated specifically that a liquidity condition should not be included.

The Department has considered these comments, but has included the credit quality and liquidity policies and procedures condition in the final exemption. Principal transactions are inherently conflicted transactions. As a result, the Department believes that unique conditions, such as the credit and liquidity requirements, address the heightened conflicts of interest and are specifically tailored to address conflicts inherent with respect to debt securities. The Department is not substituting its judgment for that of Retirement Investors; it is only setting necessary safeguards to prevent abuses by Financial Institutions relying on the exemption. Additionally, the Department notes that the exemption is not necessary for self-directed retirement accounts or transactions that do not involve fiduciary investment advice. Therefore, such truly self-directed accounts and transactions may involve the purchase of any type of investment on a principal basis.

Further, the Department does not believe the standards are unworkable. Financial Institutions regularly evaluate the credit risk associated with their investments and assess their liquidity. And it is important to note that the policies and procedures must be reasonably designed to ensure that the standards are met *at the time of the transaction;* the exemption does not require them to be satisfied for the duration of the investment. Indeed, a commenter who raised concerns about the requirement went on to point out ways a Financial Institution could reasonably consider the liquidity at the time of the transaction. This commenter stated that it is the very nature of bond trading that liquidity generally tends to diminish as bonds mature. The Department expects that a Financial Institution would consider this and other reasonably available information at the time of the transaction in designing its policies and procedures. It is also important to note that Financial Institutions may consider credit ratings as a part of a Financial Institution's policies and procedures in this respect.

[83] *See* ERISA section 408(a) and Code section 4975(c)(2).

Municipal Bonds

The exemption covers principal transactions involving municipal bonds, including tax-exempt municipal bonds. The Department cautions, however, that Financial Institutions and Investment Professionals should pay special care when recommending that Retirement Investors invest in municipal bonds. Tax-exempt municipal bonds are typically a poor choice for investors in Title I Plans and IRAs because the Plans and IRAs are already tax-advantaged and, therefore, do not benefit from paying for the bond's tax-favored status.[84]

One commenter stated that no tax-exempt investment (including tax-exempt municipal bonds and certain annuities) should be included in the exemption, absent evidence that such investments are beneficial when purchased through a retirement account. The Department believes, however, that there are certain limited circumstances where these investments may benefit a Retirement Investor. For example, a particular municipal bond may have a higher tax-equivalent yield than a comparable taxable bond. Alternatively, a fiduciary adviser may conclude based upon careful analysis that a particular tax-exempt municipal bond carries less risk than a comparable corporate bond. Accordingly, the Department has not written the exemption to flatly exclude tax-exempt investments. However, given the increased risk of imprudence when making such recommendations, Financial Institutions and Investment Professionals may wish to document the reasons for any recommendation of a tax-exempt municipal bond or other tax-exempt investment and why the recommendation is in the Retirement Investor's best interest.

Separate Exemption

One commenter asserted that principal transaction relief should be provided through a separate exemption. The commenter argued that the exemption's conditions are not sufficiently protective with respect to the unique nature of principal transactions. Instead, the commenter advocated for a separate prohibited transaction class exemption modeled after the statutory exemption for cross-trading in ERISA section 408(b)(19) and Code section 4975(d)(22). Using the statutory exemption as a model, the commenter suggested that the exemption include conditions such as minimum size requirements and a requirement that the transaction occur at the ''independent current market price.''

The Department has considered this suggestion, but has not adopted it. Although the Department agrees that the conflicts of interest in cross-trades are significant, the transactions contemplated by the statutory exemptions for cross-trades are not, in the Department's view, necessarily so analogous to the principal transactions covered by this exemption that the conditions of the statutory exemption are easily applied in this context. The statutory exemption is aimed at discretionary investment managers that are managing large accounts, while this exemption is designed to include investment advice providers who may be providing advice in the retail market. It would be difficult, for example, for the Department to arrive at a minimum size that would be appropriate for engaging in principal transactions with retail investors. The Department also believes that combining relief for principal transactions within the exemption for other transactions arising out of the provision of fiduciary investment advice assists Financial Institutions and Investment Professionals in developing a comprehensive compliance approach.

Exclusions

Section I(c) provides that certain specific transactions are excluded from the exemption. The exemption retains the exclusions as proposed. Therefore, the exemption is not available for Title I Plans if the Investment Professional, Financial Institution, or an affiliate is (1) The employer of employees covered by the Plan; or (2) a named fiduciary or plan administrator, or an affiliate, who was selected to provide advice to the Plan by a fiduciary who is not independent. The exemption excludes investment advice generated solely by an interactive website in which computer software-based models or applications provide investment advice based on personal information each investor supplies through the website, without any personal interaction or advice with an Investment Professional (*i.e.,* robo-advice). The exemption is also specifically limited to investment advice fiduciaries within the meaning of the five-part test and does not include discretionary arrangements.

Employers, Named Fiduciaries, and Plan Administrators

Section I(c)(1) of the exemption provides that the exemption does not extend to transactions involving Title I Plans if the Investment Professional, Financial Institution, or an affiliate is either (1) the employer of employees covered by the Plan; or (2) is a named fiduciary or plan administrator, or an affiliate thereof, who was selected to provide advice to the Plan by a fiduciary who is not independent of the Financial Institution, Investment Professional, and their affiliates.

The Department believes that employers generally should not be in a position to use their employees' retirement benefits as potential revenue or profit sources, without additional safeguards. Employers can always render advice and recover their direct expenses in transactions involving their employees without need of this exemption.[85]

Further, the Department does not intend for the exemption to be used by a Financial Institution or Investment Professional that is the named fiduciary or plan administrator of a Title I Plan or an affiliate thereof, unless the Financial Institution or Investment Professional is selected as an advice provider by a fiduciary (such as the employer sponsoring the Title I Plan) that is independent of them. Named fiduciaries and plan administrators have significant authority over plan operations and accordingly, the Department believes that any selection of these parties to also provide investment advice to the Title I Plan or its participants and beneficiaries should be made by an independent party who will also monitor the performance of the investment advice services.

For purposes of the exemption, the plan sponsor or other fiduciary is independent of the Financial Institution and Investment Professional if: (1) The fiduciary is not the Financial Institution, Investment Professional, or an affiliate; (2) the fiduciary does not have a relationship to or an interest in the Financial Institution, Investment Professional, or any affiliate that might affect the exercise of the fiduciary's best judgment in connection with

[84] *See e.g.,* Seven Questions to Ask When Investing in Municipal Bonds, *available at www.msrb.org/~/media/pdfs/msrb1/pdfs/seven-questions-when-investing.ashx.* (''[T]ax-exempt bonds may not be an efficient investment for certain tax advantaged accounts, such as an IRA or 401k, as the tax-advantages of such accounts render the tax-exempt features of municipal bonds redundant. Furthermore, since withdrawals from most of those accounts are subject to tax, placing a tax exempt bond in such an account has the effect of converting tax-exempt income into taxable income. Finally, if an investor purchases bonds in the secondary market at a discount, part of the gain received upon sale may be subject to regular income tax rates rather than capital gains rates.'')

[85] A few existing prohibited transaction exemptions apply to employers. *See* ERISA section 408(b)(5), a statutory exemption that provides relief for the purchase of life insurance, health insurance, or annuities, from an employer with respect to a Plan or a wholly owned subsidiary of the employer.

transactions covered by the exemption; and (3) the fiduciary does not receive and is not projected to receive within the current federal income tax year, compensation or other consideration for his or her own account from the Financial Institution, Investment Professional, or an affiliate, in excess of 2% of the fiduciary's annual revenues based upon its prior income tax year.

Some commenters urged the Department to delete the exclusion of employers as fiduciary investment advice providers to Title I Plans covering their own employees. The commenters stated that the conditions of the exemption are protective for transactions involving employees of the Financial Institution, and there is no reason to prevent employees from choosing their own advice provider and benefiting from their employer's particular area of expertise. A different commenter raised the concern that employees would lose access to a valuable service their employer provides to others. In response, the Department notes that employers will continue to be able to provide such services to employees, just as they always have, if they recoup only their direct expenses. The Department has decided to maintain the exclusion as it was proposed, because of the Department's concerns that the danger of abuse is compounded when the advice recipient receives recommendations from the employer, upon whom he or she depends for a job, to make investments in which the employer has a financial interest.

Several commenters addressed the exclusion of named fiduciaries and plan administrators, unless selected by a fiduciary that is independent of them. One commenter sought clarification with respect to a particular factual scenario in which a plan sponsor appoints a bank as a directed trustee and named fiduciary. The commenter asked whether the exemption would require the bank to be selected to provide advice to the Title I Plan by the employer, and contended that this would result in disparate treatment as compared to other fiduciary service providers. For example, the commenter stated that the Title I Plan's investment adviser can solicit rollovers without selection by the employer.

The Department responds that the exemption would require a bank that is a named fiduciary to be selected by a fiduciary that is independent of the bank, as defined in the exemption. As noted above, this exclusion is based on the significant authority of named fiduciaries and plan administrators over Title I Plan operations.

Some commenters focused on the ''independence'' requirement under which the fiduciary selecting the advice provider cannot receive more than 2% of its income in the current tax year from the Financial Institution, Investment Professional, or an affiliate. The commenters urged the Department to increase the 2% limit to as high as 20%. One commenter stated this definition was far more restrictive than any definition ever used by the Department. The Department disagrees that the 2% limitation is unduly restrictive, and notes that the Department's exemption procedure regulation provides for a presumption that a 2% limitation will indicate that a fiduciary is independent.[86] The Department did not increase the 2% limit so as to avoid any concern that compensation may impact the fiduciary's selection of an advice provider for the Title I Plan.

Pooled Employer Plans Under the SECURE Act

In connection with the exemption's exclusion of named fiduciaries and plan administrators unless selected by a fiduciary that is independent, several commenters requested additional guidance and clarification regarding the exemption's application to Pooled Employer Plans (PEPs), which were authorized by the SECURE Act, passed in 2019.[87] The SECURE Act mandates that a PEP must be established by a Pooled Plan Provider (PPP) that is designated as a named fiduciary, plan administrator, and the person responsible for specified administrative duties. Commenters envisioned that some PPPs would want to make investment advice available through PEPs, by utilizing themselves or an affiliate as the advice provider. Commenters requested clarification that an employer that participates in a PEP could be considered ''independent'' so that this exclusion would not be applicable despite the fact that the PPP or an affiliate is providing advice.

The Department believes it is premature to address issues related to PEPs, given their recent origination, unique structure, and likelihood of significant variations in fact patterns and potential business models, as the PEPs' sponsors decide how to structure their operations. In particular, the Department believes it is premature to provide any views regarding the ''independence'' of participating employers. The Department recently published a request for information on prohibited transactions applicable to PEPs and is separately considering exemptions related to these types of Plans.[88]

Robo-Advice

Section I(c)(2) of the exemption excludes from relief transactions that result from investment advice generated solely by an interactive website in which computer software-based models or applications provide investment advice that do not involve interaction with an Investment Professional (referred to herein as ''pure robo-advice''). ''Hybrid'' robo-advice arrangements, which involve both computer software models and personal investment advice from an Investment Professional, are permitted under the exemption.

A detailed statutory exemption that specifically addresses computer model advice is set forth in ERISA section 408(b)(14), (g), and Code section 4975(d)(17) and 4975(f)(8), and the regulations thereunder.[89] The statutory exemption includes specific conditions governing the operation of the computer model, including a requirement that the model apply generally accepted investment theories and that it operate in an unbiased manner, and the exemption further requires that an expert certify that the computer model meets certain of the exemption's requirements.

A number of commenters objected to the exclusion of pure robo-advice from the class exemption, arguing that there is no reason to treat it differently from other types of advice that are covered in the exemption. Commenters described robo-advice as providing a low-cost option that might become less available if it is not included in the exemption. Commenters indicated that covering pure robo-advice would allow Financial Institutions to adopt a single set of policies and procedures for all advice arrangements, and noted that the SEC does not treat robo-advice differently than other forms of advice. Some argued that the existence of a statutory exemption should not prevent the Department from issuing an administrative exemption, and that there are other examples in which multiple exemptions are available for a certain transaction. Some commenters argued that the statutory exemption is costly and cumbersome, and expressed concern about whether it extended to

[86] 29 CFR 2570.31(j) (definition of ''qualified independent fiduciary'').

[87] PEPs may not begin operating until January 1, 2021.

[88] 85 FR 36880 (June 18, 2020).

[89] 29 CFR 2550.408g–1.

rollovers, even though the exemption does not, by its terms, exclude rollovers.

The final exemption maintains the exclusion of pure robo-advice. As noted above, the statutory exemption in ERISA section 408(b)(14), (g), and Code section 4975(d)(17) and 4975(f)(8), includes specific conditions that are tailored to computer-generated investment advice. This exemption, by contrast, is tailored to investment advice that is provided through a human Investment Professional who is supervised by a Financial Institution. The conditions of this exemption are not designed to address advice without an Investment Professional. Because of the different approaches, the Department does not believe that Financial Institutions would easily be able to develop a single set of conflict mitigation policies under this exemption that would govern both hybrid and pure robo-advice arrangements. The policies and procedures required by this exemption contemplate consideration of factors beyond those that may be considered in a pure robo-advice situation. A person may design a pure robo-advice model that incorporates other incentives than those addressed here. Further, without specificity as to how Financial Institutions' policies and procedures would address pure robo-advice in a way that improved upon the existing exemption, the Department is not persuaded that extending this exemption to cover pure robo-advice is in the interests of Retirement Investors and is protective of their rights, as it must find under ERISA section 408(a)(2) and (3) and Code section 4975(c)(2)(B) and (C) before issuing a new exemption. For these reasons, the Department has decided to retain the exclusion from the exemption, as proposed.

With regard to hybrid robo-advice arrangements that are covered by the exemption, one commenter suggested that the final exemption should require an Investment Professional who uses a computer model and deviates from its recommendation to provide the Retirement Investor with a written explanation of the reasons for the deviation. However, the Department has determined generally to avoid such a prescriptive approach to disclosure in the final exemption. Without additional information about the commenter's concerns related to Investment Professionals deviating from computer generated recommendations, the Department does not believe that a specific disclosure requirement is necessary in such circumstances.

Discretionary Arrangements

Under Section I(c)(3), the exemption does not extend to transactions in which the Investment Professional is acting in a fiduciary capacity other than as an investment advice fiduciary. For clarity, Section I(c)(3) specifically cites the Department's five-part test as the governing authority for status as an investment advice fiduciary.

Several commenters opposed this exclusion and stated that the conditions of the exemption are sufficiently protective in the context of discretionary arrangements. These commenters indicated that Retirement Investors who want discretionary management services should not be treated differently than those receiving non-discretionary advice services.

After consideration of the comments, the Department is adopting this exclusion as proposed. The protections that are included in the exemption were designed specifically for non-discretionary investment advice arrangements, consistent with standards from other regulators regarding similar arrangements. The Department does not believe this will unfairly prejudice discretionary arrangements because the same pool of exemptions for discretionary arrangements currently exists that existed before this exemption was proposed. Additionally, the Department understands there are a variety of ways to avoid prohibited transactions in discretionary arrangements, including utilizing fee structures that ensure compensation does not vary based on investment choice.

Moreover, the Department believes the differences between a discretionary and non-discretionary arrangement are not insignificant. For example, the potential for conflicts in a discretionary arrangement is heightened because most, if not all, of the investment transactions will occur without interaction with the Retirement Investor. The Department does not believe that the conditions of this exemption are appropriately tailored to address such conflicts. However, the Department remains open to requests for additional prohibited transaction relief for discretionary arrangements.

Exemption Conditions

Section II of the exemption sets forth the general conditions of the exemption. Section III establishes the eligibility requirements. Section IV requires parties to maintain records to demonstrate compliance with the exemption. Section V includes the defined terms used in the exemption. These sections are discussed below. In order to obtain prohibited transaction relief under the exemption, the Financial Institution and Investment Professional must comply with all of the conditions of the exemption, and may not waive or disclaim compliance with any of the conditions. Similarly, a Retirement Investor may not agree to waive any of the conditions.

Investment Advice Arrangement—Section II

Section II sets forth conditions that govern the Financial Institution's and Investment Professional's investment advice arrangement. As discussed in greater detail below, Section II(a) requires Financial Institutions and Investment Professionals to comply with the Impartial Conduct Standards by providing advice that is in Retirement Investors' best interest, charging only reasonable compensation, and making no materially misleading statements about the investment transaction and other relevant matters. The Impartial Conduct Standards further require the Financial Institution and Investment Professional to seek to obtain the best execution of the investment transaction reasonably available under the circumstances, as required by the federal securities laws. Section II(b) requires Financial Institutions, prior to engaging in a transaction pursuant to the exemption, to provide a written disclosure to the Retirement Investor acknowledging that the Financial Institution and its Investment Professionals are fiduciaries under Title I and the Code, as applicable.[90] The disclosure must also include a written description, accurate in all material respects, regarding the services to be provided and the Financial Institution's and Investment Professional's material conflicts of interest. Financial Institutions and Investment Professionals would also be required to document and disclose the reasons that a recommendation to roll over assets is in the Retirement Investor's best interest. Under Section II(c), the Financial Institution is required to establish, maintain, and enforce written policies and procedures prudently designed to ensure that the Financial Institution and its Investment Professionals comply with the Impartial Conduct Standards. Section II(d)

[90] As noted above, the Department does not intend the exemption to expand Retirement Investors' ability, such as by requiring contracts and/or warranty provisions, to enforce their rights in court or create any new legal claims above and beyond those expressly authorized in the Act, and the Department does not believe the exemption would create any such expansion.

requires Financial Institutions to conduct an annual retrospective review.[91] Finally, Section II(e) provides a mechanism for Financial Institutions to correct certain violations of the exemption conditions and maintain relief under the exemption.

Impartial Conduct Standards—Section II(a)

Financial Institutions and Investment Professionals must comply with the Impartial Conduct Standards by providing advice that is in Retirement Investors' best interest, charging only reasonable compensation, and making no materially misleading statements about the investment transaction and other relevant matters.

Best Interest Standard

Section II(a)(1) requires investment advice that is, at the time it is provided, in the best interest of the Retirement Investor. Section V(b) of the exemption defines ''best interest'' advice as advice that ''reflects the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, and does not place the financial or other interest of the Investment Professional, Financial Institution or any affiliate, related entity or other party ahead of the interests of the Retirement Investor, or subordinate the Retirement Investor's interests to their own.''

This standard is based on longstanding concepts in the Act and the high fiduciary standards developed under the common law of trusts, and is intended to comprise objective standards of care and undivided loyalty, consistent with the requirements of ERISA section 404. These longstanding concepts of law and equity were developed in significant part to deal with the issues that arise when agents and persons in a position of trust have conflicting interests, and accordingly are well-suited to the problems posed by conflicted investment advice.

The best interest standard is an objective standard that requires the Financial Institution and Investment Professional to investigate and evaluate investments, provide advice, and exercise sound judgment in the same way that knowledgeable and impartial professionals would. The standard of care is measured at the time the advice is provided, and not in hindsight.[92] The standard does not measure compliance by reference to how investments subsequently performed or turn Financial Institutions and Investment Professionals into guarantors of investment performance; rather, the appropriate measure is whether the Investment Professional gave advice that was prudent and in the best interest of the Retirement Investor at the time the advice is provided.

The standard also provides that Financial Institutions and Investment Professionals have a duty to ''not place the financial or other interest of the Investment Professional, Financial Institution or any Affiliate, Related Entity or other party ahead of the interests of the Retirement Investor, or subordinate the Retirement Investor's interests to their own.'' The Department intends for the standard to be interpreted and applied consistently with the standard set forth in Regulation Best Interest[93] and the SEC's interpretation regarding the conduct standard for investment advisers.[94]

This best interest standard allows Investment Professionals and Financial Institutions to provide investment advice despite having a financial or other interest in the transaction, so long as they do not place their own interests ahead of the interests of the Retirement Investor, or subordinate the Retirement Investor's interests to their own. For example, in choosing between two investments equally available to the investor, it is not permissible for the Investment Professional to advise investing in the one that is worse for the Retirement Investor because it is better for the Investment Professional's or the Financial Institution's bottom line. Because the standard does not forbid the Financial Institution or Investment Professional from having an interest in the transaction, this standard does not foreclose the Investment Professional and Financial Institution from being paid, nor does it foreclose investment advice on proprietary products or investments that generate third party payments. This best interest standard also does not impose an unattainable obligation on Investment Professionals and Financial Institutions to somehow identify the single ''best'' investment for the Retirement Investor out of all the investments in the national or international marketplace, assuming such advice were even possible at the time of the transaction.

Several commenters expressed support for the best interest standard and specifically for the phrasing aligned with Regulation Best Interest's conduct standard. Commenters articulated benefits to both Retirement Investors and to Financial Institutions that will come from clarity and consistency of alignment with the SEC. Some commenters requested that the Department specifically provide a safe harbor based on compliance with the SEC's requirements. According to these commenters, the Department should not merely rely on the phrasing in the securities regulations, but should also incorporate the securities laws enforcement through the SEC and FINRA.

Some commenters objected to the incorporation of the best interest standard and other Impartial Conduct Standards as conditions of the exemption. They stated that the conduct standards are duplicative for transactions involving Title I Plans because of the standards set forth in ERISA section 404. Some specifically opposed the Department's use of a prudence standard in the best interest standard. They noted that the specific word ''prudence'' is not included in the final Regulation Best Interest or in the NAIC Model Regulation, and, therefore, including it in the exemption standard would be an area of inconsistency. In addition, some commenters opined that the application of the best interest standard, including the prudence obligations, on IRAs is not permitted under the Fifth Circuit's *Chamber* opinion. In particular, these commenters opined that the Fifth Circuit determined that the Department

[91] One commenter suggested that the exemption should be separated into different exemptions with different conditions to reflect diverse issues of Retirement Investors who are individuals, small plans, and large plans. The Department has not adopted that suggestion because of the concern that this would be overly complex for Financial Institutions to implement and could lead to concerns about technical violations of the exemptions.

[92] *See* Donovan v. Mazzola, 716 F.2d 1226, 1232 (9th Cir. 1983).

[93] Regulation Best Interests' best interest obligation provides that a ''broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer.'' 17 CFR 240.15l-1(a)(1).

[94] *See* SEC Fiduciary Interpretation, 84 FR 33671 (''An investment adviser's fiduciary duty under the Advisers Act comprises a duty of care and a duty of loyalty. This fiduciary duty requires an adviser 'to adopt the principal's goals, objectives, or ends.' This means the adviser must, at all times, serve the best interest of its client and not subordinate its client's interest to its own. In other words, the investment adviser cannot place its own interests ahead of the interests of its client.'') (internal citations omitted).

was acting outside its authority by adding to the requirements of the Code provisions that Congress chose not to apply to such accounts.

Other commenters maintained that the Department's proposed best interest standard was not sufficiently protective of Retirement Investors. Commenters noted that the SEC described its standard as ''separate and distinct from the fiduciary duty that has developed under the Advisers Act.'' These commenters argued that the Department should condition the exemption on what they referred to as a ''true'' fiduciary standard. They stated this is what Congress intended as part of the statutory framework for tax-advantaged treatment accorded to retirement investments. Some commenters specifically objected to the exemption's loyalty formulation, including that it was not a true loyalty standard and needed alternative wording such as ''without regard to'' or ''solely in the interest of.''

The Department has included the best interest standard in the final exemption as it was proposed. The Department believes that the standard, in combination with the other conditions of the exemption, will protect the interests of Retirement Investors affected by the exemption. Although the standards of ERISA section 404 already apply to transactions involving Title I Plans and their participants and beneficiaries, incorporating the Impartial Conduct Standards as conditions of the exemption requires Financial Institutions to demonstrate compliance with the standards and increases the consequence of non-compliance because of the excise tax. This creates an important incentive for Financial Institutions to ensure compliance with the standards. For that reason, the Department does not believe the standards are unnecessary or duplicative for those Retirement Investors who are Title I Plan participants or beneficiaries. The Department also is not persuaded that it should eliminate the reference to ''prudence'' from the best interest standard, given its importance in the Title I framework and longstanding application to the problems of agency that the exemption addresses.

The Department does not believe that including the Impartial Conduct Standards as conditions for transactions involving IRAs is impermissible in light of the Fifth Circuit's *Chamber* opinion. The Fifth Circuit's opinion addressed the 2016 fiduciary rule and related exemptions, particularly the perceived ''over-inclusiveness'' of the new definition of a fiduciary that the opinion indicated, in some circumstances, resulted in ordinary sales conduct activities causing a person to be classified as a fiduciary under Title I and the Code. Unlike the 2016 fiduciary rule and related exemptions, the present exemption provides relief to a more limited group of persons already deemed to be fiduciaries within the meaning of the five-part test and does not impose contract or warranty requirements on fiduciaries.[95] Further, the Fifth Circuit observed that the five-part test ''captured the essence of a fiduciary relationship known to the common law as a special relationship of trust and confidence between the fiduciary and his client.'' *Chamber,* 885 F.3d 360, 364 (2018) (citation omitted). The same five-part test exists under the Code's regulations, based on an identical definition of *fiduciary* in the Code. This exemption merely recognizes that fiduciaries of IRAs, if they seek to use this exemption for relief from prohibited transactions, should adhere to a best interest standard consistent with their fiduciary status and a special relationship of trust and confidence.

The Department also disagrees with the suggestion that the best interest standard is not a ''true'' fiduciary standard. The Department acknowledges that the Best Interest Contract Exemption and other exemptions granted in association with the 2016 fiduciary rule used a loyalty formulation of ''without regard to,'' which was described as ''a concise expression of Title I's duty of loyalty, as expressed in section 404(a)(1)(A) of ERISA and applied in the context of advice.'' [96] In connection with concerns expressed by commenters on those exemptions, however, the Department had to provide specific confirmation that the standard was not so exacting as to prevent a fiduciary from being paid.[97] The Department also provided a special definition of ''best interest'' in section IV of the exemption to accommodate concerns about proprietary products and limited menus of investment options that generate third party payments.[98] It is important to note that for decades the Department has also articulated the duty of loyalty in ERISA section 404 as prohibiting a fiduciary from ''subordinating the interests of participants and beneficiaries in their retirement income to unrelated objectives.'' [99]

As set forth above, however, the Department notes that the exemption's best interest standard requires Financial Institutions and Investment Professionals to not ''place the financial or other interests of the Investment Professional, Financial Institution or any affiliate, related entity or other party ahead of the interests of the Retirement Investor, or subordinate the Retirement Investor's interests to their own.'' The duty not to subordinate the Retirement Investor's interests to their own is the standard applicable to investment advisers, who are fiduciaries under securities laws.[100] Although the SEC indicated in Regulation Best Interest that it was not subjecting broker-dealers to ''a wholesale and complete application of the existing fiduciary standard under the Advisers Act,'' it also said, ''[a]t the time a recommendation is made, key elements of the Regulation Best Interest standard of conduct that applies to broker-dealers will be similar to key elements of the

[95] In connection with the description of the best interest standard in the proposed exemption the Department included a footnote referencing Code section 4975(f)(5), which defines ''correction'' with respect to prohibited transactions as placing a Plan or an IRA in a financial position not worse than it would have been in if the person had acted ''under the highest fiduciary standards.'' The footnote stated that while the Code does not expressly impose a duty of loyalty on fiduciaries, the exemption's best interest standard is intended to ensure adherence to the ''highest fiduciary standards'' when a fiduciary advises a Plan or an IRA owner under the Code. Commenters asked the Department to disavow this statement in the final exemption, asserting that the imposition of the Impartial Conduct Standards as an exemption condition for IRAs was rejected by the Fifth Circuit's *Chamber* opinion. The Department disagrees with the commenters' interpretation of the Fifth Circuit's opinion, and its application to this exemption which applies only to plan fiduciaries who meet the five-part test and which does not impose contract or warranty requirements on these fiduciaries.

[96] *See* Best Interest Contract Exemption, 81 FR 21002, 21026 (April 8, 2016).

[97] *Id.* at 21029.

[98] *Id.* at 21080.

[99] *See e.g.,* Advisory Opinion 2008–05A (June 27, 2008); Advisory Opinion No. 93–33A (Dec. 16, 1993); Advisory Opinion 85–36A (Oct. 23, 1985); Letter to James K. Tam (June 14, 1983); Letter to Harold G. Korbee (Apr. 22, 1981). The Department has also repeated this articulation of the loyalty standard in recent proposed and final regulations. *See* Financial Factors in Selecting Plan Investments final rule, 85 FR 72846, 72847 (Nov. 13, 2020) (In describing prior guidance on environmental, social, and corporate governance investing, noting that the Department ''has construed the requirements that a fiduciary act solely in the interest of, and for the exclusive purpose of providing benefits to, participants and beneficiaries as prohibiting a fiduciary from subordinating the interests of participants and beneficiaries in their retirement income to unrelated objectives.''). *See also* Fiduciary Duties Regarding Proxy Voting and Shareholder Rights proposed rule, 85 FR 55219, 52220–21 (September 4, 2020) (In discussing prior interpretations of proxy voting, noting that in 1994 ''the Department also reiterated its view that ERISA does not permit fiduciaries, in voting proxies or exercising other shareholder rights, to subordinate the economic interests of participants and beneficiaries to unrelated objectives.'').

[100] SEC Fiduciary Interpretation, 84 FR 33671.

fiduciary standard for investment advisers.'' [101]

Although the best interest standard is intended to be consistent with the securities law standards as discussed above, the Department declines to provide a safe harbor for compliance with the standards as interpreted by the SEC or FINRA. The Department confirms that it will coordinate with other regulators, including the SEC, on enforcement strategies and interpretive issues to the extent appropriate, but it cannot simply defer to other regulators on how best to discharge its own interpretive and enforcement responsibilities under Title I and the Code.[102] When Congress enacted the Act, it made a deliberate decision to entrust the protection of Retirement Investors to the Secretary of Labor, subject to an overarching regulatory structure that departs in significant ways from the securities laws (*e.g.,* by creating a prohibited transaction structure that flatly prohibits many transactions, such as those at issue in this exemption, unless the Department first grants an exemption after making statutorily required participant-protective findings). While the Department has exercised its discretion in this exemption to incorporate a best interest standard that it believes is consistent with the securities law standard, it nevertheless retains full interpretive responsibility over, and must account for, the Title I and Code provisions at issue in this exemption, as well as the terms of the exemption, and for the protection of Retirement Investors.

Additional Guidance on the Best Interest Standard

A few commenters requested additional guidance on the best interest standard. One commenter asked the Department to clarify how Title I's standards differed from the Impartial Conduct Standards. Another commenter asked the Department to make clear what an Investment Professional would be required to do to satisfy the standards, other than engaging in a prudent process. In this regard, the Department notes that the exemption is applicable solely to ERISA section 406 and Code section 4975; it does not provide an exemption from a Title I fiduciary's obligations under ERISA section 404.

As set forth above, the Department does not believe there is a distinction between ERISA's section 404 standards of prudence and loyalty and the Impartial Conduct Standards, given that the best interest standard includes a prudence obligation and the Department has in the past described the duty of loyalty as prohibiting fiduciaries from subordinating the interests of participants and beneficiaries in their retirement income to unrelated objectives

Financial Institutions wishing to be certain that they complied with the ERISA section 404 standard and the Impartial Conduct Standards would adopt rigorous policies and procedures to align the interests of Investment Professionals with their Retirement Investor customers, refrain from creating incentives for Investment Professionals to violate the Impartial Conduct Standards, and prudently oversee the implementation and enforcement of the policies and procedures. Investment Professionals would comply with the Financial Institution's policies and procedures, engage in a prudent process in recommending investment products, and ensure that their advice does not put the interests of the Investment Professional, Financial Institution, or other party ahead of the interests of the Retirement Investor.[103]

One commenter asked the Department to clarify the remedies available to a participant under Title I who receives fiduciary investment advice to roll over assets from a Title I Plan to an IRA. Specifically, the commenter sought confirmation that whenever a participant is the recipient of advice, the participant retains all of the rights and remedies under Title I even if the investment advice provider is selected by the participant's employer. The Department responds that individual participants and beneficiaries in a Title I Plan have a cause of action under ERISA section 502(a) for prohibited transactions, even if the investment advice provider is selected by the employer. As noted earlier, the Act does not permit exemptions to release fiduciaries from their Title I obligations under ERISA section 404 to a Plan, and its remedies remain available.

Monitoring

In connection with the best interest standard, several commenters raised concerns that the conditions of the exemption could require Financial Institutions to provide ongoing monitoring services of certain investment property. The Department stated in the preamble to the proposed exemption that:

> Financial Institutions should carefully consider whether certain investments can be prudently recommended to the individual Retirement Investor in the first place without ongoing monitoring of the investment. Investments that possess unusual complexity and risk, for example, may require ongoing monitoring to protect the investor's interests.

Some commenters interpreted this statement to require Financial Institutions and Investment Professionals to monitor certain investments. According to the commenters, any obligation for broker-dealers to monitor investments would be inconsistent with the securities laws. Another commenter stated that the monitoring requirement is inconsistent with the prudence standards because the Department's regulation at 29 CFR 2550.404a-1 regarding a fiduciary's duty of prudence in connection with investment decisions does not require account monitoring. Commenters asked the Department to confirm that the exemption does not require Financial Institutions or Investment Professionals to provide monitoring, particularly where the Financial Institution clearly discloses it will not do so. Commenters also stated the Department should not impose ongoing monitoring requirements based on a vague standard of ''unusual complexity and risk.''

Other commenters asked for more guidance on when monitoring would be required. They requested more specificity on which investments are considered complex and risky as described in the preamble of the proposed exemption. Some commenters sought the Department's assurance that annuities would not require ongoing monitoring. However, one commenter asserted that the Department's statement on monitoring did not go far enough; an ongoing fiduciary relationship should require ongoing monitoring. At the very least, this commenter noted, the Department should adopt the position that the SEC takes with regard to investment advisers' monitoring obligations, that for advice that is provided on a regular basis, there should be some duty to monitor

[101] Regulation Best Interest Release, 84 FR 33321–33322. The SEC stated that the phrasing in Regulation Best Interest (''without placing the financial or other interest . . . ahead of the interest of the retail customer'') aligns with an investment adviser's fiduciary duty, noting the discussion in the SEC Fiduciary Interpretation (''This means the adviser must, at all times, serve the best interest of its client and not subordinate its client's interest to its own. In other words, the investment adviser cannot place its own interests ahead of the interests of its client.'') 84 FR 33671.

[102] *See, e.g.,* ERISA sections 502, 504, 505, and Reorganization Plan No. 4 of 1978.

[103] One commenter asked the Department to explain the difference between the exemption's best interest standard and a suitability standard. Given the recent developments in conduct standards applicable to broker-dealers and insurance agents, the Department does not believe it is appropriate or necessary for it to addresses these differences.

consistent with the nature of that relationship.

As was stated in the proposal, the Department confirms that nothing in the final exemption requires Financial Institutions or Investment Professionals to provide ongoing monitoring services. Of course, the exemption's general prohibition against misleading statements applies, and Financial Institutions and Investment Professionals should be clear and candid with Retirement Investors about the existence, scope, and duration of any monitoring services. Accordingly, the Department does not believe it is requiring broker-dealers to engage in any activity that is not permitted under securities laws or that it is barring broker-dealers from recommending certain classes of investments. The Department did not require all Financial Institutions and Investment Professionals to offer monitoring because the exemption takes the approach of preserving the availability of a wide variety of investment advice arrangements and products. However, as part of making a best interest recommendation, the Department expects that Financial Institutions and Investment Professionals will consider whether the investment can be prudently recommended without some mechanism or plan for ongoing monitoring. To the extent that prudence requires ongoing monitoring, the final exemption does not require that such monitoring be done by the Financial Institution or Investment Professional; such monitoring could be performed by a third party, but the advice fiduciary should clearly explain the need for monitoring to the investor when making the recommendation.

In response to requests for guidance identifying specific products that will require monitoring, or what constitutes a product of unusual complexity and risk, the Department notes that Financial Institutions and Investment Professionals will need to make these decisions on a case-by-case basis. The Department expects that Financial Institutions and Investment Professionals have the expertise necessary to evaluate the need for monitoring based on all the facts and circumstances.

Reasonable Compensation

Section II(a)(2) of the exemption includes a reasonable compensation standard. The exemption provides that compensation received, directly or indirectly, by the Financial Institution, Investment Professional, and their affiliates and related entities for their services is not permitted to exceed reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2).

The obligation to pay no more than reasonable compensation to service providers has been long recognized under Title I and the Code. The statutory exemptions in ERISA section 408(b)(2) and Code section 4975(d)(2) expressly require all types of services arrangements involving Plans and IRAs to result in no more than reasonable compensation to the service provider. Investment Professionals and Financial Institutions—when acting as service providers to Plans or IRAs—have long been subject to this requirement, regardless of their fiduciary status.

The reasonable compensation standard requires that compensation not be excessive, as measured by the market value of the particular services, rights, and benefits the Investment Professional and Financial Institution are delivering to the Retirement Investor. Given the conflicts of interest associated with the commissions and other payments that would be covered by the exemption, and the potential for self-dealing, it is particularly important that Investment Professionals and Financial Institutions adhere to these statutory standards, which are rooted in common law principles.

The reasonable compensation standard applies to all transactions under the exemption, including investment products that bundle services and investment guarantees or other benefits, such as with annuities. In assessing the reasonableness of compensation in connection with these products, it is appropriate to consider the value of the guarantees and benefits as well as the value of the services. When assessing the reasonableness of a charge, one generally needs to consider the value of all the services and benefits provided for the charge, not just some. If parties need additional guidance in this respect, they should refer to the Department's interpretations under ERISA section 408(b)(2) and Code section 4975(d)(2).

One commenter expressed support for the proposed exemption's reasonable compensation requirement. However, several other commenters maintained that the requirement is not specific enough and too lenient. The commenters objected to the exemption not requiring recommendation of investments with the lowest fees. One commenter stated that, by focusing on the ''market value,'' the standard may incorporate existing practices that involve conflicts of interest and inflated prices. The same commenter stated that applying a fact-specific test to the reasonableness of fees encourages investment advice providers to contrive reasons why compensation is reasonable.

As the Department indicated in the preamble to the proposed exemption, and reiterates here, the reasonableness of fees will depend on all the facts and circumstances at the time of the recommendation. The Department outlines several of those factors below which are intended to ensure the objective reasonableness of the fee. Several factors inform whether compensation is reasonable, including the nature of the service(s) provided, the market price of the service(s) and/or the underlying asset(s), the scope of monitoring, and the complexity of the product. No single factor is dispositive in determining whether compensation is reasonable; the essential question is whether the charges are reasonable in relation to what the investor receives.

The Department did not intend to suggest that reasonableness will be assessed solely against the existing market practices. The reasonable compensation standard will not be met if the fees bear little relationship to the value of the services actually rendered. And separately, the exemption will not be satisfied if the Financial Institution does not establish, maintain, and enforce written policies and procedures prudently designed to ensure that the Financial Institution and its Investment Professionals comply with the reasonable compensation standard in connection with covered fiduciary advice and transactions.

One commenter stated that the reasonable compensation requirement is unnecessary because it is already applicable to Title I fiduciaries under ERISA section 408(b)(2).[104] Another commenter asserted that the reference to ERISA section 408(b)(2) indicated the exemption would adopt not only the substance but the established process for reasonable compensation determinations (*i.e.,* a determination made by an independent Plan or IRA fiduciary who engages the service provider).

Incorporating the reasonable compensation standard as a condition of relief in this exemption increases the consequence of non-compliance and improves the protections of the exemption. It is also a critical protection in the context of an exemption which provides relief not only for prohibited transaction violations under section 406(a) of ERISA, but for self-dealing violations under section 406(b).[105] In

[104] *See also* Code section 4975(d)(2).

[105] *See also* Code section 4975(c).

the context of this exemption, the standard serves the important function of preventing investment advice fiduciaries from overcharging their Retirement Investor customers, despite the conflicts of interest associated with their compensation.

In this regard, one commenter suggested that Investment Professionals should be required to disclose, in writing, the reasons that the Investment Professional is not recommending an investment with lower fees and the reasons the recommendation is more beneficial to the Retirement Investor. Thus, the Financial Institution would be required to demonstrate, in writing, that the compensation arising from an investment is reasonable and in the Retirement Investor's best interest.

Although the exemption places the burden on the Financial Institution and Investment Professional not to charge fees in excess of reasonable compensation, the Department declines to require documentation as suggested by the commenter. Under the exemption, the Financial Institution and Investment Professional are not required to recommend the transaction that is the lowest cost or that generates the lowest fees without regard to other relevant factors. In fact, the Department agrees with commenters that recommendations of the ''lowest cost'' security or investment strategy, without consideration of other factors, could in in some cases even violate the exemption. In addition, given the wide variety of investment products and fee structures available to investors, the commenter that asked for documentation did not provide a useful model to define lower fee investments that would serve as benchmarks for these purposes.

One commenter suggested that the exemption text should specifically provide that the cost of an investment product is a factor, although it need not be the determinative factor, in applying the best interest standard. While the Department agrees that the cost of an investment product will be a factor in every recommendation, the best interest standard envisions that all of the characteristics of an investment product—not just its cost—will be evaluated based on Retirement Investors' investment objectives, risk tolerance, financial circumstances, and needs. Therefore, the Department has not added a reference to cost to the best interest standard or elsewhere in the Impartial Conduct Standards.

Best Execution

Section II(a)(2)(B) of the exemption requires, in accordance with the federal securities laws, that the Financial Institution and Investment Professional seek to obtain the best execution of the investment transaction reasonably available under the circumstances. Financial Institutions and Investment Professionals subject to federal securities laws such as the Securities Act of 1933, the Securities Exchange Act of 1934, and the Investment Advisers Act of 1940, and rules adopted by FINRA and the Municipal Securities Rulemaking Board (MSRB), are obligated to adhere to a longstanding duty of best execution. As described recently by the SEC, ''[a] broker-dealer's duty of best execution requires a broker-dealer to seek to execute customers' trades at the most favorable terms reasonably available under the circumstances.'' [106] This condition complements the reasonable compensation standard set forth in the exemption.

The Department applies the best execution requirement consistent with the federal securities laws. Financial Institutions that are FINRA members satisfy this subsection if they comply with the best execution standards under federal securities laws and FINRA rules 2121 (Fair Prices and Commissions) and 5310 (Best Execution and Interpositioning), or any successor rules in effect at the time of the transaction, as interpreted by FINRA. Financial Institutions engaging in a purchase or sale of a municipal bond satisfy this subsection if they comply with the standards in MSRB rules G–30 (Prices and Commissions) and G–18 (Best Execution), or any successor rules in effect at the time of the transaction, as interpreted by MSRB. Financial Institutions that are subject to and comply with the fiduciary duty under section 206 of the Investment Advisers Act—which, as described by the SEC, encompasses a duty to seek best execution—will also satisfy this subsection.[107]

One commenter expressed general support but also stated that the exemption should clarify that the ''best execution'' standard for executing portfolio transactions includes not only the price of the transaction itself but, if applicable, fees and expenses including commissions that provide the most favorable total cost or proceeds reasonably obtainable under the circumstances. In response, the Department notes that the exemption's requirement that the Financial Institution and Investment Professional seek to obtain best execution is the second part of an overarching ''reasonable compensation'' condition which is not limited to best execution. As outlined above, the best execution requirement is consistent with federal securities law, and compliance by the Financial Institution and Investment Professional with the applicable statutory and regulatory provisions is sufficient to comply with the requirement. The condition builds upon Section II(a)(2)(A), which requires that compensation not exceed reasonable compensation. To the extent that the applicable securities law provisions do not address certain fees and expenses, those amounts are still captured in the overall requirement that the compensation not exceed reasonable compensation.

A number of commenters broadly objected to the inclusion of a best execution condition. The general critique was that the condition duplicates existing securities laws and is, therefore, unnecessary. In conjunction with this critique, multiple commenters argued that the best execution condition could result in the Department creating divergent and inconsistent interpretations of the best execution rule as compared to interpretations by FINRA, the SEC, and the MSRB. One commenter viewed the best execution requirement as an existing fiduciary obligation under ERISA section 404, stating that Title I fiduciaries are already obligated to seek to obtain the most favorable terms in a transaction, but should not lose the exemption for failure to do so.

The Department has considered these comments, but determined to retain the best execution condition. With respect to the exemption's application to Covered Principal Transactions, the condition will provide protection to Retirement Investors that may not be provided by the more general reasonable compensation requirement. The Department believes that the best execution requirement is a meaningful way to do so. The Department exercises its interpretive authority here to take the position that Financial Institutions and Investment Professionals that comply with applicable securities laws and their successors will satisfy this condition of the exemption, because of this requirement's origination in securities law. As a result, the Department does not believe the condition will result in divergent or inconsistent interpretations of securities laws.

Two additional commenters raised questions regarding the expansiveness of the condition. One commenter

[106] Regulation Best Interest Release, 84 FR 33373, note 565.

[107] SEC Fiduciary Interpretation, 84 FR 33674–75 (Section II.B.2 ''Duty to Seek Best Execution'').

objected to the best execution condition on the grounds that Financial Institutions might rely on third parties, such as trustees or custodians, to execute particular transactions with respect to which they provided investment advice. A second commenter requested that the Department clarify that the best execution requirement is limited to circumstances similar to those covered by FINRA rules 2121 and 5310. With respect to both of these comments, the Department notes that the best execution condition is applicable as it would otherwise be applicable under the federal securities laws.

Misleading Statements

Section II(a)(3) requires that statements by the Financial Institution and its Investment Professionals to the Retirement Investor about the recommended transaction and other relevant matters are not materially misleading at the time they are made. Other relevant matters include fees and compensation, material conflicts of interest, and any other fact that could reasonably be expected to affect the Retirement Investor's investment decisions. For example, the Department would consider it materially misleading for the Financial Institution or Investment Professional to include any exculpatory clauses or indemnification provisions in an arrangement with a Retirement Investor that are prohibited by applicable law.[108]

The Department received a few comments on this requirement in the proposal. One commenter stated this standard is unnecessary because misleading statements are already addressed by the proposal's disclosure requirement. Another commenter asked the Department to clarify what is considered a ''misleading statement.'' Other commenters suggested that the Department expand the standard to specifically include material omissions because material omissions may be equally damaging to a Retirement Investor's understanding.

The Department has not changed the specific language in Section II(a)(3) from the proposal. Misleading statements are not necessarily addressed by the exemption's disclosure requirement, which is limited to certain specific topics. Further, the Department notes that the requirement is to avoid ''*materially* misleading'' statements, so as to provide a standard for the condition and avoid uncertainty.

The Department agrees with commenters that materially misleading statements are properly interpreted to include statements that omit a material fact necessary in order to make the statements, in light of the circumstances under which they were made, not misleading. Retirement Investors are clearly best served by statements and representations that are free from material misstatements and omissions. Financial Institutions and Investment Professionals best promote the interests of Retirement Investors by ensuring that accurate communications are a consistent standard in all their interactions with their customers.

In connection with the prohibition against misleading statements in Section II(a)(3), one commenter reacted to the Department's preamble statement about exculpatory statements. The commenter objected on several grounds, including the view that this statement effectively incorporates state and local laws that may vary and, thus, undermines the Act's aim to provide a uniform national standard in the retirement space. The commenter opined that this statement creates an uncertain and unworkable standard and even Financial Institutions that attempt to comply in good faith may lose the exemption if they inadvertently fail to comply with a law.

The Department does not believe that the inclusion of an exculpatory statement that is prohibited by applicable law is fairly characterized as an inadvertent failure to comply with the law. Financial Institutions that provide fiduciary investment advice to Retirement Investors should be well aware of the laws in the jurisdictions within which they operate. If a Financial Institution fails to apprise itself of its legal responsibilities, it should not be permitted to rely upon an exemption that includes a best interest standard for advice that incorporates the principles of care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims. Permitting false and misleading statements that have the effect of dissuading a Retirement Investor from seeking lawfully available remedies is not consistent with the requirement, under Title I and the Code, that the Department find that an exemption is protective of the rights of participants and beneficiaries of Plans and IRA owners. Furthermore, the Department notes that all Title I fiduciaries remain subject to the uniform fiduciary responsibility provisions in ERISA section 404 with respect to Title I Plan assets. Finally, the Department has included provisions in the exemption, which enable fiduciaries to cure violations of the exemption conditions, under certain circumstances, and thereby avoid loss of the exemption.

Disclosure—Section II(b)

Section II(b) of the exemption requires the Financial Institution to provide certain written disclosures to the Retirement Investor prior to engaging in any transactions pursuant to the exemption. The Financial Institution must acknowledge, in writing, that the Financial Institution and its Investment Professionals are fiduciaries under Title I and the Code, as applicable, with respect to any fiduciary investment advice provided by the Financial Institution or Investment Professional to the Retirement Investor. The Financial Institution must also provide a written description of the services to be provided and material conflicts of interest arising out of the services and any recommended investment transaction. The description must be accurate in all material respects. The Financial Institution also must provide documentation of the specific reasons that any recommendation to roll over assets from one Plan or IRA to another Plan or IRA, or from one type of account to another, is in the Retirement Investor's best interest.

The disclosure obligations are designed to protect Retirement Investors by enhancing the quality of information they receive in connection with fiduciary investment advice. The disclosures should be in plain English, taking into consideration Retirement Investors' level of financial experience. The requirement can be satisfied through any disclosure, or combination of disclosures, required to be provided by other regulators so long as the disclosure required by Section II(b) is included. Once disclosure has been provided, the Financial Institution is not obligated to provide it again, except at the Retirement Investor's request or if the information has materially changed.

Written Fiduciary Acknowledgment

Section II(b)(1) of the final exemption includes the requirement to provide Retirement Investors with a written fiduciary acknowledgment as proposed. This disclosure is designed to ensure that the fiduciary nature of the

[108] *See, e.g.,* ERISA section 410 and *see also* ERISA Interpretive Bulletin 75–4—Indemnification of fiduciaries. (''The Department of Labor interprets section 410(a) as rendering void any arrangement for indemnification of a fiduciary of an employee benefit plan by the plan. Such an arrangement would have the same result as an exculpatory clause, in that it would, in effect, relieve the fiduciary of responsibility and liability to the plan by abrogating the plan's right to recovery from the fiduciary for breaches of fiduciary obligations.'')

relationship is clear to the Financial Institution and Investment Professional, as well as the Retirement Investor, at the time of the investment transaction.

This exemption gives broad relief for a wide range of activities that fiduciaries otherwise would be prohibited from engaging in. Given this wide field of action, the Department has concluded that clear disclosure is one of the necessary protections for Retirement Investors. A Financial Institution and Investment Professional that seek to provide investment advice to a Retirement Investor and otherwise engage in a relationship that satisfies the five-part test should, at a minimum (if they wish to avail themselves of this particular exemption), make a conscious up-front determination of whether they are acting as fiduciaries; tell their Retirement Investor customers that they are rendering advice as fiduciaries; and, based on their conscious decision to act as fiduciaries, implement and follow the exemption's conditions. The requirement also supports Retirement Investors' ability to choose a provider of advice that is a fiduciary within the meaning of Title I and the Code.

The written fiduciary acknowledgment supports the exemption's objectives of preserving the availability of a wide variety of business models and expanding investor choice. Retirement Investors benefit from knowing if they are receiving advice from a fiduciary. Further, this disclosure increases the likelihood that Financial Institutions and Investment Professionals will take their compliance obligations seriously. This exemption contemplates that the Financial Institution and Investment Professional will put down a marker as fiduciaries when they indeed are acting as such. Financial Institutions and Investment Professionals may not rely on the exemption merely as a back-up protection for engaging in possible prohibited transactions when their ultimate intention is to deny the fiduciary nature of their investment advice.

Model Language

To assist Financial Institutions and Investment Professionals in complying with this condition of the exemption, the Department provides the following model fiduciary acknowledgment language as an example of language that will satisfy the disclosure requirement in Section II(b)(1):

When we provide investment advice to you regarding your retirement plan account or individual retirement account, we are fiduciaries within the meaning of Title I of the Employee Retirement Income Security Act and/or the Internal Revenue Code, as applicable, which are laws governing retirement accounts. The way we make money creates some conflicts with your interests, so we operate under a special rule that requires us to act in your best interest and not put our interest ahead of yours.

In addition, although the exemption does not require it, Financial Institutions and Investment Professionals could more fully explain the exemption's terms with the following model disclosure:

Under this special rule's provisions, we must:

- Meet a professional standard of care when making investment recommendations (give prudent advice);
- Never put our financial interests ahead of yours when making recommendations (give loyal advice);
- Avoid misleading statements about conflicts of interest, fees, and investments;
- Follow policies and procedures designed to ensure that we give advice that is in *your* best interest;
- Charge no more than is reasonable for our services; and
- Give you basic information about conflicts of interest.

Discussion of Comments

A few commenters expressed support for the written fiduciary acknowledgment. A number of other commenters objected to the acknowledgment condition in the proposal. Some commenters stated that it would require them to say they were fiduciaries at the outset of a relationship, at a time when the ongoing nature of the relationship may be uncertain, which some commenters said would be unworkable. Some asserted that the written fiduciary acknowledgment requirement would deter some financial services providers from relying on the exemption because of fear of increased liability, thus causing Retirement Investors to lose access to the full range of investment advice arrangements. Several commenters argued that Financial Institutions will not be fiduciaries for all purposes, including under securities laws, and that the acknowledgement could confuse investors and also potentially undermine the purpose of the SEC's Form CRS as a comprehensive source of investor information. Some of these commenters said that they already disclose their duties under the best interest standard under Regulation Best Interest and believed that a similar disclosure would more accurately characterize their duties to Retirement Investors under the exemption. Some of these commenters also said that the proposal was inconsistent with other exemptions such as PTE 84–24, which have traditionally covered such inadvertent fiduciaries.

Some commenters said the disclosure was inconsistent with the Fifth Circuit's *Chamber* opinion because the statement would determine fiduciary status, rather than the five-part test. Other commenters argued that the fiduciary acknowledgment could create a unilateral contract between the Financial Institution and the Retirement Investor, which they said was also impermissible in light of the Fifth Circuit's *Chamber* opinion. Some expressed concern about interaction with other laws, including the possibility that the acknowledgment could be considered to create a ''contractual fiduciary duty'' under Massachusetts securities law which could impose additional requirements on broker-dealers.

Other commenters described the standard as not providing enough protection for Retirement Investors. According to these commenters, the exemption's best interest standard is not a ''true'' fiduciary standard. Some commenters also indicated the lack of a ''true'' fiduciary standard makes it misleading for Financial Institutions to disclose that they are fiduciaries and thereby causes Retirement Investors to expect protections that they will not in fact receive. These commenters pointed to the Act's legislative purpose to provide tax-advantaged accounts with *more* protection for participants than other, existing standards. Some commenters noted that the Regulation Best Interest standard is new, and the Department cannot determine that it offers the necessary protections until it has been fully tested in the market. One commenter stated that the fiduciary acknowledgement would allow investment advice providers to ''pose'' as fiduciaries and give non-fiduciary advice to Retirement Investors, who are depending on them for important decisions.

Some commenters suggested alternatives to the fiduciary acknowledgement, such as requiring an acknowledgment of the applicability of the best interest standard. Commenters said this would avoid unnecessary complexity and preserve Retirement Investors' access to low-cost, high quality advice. One commenter suggested that the Department work on an expanded version of the SEC Form CRS which would explain the standards applicable to Title I and Code fiduciaries, broker-dealers, and investment advisers. However, other commenters opposed the idea of a

disclosure of the best interest standard, expressing concern that any expansion of required disclosure would cause even more Retirement Investor confusion. According to these commenters, any problems associated with a fiduciary acknowledgment—including increased liability—could also apply to acknowledgment of the best interest standard.

The Department has carefully considered comments on the requirement to provide written acknowledgment of fiduciary status. The Department believes the acknowledgment ensures clarity as to the nature of the relationship between the parties, supports Retirement Investors' ability to choose a provider of advice that is a fiduciary within the meaning of Title I and the Code, and promotes compliance with the conditions of the exemption. To increase that clarity, the voluntary model disclosure includes disclosure of the best interest standard. Financial Institutions that do not want to act as fiduciaries can also make that clear and act accordingly. The five-part test, as interpreted above, and Interpretive Bulletin 96–1 regarding participant investment education, provide Financial Institutions and Investment Professionals a clear roadmap for determining when they are, and are not, Title I and Code fiduciaries.

The Department disagrees with commenters who stated that the disclosure could be misleading to Retirement Investors because the exemption's best interest standard is not, in their assessment, a ''true'' fiduciary standard. The exemption is only applicable to ''fiduciaries'' within the meaning of Title I and the Code. Accordingly, the acknowledgment does not mislead investors as to the nature of the advice relationship, but rather accurately recites the Financial Institution's and Investment Professional's fiduciary status under Title I and the Code. Moreover, as discussed above, although the best interest standard does not include a ''without regard to'' formulation of the loyalty standard, the standard is consistent with interpretive statements by the Department as to Title I's duty of loyalty in other contexts.

With respect to the commenters who stated they should not have to acknowledge fiduciary status if they are uncertain as to whether they satisfy the five-part test, the Department believes, in light of the broad scope of relief in the exemption, that it is critical for Financial Institutions and Investment Professionals who choose to rely on the exemption to determine up-front if they intend to act as fiduciaries, and structure their relationship with the Retirement Investor accordingly. Financial Institutions are unlikely to comply fully with the exemption if they are simply relying on the exemption as a fallback position in the event that a primary argument of non-fiduciary status fails. Financial services providers that are not fiduciaries have no need of this exemption. Financial services providers that are fiduciaries, however, have a statutory obligation to adhere to the prohibited transaction rules or meet the terms of the exemption. Compliance with the law turns on financial services providers knowing whether or not they are acting as fiduciaries and acting in accordance with that understanding.

This exemption is not designed as a backup method of compliance for Financial Institutions that intend to deny the fiduciary nature of their investment advice despite their actions to the contrary. Instead, it is intended to provide broad relief for parties who are indeed fiduciaries under the five-part test, as manifested by their purposes and actions, and who implement fiduciary structures to govern their relationship with their customers. In response to comments asserting inconsistency of this exemption with PTE 84–24, which does not require written fiduciary acknowledgment, the Department responds that it is the responsibility of the Department to craft exemptions to ensure they are protective of and in the interests of plans and plan participants. The conditions in the Department's exemptions are designed to address the scope of the relief in the exemption and the attendant conflicts of interest. The Department has determined that the written fiduciary acknowledgment serves as an important safeguard in connection with the very broad grant of relief in this exemption from the self-dealing prohibitions of Title I and the Code. Other pre-existing prohibited transaction exemptions that do not have a fiduciary acknowledgment as a requirement, including statutory exemptions, remain available as alternatives.

As for the related argument that some financial service providers will withdraw their services rather than provide their Retirement Investor customers a written fiduciary acknowledgment, the Department does not believe that will have significant effects on Retirement Investors' choices. The exemption in fact offers new exemptive relief for Financial Institutions and Investment Professionals that provide fiduciary investment advice to Retirement Investors. Pre-existing exemptions, with different conditions, remain in place as alternatives. And, for Financial Institutions and Investment Professionals that are not fiduciaries, this exemption is unneeded.

The Department also does not believe that the possibility of investor confusion or lack of understanding of the term ''fiduciary,'' or concerns about the interaction with SEC Form CRS, present sound bases for eliminating the requirement. The acknowledgment does not contradict SEC Form CRS, and it is limited to fiduciary investment advice as defined in Title I and the Code. The Department believes that the model acknowledgment and additional voluntary model disclosure set forth above meets the objectives of the exemption by communicating the fiduciary status of the Financial Institution and Investment Professional as well as the requirement that they are operating under the exemption's best interest standard.

The Department does not intend that the fiduciary acknowledgment or any of the disclosure obligations create a private right of action as between a Financial Institution or Investment Professional and a Retirement Investor, and it does not intend that any of the exemption's terms, including the acknowledgement, give rise to any causes of action beyond those expressly authorized by statute.[109] Similarly, the fiduciary acknowledgement does not create a contractual fiduciary duty. ERISA section 502(a) provides a cause of action for fiduciary breaches and prohibited transactions with respect to Title I Plans (but not IRAs). Code section 4975 imposes a tax on disqualified persons participating in a prohibited transaction involving Plans and IRAs (other than a fiduciary acting only as such). These are the sole remedies for engaging in non-exempt prohibited transactions. The exemption does not create any new causes of action, nor does it require firms to make enforceable contractual commitments or give enforceable warranties to Retirement Investors, as was true of the 2016 fiduciary rulemaking which the Fifth Circuit set aside in its *Chamber* opinion.

[109] The SEC similarly stated with respect to its Form CRS, which describes the conduct standard applicable to broker-dealers and investment advisers, that it is not intended to create a private right of action. Form CRS Relationship Summary Release, 84 FR 33530. *See also* Regulation Best Interest Release 84 FR 33327 (''Furthermore, we do not believe Regulation Best Interest creates any new private right of action or right of rescission, nor do we intend such a result.'').

Description of Services and Material Conflicts of Interest

Under Section II(b)(2) of the exemption, the Financial Institution must also provide a written description of the services to be provided and material conflicts of interest arising out of the services and any recommended investment transaction. The description must be accurate in all material respects. The Department believes disclosure of these items is necessary to ensure Retirement Investors receive information to assess the services that will be provided and related conflicts of interest. The disclosure requirement is principles-based and intended to allow flexibility to apply to a wide variety of business models and practices.

While one commenter agreed with the Department that a principles-based approach to disclosure provides the flexibility necessary to apply to a wide variety of business models with respect to the services and conflict disclosure requirements, some commenters contended the required disclosures would be insufficiently protective of Retirement Investors. Some commenters focused on the Department's position in the 2016 rulemaking that disclosure alone is ineffective in mitigating the impact of conflicts of interest.

Some commenters opposed the ability to satisfy the disclosure requirement through disclosures required to be provided by other regulators, particularly in cases where such disclosures may not be in plain English. Commenters argued that other disclosure regimes, such as Forms CRS and ADV, are not sufficient and are not designed to comply with the Act. The same commenters also stated that the Department should ensure that Retirement Investors receive accurate, not misleading, information that does not omit any material conditions or information including information that the Financial Institution or Investment Professional knows or should know that the Retirement Investors needs to determine whether to maintain the advice relationship and/or investment(s). Some commenters supported allowing disclosure requirements to be satisfied by using disclosures such as Forms ADV and CRS.

A commenter suggested specific additional items, perhaps in a model form, that should be included in the disclosure, including an estimate of the retirement savings needs of each participant and that the Department should develop a model disclosure and/or test proposed disclosures for their effectiveness. Another commenter suggested that the Department should develop a highly prescriptive, one-page model form that would allow consumers to compare service providers. Other commenters requested full safe harbors based on disclosure requirements under securities laws or insurance laws.

After consideration of the comments, the Department has determined to adopt the disclosure provisions as they were proposed. The Department believes the exemption's disclosure of the provided services and associated conflicts is appropriate and important, and it is by no means the sole protection in the exemption. The disclosure requirement works in concert with the other protections, such as the Impartial Conduct Standards and policies and procedures, and reinforces the exemption's important focus on conflict mitigation. The Department additionally stresses that conflict mitigation is not the sole purpose of disclosure, as some comments appeared to assume. In the Department's view, disclosure also promotes consumer choice and permits Retirement Investors to enter into a professional relationship and make investments with a clear understanding of the nature of that relationship and of the investments' salient features. These are important values, independent of their impact in mitigating conflicts.

The Department's approach in the proposal allowed for the disclosure to be satisfied through disclosures provided pursuant to other regulators' requirements. Since the Department's 2016 rulemaking, other regulators have developed additional conflict of interest disclosure requirements and oversight that provide a greater measure of accountability and investor protection in the marketplace. Permitting use of other regulators' disclosures was intended to minimize the potential for duplicative and voluminous disclosures which could contribute to reduced effectiveness. For this reason, the Department has declined to offer a model disclosure with respect to this aspect of the disclosure or add additional specific items to the required disclosure. Although the Department supports participants receiving information about retirement savings needs, for example, that type of a required disclosure is beyond the scope of this exemption proceeding.

In response to commenters who expressed concern that the exemption's approach would not ensure accurate and complete disclosures, the Department responds that the exemption text requires the disclosure of services to be provided and material conflicts of interest to be ''accurate and not misleading in all material respects.'' Inaccurate disclosures will not satisfy the exemption conditions, nor will disclosures with material omissions. However, the Department declines to specify that the disclosure must provide information that the Financial Institution or Investment Professional knows or should know the Retirement Investor needs to determine whether to maintain the advice relationship and/or the investments, out of concern that this sets up a standard for disclosure that may be difficult to satisfy.

A commenter urged the Department to delete the written fiduciary acknowledgment and, instead, consistent with Regulation Best Interest, require disclosure instead of all material facts relating to the scope and terms of the relationship and all material facts relating to conflicts of interest that are associated with the recommendation. As discussed above, the Department has retained the written fiduciary acknowledgment in the final exemption as well as the requirement to disclose in writing the services to be provided and the material conflicts of interest. The Department did not adopt the approach taken in Regulation Best Interest, despite the belief that the exemption's disclosure requirements involve similar information, because the exemption is available to Financial Institutions that are not subject to Regulation Best Interest and Department believes that a specific disclosure of fiduciary status is important to the goals of this exemption.

However, the Department confirms that, like the Regulation Best Interest requirements, the standard for materiality for purposes of this obligation is consistent with the one the Supreme Court articulated in *Basic* v. *Levinson,*[110] and, in the context of this exemption, the standard of materiality is centered on those facts that a reasonable Retirement Investor, as defined in the exemption, would consider important. Material conflicts of interest that would be required to be disclosed under the exemption would include, for example, conflicts associated with proprietary products, payments from third parties, and compensation arrangements.

Commenters also requested additional guidance regarding satisfaction of the exemption's disclosure obligations through (1) the use of disclosures required by other regulators or other Title I and Code requirements, or (2) safe harbors when such disclosures are used. Commenters argued this would avoid duplication and Retirement Investor confusion. In doing so, most commenters emphasized a desire to ensure harmonization between the

[110] *Basic, Inc.* v. *Levinson,* 485 U.S. 224 (1988).

exemption condition and other disclosure regimes.

While the exemption does not include specific safe harbors, the Department confirms that Financial Institutions may rely, in whole or in part, on other regulatory disclosures to satisfy certain aspects of this disclosure requirement, for example, the disclosures required under Regulation Best Interest and Form CRS, applicable to broker-dealers; Form ADV and Form CRS, applicable to registered investment advisers; and disclosures required under insurance and banking laws when such disclosures cover services to be provided and the Financial Institution's and Investment Professional's material Conflicts of Interest. Avoiding duplication of disclosures is important and the Department reiterates that the disclosure standard under this exemption may be satisfied in whole, or in part, by using other required disclosures to the extent those disclosures include information required to be disclosed by the exemption. Allowing the use of other disclosures to meet the disclosure standard under this exemption should serve to harmonize this exemption's conditions with those of other disclosure regimes.

The Department also confirms that the disclosure required by the exemption may be included with or accompanied by the disclosure provided to responsible Plan fiduciaries under 29 CFR 2550.408b–2, as applicable, and that such disclosures may satisfy, in whole or in part, the disclosure obligations under this exemption when the fiduciary of the Plan is the Retirement Investor receiving advice, as defined in Section V(k)(3). However, if advice is provided to individual Plan participants, disclosure to the Plan fiduciary will not satisfy the disclosure obligation under the exemption. In such cases, the Retirement Investor is the individual participant receiving the investment advice, as defined in Section V(k)(1), and the disclosure obligation applies to that particular individual.

The Department cautions Financial Institutions that the requirements under this exemption are not merely a ''check-the-box'' activity. Rather, it is imperative that Financial Institutions engage in a careful analysis to identify their material conflicts so that they and their Investment Professionals are able to provide accurate disclosures and make recommendations that satisfy the best interest standard. The Department notes that although disclosures are required under the statutory exemption in ERISA section 408(b)(2) and the accompanying regulation at 29 CFR 2550.408b–2, the 408(b)(2) disclosures do not require an accompanying focus on conflict mitigation. Relatedly, the 408(b)(2) statutory exemption does not provide prohibited transaction relief from the self-dealing prohibited transactions in ERISA section 406(b).

Documentation of Rollover Recommendation

Section II(b)(3) of the final exemption requires Financial Institutions to provide Retirement Investors, prior to engaging in a rollover recommended pursuant to the exemption, with documentation of the specific reasons that the recommendation to roll over assets is in the best interest of the Retirement Investor. This requirement extends to recommended rollovers from a Plan to another Plan or IRA as defined in Code section 4975(e)(1)(B) or (C), from an IRA as defined in Code section 4975(e)(1)(B) or (C) to a Plan, from an IRA to another IRA, or from one type of account to another (*e.g.,* from a commission-based account to a fee-based account). The requirement to document the specific reasons for these recommendations is part of the required policies and procedures, in Section II(c)(3).

Rollover recommendations are a primary concern of the Department, as Financial Institutions and Investment Professionals may have a strong economic incentive to recommend that investors roll over assets into one of their institution's IRAs, whether from a Plan or from an IRA account at another Financial Institution, or even between different account types. The decision to roll over assets from a Title I Plan to an IRA, in particular, may be one of the most important financial decisions that Retirement Investors make, as it may have a long-term impact on their legal rights and remedies and their retirement security.

The requirement to document the reasons that a rollover is in the best interest of the Retirement Investor is included in the exemption's policies and procedures provision to ensure that Financial Institutions and Investment Professionals take the time to form a prudent recommendation, and that a record is available for later review. The written record serves an important role in protecting Retirement Investors during this significant decision. The final exemption also includes the additional new provision in Section II(b)(3) requiring this documentation be provided to the Retirement Investor. Because of the special importance of rollover recommendations, the Department has concluded that Retirement Investors should be provided with the rollover documentation.

Some commenters on the proposal expressed support for the requirement to document the reasons for rollover recommendations, although some suggested it be expanded to provide additional protections. One suggestion was for the requirement to apply to all recommendations or at least to an expanded list of consequential recommendations beyond rollovers. One commenter suggested that the written documentation of all recommendations should demonstrate how the recommendations comply with the Financial Institution's written policies and procedures. Commenters also suggested additional factors to consider and document, including a clear examination of the long-term impact of any increased costs and why the added benefits justify those added costs, as well as consideration of economically significant features—such as surrender schedules and index annuity cap and participation rate—that the commenter indicated providers use in lieu of direct fees. One commenter provided an example of how the documentation could look, including scoring alternative investments. Another commenter indicated that the documentation requirement is not fully protective unless the documentation is provided to the Retirement Investor.

Other commenters urged the Department not to include this condition in the final exemption. They wrote that the documentation requirement was overly burdensome on Financial Institutions, generally is not required in other exemptions, and would not provide meaningful protections to Retirement Investors. Commenters stated it may be difficult to obtain the required information and noted that the SEC chose specifically not to include this requirement in Regulation Best Interest, even though the SEC did encourage it as a good practice.[111]

Some commenters felt that the specific considerations identified in the preamble were too prescriptive, and the exemption should instead rely on a more principles-based approach, such as the Financial Institutions' reasonable oversight of Investment Professionals. A few commenters requested clarification that the factors included in the

[111] Regulation Best Interest Release, 84 FR 33360 (''Similarly, we encourage broker-dealers to record the basis for their recommendations, especially for more complex, risky or expensive products and significant investment decisions, such as rollovers and choice of accounts, as a potential way a broker-dealer could demonstrate compliance with the Care Obligation.'').

preamble are merely factors that Financial Institutions ''may include'' in their documentation but that Financial Institutions are ultimately permitted to use their judgment to determine the appropriate factors to be considered, depending on the facts and circumstances of particular Retirement Investors. On the other hand, a commenter supported the factors and suggested that the Department should include them in the exemption text.

Certain commenters expressed further concern that the preamble discussion of the requirement did not appropriately weigh the benefits of a rollover (including the loss of the professional expertise and advice if the Retirement Investor chooses to stay in a workplace Plan) or other factors that are important to a Retirement Investor (such as access to distribution options, asset consolidation, and access to discretionary asset management). A commenter also asserted that the documentation should not extend to recommendations related to IRA transfers and transfers between brokerage and advisory accounts, asserting that these transfers are not irrevocable.

Some commenters were concerned about potential enforcement related to this provision of the exemption. One asked the Department to state that Financial Institutions are not required to review and approve each recommendation on a case by case basis. Another requested a non-enforcement policy so that a Financial Institution would not lose the exemption if an Investment Professional failed to document the reasons for any specific transaction, as long as the Financial Institution worked diligently and in good faith to implement technology and systems to efficiently document and supervise rollover recommendations. One commenter requested a safe harbor from the requirement to document rollover recommendations as long as Regulation Best Interest is satisfied.

Upon consideration of the comments, the Department has determined to include the documentation requirement in the exemption, as proposed. Given the importance of these decisions, the Department does not find it unnecessarily burdensome to require Financial Institutions and Investment Professionals to document their reasons for the recommendation. The documentation can provide an important opportunity for evaluation and oversight of these recommendations by Financial Institutions, Retirement Investors, and the Department, and is appropriate in the context of this broad exemption. Requiring specific documentation for rollover transactions provides appropriate protection of Retirement Investors while minimizing the burden on Financial Institutions that would be attached to documentation of all recommendations. By additionally requiring that the rollover documentation be provided to the Retirement Investor, the Department believes that the Retirement Investor will be better positioned to understand the significance of a rollover decision and how acting upon a rollover recommendation will satisfy the best interest standard under this exemption. The Department has retained the scope of the documentation requirement to include IRA transfers and transfers between brokerage and advisory accounts, even though those decisions may not be irrevocable, because they may involve significant cost, particularly over the long term.

With respect to recommendations to roll assets out of an Title I Plan and into an IRA, the factors that a Financial Institution and Investment Professional should consider and document include the following: The Retirement Investor's alternatives to a rollover, including leaving the money in his or her current employer's Plan, if permitted, and selecting different investment options; the fees and expenses associated with both the Plan and the IRA; whether the employer pays for some or all of the Plan's administrative expenses; and the different levels of services and investments available under the Plan and the IRA. For rollovers from another IRA or changes from a commission-based account to a fee-based arrangement, a prudent recommendation would include consideration and documentation of the services that would be provided under the new arrangement. The Department agrees with commenters that the long-term impact of any increased costs and the reason(s) why the added benefits justify those added costs, as well as the impact of features such as surrender schedules and index annuity cap and participation rates, should be considered as part of any rollover recommendation, as relevant.

In response to commenters who asked whether these factors cited in the proposal's preamble are required to be documented in all cases, or whether they are suggested considerations, it is the Department's view that these factors are relevant to a prudent fiduciary's analysis of a rollover. It would be difficult to justify a rollover recommendation that did not consider these factors. Of course, the discussion of factors identified above is not intended to suggest that Financial Institutions and Investment Professionals may not consider other factors, including those that are important to a particular Retirement Investor, as part of their rollover recommendation.[112] For that reason, the Department has not added the specific factors identified in the preamble to the exemption text, as a commenter suggested.[113]

To satisfy this condition for Title I Plan to IRA rollovers, the Department expects that Investment Professionals and Financial Institutions evaluating this type of potential rollover will make diligent and prudent efforts to obtain information about the existing Title I Plan and the participant's interests in it. In general, such information should be readily available as a result of DOL

[112] For example, in the Regulation Best Interest Release, the SEC identified a number of factors that should be considered by broker-dealers in determining whether a particular account would be in a particular retail customer's best interest, including (1) the services and products provided in the account (ancillary services provided in conjunction with an account type, account monitoring services, etc.); (2) the projected cost to the retail customer of the account; (3) alternative account types available; (4) the services requested by the retail customer; and (5) the retail customer's investment profile. The SEC also cited factors that should be considered by broker-dealers in making a recommendation to roll over Title I Plan assets to an IRA, including: Fees and expenses; level of service available; available investment options; ability to take penalty-free withdrawals; application of required minimum distributions; protection from creditors and legal judgments; holdings of employer stock; and any special features of the existing account. 84 FR 33382–83.

[113] A commenter suggested a number of other factors that should be documented as part of the rollover recommendation, including: any incentives and/or fees the Financial Institution and/or the Investment Professional receives if they keep the account when employees leave their employer (*i.e.,* maintaining the rollover account) or if they obtain additional fees for investments of the participants outside of the Plan; and fees and historic rates of return comparing the rollover recommendation and its proposed investment with the alternative(s), including leaving the assets in the current Plan, in a chart, over a 1, 5, and 10-year period. While the Department has chosen to take a less prescriptive and burdensome approach to the documentation and disclosure requirements than the commenter suggested, the Department stresses that Retirement Investors' interests should be protected by the overarching obligations to adhere to the Impartial Conduct Standards and to implement policies and procedures that require mitigation of conflicts of interest to the extent that a reasonable person reviewing the Financial Institution's policies and procedures and incentive practices would conclude that they do not create an incentive for a Financial Institution or Investment Professional to place their interests ahead of the interest of the Retirement Investor. The Department also agrees that a prudent fiduciary would consider the impact of fees and returns under alternative investments over time-horizons consistent with the Plan participant's financial interests and needs. Such analyses, however, should turn on the fiduciary's assessment of the unique facts and circumstances applicable to the Plan participant, as opposed to a single standardized analysis mandated by the Department for all cases.

regulations mandating disclosure of Plan-related information to the Plan's participants (*see* 29 CFR 2550.404a–5). If the Retirement Investor is unwilling to provide the information, even after a full explanation of its significance, and the information is not otherwise readily available, the Financial Institution and Investment Professional should make a reasonable estimation of expenses, asset values, risk, and returns based on publicly available information. The Financial Institution and Investment Professional should document and explain the assumptions used and their limitations. In such cases, the Investment Professional could rely on alternative data sources, such as the most recent Form 5500 or reliable benchmarks on typical fees and expenses for the type and size of Plan at issue.

A few commenters suggested that Financial Institutions and Investment Professionals should not have to go beyond any information provided by Retirement Investors. One commenter suggested that Investment Professionals should not be compelled to make an estimate and should be permitted to include in the documentation: Any reasons why, in the absence of certain information, other information supports a recommendation; the fact that the Retirement Investor was unwilling to provide the relevant information; and/or that the Investment Professional after best efforts, was unable to obtain the relevant information. The Department concurs that the documentation can include these statements, but notes that the statements would not be sufficient as an alternative to the estimates described in the previous paragraph.

Several commenters reacted to the proposed exemption's preamble statement that the documentation should address the Retirement Investor's alternatives to a rollover, including leaving the money in his or her current employer's Plan, if permitted, and selecting different investment options. A commenter queried whether Investment Professionals would be required to reallocate plan investments into an ideal asset allocation. Some insurance industry commenters expressed concern that the requirement would cause them to evaluate non-insurance options which they asserted was not permitted under insurance laws. The preamble statement was not intended, however, to suggest that Investment Professionals need to make advice recommendations as to investment products they are not qualified or legally permitted to recommend. Instead, the Department was merely indicating that a rollover recommendation should not be based solely on the Retirement Investor's existing allocation without any consideration of other investment options in the Plan.[114] A prudent fiduciary would carefully consider the options available to the investor in the Plan, including options other than the Retirement Investor's existing plan investments, before recommending that the participant roll assets out of the Plan.

Likewise, the Department notes that nothing in the exemption or the Impartial Conduct Standards prohibits investment advice by ''insurance-only'' agents or requires such insurance specialists to render advice with respect to other categories of assets outside their specialty or expertise. An Investment Professional should disclose any limitation on the types of products he or she recommends, and refrain from recommending an annuity if it is not in the best interest of the Retirement Investor. If, for example, it would not be in the investor's best interest for the investor to purchase an annuity in light of the investor's liquidity needs, existing assets, lack of diversification, financial resources, or other considerations, the Investment Professional should not recommend the annuity purchase, even if that means the agent cannot make a sale.

The exemption also does not mandate that a Financial Institution review documentation of each and every rollover recommendation. However, depending on the Financial Institution's business model and the other methods available to mitigate conflicts of interest, regular review of some or all rollover recommendations may be an effective approach to compliance with the exemption. Because of the importance of this condition, the Department declines to provide a non-enforcement policy related to an Investment Professional's failure to document the recommendation or a safe harbor for general compliance with Regulation Best Interest. However, an isolated failure will only expose the Financial Institution to liability for that recommended transaction.

Timing of the Disclosure

Some commenters urged the Department to modify the timing requirements of the disclosure. A few requested that, consistent with Regulation Best Interest, the Department allow the disclosure to be provided ''prior to or at the time of the recommendation.'' Another commenter was concerned that Retirement Investors would not have sufficient time to review the information, and suggested that the disclosures should be provided 14 days before the close of the recommended transaction.

The Department has included the disclosure timing requirements in the final exemption as proposed. Because the exemption requires the disclosure to be provided prior to the transaction, parties wishing to provide disclosure at the time of the recommendation would be permitted to do so. The Department has not adopted the suggestion that the exemption require disclosure at least 14 days before the close of a recommended transaction due to concerns that this requirement could create an artificial timeframe that may, depending on the circumstances, prevent a Retirement Investor from entering into a beneficial transaction in a timely fashion.

Policies and Procedures—Section II(c)

Section II(c)(1) of the exemption establishes an overarching requirement that Financial Institutions establish, maintain, and enforce written policies and procedures prudently designed to ensure that the Financial Institution and its Investment Professionals comply with the Impartial Conduct Standards. Under Section II(c)(2), Financial Institutions' policies and procedures are required to mitigate conflicts of interest to the extent that a reasonable person reviewing the policies and procedures and incentive practices as a whole would conclude that they do not create an incentive for a Financial Institution or Investment Professional to place their interests ahead of the interest of the Retirement Investor.[115]

As defined in section V(c), a *Conflict of Interest* is ''an interest that might incline a Financial Institution or Investment Professional—consciously or unconsciously—to make a recommendation that is not in the Best Interest of the Retirement Investor.'' Conflict mitigation is a critical condition of the exemption, and is important to the required findings under ERISA section 408(a) and Code section

[114] FINRA has recognized that broker-dealers making a rollover recommendation should consider investment options among other factors. ''The importance of this factor will depend in part on how satisfied the investor is with the options available under the plan under consideration. For example, an investor who is satisfied by the low-cost institutional funds available in some plans may not regard an IRA's broader array of investments as an important factor.'' *See* Regulatory Notice 13–45, *supra* note 42.

[115] Section II(c)(3) of the exemption, regarding documentation of the reasons for a rollover recommendation, is discussed above in the section on the disclosure of the documentation.

4975(c)(2), that the exemption is in the interests of, and protective of, Retirement Investors.

To comply with Section II(c)(2) of the exemption, Financial Institutions would need to identify and carefully focus on the conflicts of interest in their particular business models that may create incentives to place their interests ahead of the interest of Retirement Investors. Under the exemption condition, Financial Institutions' policies and procedures must be prudently designed to, among other things, protect Retirement Investors from recommendations to make excessive trades, or to buy investment products, annuities, or riders that are not in the investor's best interest or that allocate excessive amounts to illiquid or risky investments. Examples of policies and procedures and conflict mitigation strategies are provided later in this preamble.

Some commenters on the proposal expressed the view that the policies and procedures requirement was not sufficiently protective because it is based on the exemption's best interest standard, which the commenters believed was not a ''true'' fiduciary standard. Further, the commenters indicated that the exemption should include substantive provisions regarding the policies and procedures, beyond the statement that they must be prudent. One commenter suggested a number of specific provisions, including a description of the criteria that will be applied in determining that the recommendation did not place the interests of the Financial Institution or Investment Professional ahead of the interests of the Retirement Investor; a description of how the Financial Institution and Investment Professional will mitigate conflicts of interest; a requirement that the Financial Institution and investment professionals maintain written records showing the basis for each recommendation and how it complies with the written policies and procedures; the engagement of an independent compliance officer; identification, in the annual report, of the compliance officer and his or her qualifications; a statement describing the scope of the review conducted by the compliance officer; to the extent the self-review uncovers any violations of the policies and procedures, an unwinding of the transaction(s); and distribution of the self-review to all Retirement Investors receiving conflicted fiduciary investment advice. Another commenter expressed concern that the stated intention of the policies and procedures requirement did not align with what the proposal indicated would actually be accepted as demonstrating compliance.

In the proposal, Section II(c)(2) provided that a Financial Institution's policies and procedures would be required to mitigate conflicts of interest to the extent that the policies and procedures, and the Financial Institution's incentive practices, when viewed as a whole, are prudently designed to avoid misalignment of the interests of the Financial Institution and Investment Professionals and the interests of Retirement Investors. Some commenters criticized the proposal's approach to conflict mitigation, asserting that the proposal's terms were vague and lacked sufficient specifics. For instance, one commenter noted disapprovingly that the proposal required that policies and procedures be designed to ''mitigate'' conflicts of interest rather than ''eliminate'' them. Another commenter took issue with the proposal's suggestion that financial institutions should simply ''consider minimizing'' incentives that operate at the firm level. The commenter opined that the exemption's language does not address how to minimize the conflicts associated with receipt of revenue sharing payments, for instance.

Commenters also objected to the alignment of the best interest standard with the SEC's regulatory standards, which they asserted were intentionally designed to avoid disruption of broker dealers' highly conflicted business model. These commenters described the SEC standards as allowing that the vast majority of conflicted practices to continue unabated, and they said the same would be the case in the exemption. At the September 3, 2020, public hearing, several commenters warned the Department that the Regulation Best Interest standards were untested, and it was premature for the Department to rely on the SEC. Some commenters urged the Department to go further and describe specific lines of prohibited conduct.

Commenters also criticized the proposal for suggesting that significant conflicts of interest can be addressed through more rigorous supervision, stating that firms often have no incentive to constrain the conduct that their practices encourage. One commenter pointed specifically to the preamble's statement that a firm with ''significant variation in compensation across different investment products would need to implement more stringent supervisory oversight,'' and noted that, in practice, when firms' bottom lines also benefit from recommending the higher compensating investment products, they will likely turn a blind eye when their financial professionals improperly push those products.

On the other hand, a few commenters urged the Department to increase alignment of the policies and procedures with securities laws, including Regulation Best Interest. A commenter requested the Department to clarify that, consistent with their understanding of Regulation Best Interest, firm-level conflicts must be disclosed or eliminated and any conflicts for the Investment Professional must be disclosed and mitigated. Other commenters asked that the wording of the policies and procedures be aligned to a greater degree with Regulation Best Interest and that the Department make clear that the satisfaction of other existing regulatory standards will satisfy the relevant conditions of the exemption for investment advice providers in order to eliminate confusion. Several commenters also asked the Department to acknowledge that ''prudently'' developed policies and procedures are the same as ''reasonably'' developed policies and procedures, or to simply revise the exemption requirement to use the term ''reasonably designed'' in accord with the text of Regulation Best Interest. These commenters opined that the difference between ''prudence'' and ''reasonableness'' was either unclear or nonexistent. One commenter urged the Department to adopt a definition of commission-based incentives limited to ones where incentives are tied to the sale of specific financial or insurance products within a limited period of time.

After consideration of all comments, the Department has adopted Section II(c)(1) as proposed. As discussed above, the Department believes that the best interest standard in the exemption is consistent with Title I's fiduciary standard and that it is sufficiently protective of Retirement Investors' interests. As the Department intends to retain interpretive authority with respect to satisfaction of the standards, it does not agree with commenters that it is necessary to defer action until further evaluation of the impact of Regulation Best Interest.

However, the Department has revised Section II(c)(2) to provide that Financial Institutions' policies and procedures must mitigate conflicts of interest ''to the extent that a reasonable person reviewing the policies and procedures and incentive practices as a whole would conclude that they do not create an incentive for a Financial Institution or Investment Professional to place their interests ahead of the interest of the Retirement Investor.'' The Department believes this revised phrasing provides a standard that more clearly communicates the intent that incentives must be mitigated, and provides a standard of mitigation based on the view of a ''reasonable person.'' The preamble to the proposed exemption communicated this type of ''reasonable person'' standard in discussing the meaning of the proposal's standard to avoid misalignment of interests.[116]

The standard retains the requirement that the policies and procedures and incentive practices must be viewed as a whole, so that Financial Institutions have flexibility in adopting practices that both mitigate compensation incentives and use supervisory oversight to prudently ensure that the standard is satisfied. The exemption's policies and procedures requirement is deliberately principles-based, enabling multiple types of Financial Institutions and Investment Professionals to rely upon the exemption in connection with providing investment advice to Retirement Investors. The Department agrees, however, with the commenter that suggested that the Financial Institution's written policies and procedures would necessarily express the criteria for determining that the exemption's standards will be met and describe the Financial Institution's conflict mitigation methods.[117]

Although some commenters requested the elimination of certain practices or asserted that the exemption should include more specific provisions regarding conflict mitigation, the Department has maintained the approach from the proposal. The Department disagrees with the commenters who stated that the vast majority of conflicted practices can continue unabated under the exemption. This claim is expressly contrary to the proposal's requirement that the policies and procedures be prudently designed to avoid misalignment of the interests of the Financial Institution and Investment Professional with the Retirement Investors they serve, which was clarified in this final exemption as discussed above.

As stated in the preamble to the proposal, Financial Institutions that continue to offer transaction-based compensation would focus on both financial incentives to Investment Professionals and supervisory oversight of investment advice to meet the standards. The exemption lacks additional specific mandates regarding conflict mitigation in order to accommodate the wide variety of business models used throughout the financial services industry. The type and degree of conflicts is susceptible to change over time. The Department believes that prescriptive conflict mitigation provisions would decrease the utility of the exemption, now and in the future.

Although a commenter criticized the suggestion that supervisory oversight can be protective, the Department believes that it is an important component of a Financial Institution's policies and procedures. Given that the exemption permits Investment Professionals to be compensated on a transactional basis, it is not possible to fully mitigate compensation incentives and accordingly Financial Institutions will always be required to oversee recommendations. In this regard, the Department declines to adopt the position suggested by a commenter that, for purposes of the exemption, commission-based incentives are limited to ones where incentives are tied to the sale of specific financial or insurance products within a limited period of time. Among other things, this approach would be inconsistent with the broad definition of a conflict of interest in the exemption, as an interest that might incline a Financial Institution or Investment Professional—consciously or unconsciously—to make a recommendation that is not in the Best Interest of the Retirement Investor.

As described above, one commenter identified a number of sales practices the commenter believed would still be permitted under the exemption, and stated that the exemption should more clearly limit incentive practices that a reasonable person would view as creating incentives to recommend investments that are not in Retirement Investors' best interest. The Department notes that the preamble to the proposal described the exemption as requiring this level of conflict mitigation, and the final exemption was revised to use that standard so that the meaning would be clearer.[118] Therefore, for example, the final exemption would not permit Financial Institutions to pay Investment Professionals significantly more to recommend one investment product over another, without putting in place stringent oversight mechanisms to ensure that the compensation structure does not incentivize recommendations that do not adhere to the exemption's standards.

The Department notes that regulators in the securities and insurance industry have adopted provisions requiring policies and procedures to eliminate sales contests and similar incentives such as sales quotas, bonuses, and non-cash compensation that are based on sales of certain investments within a limited period of time.[119] The Department intends to apply a principles-based approach to sales contests and similar incentives. To satisfy the exemption's standard of mitigation, Financial Institutions would be required to carefully consider all performance and personnel actions and practices that could encourage violation of the Impartial Conduct Standards.[120]

The Department further notes that the exemption's obligation to mitigate conflicts is not limited to conflicts of Investment Professionals. The conflict mitigation requirement in the policies and procedures obligation extends to the Financial Institution's own interests, including interests in proprietary products and limited menus of investment options that generate third party payments. The Department believes this exemption's standard of mitigation ensures that Financial Institutions will take a broad-based approach to addressing their conflicts of interest, which will provide a strong threshold foundation for the formulation of best interest investment recommendations.

In response to commenters seeking guidance on the differences, if any, between the prudence standard under this part of the exemption and the reasonableness standards under the federal securities laws, the Department states that it does not have interpretive authority over the federal securities laws, and declines to provide interpretations as to how these standards may differ. The prudence requirement indicates a level of care,

[116] 85 FR 40845.

[117] The commenter's other specific suggestions related to documentation of recommendations and to the retrospective review are discussed in the sections of the preamble on those requirements of the exemption.

[118] *See* 85 FR 40845.

[119] Regulation Best Interest Release, 84 FR 33394–97; NAIC Model Regulation, Section 6.C.(2)(h).

[120] None of the conditions of the exemption are intended to categorically bar the provision of employee benefits to insurance company statutory employees, despite the practice of basing eligibility for such benefits on sales of proprietary products of the insurance company. *See* Code section 3121.

skill, and diligence that a person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.

The Department offers the following examples of business models and practices that may present conflicts of interest that a Financial Institution would address through its policies and procedures:

Example 1: A Financial Institution anticipates that prohibited conflicts of interest related to compensation in its business model will only arise in connection with advice to roll over Plan or IRA assets, because after the rollover, the Financial Institution and Investment Professional will provide ongoing investment advice and be compensated on a level-fee basis. The Financial Institutions decides to seek prohibited transaction relief in connection with rollover conflicts by relying upon the exemption.[121] The Financial Institution's policies and procedures would focus on rollover recommendations.[122] Additionally, the policies and procedures should appropriately address how to document rollover recommendations, consistent with the requirement in Section II(c)(3) to document the reason for a rollover recommendation and why such recommendation is in the best interest of the Retirement Investor.

Example 2: A Financial Institution intends to receive transaction-based compensation, and generate compensation for the Financial Institution and its Investment Professionals based on transactions that occur in a Retirement Investor's accounts, such as through commissions. The Financial Institution's policies and procedures would address the incentives created by these compensation arrangements.

Example 3: Insurance company Financial Institutions can comply with the new exemption by supervising independent insurance agents, or by creating oversight and compliance systems through contracts with insurance intermediaries. The Financial Institution and/or intermediary would address incentives created with respect to independent agents' recommendations of the Financial Institution's insurance or annuity products.

In connection with these examples, following is a discussion of various possible components of effective policies and procedures. While the Department is not adjusting the policies and procedures to provide a safe harbor for compliance with securities or other law, many of the conflict mitigation approaches identified below were identified by the SEC in Regulation Best Interest.[123]

Commission-Based Compensation Arrangements

Financial Institutions that compensate Investment Professionals through transaction-based payments and incentives would be required to minimize the impact of these compensation incentives on fiduciary investment advice to Retirement Investors, so that the Financial Institution would be able to meet the exemption's standard of conflict mitigation set forth in Section II(c)(2). As noted above, this standard would require mitigation of conflicts to the extent that a reasonable person reviewing the policies and procedures and incentive practices as a whole would conclude that they do not create an incentive for a Financial Institution or Investment Professional to place their interests ahead of the interest of the Retirement Investor.

For commission-based compensation arrangements, Financial Institutions would be encouraged to focus on financial incentives to Investment Professionals and supervisory oversight of investment advice. These two aspects of the Financial Institution's policies and procedures would complement each other, and Financial Institutions could retain the flexibility, based on the characteristics of their businesses, to adjust the stringency of each component provided that the exemption's overall standards would be satisfied. Financial Institutions that significantly mitigate commission-based compensation incentives would have less need to rigorously oversee individual Investment Professionals and individual recommendations. Conversely, Financial Institutions that have significant variation in compensation across different investment products would need to implement the policies and procedures by using more stringent supervisory oversight.[124]

In developing compliance structures, the Department expects that Financial Institutions will also look to conflict mitigation strategies identified by the Financial Institutions' other regulators. For illustrative purposes only, the following are non-exhaustive examples of practices identified as options by the SEC that could be implemented by Financial Institutions in compensating Investment Professionals: (1) Avoiding compensation thresholds that disproportionately increase compensation through incremental increases in sales; (2) minimizing compensation incentives for employees to favor one type of account over another; or to favor one type of product over another, proprietary or preferred provider products, or comparable products sold on a principal basis, for example, by establishing differential compensation based on neutral factors; (3) eliminating compensation incentives within comparable product lines by, for example, capping the credit that an associated person may receive across mutual funds or other comparable products across providers; (4) implementing supervisory procedures to monitor recommendations that are: Near compensation thresholds; near thresholds for firm recognition; involve higher compensating products, proprietary products, or transactions in a principal capacity; or, involve the rollover or transfer of assets from one type of account to another (such as recommendations to roll over or transfer assets in a Title I Plan account to an IRA) or from one product class to another; (5) adjusting compensation for associated persons who fail to

[121] In general, after the rollover, the ongoing receipt of compensation based on a fixed percentage of the value of assets under management may not require a prohibited transaction exemption. However, the Department cautions that certain practices such as ''reverse churning'' (*i.e.* recommending a fee-based account to an investor with low trading activity and no need for ongoing advice or monitoring) or recommending holding an asset solely to generate more fees may be prohibited transactions. This exemption would not be available for such practices because they would not satisfy the Impartial Conduct Standards.

[122] As explained earlier, it is the Department's view that a recommendation to roll assets out of a Plan is advice with respect to moneys or other property of the Plan. Advice to take a distribution of assets from a Title I Plan is advice to sell, withdraw, or transfer investment assets currently held in the Plan. A distribution recommendation commonly involves either advice to change specific investments in the Plan or to change fees and services directly affecting the return on those investments.

[123] As one commenter noted, the scope of Regulation Best Interest and the Department's exemption do not overlap precisely. Therefore, the commenter asked the Department to acknowledge that Financial Institutions developing policies and procedures will need to address interactions with Retirement Investors that are not addressed in Regulation Best Interest. This is another reason that the Department intends to maintain interpretive authority with respect to the exemption.

[124] This is not to suggest that a Financial Institution that analyzes the conflicts associated with commission-based compensation incentives does not need to engage in a separate mitigation analysis with respect to the conflicts specifically associated with rollover recommendations as opposed to non-rollover recommendations. Nor does it suggest that every financial incentive can be effectively mitigated through oversight, no matter how severe the conflict of interest. As reflected in the SEC's ban on time-limited sales contests, some incentive structures are too prone to abuse to permit as part of firm policies and procedures.

adequately manage conflicts of interest; and (6) limiting the types of retail customer to whom a product, transaction or strategy may be recommended.[125]

Financial Institutions also must review and mitigate incentives at the Financial Institution level. Firms should establish or enhance the review process for investment products that may be recommended to Retirement Investors. This process should include procedures for identifying and mitigating conflicts of interest associated with the product or declining to recommend a product if the Financial Institution cannot effectively mitigate associated conflicts of interest.[126]

Insurance Companies

To comply with the exemption, insurance company Financial Institutions could adopt and implement supervisory and review mechanisms and avoid improper incentives that preferentially push the products, riders, and annuity features that might incentivize Investment Professionals to provide investment advice to Retirement Investors that does not meet the Impartial Conduct Standards. Insurance companies could implement procedures to review annuity sales to Retirement Investors under fiduciary investment advice arrangements to ensure that they were made in satisfaction of the Impartial Conduct Standards, much as they may already be required to review annuity sales to ensure compliance with state-law suitability requirements.[127]

In this regard, as discussed above, insurance company Financial Institutions would be responsible only for an Investment Professional's recommendation and sale of products offered to Retirement Investors by the insurance company in conjunction with fiduciary investment advice, and not to product sales of unrelated and unaffiliated insurers.[128]

Insurance companies could also create a system of oversight and compliance by contracting with an insurance intermediary or other entity to implement policies and procedures designed to ensure that all of the agents associated with the intermediary adhere to the conditions of this exemption. The intermediary could, for example, take action directly aimed at mitigating or eliminating compensation incentives. The intermediary could also review documentation prepared by insurance agents to comply with the exemption, as may be required by the insurance company, or use third-party industry comparisons available in the marketplace to help independent insurance agents recommend products that are prudent for the Retirement Investors they advise.

Periodic Review of Policies and Procedures

The Department notes that Financial Institutions complying with the exemption would need to review their policies and procedures periodically and reasonably revise them as necessary to ensure that the policies and procedures continue to satisfy the conditions of this exemption. In particular, the exemption requires ongoing vigilance as to the impact of conflicts of interest on the provision of fiduciary investment advice to Retirement Investors. As a matter of prudence, Financial Institutions should regularly review their policies and procedures to ensure that they are achieving their intended goal of ensuring compliance with the exemption and the provision of advice that satisfies the Impartial Conduct Standards. For example, to the extent new products, lines of business, or compensation structures are introduced, Financial Institutions should consider whether their policies and procedures continue to be appropriate and effective. To the extent that the policies are failing to achieve their goal of ensuring compliance, the deficiencies should be corrected.

Proprietary Products and Limited Menus of Investment Products

The best interest standard can be satisfied by Financial Institutions and Investment Professionals that provide investment advice on proprietary products or on a limited menu of investment options, including limitations to proprietary products[129] and products that generate third party payments.[130] Product limitations can serve a beneficial purpose by allowing Financial Institutions and Investment Professionals to develop increased familiarity with the products they recommend. At the same time, limited menus, particularly if they focus on proprietary products and products that generate third party payments, can result in heightened conflicts of interest. Financial Institutions and their affiliates and related entities may receive more compensation than they would for recommending other products, and, as a result, Investment Professionals and Financial Institutions may have an incentive to place their interests ahead of the interest of the Retirement Investor.

As the Department explained in the proposal, Financial Institutions and Investment Professionals providing investment advice on proprietary products or on a limited menu can satisfy the conditions of the exemption. They can do so by providing complete and accurate disclosure of their material conflicts of interest in connection with such products or limitations and adopting policies and procedures that mitigate conflicts to the extent that a reasonable person reviewing the policies and procedures and incentive practices as a whole would conclude that they do not create an incentive for a Financial Institution or Investment Professional to place their interests

[125] Regulation Best Interest Release, 84 FR 33392.

[126] For additional discussion of Financial Institution conflicts, see the preamble discussion below, ''Proprietary Products and Limited Menus of Investment Products.''

[127] *Cf.* NAIC Model Regulation, Section 6.C.(2)(d) (''The insurer shall establish and maintain procedures for the review of each recommendation prior to issuance of an annuity that are designed to ensure that there is a reasonable basis to determine that the recommended annuity would effectively address the particular consumer's financial situation, insurance needs and financial objectives. Such review procedures may apply a screening system for the purpose of identifying selected transactions for additional review and may be accomplished electronically or through other means including, but not limited to, physical review. Such an electronic or other system may be designed to require additional review only of those transactions identified for additional review by the selection criteria''); and (e) (''The insurer shall establish and maintain reasonable procedures to detect recommendations that are not in compliance with subsections A, B, D and E. This may include, but is not limited to, confirmation of the consumer's consumer profile information, systematic customer surveys, producer and consumer interviews, confirmation letters, producer statements or attestations and programs of internal monitoring. Nothing in this subparagraph prevents an insurer from complying with this subparagraph by applying sampling procedures, or by confirming the consumer profile information or other required information under this section after issuance or delivery of the annuity''). The prior version of the model regulation, which was adopted in some form by a number of states, also included similar provisions requiring systems to supervise recommendations. *See* Annuity Suitability (A) Working Group Exposure Draft, Adopted by the Committee Dec. 30, 2019, *available at www.naic.org/documents/committees_mo275.pdf.* (comparing 2020 version with prior version).

[128] *Cf. id.,* Section 6.C.(4) (''An insurer is not required to include in its system of supervision: (a) A producer's recommendations to consumers of products other than the annuities offered by the insurer'').

[129] Proprietary products include products that are managed, issued, or sponsored by the Financial Institution or any of its affiliates.

[130] Third party payments include sales charges when not paid directly by the Plan or IRA; gross dealer concessions; revenue sharing payments; 12b–1 fees; distribution, solicitation or referral fees; volume-based fees; fees for seminars and educational programs; and any other compensation, consideration or financial benefit provided to the Financial Institution or an affiliate or related entity by a third party as a result of a transaction involving a Plan or an IRA.

ahead of the interest of the Retirement Investor.

The Department envisions that Financial Institutions complying with the Impartial Conduct Standards and policies and procedures would carefully consider their product offerings and form a reasonable conclusion about whether the menu of investment options would permit Investment Professionals to provide fiduciary investment advice to Retirement Investors in accordance with the Impartial Conduct Standards. The exemption would be available if the Financial Institution prudently concludes that its offering of proprietary products, or its limitations on investment product offerings, in conjunction with the policies and procedures, would not create an incentive for Financial Institutions or Investment Professionals to place their interests ahead of the interest of the Retirement Investor.

Several commenters expressed general support for the Department's approach to proprietary products and limited menus. One commenter noted that practical considerations call for limiting the investment menu when thousands of mutual funds and securities exist on a Financial Institution's platform. Another commenter agreed that Financial Institutions would form a reasonable conclusion about whether the limited menu supports recommendations that satisfy the Impartial Conduct Standards.

Some commenters expressed concern about the exemption's coverage of recommendations involving proprietary products or limited menus because it would allow recommendations of poorly performing, high commission products. One commenter stated the exemption should not extend to such recommendations, as they create the largest potential for conflicts that cannot be fully eliminated, and suggested that the Department require that such recommendations be handled through the individual prohibited transaction exemption process. Another commenter indicated that the proposal did not address some ''non-financial structures'' used in connection with rollovers, such as requirements imposed by service providers for investors to fill out lengthy forms in order to roll plan assets over to third-party entities, while simultaneously providing simple and easy mechanisms for rollovers from the Plan into proprietary products maintained by the provider. Another commenter thought the exemption should specifically require Financial Institutions to document their conclusions as to why their offering of proprietary products or limited menus, in conjunction with the policies and procedures, would not cause a misalignment of their interests with Retirement Investors.

In response to comments, the Department has not restricted the exemption to exclude recommendations of proprietary products and products from a limited menu, or required them to be addressed solely through individual exemptions. The Department believes that the conditions of the class exemption, including the best interest standard, appropriately address concerns about proprietary products. The Department has not added a specific requirement that Financial Institutions document their conclusions as to why their offering of proprietary products or limited menus, in conjunction with the policies and procedures, would not create an incentive for the Financial Institutions or Investment Professionals to place their interests ahead of the interest of the Retirement Investor. However, the Department notes that this is a best practice and may serve the interests of Financial Institutions since they are required under Section IV to keep records demonstrating compliance with the exemption. Even though there is no specific documentation requirement, the Department expects a Financial Institution would be able to explain clearly the process it used in making this determination. The Department also cautions Financial Institutions and Investment Professionals about practices that selectively promote Retirement Investors' purchase of products that are not in their best interest in the manner suggested by the commenter above (*e.g.,* by making it much more burdensome for the Retirement Investor to rollover assets to one investment rather than another). Even if the practices do not directly involve the provision of fiduciary advice, they potentially undermine the required policies and procedures to mitigate conflicts of interest and may facilitate violations of fiduciary standards. Such practices should also be a matter of concern for the fiduciaries responsible for hiring the Financial Institutions and Investment Professionals to provide plan services.

A few commenters sought clarification of the Department's preamble statement that a Financial Institution's policies and procedures should extend to circumstances in which the Financial Institution or Investment Professional determines that its proprietary products or limited menu do not offer Retirement Investors an investment option in their best interest when compared with other investment alternatives available in the marketplace. They sought confirmation that the Department did not intend to require Financial Institutions to compare their product offerings to all available investment alternatives, a confirmation they stated is consistent with guidance provided by the SEC on Regulation Best Interest. These commenters asserted that imposing such a requirement would serve to limit investor access to prudent investment advice, and could potentially require Investment Professionals that are insurance-only agents to compare annuities against securities, which they are not be licensed to sell, and which would potentially cause compliance issues under state securities laws.

The Department confirms that the exemption does not require Financial Institutions to compare proprietary products with all other investment alternatives available in the marketplace. There is no obligation to perform an evaluation of every possible alternative, including those the Financial Institution or Investment Professional are not licensed to recommend, and the exemption does not contemplate that there is a single investment that is in a Retirement Investor's best interest. The exemption merely provides that Financial Institutions and Investment Professionals cannot use a limited menu to justify making a recommendation that does not meet the Impartial Conduct Standards.

Retrospective Review—Section II(d)

Section II(d) of the exemption requires Financial Institutions to conduct a retrospective review, at least annually, that is reasonably designed to assist the Financial Institution in detecting and preventing violations of, and achieving compliance with, the Impartial Conduct Standards and the policies and procedures governing compliance with the exemption. While mitigation of Financial Institutions' and Investment Professionals' conflicts of interest is critical, Financial Institutions must also monitor Investment Professionals' conduct to detect advice that does not adhere to the Impartial Conduct Standards or the Financial Institution's policies and procedures.

The methodology and results of the retrospective review must be reduced to a written report that is provided to one of the Financial Institution's Senior Executive Officers.

That officer is required to certify annually that:

(A) The officer has reviewed the report of the retrospective review;

(B) The Financial Institution has in place policies and procedures prudently

designed to achieve compliance with the conditions of this exemption; and

(C) The Financial Institution has in place a prudent process to modify such policies and procedures as business, regulatory and legislative changes and events dictate, and to test the effectiveness of such policies and procedures on a periodic basis, the timing and extent of which is reasonably designed to ensure continuing compliance with the conditions of this exemption.

This retrospective review, report and certification must be completed no later than six months following the end of the period covered by the review. The Financial Institution is required to retain the report, certification, and supporting data for a period of six years. If the Department requests the written report, certification, and supporting data within those six years, the Financial Institution would make the requested documents available within 10 business days of the request, to the extent permitted by law including 12 U.S.C. 484. The Department believes that the requirement to provide the written report within 10 business days will ensure that Financial Institutions diligently prepare their reports each year, resulting in meaningful protection of Retirement Investors.

Financial Institutions can use the results of the review to find more effective ways to ensure that Investment Professionals are providing investment advice in accordance with the Impartial Conduct Standards and to correct any deficiencies in existing policies and procedures. Requiring a Senior Executive Officer to certify review of the report is a means of creating accountability for the review. This would serve the purpose of ensuring that more than one person determines whether the Financial Institution is complying with the conditions of the exemption and avoiding non-exempt prohibited transactions. If the officer does not have the experience or expertise to determine whether to make the certification, he or she would be expected to consult with a knowledgeable compliance professional to be able to do so.

The retrospective review is based on FINRA rules governing how broker-dealers supervise associated persons,[131] adapted to focus on the conditions of the exemption. The Department is aware that other Financial Institutions are subject to regulatory requirements to review their policies and procedures;[132] however, for the reasons stated above, the Department believes that the specific certification requirement in the exemption will serve to protect Retirement Investors in the context of conflicted investment advice transactions.

Several commenters expressed support for a retrospective review but indicated the provision needs strengthening. One commenter stated that the requirement would be strengthened if the best interest standard is strengthened.[133] One commenter suggested several methods of strengthening the exemption's retrospective review requirements, including requiring an independent audit, requiring appointment of a compliance officer and identification of the compliance officer and his or her qualifications in the report, and requiring the report of the retrospective review to be provided to Retirement Investors. One commenter provided an example of how the report could look and criticized the Department's statement that sampling would be permitted, asserting that the concentration of noncompliance is more likely to occur in large transactions. A few commenters stated the exemption should specify consequences of violations of the policies and procedures when such violations do not rise to the level of egregious patterns of misconduct.

A number of commenters opposed the requirement, stating it is burdensome, costly and unnecessary. As support for this assertion, some commenters stated that other exemptions do not include this condition and it also is not a requirement of Regulation Best Interest. Some commenters urged the Department to avoid what they viewed as a separate ''prescriptive'' requirement in terms of ensuring that Financial Institutions satisfy the conditions of the exemption, in favor of a review incorporated into a firm's policies and procedures. Some asserted that the other exemption conditions will provide a sufficient compliance structure and the consequences of failing to comply with the exemption will provide sufficient incentive for Financial Institutions to oversee their own compliance. One commenter said wording of the condition was too vague and could expose Financial Institutions to liability for not meeting the standard. A few commenters suggested eliminating subsections (B) and (C) of the certification requirement, and, instead, merely referencing Section II(c)'s policies and procedures requirement.[134] Another commenter asked the Department to provide a safe harbor based on compliance with FINRA's similar review requirement.

As further described below, the Department has adopted the retrospective review requirement largely as proposed based on the view that compliance review is a critical component of a Financial Institution's policies and procedures. Without this specific requirement, some Financial Institutions may take the position that adoption of policies and procedures is sufficient, without paying attention to whether the policies and procedures are prudently designed and whether Investment Professionals are complying with the policies and procedures and the Impartial Conduct Standards. The Department does not agree with those commenters who claimed such a review was unnecessary or overly burdensome.

While some commenters expressed concern that the retrospective review needed strengthening, the Department notes the review must be signed and certified. The Department believes that requiring the results to be reduced to a written document certified by a Senior Executive Officer increases the likelihood that isolated compliance failures will be corrected before they become systemic. Although some commenters expressed the general view that the exemption relies upon self-policing, the requirement that Financial Institutions make their report available to the Department within 10 business days upon request ensures that the Department retains an appropriate level of oversight over exemption compliance.

To maintain this principles-based approach, the Department did not mandate specific detailed components of the retrospective review. Financial Institutions will be free to design the review process in the context of their own business models and the particular conflicts of interest they face. Although the exemption does not specify that a compliance officer must be appointed, the Department envisions that Financial Institutions will, as a practical matter,

[131] *See* FINRA rules 3110, 3120, and 3130.

[132] *See, e.g.,* Rule 206(4)–7(b) under the Investment Advisers Act of 1940.

[133] The best interest standard and the comments received on it are discussed above in ''Impartial Conduct Standards.''

[134] Subsection (B) requires certification that ''[t]he Financial Institution has in place policies and procedures prudently designed to achieve compliance with the conditions of this exemption;'' and subsection (C) requires certification that ''[t]he Financial Institution has in place a prudent process to modify such policies and procedures as business, regulatory and legislative changes and events dictate, and to test the effectiveness of such policies and procedures on a periodic basis, the timing and extent of which is reasonably designed to ensure continuing compliance with the conditions of this exemption.''

assign a compliance role to an appropriate officer.

The Department did not narrow subsections (B) and (C) of the certification requirements merely to reference the requirements of Section II(c) as suggested by a few commenters. The broader certification properly focuses the Financial Institution's assessment of the ongoing effectiveness of the policies and procedures, the periodic testing of those policies and procedures, and the need to make modifications to the extent they are not working. A strong process to review the effectiveness of the Financial Institution's policies and procedures and to make course corrections as necessary is critical to the protection of Retirement Investors affected by the exemption.

In the proposal, the Department indicated that it envisioned that the review would involve testing a sample of transactions to determine compliance. In response to a comment that indicated sampling may not be appropriate since non-compliance may occur more frequently with respect to large transactions, the Department clarifies that an appropriate retrospective review would be aimed at detecting non-compliance across a wide range of transactions types and sizes, large and small, identifying deficiencies in the policies and procedures, and rectifying those deficiencies. For large Financial Institutions that conduct large numbers of transactions each year, sampling may not be the sole means of testing compliance, but it is an important and necessary component of any prudent review process, and should be performed in a manner designed to identify potential violations, problems, and deficiencies that need to be addressed.

The Department considered the alternative of requiring a Financial Institution to engage an independent party to provide an external audit, as suggested by a commenter. Because of the potential costs of such audits, and the exemption's reliance on the retrospective review process, the Department elected not to impose this additional requirement. The Department is not convinced that an independent, external audit would yield sufficient benefits in addition to the results of the retrospective review to justify the increased cost, especially in the case of smaller Financial Institutions without any past practice of actions that may render it ineligible to rely on this class exemption. The Department also has not included a requirement that the report of the retrospective review be provided to all Retirement Investors. As discussed below in the section on recordkeeping, the Department believes that Financial Institutions' internal compliance documents should be available to regulators but not Retirement Investors, so as to promote full identification and remediation of compliance issues without undue concern about the widespread disclosure of the issues.

The Department does not believe the requirement is too vague for Financial Institutions to know how to comply. The requirement that the review be ''reasonably designed'' is consistent with reasonableness as a term commonly used in a variety of legal settings, and especially under the Act. Further, as noted above, the Department provided this approach to allow Financial Institutions flexibility in designing their compliance reviews.

Although a retrospective review is not a requirement of Regulation Best Interest, as one commenter pointed out, the Department notes that an analogous requirement is already applicable to broker-dealers under FINRA rules. The Department declines to provide a safe harbor based on compliance with the FINRA rule because that rule is aimed at reviewing compliance with FINRA rules, not the Financial Institution's separate compliance with the terms of this exemption.

Some commenters said that a retrospective review was an unusual requirement for a class exemption, and that the Department had not pointed to any noncompliance to warrant such a condition. The Department, however, has routinely made independent audits a condition in individual exemptions. It is important that entities comply with the terms of the exemption and that the Department can readily verify such compliance. Here, the Department continues to believe that a retrospective review, which is less costly than an audit, strikes the appropriate balance for this class exemption. Additionally, the Department notes that it frequently imposes a recordkeeping requirement documenting compliance as a condition of exemption. In drafting a principles-based exemption that works with different business models, the Department has determined that this retrospective review is a crucial way to determine compliance with the exemption, and to ensure covered entities review, enforce, and update their policies and procedures as needed.

In response to commenters who asked the Department to specify the consequences of a violation discovered in the retrospective review, and other commenters who asked for the ability to correct compliance issues uncovered during the review, the Department has included a self-correction feature in the final exemption, as described below. If self-correction is not available or a Financial Institution decides not to self-correct, then the Financial Institution remains liable for a prohibited transaction associated with the transaction for which there was a failure.

One commenter stated that the Department should not require Financial Institutions to provide the report within 10 business days of request by the Department because Financial Institutions may have legitimate difficulties meeting this requirement. However, this aspect of the exemption provides an important mechanism for the Department to ensure that Financial Institutions are taking their roles under the exemption seriously. The Department does not intend for Financial Institutions to prepare a retrospective review only after it has been requested by the Department. The exemption provides a separate deadline for the completion of each annual review, so the obligation to provide the accompanying report within 10 business days of request will only apply to completed reports. For this reason, the Department has not extended the 10 business-day period.[135]

Another commenter requested a transition period for the retrospective review through 2022, for the creation and testing of the report that is required in connection with the retrospective review. The commenter suggested that so long as the Financial Institution is working towards creating and testing the process, it should be able to use the exemption. As there is not a specified form of the report, the Department does not believe an additional transition period is warranted. Because the report is annual and retrospective, preparation of the first report would not need to begin until at least one year after the exemption's effective date, and the report does not need to be completed for an additional six months after that. The Department believes this will give the Financial Institution sufficient time to create and test its reporting methods. Furthermore, Financial Institutions that are subject to the FINRA regulation should already be conducting a similar type of review. The Department believes it would be inconsistent with the principles and protective nature of the

[135] Another commenter stated that the retrospective review should be required only once every three years. The Department has not adopted this suggestion. A review that is conducted as infrequently as once every three years would be unlikely to identify compliance concerns within a reasonable amount of time so as to prevent more systemic violations.

exemption to further delay implementation of the retrospective review.

One commenter addressed the interaction of banking law with the requirement in Section II(d)(5) to provide the report of the retrospective review, the certification and supporting data available to the Department. The commenter stated that a provision of the National Bank Act, 12 U.S.C. 484, prohibits any person from exercising visitorial powers over national banks and federal savings associations except as authorized by federal law. The commenter requested that Section II(d)(5) be revised with the addition, at the end of the sentence, of, ''except as prohibited under 12 U.S.C. 484.'' Without conceding that the Department's authority is limited by this provision, the Department has made the requested edit.

One commenter indicated that the Department does not have jurisdiction to enforce the prohibited transaction rules for transactions involving IRAs, so the Department's interest in and access to the report of the retrospective review should be limited to Title I Plan transactions. As the agency with authority to grant prohibited transaction exemptions under the Code, the Department retains the ability to determine whether the conditions of an exemption are being met by reviewing records for the purpose of determining parties' compliance for IRAs.[136]

Senior Executive Officer Certification

While the proposal stated that the Financial Institution's chief executive officer (or equivalent) must certify the retrospective review, the final exemption provides, instead, that the retrospective review may be certified by any of the Financial Institution's Senior Executive Officers. The exemption defines a ''Senior Executive Officer'' as any of the following: The chief compliance officer, the chief executive officer, president, chief financial officer, or one of the three most senior officers of the Financial Institution. In making this change, the Department accepts the views of a number of commenters that stated that the CEO should not be the only person who can provide a certification regarding the retrospective review. The Department does not believe that permitting the Financial Institution to choose whichever Senior Executive Officer it believes is most appropriate to perform the certification alters the protective nature of this condition. As commenters pointed out, other officers than the CEO, such as the chief compliance officer, may have more information, specific training, and be better able to understand the retrospective review. Further, no matter which Senior Executive Officer is selected to provide the certification, the definition of a Senior Executive Officer ensures that an officer of sufficient authority within the Financial Institution will be held accountable for oversight of exemption compliance. In this way, the Department believes that requiring certification will help reinforce a culture of compliance within the Financial Institution.

One commenter raised concerns regarding the applicability of the CEO certification requirement in the banking regulatory environment, stating that this type of certification is unusual for bank CEOs. Another commenter worried more broadly that a CEO certification might interfere with other financial certifications required of the CEO or unduly burden corporate governance. The Department believes that allowing the certification to be performed by any Senior Executive Officer addresses these concerns while still preserving the protective nature of the condition.

Some commenters objected to the certification requirement as a whole. They argued that the certification is burdensome and increases liability exposure without necessarily improving compliance. Others asserted certification is not required under Regulation Best Interest or the NAIC Model Regulation. On the other hand, some commenters acknowledged the similar existing requirements under FINRA but argued the requirement would be duplicative or should be harmonized.

The certification provides an important protection of Retirement Investors by creating accountability for the retrospective review and report at an executive level within the Financial Institution. Without a requirement that a Senior Executive Officer be held accountable by certifying the review, there is no assurance that any person in the leadership of a Financial Institution will review or be aware of its contents. The Department is required to find that the exemption is protective of, and in the interests of, Plans and their participants and beneficiaries, and IRA owners. This condition is important to the Department's ability to make these required findings.

One commenter indicated that an exemption with the certification requirement would not be considered ''deregulatory'' as was stated in the proposal. The Department responds that the exemption as a whole is deregulatory because it provides a broader and more flexible means for investment advice fiduciaries to Plans and IRAs to engage in certain transactions that would otherwise be prohibited under Title I and the Code. Financial Institutions remain free to structure their business in a manner that complies with the statutes and their prohibitions, or to request an individual exemption tailored to their specific business.

Finally, one commenter requested that the Department state that signing the certification does not implicate personal liability for the signing officer under the Act. The Department responds that signing the certification would not, in and of itself, impact the officer's personal liability under the Act; any such liability would be based on the officer's status as a fiduciary, the Act's statutory framework, and other relevant facts and circumstances.

Self-Correction—Section II(e)

The Department has added a new Section II(e) to the exemption, under which Financial Institutions will be able to correct certain violations of the exemption. Under the new Section II(e), the Department will not consider a non-exempt prohibited transaction to have occurred due to a violation of the exemption's conditions, provided: (1) Either the violation did not result in investment losses to the Retirement Investor or the Financial Institution made the Retirement Investor whole for any resulting losses; (2) the Financial Institution corrects the violation and notifies the Department via email to *IIAWR@dol.gov* within 30 days of correction; (3) the correction occurs no later than 90 days after the Financial Institution learned of the violation or reasonably should have learned of the violation; and (4) the Financial Institution notifies the persons responsible for conducting the retrospective review during the applicable review cycle, and the violation and correction is specifically set forth in the written report of the retrospective review.

While this section was not a part of the proposal, several commenters raised the issue of instituting a self-correction procedure as it related to the Department's proposal requiring a retrospective review. Commenters requested that the Department provide a means for Financial Institutions, acting in good faith, to avoid loss of the exemption for violations of the conditions. Some commenters focused on minor or technical violations, others on violations in connection with specific conditions, such as allowing a

[136] *See* Reorganization Plan No. 4 of 1978 and discussion *supra.*

correction for failure to provide disclosures. Some pointed to existing methods of correction allowed by the Department and other regulators, including the Department's regulation under ERISA section 408(b)(2).[137] One commenter specified that there should be a correction process in connection with the retrospective review, because failure to include this could put Financial Institutions in a difficult position of having discovered technical violations but not being able to cure them without being subject to an excise tax for the prohibited transaction.

Upon consideration of the comments, the Department determined to provide this self-correction procedure. Although many commenters cited minor or technical violations, the Department does not view violations of any condition of the exemption as necessarily minor or technical. Accordingly, the section allows for correction even if a Retirement Investor has suffered investment losses, provided that the Retirement Investor is made whole. The Department believes that the self-correction provision will provide Financial Institutions with an additional incentive to take the retrospective review process seriously, timely identify and correct violations, and use the process to correct deficiencies in their policies and procedures, so as to avoid potential future penalties and lawsuits.

Eligibility—Section III

Section III of the exemption identifies circumstances under which an Investment Professional or Financial Institution will become ineligible to rely on the exemption for a period of 10 years. The grounds for ineligibility involve certain criminal convictions or certain egregious conduct with respect to compliance with the exemption. Ineligible parties may rely on an otherwise available statutory exemption or administrative class exemption, or the parties can apply for an individual prohibited transaction exemption from the Department. This will allow the Department to give special attention to parties with certain criminal convictions or with a history of egregious conduct regarding compliance with the exemption.

Many commenters expressed concern that the conditions of the proposed exemption were not sufficiently enforceable to provide meaningful protections. Commenters noted that, unlike the Best Interest Contract Exemption granted in connection with the 2016 fiduciary rule, this exemption did not include a contract or other means of making the Impartial Conduct Standards enforceable. Therefore, IRA owners would not have a mechanism to enforce the requirements of the exemption, and the Department lacks direct enforcement authority over Plans not covered by Title I. Even with respect to Retirement Investors in ERISA-covered Plans, some commenters described the structure of the exemption as effectively allowing the financial services industry to self-regulate; they said the exemption would permit the ''fox to guard the henhouse.'' One commenter specifically criticized the proposed exemption's eligibility provision as too weak to prevent or punish violations of the exemption. Other commenters were concerned that the eligibility provision did not provide any incentive for Financial Institutions to comply with the requirements of the exemption.

Other commenters objected to the exemption including any eligibility provision, arguing that the Department's investigative authority and existing consequences for prohibited transactions are sufficient. Some raised concerns that the exemption's eligibility provision has no basis in the statute and may be unconstitutional. Some acknowledged that the Department's QPAM class exemption has a similar provision related to criminal convictions, but one commenter argued this too, is impermissible.[138] Some commenters cited the Fifth Circuit's *Chamber* opinion as support for the position that the eligibility provision impermissibly expands the Department's enforcement authority over IRAs. One commenter indicated that the eligibility provision would only serve to increase compliance complexity, costs, and burdens, along with compliance uncertainty, under the exemption.

The Department has considered comments on the eligibility provision in Section III and has adopted it generally as proposed, but with non-substantive revisions.[139] The Department disagrees with commenters that expressed the view that the exemption is essentially self-regulatory and that the Department should not proceed with the exemption because it lacks an express enforcement mechanism for IRA owners. The Department believes that the eligibility provision will encourage Financial Institutions and Investment Professionals to maintain an appropriate focus on compliance with legal requirements and with the exemption, and, therefore, it has not eliminated them as overly burdensome, as suggested by a commenter. The Department intends to use its investigative, enforcement, and referral authority to enforce compliance with the exemption, and it will impose ineligibility on Financial Institutions or Investment Professionals that demonstrate the type of compliance issues described in the exemption. The Department notes that, in developing the exemption, it was mindful of the Fifth Circuit's *Chamber* opinion holding that the Department did not have authority to include certain contract requirements in the new exemptions enforceable by IRA owners granted as part of the 2016 fiduciary rulemaking. The Department's approach was designed to avoid any potential for disruption in the market for investment advice that may occur related to a contract requirement.

The Department disagrees that this eligibility provision is problematic simply because only one other class exemption includes this condition. It is the responsibility of the Department to craft exemptions to ensure they are protective of and in the interests of plans and plan participants. The conditions in the Department's exemptions are designed to address the conflicts of interest raised by the transactions covered by the exemption. The Department has determined that limiting eligibility in this manner serves as an important safeguard in connection with this very broad grant of relief from the self-dealing prohibitions of ERISA and the Code in this exemption.

The specific provision governing eligibility and the comments received on the provision are discussed in the next sections.

Criminal Convictions

An Investment Professional or Financial Institution will become ineligible upon the conviction of any crime described in ERISA section 411 arising out of provision of advice to Retirement Investors, except as described below. Crimes described in ERISA section 411 are likely to directly contravene the Investment Professional's or Financial Institution's ability to maintain a high standard of integrity and will cast doubt on their ability to act in accordance with the Impartial Conduct Standards. The Department intends that the phrase

[137] 29 CFR 2550.408b–2(c)(1)(vii).

[138] *See* PTE 84–14, Class Exemption for Plan Asset Transactions Determined by Independent Qualified Professional Asset Managers, 49 FR 9494 (Mar. 13, 1984) as corrected at 50 FR 41430 (Oct. 10, 1985), as amended at 67 FR 9483 (Mar. 1, 2002), 70 FR 49305 (Aug. 23, 2005), and 75 FR 38837 (July 6, 2010).

[139] As described in more detail below, all references to the ''Office of Exemption Determinations'' have been replaced with references to the ''Department.''

''arising out of the provision of advice to Retirement Investors'' be interpreted broadly to include, for example, a Financial Institution or Investment Professional embezzling money from the account of a Retirement Investor to whom they provide or provided investment advice.

An Investment Professional will automatically become ineligible after a criminal conviction in ERISA section 411 arising out of provision of advice to Retirement Investors. However, a Financial Institutions with such a criminal conviction may submit a petition to the Department and seek a determination that continued reliance on the exemption would not be contrary to the purposes of the exemption. Petitions must be submitted within 10 business days of the conviction to the Department by email at *IIAWR@dol.gov.*

Following submission of the petition, the Financial Institution has the opportunity to be heard, in person or in writing or both. Because of the 10-business day timeframe for submitting a petition, the Department does not expect the Financial Institution to set forth its entire position or argument in its initial petition. The opportunity to be heard in person will allow the Financial Institution to address the facts and circumstances more fully. The opportunity to be heard will be limited to one in-person conference unless the Department determines in its sole discretion to allow additional conferences.

The Department's determination as to whether to grant a Financial Institution's petition to continue relying on the exemption following a criminal conviction will be based solely on its discretion. In determining whether to grant the petition, the Department will consider the gravity of the offense; the relationship between the conduct underlying the conviction and the Financial Institution's system and practices in its retirement investment business as a whole; the degree to which the underlying conduct concerned individual misconduct, corporate managers, and/or policy; how recently the underlying conduct occurred and any related lawsuit; remedial measures taken by the Financial Institution upon learning of the underlying conduct; and such other factors as the Department determines in its discretion are reasonable in light of the nature and purposes of the exemption. The Department will consider whether any extenuating circumstances indicate that the Financial Institution should be able to continue to rely on the exemption despite the conviction. In sum, the Department will focus on the Financial Institution's ability to fulfill its obligations under the exemption for the protection of Retirement Investors.

Upon making a determination as to a Financial Institution's petition, the Department will provide a written determination to the Financial Institution that states the basis for the determination. Denial of a Financial Institution's petition will not necessarily indicate that the Department will not entertain a separate individual exemption request submitted by the same Financial Institution; however, any individual exemption is likely to be subject to additional protective conditions. The final exemption provides that Financial Institution will have 21 days after denial of the petition before becoming ineligible. This will allow Financial Institutions, and other Financial Institutions in the same Controlled Group, to assess their legal and operational options.

Some commenters on the proposal expressed general agreement that a Financial Institution that is convicted of a crime should be ineligible for the exemption. One commenter believed there are due process concerns if ineligibility occurs at the time of conviction rather than allowing for an appeal. Other commenters stated that the Department can take action under ERISA section 411 to seek to disqualify an entity from acting as a fiduciary so a provision in the exemption is unnecessary.

The Department believes that the criminal basis for ineligibility is appropriately applied in the context of both Title I Plans and IRAs. Despite the availability of action under ERISA section 411, it is appropriate to condition further reliance on the broad relief in the exemption more directly on the lack of such convictions, without the Department having to take further action. The Department does not agree that the application of the crimes listed in ERISA section 411 would not be permitted by the Fifth Circuit's *Chamber* opinion. The 2016 fiduciary rule and related exemptions did not contain a comparable provision, and the Fifth Circuit did not address the issue. As part of its authority to craft exemptions and make findings under ERISA section 408(a) and Code section 4975(c)(2), the Department is permitted to impose reasonable protective conditions, including those related to the conduct of those entrusted with investors' funds. The Department does not view ERISA section 411 or the statutory penalties for exemption noncompliance as creating a negative inference that prohibits a criminal prohibition as part of this exemption, whether in the Title I or Code context, especially when both provisions share the same essential purpose. Further, the only consequence flowing from a violation of the criminal conviction provision of this exemption is the loss of eligibility to use the exemption; no further penalties attach.

The Department also does not believe that the eligibility provision raises due process issues. The exemption specifically entitles the Financial Institution to submit a petition informing the Department of the conviction and seeking a determination that the Financial Institution's continued reliance on the exemption would not be contrary to the purposes of the exemption. This process constitutes notice and an opportunity to be heard, and parties aggrieved by the denial of an exemption can appeal that final agency action under the Administrative Procedure Act. The Department also does not believe it is appropriate to defer ineligibility until the conclusion of an appeal because of the significant delay that an appeal may entail, during which time Retirement Investors' interests may be at risk.

The Department has also clarified, in response to another comment, that ineligible parties under this exemption may alternatively rely on a statutory exemption or an administrative class exemption, if one is available. Ineligible Financial Institutions may also request an individual exemption, subject to additional protective conditions as warranted, and with the same appeal rights.

Conduct With Respect to Compliance With the Exemption

Investment Professionals and Financial Institutions will also become ineligible if they are issued a written ineligibility notice from the Department stating that they (i) engaged in a systematic pattern or practice of violating the conditions of the exemption, (ii) intentionally violated the conditions of the exemption, or (iii) provided materially misleading information to the Department in connection with the Investment Professional's or Financial Institution's conduct under the exemption. These categories of noncompliance militate against the Investment Professional or Financial Institution continuing to rely on the broad prohibited transaction relief in the class exemption. Provided that a Financial Institution has established, maintained and enforced prudent policies and procedures as required by this exemption, a minor number of isolated violations of the conditions of the exemption does not

constitute a systematic pattern or practice.

The exemption sets forth a process governing the issuance of the written ineligibility notice, as follows. Prior to issuing a written ineligibility notice, the Department will issue a written warning to the Investment Professional or Financial Institution, as applicable, identifying specific conduct that could lead to ineligibility, and providing a six-month opportunity to cure. At the end of the six-month period, if the Department determines that the conduct has persisted, it will provide the Investment Professional or Financial Institution with the opportunity to be heard, in person or in writing, before the Department issues the written ineligibility notice. If a written ineligibility notice is issued, it will state the basis for the determination that the Investment Professional or Financial Institution engaged in conduct warranting ineligibility. The final exemption provides that Financial Institution will have 21 days after the date of the written ineligibility notice before becoming ineligible. This will allow Financial Institutions, and other Financial Institutions in the same Controlled Group, to assess their legal and operational options.

A number of commenters expressed opposition to this basis of ineligibility in the proposed exemption. Most of the opposition centered on the proposal's specific references to the Office of Exemption Determinations (OED) in determining ineligibility. Commenters stated that the standards in the exemption are not objective or detailed and asserted this could result in a violation of due process, inconsistency, and unfairness. Further, because of these concerns, one commenter requested an appeals process beyond OED and another requested the use of administrative law judges. Some commenters raised concerns about the QPAM exemption and a few commenters cited a GAO report regarding OED procedures as evidence that OED should not be permitted to oversee this process.[140] Some commenters cited a recent Supreme Court case, *Lucia* v. *SEC,* which they said struck down a similar structure.[141] Other commenters stated that this eligibility provision overstepped the Department's authority.

In response to commenters, the eligibility provision has been non-substantively revised to state that the Department will determine eligibility. This will ensure that the Department, acting under the direction of the Secretary of Labor, maintains full responsibility for eligibility determinations under the exemption. As laid out in the Reorganization Plan No. 4 of 1978, the Secretary of Labor has the authority to issue exemptions, oversee fiduciary conduct and prohibited transactions. Accordingly, the Department disagrees with those commenters who claim the Department lacks the appropriate authority, or is overstepping its role. On the contrary, the Department is acting squarely within the authority granted to it to issue regulations, rulings, opinions, and exemptions under Code section 4975. The Department believes that the eligibility provision does not need additional adjustments given that the exemption specifies an extensive process before a written ineligibility notice will be issued. The Department has clarified, in response to a comment, that ineligible parties under this exemption may alternatively rely on a statutory exemption or an administrative class exemption, if one is available.

The Department also disagrees with those commenters who claim that the ineligibility provision is too vague as to be meaningful. The exemption clearly states that an entity will be provided with a statement of the specific conduct at issue, and will be provided with a six-month period to cure the conduct. Commenters expressed concerned that the Department did not provide a specific number of violations a Financial Entity may commit before such violations become egregious (and, therefore, disqualifying). The Department has crafted a principles-based exemption, and does not consider it appropriate to set forth all of the possible ways in which an entity may engage in egregious conduct. The Department continues to believe that providing entities with specific notice and an opportunity to cure better balances the issues at stake.

The Department also notes that, in connection with its earlier response to a commenter, clarifying that the scope of relief in this exemption extends to foreign affiliates of Financial Institutions,[142] so too does the application of the eligibility provision regarding egregious conduct with respect to compliance with the exemption. As that commenter indicated, including relief for foreign affiliates is important, given the increasingly global nature of retirement services. The Department agrees, and, therefore, impresses upon Financial Institutions the importance of ensuring proper oversight of foreign affiliates with respect to compliance with the conditions of the exemption. If a foreign affiliate performs services in connection with a transaction covered by this exemption, but does so in a manner that is in violation of the conditions of this exemption, this will subject the Financial Institution to possible ineligibility under Section III(a)(2).

Scope of Ineligibility

A Financial Institution's ineligibility would be triggered by its own conviction or receipt of a written ineligibility notice, or by the conviction or receipt of such a notice by another Financial Institution in the same Controlled Group. A Financial Institution is in the same Controlled Group with another Financial Institution if it would be considered in the same ''controlled group of corporations'' or ''under common control'' with the Financial Institution, as those terms are defined in Code section 414(b) and (c), in each case including the accompanying regulations. The Department is including in the eligibility provision other Financial Institutions in the same Controlled Group to ensure that a Financial Institution facing ineligibility for its actions affecting Retirement Investors cannot simply transfer its fiduciary investment advice business to another Financial Institution that is closely related and that also provides fiduciary investment advice to Retirement Investors, thus avoiding ineligibility entirely. The definition of Controlled Group is narrowly tailored to cover only other investment advice fiduciaries that share significant ownership. This definition ensures that a Financial Institution would not become ineligible based on the actions of an entity engaged in unrelated services that happens to share a small amount of common ownership.

The proposed exemption provided that a Financial Institution is in a Control Group with another Financial Institution if, directly or indirectly, the Financial Institution owns at least 80 percent of, is at least 80 percent owned by, or shares an 80 percent or more owner with, the other Financial Institution. If the Financial Institutions are not corporations, the proposal provided that ownership would be defined to include interests in the Financial Institution such as profits interest or capital interests in which,

[140] Individual Retirement Accounts, Formalizing Labor's and IRS's Collaborative Efforts Could Strengthen Oversight of Prohibited Transactions, GAO–19–495 (June 2019), *available at www.gao.gov/assets/700/699575.pdf.*

[141] 585 U.S. __, 138 S.Ct. 2044 (2018).

[142] *See* discussion on Scope of Relief—Section I, Affiliates and Related Entities.

directly or indirectly, the Financial Institution owns at least 80 percent of, is at least 80 percent owned by, or shares an 80 percent or more owner with, the other Financial Institution. For purposes of this provision, the proposal provided if the Financial Institutions are not corporations, ownership would be defined to include interests in the Financial Institution such as profits interest or capital interests.

The Department stated in the proposal that the 80 percent threshold is consistent with the Code's rules for determining when employees of multiple corporations should be treated as employed by the same employer, citing Code section 414(b). The Department also sought comment on this approach. In response, one commenter asserted that different forms of ownership would make it difficult to determine how to apply the 80% threshold suggested. Accordingly, the Department revised the definition to directly incorporate both definitions in both Code section 414(b) and 414(c) which address these arrangements. The Department believes these provisions will provide a well-known frame of reference for Financial Institutions and avoid uncertainty as to how the definition will be applied.

A few other commenters opposed including Control Group members within the eligibility provision, as proposed. These commenters asserted that a common parent is not an indicator of any other connection between corporate entities; rather, these commenters stated that affiliates typically maintain different policies and procedures. One commenter asserted that conduct by the Financial Institution's affiliates may not relate to investment advice or conduct involving Title I Plans or IRAs. This commenter stated that affiliates typically maintain different compliance policies and procedures and a Financial Institution and its affiliates are managed by different officers and compliance staff. Another commenter asserted that a Financial Institution may not know of the conviction of another Financial Institution in the same Controlled Group within 10 business days. Another commenter stated that independent firms may have common ownership but different business models or professional culture.

The Department has not revised its approach in response to these comments. The eligibility provision and the definition of Controlled Group are narrowly drafted so that they identify conduct involving services to Retirement Investors, and also are limited to Financial Institutions, within the meaning of the exemption, that are Controlled Group members with a high level of common ownership. The Department continues to believe that the tailored definition of Controlled Group and provision that a Financial Institution becomes ineligible on the 10th business day after conviction ensures that there is a culture of compliance across the Controlled Group for entities engaging in this otherwise prohibited transaction. The Department notes that given the high level of ownership, it is not unreasonable for the Financial Institution be aware of the conviction of another Financial Institution in the same Controlled Group and it should not be difficult for Financial Institutions to keep track of such convictions. Accordingly, the Department has not adjusted the 10 business-day deadline.

Period of Ineligibility

The period of ineligibility under Section III is 10 years; however, the eligibility provision would apply differently to Investment Professionals and Financial Institutions. An Investment Professional that is convicted of a crime would become ineligible immediately upon the date the Investment Professional is convicted by a trial court, regardless of whether that judgment remains under appeal, or upon the date of the written ineligibility notice from the Department, as applicable.

Financial Institutions, on the other hand, would have a one-year winding down period after becoming ineligible, during which they may continue to rely on the exemption, as long as they comply with the exemption's other conditions during that year. The winding down period begins 10 business days after the date of the trial court's judgment, regardless of whether that judgment remains under appeal. Financial Institutions that timely submit a petition regarding the conviction would become ineligible 21 days after the date of a written notice of denial from the Department. Financial Institutions that become ineligible due to conduct with respect to exemption compliance would become ineligible 21 days after the date of the written ineligibility notice from the Department and begin their winding down period at that point.

Financial Institutions or Investment Professionals that become ineligible to rely on this exemption may rely on a statutory or administrative class prohibited transaction exemption if one is available or may seek an individual prohibited transaction exemption from the Department. The Department encourages any Financial Institution or Investment Professional facing allegations that could result in ineligibility, or that otherwise determines it may need individual prohibited transaction relief, to begin the application process as soon as possible. An applicant is not guaranteed an individual exemption, even if one is proposed. If an exemption is proposed, the Department is required to provide notice and a period of public comment and to consider those comments before granting an exemption. If an individual exemption applicant becomes ineligible and the Department has not granted a final individual exemption, the Department will consider additional retroactive relief, consistent with its policy as set forth in 29 CFR 2570.35(d). Retroactive relief may require inclusion of additional exemption conditions.

Recordkeeping—Section IV

Under Section IV of the exemption, Financial Institutions must maintain records for six years demonstrating compliance with the exemption. The Department generally includes a recordkeeping requirement in its administrative exemptions to ensure that parties relying on an exemption can demonstrate, and the Department can verify, compliance with the conditions of the exemption. Section IV requires that the records be made available, to the extent permitted by law, to any authorized employee of the Department or the Department of the Treasury.

To demonstrate compliance with the exemption, Financial Institutions are required to maintain, among other things, documentation of rollover recommendations; their written policies and procedures adopted pursuant to Section II(c); and the report of the retrospective review, certification, and supporting data. Except with respect to rollovers, the Department does not expect Financial Institutions to document the reason for every investment recommendation made pursuant to the exemption. However, documentation may be especially important for recommendations of particularly complex products or recommendations that might, on their face, appear inconsistent with the best interest standard.

One commenter supported the recordkeeping requirement as proposed but recommended extending the recordkeeping requirement to 10 years. The Department declines to extend the time period. The six-year time period is consistent with standard recordkeeping requirements imposed in many existing exemptions, and it is consistent with the

statute of limitation set forth in ERISA section 413.

Other commenters opposed the scope of access to records in the proposed exemption. The proposal provided that records should be available for review by the following parties in addition to the Department: Any fiduciary of a Plan that engaged in an investment transaction pursuant to this exemption; any contributing employer and any employee organization whose members are covered by a Plan that engaged in an investment transaction pursuant to this exemption; or any participant or beneficiary of a Plan, or IRA owner that engaged in an investment transaction pursuant to this exemption. Several commenters stated that allowing parties other than the Department to review records would increase the burden placed on Financial Institutions. In particular, they expressed the view that parties might overwhelm Financial Institutions with requests for information in order to generate claims for use in litigation. Fear of potential litigation could, in turn, they argued, lead to a ''culture of quiet'' in which employees of Financial Institutions elect not to address compliance issues because of the fear of this disclosure.

In response to these comments, the Department has revised the final exemption's recordkeeping provisions so that access is limited to the Department and the Department of the Treasury, although, in connection with this change, the Department has revised Section II(b) of the exemption, as described above, to provide Retirement Investors with documentation of the reasons that a rollover recommendation made to them was in their best interest. The Department accepts that Financial Institutions may have concerns about internal compliance records, particularly the record of their retrospective reviews, becoming widely accessible. However, the Department believes that it is important for the exemption to be conditioned on Retirement Investors receiving documentation of the reasons for rollover recommendations made to them, to allow them to carefully evaluate those important recommendations. The Department also notes that even if the exemption does not require disclosure of certain records, Financial Institutions would not be precluded from providing them voluntarily as a matter of customer relations.

One commenter raised concerns that the proposal's recordkeeping requirements were inconsistent with certain ''visitorial powers'' under banking law, discussed above. The Department notes that the exemption, as well as the proposal, contains the limiting language ''to the extent permitted by law including 12 U.S.C. 484,'' which the Department believes substantially addresses these concerns.

A few commenters also asserted that the Department should not be permitted to request records regarding IRA transactions because the Department does not have enforcement jurisdiction over IRAs, and under the Fifth Circuit's *Chamber* opinion, the records provision would be an impermissible attempt to usurp enforcement jurisdiction. In conjunction with this, one commenter suggested the Internal Revenue Service should be able to obtain records regarding IRAs. While the Department may lack certain enforcement jurisdiction with respect to IRAs, it does not lack the ability to issue exemptions to the prohibited transaction provisions under Code section 4975.[143] The Department has authority to grant prohibited transaction exemptions, as well as the associated authority to determine whether the conditions of its exemption are being met by reviewing records for the purpose of determining that compliance. The Department does not, based on those same grounds, agree that a recordkeeping requirement that impacts IRAs is inconsistent with the Fifth Circuit's *Chamber* opinion, which did not specifically address the issue. However, the Department has added the Department of the Treasury, which includes the Internal Revenue Service, as an additional regulator that can obtain a Financial Institution's records under the exemption.

Lastly, one commenter was concerned about the application of a 30-day requirement to notify the Department of a decision to withhold documents from parties other than the Department. Because the exemption has been modified to only provide for the Department's and the Department of the Treasury's review, the commenter's concern has been addressed.

Effective Date

The exemption is effective 60 days after its publication in the **Federal Register**. This responds to several commenters who urged the Department to make the exemption available promptly. Some commenters requested that the exemption be effective immediately upon publication in the **Federal Register**, rather than after 60 days. Another commenter, however, suggested that the exemption should be effective no earlier than July 1, 2021, 180 days after the publication of the exemption, or 90 days after the end of the current public health emergency, because of market turmoil and COVID–19.

The Department has retained the 60 day effective date timeframe to permit transmittal of the exemption to Congress and the Comptroller General for review in accordance with the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). As stated above, parties can continue to rely on FAB 2018–02 for one year following publication of the final exemption, so there will be a transition period for Financial Institutions to develop compliance structures. The Department has not delayed the effective date as suggested by one commenter. The Department believes that the exemption's conditions provide protections of Retirement Investors even in the event of market turmoil, and, therefore, a delay in the effective date is not in the interests of Retirement Investors.

Procedural Issues

Following the proposal, the Department received comments about the process it has followed in this exemption proceeding. Some commenters requested that the Department extend the proposed exemption's 30-day comment period. Many commenters also requested the Department hold a public hearing, which it did on September 3, 2020, although a few other commenters asserted that the procedure establishing the hearing was improper. Commenters in particular pointed to the more extensive comment period provided in the Department's 2016 fiduciary rulemaking.

The Department believes that its procedure with respect to the proposal was appropriate under applicable requirements, including the Administrative Procedure Act. The Department received and carefully reviewed 106 comments on the proposal. Further, the Department accommodated all requests by commenters to testify at the hearing, and this resulted in 21 organizations testifying. This hearing was broadcast publicly, and all interested parties were invited to watch the hearings. The hearings gave the Department time to hear oral testimony from these 21 different organizations, and question them on aspects of the comments and their testimony. Moreover, the general issues and concerns raised by the proposal have been subject to significant amounts of commentary and discussion between the Department and the public

[143] *See* supra note 6.

since October 2010. In light of the narrower issues raised in the present exemption project as opposed to the 2016 fiduciary rulemaking, as well as the public record developed on the proposal, the Department does not believe that the shorter comment period indicates an insufficient opportunity for public comment.

Reinsertion of the Five-Part Test for Investment Advice Fiduciary Status

On the same day as the Department published the proposed exemption, the Department issued a technical amendment to 29 CFR 2510–3.21 instructing the Office of the Federal Register to remove language that was added in 2016 and reinsert the text of the 1975 regulation. The 1975 regulation established the five-part test for investment advice fiduciary status.

Many commenters on the Department's proposed exemption addressed the Department's technical amendment reinserting the five-part test. Some commenters supported the technical amendment, stating that it provides welcome certainty to the regulated community as to the current legal definition of an investment advice fiduciary. Some commenters indicated that the five-part test properly defines an investment advice fiduciary. Some expressed the view that reinsertion of the five-part test was the appropriate response to the Fifth Circuit's *Chamber* opinion.

Many commenters expressed significant opposition to the reinsertion of the five-part test via the technical amendment, and the five-part test in general. They stated that the five-part test was established before the prevalence of 401(k) plans and IRAs, and is now outdated and ill-suited to address the complex investment products offered in today's marketplace. They also said the five-part test is narrower than the statutory definition in Title I and the Code, which defines a fiduciary as anyone who ''renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of such plan, or has any authority or responsibility to do so.'' [144] These commenters said despite the Department's preamble interpretation regarding rollovers, many rollovers would occur without the protections of a fiduciary standard.

Commenters criticized several of the individual elements of the five-part test. The ''regular basis'' prong in particular, they said, creates loopholes for financial professionals to avoid fiduciary status while holding themselves out as trusted advisers. Some commenters particularly pointed to transactions involving non-securities which they said can involve significant conflicts of interest and may often be considered one-time transactions. Commenters also stated that the regular basis prong will mean that advice to a plan sponsor regarding investment options in a Title I Plan will rarely be fiduciary advice, which will adversely affect Plan participants' investment options. The commenters also stated that disclaimers of a 'mutual agreement' or that the advice will serve as 'a primary basis' for investment decisions will be used to avoid application of the fiduciary standard. As a result of all these factors, the commenters said Retirement Investors would be harmed by unchecked conflicts of interest.

Some of the commenters raised legal arguments in connection with the technical amendment reinserting the five-part test. The commenters stated the Department had discretion as to whether to reinstate the five-part test, and, therefore, should have provided notice, economic analysis, and an opportunity for public comment before it took action.

While this exemption proceeding interprets aspects of the five-part test, including by providing a new interpretation as to how it applies to rollovers, this exemption has not put at issue the five-part test itself as codified at 26 CFR 54.4975–9 and 29 CFR 2510.3–21. Thus, these comments are outside the scope of this exemption proceeding.

Additionally, as stated in its technical amendment, the five-part test was reinstated by the Fifth Circuit's decision in *Chamber,* not by any discretionary action of the Department. As a result of that decision, the 2016 fiduciary regulation and associated exemptions were vacated *in toto.* The Department merely directed the Office of the Federal Register to update the Code of Federal Regulations to correctly reflect current law.

Finally, as explained below regarding the need for this rulemaking, this exemption appropriately takes into account the reasoning in the Fifth Circuit's *Chamber* opinion and changes in the regulatory landscape that have occurred since the 2016 fiduciary rulemaking.

Regulatory Impact Analysis

Executive Orders 12866 and 13563 Statement

Executive Orders 12866 [145] and 13563 [146] 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). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, ''significant'' regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely and materially affect 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) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The Department anticipates that this exemption is economically significant within the meaning of section 3(f)(1) of Executive Order 12866. Therefore, the Department provides the following assessment of the potential benefits and costs associated with this exemption. In accordance with Executive Order 12866, this exemption was reviewed by OMB.

The final exemption will be transmitted to Congress and the Comptroller General for review in accordance with the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). Pursuant to the Congressional Review Act, OMB has designated this final exemption as a ''major rule,'' as defined by 5 U.S.C. 804(2), because it

[144] ERISA section 3(21)(A)(ii); Code section 4975(e)(3)(B).

[145] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[146] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).

would be likely to result in an annual effect on the economy of $100 million or more.

Need for Regulatory Action

Participants in individual participant-directed defined contribution Plans (DC Plans) and IRA investors are responsible for investing their retirement savings, and they often seek high quality, impartial advice from financial service professionals to make prudent investment decisions. This is especially true as the share of total plan participation attributable to Defined Contribution (DC) Plans continues to grow. In 2017, 83 percent of DC Plan participation was attributable to 401(k) Plans, and 98 percent of 401(k) Plan participants were responsible for directing some or all of their account investments.[147]

Following the Fifth Circuit's *Chamber* opinion, the Department issued a temporary enforcement policy under FAB 2018–02 and announced its intent to provide additional guidance in the future. Since then, as discussed earlier in this preamble, the regulatory landscape has changed as other regulators, including the SEC, have adopted enhanced conduct standards for financial services professionals.[148]

Some commenters claimed that the Department changed its previous position from its 2016 fiduciary rulemaking without providing detailed justification. In response to these comments, the Department more clearly specifies some of the factors that compelled it to take this action. First, the Department's current action follows and is guided by the Fifth Circuit's *Chamber* opinion decision that vacated the Department's 2016 fiduciary rule and associated exemptions, *in toto*. The Department carefully studied the court's decision and developed this exemption consistent with it. Second, the regulatory landscape has changed since the Department issued the 2016 fiduciary rule and exemptions. At that time, no other regulators had adopted enhanced conduct standards of financial service professionals. Currently, other regulators such as the SEC and state insurance commissioners have adopted or are currently in the process of enhancing the conduct standards of financial service professionals. These developments encourage the Department to take these regulatory changes into account when taking this action.

For instance, at the Department's September 3, 2020, public hearing on the proposed exemption, a witness testified that financial services firms made fundamental changes in their business models for several years after the Department issued its 2016 fiduciary rule and the SEC issued Regulation Best Interest. Those changes include new commission and fee schedules, the elimination of certain products and services, and third-party revenue sources, modified compensation and incentive programs, and caps on mutual fund and annuity upfront fees and trailing commissions. Additionally, according to data in studies cited by some commenters, the Department's 2016 fiduciary rulemaking also correlated with financial service professionals transitioning to lower-fee products, which has remained the case even after the rulemaking was vacated by the Fifth Circuit, but when FAB 2018–02 was in effect.

In sum, the Department considered the changes in regulatory landscape, business practices, and product offerings as it developed this exemption. To the extent Financial Institutions have already implemented measures to mitigate conflicts of interest and reduce related investor harms, the benefits of this exemption will be reduced. Similarly, to the extent Financial Institutions have already incurred costs to comply with other regulators' actions and the Department's 2016 fiduciary rulemaking, the costs of this exemption also will be reduced. Accordingly, these changes are reflected in the baseline that the Department applies when it evaluates the benefits and costs associated with this exemption that are discussed below.

Given this background, the Department believes that it is appropriate to replace the relief provided in FAB 2018–02 with a permanent exemption. The exemption will provide Financial Institutions and Investment Professionals with broader, more flexible prohibited transaction relief than is currently available, while safeguarding the interests of Retirement Investors. Offering a permanent exemption based on FAB 2018–02 will provide certainty to Financial Institutions and Investment Professionals that currently may be relying on the temporary enforcement policy.

Benefits

This exemption will generate several benefits. It will provide Financial Institutions and Investment Professionals with flexibility to choose between this new exemption or existing exemptions, depending on their needs and business models. In this regard, the exemption will help preserve different business models, compensation arrangements, and products that meet different needs in the market. This can, in turn, help preserve the existing wide availability of investment advice arrangements and products for Retirement Investors. Furthermore, the exemption will provide certainty for Financial Institutions and Investment Professionals that opted to comply with the enforcement policy the Department announced in FAB 2018–02 to continue with, and build upon, that compliance approach. Further, the exemption will ensure that investment advice satisfying the Impartial Conduct Standards is widely available to Retirement Investors without interruption.

As described above, in FAB 2018–02, the Department announced a temporary enforcement policy that would apply until the issuance of further guidance. Its designation as ''temporary'' communicated its status as a transitional measure following the vacatur of the Department's 2016 fiduciary rulemaking. FAB 2018–02 was not intended to represent a permanent approach for prohibited transaction relief. This is due in part to the fact that FAB 2018–02 allows Financial Institutions to avoid enforcement action by the Department, but it does not (and cannot) provide relief from private litigation related to prohibited transactions.

In addition to the more permanent relief it will provide, this exemption will have more specific conditions than FAB 2018–02, which requires only good faith compliance with the Impartial Conduct Standards. The conditions in the exemption are designed to support the provision of investment advice that meets the Impartial Conduct Standards. For example, the required policies and procedures and retrospective review work in concert with the Impartial Conduct Standards to help Financial

[147] *Private Pension Plan Bulletin Historic Tables and Graphs 1975–2017,* Employee Benefits Security Administration (Sep. 2018), *www.dol.gov/sites/dolgov/files/ebsa/researchers/statistics/retirement-bulletins/private-pension-plan-bulletin-historical-tables-and-graphs.pdf.*

[148] The SEC's Regulation Best Interest went into effect June 30, 2020. Although not a regulatory agency, the NAIC approved revisions to Model Regulation 275 in February 2020 and recommended adoption by state insurance regulators. According to a commenter in the insurance industry, the updated NAIC's Model Regulation 275 has been finalized in two states (Arizona and Iowa), and four others (Idaho, Kentucky, Ohio, and Rhode Island) have publicly stated their intention to pursue adoption in late 2020 or early 2021. Other commenters expect the updated NAIC Model Regulation to be adopted in a majority of states within the next two to three years. These commenters also stated that the Dodd-Frank Act requires adoption of the NAIC Model Regulation amendments within five years to maintain exclusive state regulation of fixed annuity and insurance products.

Institutions comply with the standards that will protect Retirement Investors.

Some Financial Institutions may consider whether to rely on the Department's existing exemptions rather than adopt the specific conditions in this new exemption. The existing exemptions generally condition relief on disclosure and cover narrowly tailored transactions and types of compensation arrangements as well as the parties that may rely on the exemption. For example, the existing exemptions were never amended to clearly cover third-party compensation arrangements, such as revenue sharing, that developed over time. Investment advice fiduciaries relying on some of the existing exemptions will be limited to the types of compensation that tend to be more transparent to Retirement Investors, such as commission payments.

For a number of reasons, Financial Institutions may decide to rely on this new exemption, instead of the Department's existing exemptions. First, this exemption is broadly available for a wide variety of investment advice transactions and compensation arrangements, which gives Financial Institutions greater flexibility and simplifies compliance. Additionally, Financial Institutions may determine that there is a marketing advantage to acknowledging their fiduciary status with respect to Retirement Investors, as required by the new exemption.

Some commenters questioned the effectiveness of this disclosure because investors may decline to read or not fully understand such disclosures. In response to these concerns, the Department strongly encourages Financial Institutions to design disclosures that are easy to understand and written in plain English. The Department has provided model language that Financial Institutions may use for this purpose. The Department believes this required disclosure will further help Retirement Investors to make informed investment decisions.

In addition, one study suggests that disclosure requirements sometimes directly affect disclosers' actions. It showed that disclosers sometimes made changes to their practices before sending disclosures to consumers, especially when corporate reputation is particularly important. For example, corporate managers concerned with protecting market share or reputation often introduced lines of healthy products or tightened corporate governance before the public responded.[149] This suggests that disclosures can be effective even when investors may not read or not fully understand them.

As the exemption will apply to multiple types of investment advice transactions, it will potentially allow Financial Institutions to rely on one exemption for investment advice transactions under a single set of conditions. This approach may allow Financial Institutions to streamline compliance, as compared to relying on multiple exemptions with multiple sets of conditions, resulting in a lower overall compliance burden for some Financial Institutions.

This exemption's alignment with other regulatory conduct standards can result in a reduction in overall regulatory burden as well. As discussed earlier in this preamble, the exemption was developed in consideration of other regulatory conduct standards. The Department envisions that Financial Institutions and Investment Professionals that have already developed, or are in the process of developing, compliance structures for other regulators' standards will be able to rely on the new exemption while incurring less costs than they otherwise would if other regulators' compliance structures did not exist.

As discussed above, the Department believes that the exemption will provide significant protections for Retirement Investors. The exemption relies in large measure on Financial Institutions' reasonable oversight of Investment Professionals and their adoption of a culture of compliance. Accordingly, in addition to the Impartial Conduct Standards, the exemption includes conditions designed to support investment advice that meets those standards, such as the provisions requiring written policies and procedures, documentation of rollover recommendations, and retrospective review. However, the exemption will not expand Retirement Investors' ability to enforce their rights in court or create any new legal claims above and beyond those expressly authorized in Title I or the Code, such as through required contracts and warranty provisions.

Finally, this exemption provides that Financial Institutions and Investment Professionals with certain criminal convictions or that engage in egregious conduct with respect to compliance with the exemption would become ineligible to rely on the exemption, for a period of 10 years. Engaging in these types of conduct would suggest that the Financial Institution or Investment Professional is not able or willing to maintain a high standard of integrity and will cast doubt on their ability to act in accordance with the Impartial Conduct Standards. This will allow the Department to give special attention to parties with certain criminal convictions or with a history of egregious conduct regarding compliance with the exemption which should provide significant protections for Retirement Investors while preserving wide availability of investment advice arrangements and products.

Although the Department expects this exemption to generate significant benefits, it does not have sufficient data to quantify such benefits. However, the Department expects the benefits to justify the compliance costs associated with this exemption because it creates an additional pathway for Financial Institutions to comply with the prohibited transaction provisions in Title I and the Code. This new pathway is broader than existing exemptions, and, thus, applies to a wider range of transactions and compensation arrangements and products than the relief that is currently available. The Department anticipates that entities will generally take advantage of this exemptive relief only if it is less costly than other alternatives currently available, including avoiding prohibited transactions or complying with an existing exemption. The Department requested comments in the proposal about the specific benefits that may flow from the exemption and invited commenters to submit quantifiable data that would support or contradict the Department's expectations about benefits. In response, the Department received no comments or data that could help it quantify the benefits associated with this exemption.

[149] Mary Graham, *Democracy by Disclosure: The Rise of Technopopulism* (2002). When Congress required manufacturers to disclose how many pounds of toxic chemicals they released into the air, water, and land and required chief executives to sign off on these reports, some chief executives became aware of total toxic pollutions for the first time and publicly announced the future reductions at the same time or before they issued their reports. In response to the Nutrition Labeling and Education Act (NLEA), which mandated the uniform nutrition label, some food companies added healthier options. Furthermore, some food companies added healthier products before the NLEA was implemented but after enacted. (See Christine Moorman, *Market-Level Effects of Information: Competitive Responses and Consumer Dynamics,* Journal of Marketing Research, Vol. 35, No. 1 (Feb., 1998). Another experimental study shows that when advisors have a choice to accept or reject conflicts of interest, advisors who would have to disclose their conflict would more likely to reject conflicts of interest, so that they have nothing to disclose except the absence of conflicts. (See Sah, Sunita, and George Loewenstein. ''Nothing to declare: Mandatory and voluntary disclosure leads advisors to avoid conflicts of interest.'' *Psychological science* 25.2 (2014): 575–584.).

Costs

To estimate compliance costs associated with the exemption, the Department considers the changed regulatory baseline. For example, the Department assumes affected entities will likely incur only incremental costs if they are already subject to another regulator's similar rules or requirements. Because this exemption is intended to align significantly with other regulators' rules and standards of conduct, the Department expects that satisfying the exemption conditions will not be unduly burdensome. The Department estimates that the exemption would impose costs of more than $87.8 million in the first year and $78.9 million in each subsequent year.[150] Over 10 years, the costs associated with the exemption would total approximately $562 million, annualized to $80.1 million per year (using a seven percent discount rate).[151] Using a perpetual time horizon (to allow the comparisons required under E.O. 13771), the annualized costs in 2016 dollars are $57 million at a seven percent discount rate. These costs are broken down and explained below. More details are provided in the Paperwork Reduction Act section as well. The Department solicited any quantifiable data that would support or contradict any aspect of its analysis and received none.

The Department also requested comments on this overall estimate and the cost burdens across different entities. In response, the Department received several comments concerning its proposed cost burden analysis. After careful reviews of those comments, the Department revised its cost estimate upward from the proposed cost estimate. For example, in the proposal, the Department applied an hourly rate for compliance attorneys based on the U.S. Bureau of Labor Statistics' average attorney hourly rate.[152] Because this rate is significantly lower than the average senior compliance officer's hourly wage, one commenter noted that the wage suggested the Department believed such compliance activities would be handled by junior attorneys, rather than more senior compliance counsel. In response, the Department's new cost burden analysis relies on a higher hourly wage rate that reflects the hourly wage of senior compliance attorneys in the financial services sector.[153] Details of the comments and the Department's revised cost estimates are discussed below.

Affected Entities

As a first step in its analysis, the Department examines the entities likely to be affected by the exemption. The exemption will potentially impact SEC- and state-registered investment advisers (IAs), broker-dealers (BDs), banks, and insurance companies, as well as their employees, agents, and representatives. The Department acknowledges that not all these entities will serve as investment advice fiduciaries to Plans and IRAs within the meaning of Title I and the Code. Additionally, because other exemptions are also currently available to these entities, it is unclear how widely Financial Institutions will rely upon this exemption and which firms are most likely to choose to rely on it. To err on the side of caution, the Department includes all entities eligible for this relief in its cost estimate. The Department solicited comments about which, and how many, entities would likely use this exemption. Although no commenters provided precise counts of entities that would use this exemption, many commenters expressed their support for an exemption that is broad and flexible enough to cover a wide range of transactions and circumstances. They further expressed their interest in consolidating multiple exemptions into one exemption to streamline compliance. As discussed earlier in this preamble, the Department clarified points raised by commenters and considered all comments in finalizing this exemption. Thus, the Department expects that this exemption will be widely used across different entities.

Broker-Dealers (BDs)

As of December 2018, there were 3,764 registered BDs. Of those, 2,766, or approximately 73.5 percent, reported retail customer activities, while 998 were estimated to have no retail customers.[154] The Department does not have information about how many BDs provide investment advice to Retirement Investors, which, as defined in the exemption include Plan fiduciaries, Plan participants and beneficiaries, and IRA owners. However, according to one compliance survey, about 52 percent of IAs provide services to retirement plans.[155] Assuming the same percentage of BDs provide advice to retirement plans, nearly 2,000 BDs will be affected by the exemption.[156] This exemption may also impact BDs that provide investment advice to Retirement Investors that are Plan participants or beneficiaries, or IRA owners, but the Department does not have a basis to estimate the number of these BDs. The Department assumes that such BDs would be considered as providing recommendations to retail customers under the SEC's Regulation Best Interest.

To continue providing investment advice to retirement plans with respect to transactions that otherwise would be prohibited under Title I and the Code, this group of BDs will be able to rely on the exemption.[157] Because BDs with retail customers are subject to the SEC's Regulation Best Interest, they already comply with standards substantially similar to those set forth in the exemption.

SEC-Registered Investment Advisers (IAs)

As of December 2018, there were approximately 13,299 SEC-registered IAs.[158] Generally, an IA must register with the appropriate regulatory authorities—the SEC or state securities

[150] These estimates rely on the Employee Benefits Security Administration's 2018 labor rate estimates. See *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculation,* Employee Benefits Security Administration (June 2019), *www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*

[151] The costs would be $682 million over 10-year period, annualized to $79.9 million per year, if a three percent discount rate were applied.

[152] In the proposal, the Department used $138.41 as an attorney's hourly rate. For more details about the Department's methodologies, see *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculation,* Employee Benefits Security Administration (June 2019), *www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*

[153] In the final exemption, the Department used $365.39 as an attorney's hourly rate. This is an hourly rate estimate for an in-house compliance counsel, obtained from the SEC's Regulation Best Interest Release, 84 FR 33455, footnote 1304: Hour for in-house compliance counsel. *Available at www.govinfo.gov/content/pkg/FR-2019-07-12/pdf/2019-12164.pdf.*

[154] Regulation Best Interest Release, 84 FR 33407.

[155] *2019 Investment Management Compliance Testing Survey,* Investment Adviser Association (Jun. 18, 2019), *https://higherlogicdownload.s3.amazonaws.com/INVESTMENTADVISER/aa03843e-7981-46b2-aa49-c572f2ddb7e8/UploadedImages/about/190618_IMCTS_slides_after_webcast_edits.pdf.*

[156] If this assumption is relaxed to include all BDs, the costs would increase by $2.8 million for the first year.

[157] The Department's estimate of compliance costs does not include any state-registered BDs because the exception from SEC registration for BDs is very narrow. *See Guide to Broker-Dealer Registration,* Securities and Exchange Commission (Apr. 2008), *www.sec.gov/reportspubs/investor-publications/divisionsmarketregbdguidehtm.html.*

[158] Form CRS Relationship Summary Release, 84 FR 33564.

authorities.[159] IAs registered with the SEC are generally larger than state-registered IAs, both in staff and in regulatory assets under management (RAUM).[160] SEC-registered IAs that provide investment advice to retirement plans and other Retirement Investors would be directly affected by the exemption.

Some IAs are dual-registered as BDs. To avoid double counting when estimating compliance costs, the Department counted dually-registered entities as BDs and excluded them from the burden estimates of IAs.[161] Therefore, the Department estimates there to be 12,940 SEC-registered IAs, a figure produced by subtracting the 359 dually-registered IAs from the 13,299 SEC-registered IAs.

Similar to BDs, the Department assumes that about 52 percent of SEC-registered IAs provide investment advice to retirement plans.[162] Applying this assumption, the Department estimates that approximately 6,729 SEC-registered IAs currently provide investment advice to retirement plans. An inestimable number of IAs may provide advice only to Retirement Investors that are Plan participants or beneficiaries or IRA owners, rather than the workplace retirement plans themselves. These IAs are fiduciaries, and they already operate under standards substantially similar to those required by the exemption.[163] Accordingly, the exemption will pose no more than a nominal burden for these entities.

State-Registered Investment Advisers

As of December 2018, there were 16,939 state-registered IAs.[164] Of these state-registered IAs, 13,793 provide advice to retail investors, while 3,146 do not.[165] State-registered IAs tend to be smaller than SEC-registered IAs, both in RAUM and staff. For example, according to one survey of both SEC- and state-registered IAs, about 47 percent of respondent IAs reported 11 to 50 employees.[166] In contrast, an examination of state-registered IAs reveals about 80 percent reported only up to two employees.[167] According to one report, 64 percent of state-registered IAs manage assets under $30 million.[168] A study by the North American Securities Administrators Association found that about 16 percent of state-registered IAs provide advice or services to retirement plans.[169] Based on this study, the Department assumes that 16 percent of state-registered IAs provide investment advice to retirement plans. Thus, the Department estimates that approximately 2,710 state-registered IAs provide advice to retirement plans and other Retirement Investors.

Insurance Companies

The exemption will affect insurance companies, which primarily are regulated by states. No single regulator records a national-level count of insurance companies. Although state regulators track insurance companies, the total number of insurance companies cannot be calculated by aggregating individual state totals because individual insurance companies often operate in multiple states. However, the NAIC estimates there were approximately 386 insurance companies directly writing annuities in 2018. Some of these insurance companies may not sell any annuity contracts in the IRA or Title I retirement plan markets.[170] Furthermore, insurance companies can rely on other existing exemptions instead of this exemption. Some insurance industry commenters questioned whether the Department's existing exemptions offer realistic alternatives. In response to these concerns, the Department clarified earlier in this preamble that insurance companies can rely on other existing exemptions if such exemptions better fit their current business models. In the proposal, the Department invited comments about how many insurance companies would use this exemption. No commenters provided data that could help the Department more precisely quantify the number of insurance companies that will rely on this exemption or the associated compliance costs. Due to lack of data, the Department includes all 386 insurance companies in its cost estimate, although this likely presents an upper bound.

Banks

There are 5,066 federally insured depository institutions in the United States.[171] Banks will be permitted to act as Financial Institutions under the exemption if they or their employees are investment advice fiduciaries with respect to Retirement Investors. The Department nevertheless believes that most banks will not be affected by the exemption for the reasons discussed below.

The Department understands that banks most commonly use ''networking arrangements'' to sell retail non-deposit investment products (RNDIPs), including, among other products, equities, fixed-income securities, exchange-traded funds, and variable annuities.[172] Under such arrangements,

[159] Generally, a person that meets the definition of ''investment adviser'' under the Advisers Act (and is not eligible to rely on an enumerated exclusion) must register with the SEC, unless it: (i) Is prohibited from registering under Section 203A of the Advisers Act, or (ii) qualifies for an exemption from the Act's registration requirement. An adviser precluded from registering with the SEC may be required to register with one or more state securities authorities.

[160] After the Dodd-Frank Wall Street Reform and Consumer Protection Act, an IA with $100 million or more in regulatory assets under management generally registers with the SEC, while an IA with less than $100 million registers with the state in which it has its principle office, subject to certain exceptions. For more details about the registration of IAs, see *General Information on the Regulation of Investment Advisers,* Securities and Exchange Commission (Mar. 11, 2011), *www.sec.gov/divisions/investment/iaregulation/memoia.htm;* see also *A Brief Overview: The Investment Adviser Industry,* North American Securities Administrators Association (2019), *www.nasaa.org/industry-resources/investment-advisers/investment-adviser-guide/.*

[161] The Department applied this exclusion rule across all types of IAs, regardless of registration (SEC registered versus state only) and retail status (retail versus nonretail).

[162] 2019 Investment Management Compliance Testing Survey, *supra* note 155.

[163] *SEC Standards of Conduct Rulemaking: What It Means for RIAs,* Investment Adviser Association (July 2019), *https://higherlogicdownload.s3.amazonaws.com/INVESTMENTADVISER/aa03843e-7981-46b2-aa49-c572f2ddb7e8/UploadedImages/resources/IAA-Staff-Analysis-Standards-of-Conduct-Rulemaking2.pdf.*

[164] This excludes state-registered IAs that are also registered with the SEC or dual registered BDs.

[165] Form CRS Relationship Summary Release.

[166] 2019 Investment Management Compliance Testing Survey, *supra* note 155.

[167] *2019 Investment Adviser Section Annual Report,* North American Securities Administrators Association (May 2019), *www.nasaa.org/wp-content/uploads/2019/06/2019-IA-Section-Report.pdf.*

[168] *2018 Investment Adviser Section Annual Report,* North American Securities Administrators Association (May 2018), *www.nasaa.org/wp-content/uploads/2018/05/2018-NASAA-IA-Report-Online.pdf.*

[169] 2019 Investment Adviser Section Annual Report, *supra* note 167.

[170] One comment letter from the insurance industry stated that about half of annuity products sold by insurance agents were IRA or tax-qualified products. This suggests that fewer than 386 of the insurers included in this analysis will be affected by this exemption. However, the comment did not provide data quantifying the number of insurers likely to be affected by or likely to use this exemption.

[171] The FDIC reports there are 4,430 Commercial banks and 636 Savings Institutions (thrifts) for 5,066 FDIC- Insured Institutions as of June 30, 2020. For more details, see *Statistics at a Glance,* Federal Deposit Insurance Corporation (Jun 30, 2020), *www.fdic.gov/bank/statistical/stats/2020jun/industry.pdf.*

[172] For more details about ''networking arrangements,'' see *Conflict of Interest Final Rule, Regulatory Impact Analysis for Final Rule and Exemptions,* U.S. Department of Labor (Apr. 2016), *www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/completed-rulemaking/1210-AB32-2/ria.pdf.* Financial Institutions that are broker-dealers, investment advisers, or insurance companies that participate in networking arrangements and provide fiduciary

bank employees are limited to performing only clerical or ministerial functions in connection with brokerage transactions. However, bank employees may forward customer funds or securities and may describe, in general terms, the types of investment vehicles available from the bank and BD under the arrangement. Similar restrictions exist with respect to bank employees' referrals of insurance products and IAs. Because of these limitations, the Department believes that in most cases such referrals will not constitute fiduciary investment advice within the meaning of the exemption. Due to the prevalence of banks using networking arrangements for transactions related to RNDIPs, the Department believes that most banks will not be affected with respect to such transactions.[173]

The Department does not have sufficient data to estimate the costs to banks of any other investment advice services, because it does not know how frequently banks use their own employees to perform activities that would be otherwise prohibited. The Department invited comments on the magnitude of such costs and solicited data that would facilitate their quantification in the proposal. No comments expressly discussed costs to banks nor provided data for the Department to quantify the compliance burden, if any, imposed on banks.

Costs Associated With Disclosures

The Department estimates the compliance costs associated with the exemption's disclosure requirement will be approximately $2 million in the first year and $0.2 million per year in each subsequent year.[174]

Section II(b) of the exemption requires Financial Institutions to acknowledge, in writing, their status as fiduciaries under Title I and the Code, as applicable. In addition, Financial Institutions must furnish a written description of the services they provide and any material conflicts of interest. For many entities, including IAs, this condition will impose only modest additional costs, if any at all. Most IAs already disclose their status as a fiduciary and describe the types of services they offer in Form ADV. As of June 30, 2020, BDs with retail investors are also required to provide disclosures about services provided and conflicts of interest on Form CRS and pursuant to the disclosure obligation in Regulation Best Interest. Even among entities that currently do not provide such disclosures, such as insurance companies and some BDs, the Department believes that developing disclosures required in this exemption will not substantially increase costs because the required disclosures are clearly specified and limited in scope.

Not all entities will decide to use the exemption. Some may instead rely on other existing exemptions that better align with their business models. However, for this cost estimation, the Department assumes that all eligible entities will use the exemption and incur, on average, modest costs.

The Department estimates that developing disclosures that acknowledge fiduciary status and describe the services offered and any material conflicts of interest will cost regulated parties approximately $1.9 million in the first year.[175]

The Department estimates that it will cost Financial Institutions about $0.2 million to print and mail required disclosures to Retirement Investors, but it assumes most required disclosures will be electronically delivered to Retirement Investors.[176] The Department assumes that approximately 92 percent of participants who roll over their plan assets to IRAs will receive required disclosures electronically.[177] According to one study, approximately 3.6 million accounts in defined contribution plans were rolled over to IRAs in 2019.[178] Of those, slightly less than half, 1.8 million, were rolled over by financial services professionals.[179] Therefore, prior to transactions necessitated by rollovers, participants are likely to receive required disclosures from their Investment Professionals. In some cases, Financial Institutions and Investment Professionals may send required disclosures to participants, particularly those with participant-directed defined contribution accounts, before providing investment advice.

The Financial Institution now must provide documentation of the specific reasons that any rollover recommendation is in the Retirement Investor's best interest to the Retirement Investor. The Department estimates and presents costs associated with documenting rollover recommendations in the section below. Beyond the cost associated with producing the documentation, Financial Institutions may incur additional costs to provide such documentation to Retirement Investors. The Department expects that once the Financial Institutions document rollover recommendations, any additional costs for providing the documentation, such as printing and mailing costs, will be somewhat modest.[180]

investment advice would be included in the counts in their respective sections.

[173] A comment letter from the banking industry described various interactions with customers, including those related to RNDIP and IRA investment programs. According to this commenter, there are generally two types of bank IRA investment programs available for retirement customers: (i) Customer-directed bank IRA–CD and other bank deposit programs, and (ii) bank discretionary IRA programs. This commenter stated that they believe neither program would be required to rely on the exemption, which implies that most banks will not be affected by this exemption.

[174] Except where specifically noted, all cost estimates are expressed in 2019 dollars throughout this document.

[175] A written acknowledgment of fiduciary status would cost approximately $0.6 million, while a written description of the services offered and any material conflicts of interest would cost another $1.3 million. The Department assumes that 11,782 Financial Institutions, comprising 1,957 BDs, 6,729 SEC-registered IAs, 2,710 state-registered IAs, and 386 insurers, are likely to engage in transactions covered under this exemption. For a detailed description of how the number of entities is estimated, see the Paperwork Reduction Act section, below. The $0.6 million cost associated with a written acknowledgment of fiduciary status is calculated as follows. The Department assumes that it will take each retail BD firm 15 minutes, each nonretail BD or insurance firm 30 minutes, and each registered IA five minutes to prepare a disclosure conveying fiduciary status at an hourly labor rate of $365.39, resulting in cost burden of $584,130. Accordingly, the estimated per-entity cost ranges from $30.45 for IAs to $182.7 for non-retail BDs and insurers. The $1.3 million costs associated with a written description of the services offered and any material conflicts of interest are calculated as follows. The Department assumes that it will take each retail BD or IA firm five minutes, each small nonretail BD or small insurer 60 minutes, and each large nonretail BDs or larger insurer five hours to prepare a disclosure conveying services provided and any conflicts of interest at an hourly labor rate of $365.39, resulting in cost burden of $1,348,628. Accordingly, the estimated per-entity cost ranges from $30.45 for retail broker-dealers and IAs to $182.7 for large non-retail BDs and insurers.

[176] The Department estimates that approximately 1.8 million Retirement Investors are likely to engage in transactions covered under this PTE, of which 8.1 percent are estimated to receive paper disclosures. Distributing paper disclosures is estimated to take a clerical professional one minute per disclosure, at an hourly labor rate of $64.11, resulting in a cost burden of $151,341. Assuming the disclosures will require two sheets of paper at a cost $0.05 each, the estimated material cost for the paper disclosures is $14,164. Postage for each paper disclosure is expected to cost $0.55, resulting in a printing and mailing cost of $92,063.

[177] The Department estimates approximately 56.4 percent of participants receive disclosures electronically based on data from various data sources including the National Telecommunications and Information Agency (NTIA). In light of the 2020 Electronic Disclosure Regulation, the Department estimates that additional 35.5 percent of participants receive their disclosures electronically. In total, 91.9 percent of participants are expected to receive disclosures electronically.

[178] *U.S. Retirement-End Investor 2020: Helping Participants Navigating Uncertainty,* The Cerulli Report (2020).

[179] *Id.*

[180] The costs associated with documenting rollover recommendations are estimated and discussed in more details below in the section entitled ''Costs associated with rollover

Continued

The Department sought further comments in the proposed RIA on the costs associated with the required disclosures. In response, a commenter argued that the associated hourly wage of a legal professional used in the Department's cost estimate did not correspond to that of a compliance counselor. The Department acknowledges the importance of taking into account the level of experience and specialization of legal professionals in charge of compliance testing. Accordingly, the Department updated its legal professional's hourly labor rate to reflect the typical compensation of those who provide such services to Financial Institutions.[181]

Costs Associated With Written Policies and Procedures

The Department estimates that developing policies and procedures prudently designed to ensure compliance with the Impartial Conduct Standards will cost approximately $4.4 million in the first year.[182]

The estimated compliance costs reflect the different regulatory baselines under which various entities are currently operating. For example, IAs already operate under a fiduciary standard substantially similar to that required under the exemption,[183] and report how they address conflicts of interests in Form ADV.[184] Similarly, BDs subject to the SEC's Regulation Best Interest also operate under a standard that is substantially similar to the exemption. To comply fully with the exemption, however, these entities may need to review and amend their existing policies and procedures. These additional steps will impose additional, but not substantial, costs at the Financial Institution level.

Insurers and non-retail BDs currently operating under a suitability standard in most states and largely relying on transaction-based forms of compensation, such as commissions, will be required to establish written policies and procedures that comply with the Impartial Conduct Standards if they choose to use this exemption. These activities will likely involve higher cost increases than those experienced by IAs and retail BDs. To a large extent, however, the entities facing potentially higher costs will likely elect to continue to rely on other existing exemptions. In this regard, the burden estimates on these entities are likely overestimated to the extent that many of them would not use this exemption.

Smaller entities may have less complex business practices and arrangements than their larger counterparts, it may cost less for these entities to comply with the exemption. This is reflected in the compliance cost estimates presented in this economic analysis.

Costs Associated With Annual Report of Retrospective Review

Section II(d) of the exemption requires Financial Institutions to conduct an annual retrospective review reasonably designed to ensure that the Financial Institution is in compliance with the Impartial Conduct Standards and its own policies and procedures. Section II(d) further requires the institution to produce a written report on the review that is certified by a Senior Executive Officer of the institution. In the proposal, the Department required certification by the chief executive officer of the Financial Institution, however several comments stated that this requirement is overly burdensome and unnecessary. After careful deliberation, the Department changed the requirement to allow certification from a Senior Executive Officer, which is defined to include any of the following: The chief compliance officer, chief executive officer, president, chief financial officer, or one of the three most senior officers of the Financial Institution, to reduce any unnecessary burden. Furthermore, by having a Senior Executive Officer certify the report, any inadequacies or irregularities may be detected during the review process and addressed appropriately before becoming systematic failures.

Some commenters suggested that this requirement could create the perverse incentive for a Financial Institution to carefully craft the language in the report to avoid any suggestion that any violation has occurred or even that its compliance could be improved. These commenters were particularly concerned because the penalty of noncompliance is severe—loss of exemption and exposure to litigation. In response to these comments, the Department amended the rule to allow Financial Institutions to self-correct certain violations of the exemption by following the procedures specified in Section II(e). Furthermore, Section IV now requires Financial Institution to make records available, to the extent permitted by law, to any authorized employee of the Department and the Department of the Treasury, not to others.[185] The Department believes that these changes will minimize any perverse incentives and encourage Financial Institutions to use the retrospective review process for its intended purposes—to (1) detect any business models creating conflicts of interests, (2) test the adequacies of the policies and procedures, (3) identify any compliance areas for improvements, and (4) update and modify its compliance system based on the review results. As a result, protection for Retirement Investors will be strengthened without imposing any unnecessary burden on Financial Institutions.

The Department estimates that this requirement will impose $15.9 million

documentation.'' To avoid double-counting, this section only includes associated distribution costs of such documentation. As discussed above, the Department estimates that approximately 92 percent of Retirement Investors will receive disclosures electronically, eliminating printing and mailing costs. Thus, providing rollover documentation will increase costs by approximately $240,000.

[181] The hourly wage estimate for an in-house compliance counsel was obtained from Regulation Best Interest Release, 84 FR 33455, note 1304, *www.govinfo.gov/content/pkg/FR-2019-07-12/pdf/2019-12164.pdf.*

[182] The Department assumes that 11,782 Financial Institutions, comprising 1,957 BDs, 6,729 SEC-registered IAs, 2,710 state-registered IAs, and 386 insurers, are likely to engage in transactions covered under this exemption. For a detailed description of how the number of entities is estimated, see the Paperwork Reduction Act section, below. The Department assumes that it will take a legal professional, at an hourly labor rate of $365.39, 22.5 minutes at each small retail BD, 45 minutes at each large retail BD, five hours at each small nonretail BD, 10 hours at each large nonretail BD, 15 minutes at each small IA, 30 minutes at each large IA, five hours at each small insurer, and 10 hours at each large insurer to meet the requirement. This results in a cost burden estimate of $4,393,011. Accordingly, the estimated per-entity cost ranges from $91.35 for small IAs to $3,653.90 for large non-retail BDs and insurers. These compliance cost estimates are not discounted.

[183] *See* SEC Fiduciary Interpretation, 84 FR 33669.

[184] *See Form ADV,* 17 CFR 279.1 (1979). (Part 2A of Form ADV requires IAs to prepare narrative brochures that contain information such as the types of advisory services offered, fee schedules, disciplinary information, and conflicts of interest. For example, item 10.C of part 2A asks IAs to identify if certain relationships or arrangements create a material conflict of interest, and to describe the nature of the conflict and how to address it. If an IA recommends or selects other IAs for its clients, and receives compensation directly or indirectly from those advisers that creates a material conflict of interest, or has other business relationships with those advisers that create a material conflict of interest, an adviser must describe these practices, discuss the material conflicts of interest these practices create, and how the adviser addresses them. *See* Item 10.D of Part 2A of Form ADV.)

[185] In the proposal, Section IV required that the records be made available to (1) any authorized employee of the Department, (2) any fiduciary of a Plan that engaged in an investment transaction pursuant to this exemption, (3) any contributing employer and any employee organization whose members are covered by a Plan that engaged in an investment transaction pursuant to this exemption, or (4) any participant or beneficiary of a Plan or an IRA owner that engaged in an investment transaction pursuant to this exemption.

in costs in the first year.[186] FINRA requires BDs to establish and maintain a supervisory system reasonably designed to facilitate compliance with applicable securities laws and regulations,[187] to test the supervisory system, and to amend the system based on the testing.[188] Furthermore, the BD's chief executive officer (or equivalent officer) must annually certify that it has processes in place to establish, maintain, test, and modify written compliance policies and written supervisory procedures reasonably designed to achieve compliance with FINRA rules.[189]

Many insurance companies are already subject to similar standards.[190] For instance, the NAIC's Model Regulation contemplates that insurance companies establish a supervision system that is reasonably designed to comply with the Model Regulation and annually provide senior management with a written report that details findings and recommendations on the effectiveness of the supervision system.[191] States that have adopted the Model Regulation also require insurance companies to conduct annual audits and obtain certifications from senior managers. Based on these regulatory baselines, the Department believes the compliance costs attributable to this requirement will be modest.

SEC-registered IAs are already subject to Rule 206(4)–97, which requires them to adopt and implement written policies and procedures reasonably designed to ensure compliance with the Advisers Act, and rules adopted thereunder, and review them annually for adequacy and the effectiveness of their implementation. Under the same rule, SEC-registered IAs must designate a chief compliance officer to administer the policies and procedures. However, they are not required to produce a report detailing findings from its audit. Nonetheless, many seem to voluntarily produce reports after conducting internal reviews. One compliance testing survey reveals that about 92 percent of SEC-registered IAs voluntarily provide an annual compliance program review report to senior management.[192] Relying on this information, the Department estimates that only eight percent of SEC-registered IAs advising retirement plans will start to produce a retrospective review report for this exemption.[193] The rest will incur some incremental costs to revise their existing review reports to fully satisfy the conditions related to this requirement.

Due to lack of data, the Department based the cost estimates associated with state-registered IAs on the assumption that eight percent of state-registered IAs advising retirement plans currently do not produce compliance review reports, and, thus, will incur costs associated with the oversight conditions in the exemption. As discussed above, compared with SEC-registered IAs, state-registered IAs tend to be smaller in terms of RAUM and staffing, and, thus, may not have formal procedures in place to conduct retrospective reviews to ensure regulatory compliance. If that were often the case, the Department's assumption would likely underestimate costs. However, because state-registered IAs tend to be smaller than their SEC-registered counterparts, they tend to handle fewer transactions, limit the range of transactions they handle, and have fewer employees to supervise.[194] Therefore, the costs associated with establishing procedures to conduct internal retrospective reviews and produce compliance reports will likely be low.

One commenter mentioned that the Financial Institutions would likely revise their retrospective review reports to fully comply with the exemption even if they already produce the reports to comply with other regulators or to voluntarily improve their compliance system. The Department accepted this comment and incorporated in its compliance cost estimates potential burden increases on all entities relying on this exemption regardless of whether they already produce reports. However, the Department believes that this burden increase will be incremental, because the Department takes a principles-based approach in the exemption and provides Financial Institutions with flexibility to design and perform this review in a way that works best with their business model. Therefore, the Department expects Financial Institutions to develop and implement procedures that are least burdensome and work with their current system to meet the standard set forth in the exemption.

According to another commenter, the Department did not estimate sufficient time for a certifying official to review and certify the retrospective review report. No commenters provided data the Department could use to more accurately estimate the burden associated with this requirement. Despite this lack of data, in response to these comments, the Department substantially increased its estimated burden associated with certification to dispel any misconception that this

[186] The Department assumes that 794 Financial Institutions, comprising 20 BDs, 538 SEC-registered IAs, 217 state-registered IAs, and 20 insurers, would be likely to incur costs associated with producing a retrospective review report. The Department estimates it will take a legal professional, at an hourly labor rate of $365.39, five hours for small firms and ten hours for large firms to produce a retrospective review report, resulting in an estimated cost burden of $2,569,337. The per-entity cost estimate ranges from $1,826.95 for small entities to $3,653.9 for large entities. In addition, the Department assumes that 11,782 Financial Institutions, comprising 1,957 BDs, 6,729 SEC-registered IAs, 2,710 state-registered IAs, and 386 insurers, would be likely to incur costs associated with adding and modifying this report. The Department estimates it will take a legal professional one hour for small firms and two hours for large firms to add and modify the report, resulting in an estimated cost burden of $7,573,614. The estimated per-entity cost ranges from $365.39 for small entities to $730.78 for large entities. Lastly, the Department also assumes that 9,845 Financial Institutions, comprising 20 BDs, 6,729 SEC-registered IAs, 2,710 state-registered IAs, and 386 insurers, would be likely to incur costs associated with reviewing and certifying the report. The Department estimates it will take a certifying officer two hours for small firms and four hours for large firms to review the report and certify the exemption, resulting in an estimated cost burden of $5,750,451. The estimated per-entity cost ranges from $331.26 for small entities to $584.12 for large entities. For a detailed description of how the number of entities for each cost burden is estimated, see the Paperwork Reduction Act section.

[187] *Rule 3110. Supervision,* FINRA Manual, *www.finra.org/rules-guidance/rulebooks/finra-rules/3110.*

[188] *Rule 3120. Supervisory Control System,* FINRA Manual, *www.finra.org/rules-guidance/rulebooks/finra-rules/3120.*

[189] *Rule 3130. Annual Certification of Compliance and Supervisory Processes,* FINRA Manual, *www.finra.org/rules-guidance/rulebooks/finra-rules/3130.*

[190] The previous NAIC Suitability in Annuity Transactions Model Regulation (2010) was adopted by many states before the newer NAIC Model Regulation was approved in 2020. Both previous and updated Model Regulations contain standards similar to that of the written report of retrospective review required under the proposed exemption.

[191] *Suitability in Annuity Transactions Model Regulation,* NAIC Regulation, Section 6.C.(2)(i). (The same requirement is found in the previous NAIC Suitability in Annuity Transactions Model Regulation (2010), Section 6.F.(1)(f).)

[192] *2019 Investment Management Compliance Testing Survey,* Investment Adviser Association (Jun. 18, 2019), *https://www.acacompliancegroup.com/blog/2019-investment-management-compliance-testing-survey-results.*

[193] One commenter questioned the Department's assumption that only the eight percent of SEC- and state-registered IAs that do not currently produce reports will incur costs to produce them. According to this commenter, to fully comply with this exemption, most of the IAs that currently produce reports will need to somewhat modify their current reports. The Department incorporated this comment in this analysis and now assumed that all entities will likely see somewhat modest increases in their costs to make any additional entries in their reports. For more details, see the discussion later in this section.

[194] An examination of state-registered IAs reveals about 80 percent reported only up to two employees. *See* supra note 167.

requirement is a mere formality.[195] The Department expects the certification process will facilitate on-going communications about compliance issues among senior executives and compliance staffers.

In sum, the Department estimates that the costs associated with the retrospective review requirement of the exemption will be approximately $15.9 million in the first year.

Costs Associated With Rollover Documentation

In 2019, slightly more than 3.6 million defined contribution plan accounts rolled over to an IRA, while 0.5 million accounts rolled over to other defined contribution plans.[196] Not all rollovers were managed by financial services professionals. As discussed above, slightly less than half of all rollovers from plans to IRAs were handled by financial services professionals, while the rest were self-directed.[197] Based on this information, the Department estimates slightly less than 1.8 million participants obtained advice from financial services professionals.[198] These rollovers tended to be larger than the self-directed rollovers. For example, in 2019, the average account balance of rollovers by financial services professionals was $169,000, whereas the average account balance of self-directed rollovers was $109,000.[199] Some of these rollovers likely involved financial services professionals who were not fiduciaries under the Department's five-part investment advice fiduciary test; thus, the actual number of rollovers affected by this exemption is likely lower than 1.8 million.

Many commenters discussed various issues concerning rollovers in the five-part test context. In discussing rollovers, they sometimes distinguished new relationships between financial services professionals and investors from existing relationships. A close inspection of rollover data suggests that most rollovers do not occur in a vacuum. Specifically, 87 percent of rollovers handled by financial services professionals were executed by professionals with whom investors had an existing relationship, while only 13 percent were handled by new financial services professionals.[200] Furthermore, rollovers handled by existing financial service professionals were, on average, larger ($174,000) than rollovers handled by new financial service professionals ($132,000).[201]

The exemption requires Financial Institutions to document why a recommended rollover is in the best interest of Retirement Investors and provide that documentation to the Retirement Investor. As a best practice, the SEC already encourages firms to record the basis for significant investment decisions, such as rollovers, although doing so is not required under Regulation Best Interest.[202] In addition, some firms may voluntarily document significant investment decisions to demonstrate compliance with applicable law, even if not required.[203] Therefore, in the proposal, the Department stated that it expects many Financial Institutions already document significant decisions like rollovers.

One commenter disagreed with the Department, stating that the Department's expectation was not realistic. However, a report commissioned by this commenter found that slightly more than half (52 percent) of asset management firms implementing Regulation Best Interest require their financial service professionals to document rollover recommendations. About half require documentation on all recommendations, while 56 percent require documentation for specific product recommendations, such as mutual funds and variable annuities.[204] Since Regulation Best Interest is now in effect, the Department expects that these Financial Institutions already are implementing these policies and procedures. Therefore, the Department assumes that 52 percent of Financial Institutions already require documentation for rollover recommendations, and, thus, will face no more than an incremental burden increase.[205] The remaining 48 percent will face a larger burden increase to implement new documentation procedures for rollover recommendations.

In estimating costs associated with rollover documentations, the Department faces uncertainty in determining the number of rollovers affected by the exemption. The Department assumes that 67.4 percent of rollovers involving financial services professionals will be affected by the exemption.[206] Using this assumption, the estimated costs will be $65 million per year.[207] The Department acknowledges that uncertainty still remain, because the lack of available data makes it difficult to estimate how many financial services professionals may act in a fiduciary capacity when making certain rollover recommendations that meet all elements

[195] The Department assumes that it will take the certifying officer two hours (small firms) or four hours (large firms). If we assume that an average person reads 250 words per minute, this individual can read 30,000 words for two hours or 60,000 words for four hours. This implies a retrospective review report would be approximately 125 pages to 250 pages if this report is written in double space with 12 font size.

[196] U.S. Retirement-End Investor 2020, *supra* note 178. (To estimate costs associated with documenting rollovers, the Department did not include rollovers from plans to plans because plan-to-plan rollovers are unlikely to be mediated by Investment Professionals. Also plan-to-plan rollovers occur far less frequently than plan-to-IRA rollovers. Thus, even if plan-to-plan rollovers were included in the cost estimation, the impact would likely be small.)

[197] *Id.*

[198] Another report suggested that a higher share, 75 percent, of households owning IRAs held their IRAs through Investment Professionals. The same report indicated that about half of traditional IRA-owning households with rollovers primarily relied on professional financial advisers for their rollover decisions. Note that this is household level data based on an IRA owners' survey, which was not particularly focused on rollovers. (*See* Sarah Holden & Daniel Schrass, *The Role of IRAs in US Households' Saving for Retirement, 2019, ICI Research Perspective,* vol. 25, no. 10 (Dec. 2019).)

[199] U.S. Retirement-End Investor 2020, *supra* note 178.

[200] *Id.*

[201] *Id.*

[202] Regulation Best Interest Release, 84 FR 33360.

[203] According to a comment letter about the proposed Regulation Best Interest, BDs have a strong financial incentive to retain records necessary to document that they have acted in the best interest of clients, even if it is not required. Another comment letter about the proposed Regulation Best Interest suggests that BDs generally maintain documentation for suitability purposes.

[204] *Regulation Best Interest: How Wealth Management Firms are Implementing the Rule Package,* Deloitte (Mar. 6, 2020). (This report is based on a survey given to 48 SIFMA member firms providing financial advice and related services to retail customers. The survey ended on December 2, 2019. Ninety percent of survey participant firms were dual registrants.)

[205] Therefore, the Department estimates that 52 percent of rollovers are done by financial professionals whose institutions already require such documentations.

[206] In 2019, a survey was conducted on financial services professionals who hold more than 50 percent of their practice's assets under management in employer-sponsored retirement plans. These financial services professionals include both BDs and IAs. Forty-five percent of those surveyed indicated that they make a proactive effort to pursue IRA rollovers from their DC plan clients, and approximately 32.6 percent reported that they function in a non-fiduciary capacity. Therefore, the Department assumes that approximately 67.4 percent of financial service professionals serve their Plan clients as fiduciaries. (*See U.S. Defined Contribution 2019: Opportunities for Differentiation in a Competitive Landscape,* The Cerulli Report (2019).) The Department assumes that 67.4 percent of 1.8 million rollovers involving financial service professionals will likely be affected by this exemption.

[207] The Department assumes that financial advisors whose firms do not currently document rollover justifications will take, on average, 30 minutes per rollover to comply with this exemption. In contrast, financial advisors whose firms already require such documentation will take, on average, an additional five minutes per rollover to fully satisfy the requirement. The Department estimates over 335,000 burden hours in aggregate and slightly more than $65 million assuming $194.77 hourly rate for a personal financial advisor.

of the five-part test, and, thus, will be affected by the exemption. The Department invited comments and data that could help it more precisely estimate the number of rollovers affected by the exemption and did not receive any comments countering its 67.4 percent assumption. Therefore, the Department maintained that assumption in its cost estimate.

In addition, the Department invited comments about financial services professionals' practices related to documenting rollover recommendations, particularly whether financial services professionals often use a form with a list of common reasons for rollovers and how long, on average, it would take for a financial services professional to document a rollover recommendation. One commenter stated that the Department's proposed estimate was ambitious but reasonable, particularly for firms using compliance software to automate this process. This commenter, however, pointed out that the Department did not take into account the cost associated with purchasing compliance software. According to this commenter, the Department's low estimate for time spent documenting rollovers suggests that hasty and superficial analysis would satisfy this requirement. The Department fervently disagrees with this claim. As explained in the proposal, the Department did not expect this requirement to create an undue burden for the following reasons: (1) Financial services professionals generally seek and gather information on investor profiles in accordance with other regulators' rules; and (2) as a best practice, financial professionals often discuss the basis for their recommendations and associated risks with their clients.[208] Because financial professionals already collect relevant information and discuss the basis for certain recommendations with clients, the Department believes that it would be relatively easy for them to document such information with respect to rollover recommendations.

In addition, as discussed above, a report indicates that the majority of wealth management firms already require their financial service professionals to document rollover recommendations in response to Regulation Best Interest.[209] According to the same report, almost eight in ten firms that require such documentation use a predetermined list for this purpose.[210] Furthermore, approximately three out of four firms surveyed indicated that they would change their technology in response to Regulation Best Interest before it became effective.[211] Some Financial Institutions might have elected not to enhance their technologies in the wake of Regulation Best Interest because they recently updated their technology capabilities or decided to rely more on manual processes. This implies that most Financial Institutions are not likely to incur large technological costs, such as purchasing compliance software to comply with this exemption. Therefore, the Department assumes Financial Institutions that have not enhanced technology capabilities for other regulator's rule will take a mixed approach, combining current technology solutions with manual processes.

In sum, the Department estimates that Financial Institutions already requiring rollover documentation will face no more than a nominal burden increase, and only to the extent that their current compliance systems do not meet the requirements of this exemption. Those firms currently not documenting rollover recommendations will likely face a larger, but still somewhat limited, burden increase due to the reasons discussed above.

Costs Associated With Recordkeeping

Section IV of the exemption requires Financial Institutions to maintain records demonstrating compliance with the exemption for six years. The Financial Institutions are required to make records available to the Department and the Department of the Treasury. Recordkeeping requirements in Section IV are generally consistent with requirements made by the SEC and FINRA.[212] In addition, the recordkeeping requirements correspond to the six-year period in section 413 of ERISA. The Department understands that many firms already maintain records, as required in Section IV, as part of their regular business practices. Therefore, the Department expects that the recordkeeping requirement in Section IV would impose a negligible burden.[213] The Department solicited comments regarding the recordkeeping burden in the proposed regulatory impact analysis but did not receive any comments disagreeing with the Department's approach. Therefore, the Department took the same approach in this final regulatory impact analysis.

Table 1 provides a summary of the associated costs discussed.

[208] FINRA, Reg BI and Form CRS Firm Checklist. Also Regulation Best Interest Release 84 FR 33360 (July 12, 2019).

[209] *Regulation Best Interest: How Wealth Management Firms are Implementing the Rule Package,* Deloitte (Mar. 6, 2020). The participating firms in this study included dual-registrants, BDs and RIAs that were owned by or affiliated with banks, holding companies, insurance companies, and trust companies, as well as independent dually-registered BDs and RIAs. 90% of participating firms were dual registrants.

[210] *Id.*

[211] *Id.*

[212] The SEC's Regulation Best Interest amended Rule 17a–4(e)(5) requires that BDs retain all records of the information collected from or provided to each retail customer pursuant to Regulation Best Interest for at least six years after the date the account was closed or the date on which the information was last replaced or updated, whichever comes first. FINRA Rule 4511 also requires its members to preserve for a period of at least six years those FINRA books and records for which there is no specified period under the FINRA rules or applicable Exchange Act rules.

[213] The Department notes that the insurers most likely to use the exemption are generally not subject to the SEC's Regulation Best Interest and FINRA rules. The Department understands, however, that some states' insurance regulations require insurers to retain similar records for less than six years. For example, some states require insurers to maintain records for five years after the insurance transaction is completed. Thus, the recordkeeping requirement of the proposed exemption will likely impose an additional burden on the insurers that rely on this exemption. However, the Department expects most insurers to maintain records electronically. Electronic storage prices have decreased substantially as cloud services become more widely available. For example, cloud storage space costs, on average, $0.018 to $0.021 per GB per month. Some estimate that approximately 250,000 PDF files or other typical office documents can be stored on 100GB. Accordingly, the Department believes that maintaining records in electronic storage for an additional year or two will not impose a significant cost burden on the affected insurers. (For more detailed pricing information of three large cloud service providers, *see https://cloud.google.com/products/calculator, https://azure.microsoft.com/en-us/pricing/calculator,* or *https://calculator.s3.amazonaws.com/index.html.*)

TABLE 1—ASSOCIATED COSTS SUMMARY

[$ Millions]

Requirement	First year	Subsequent years
Disclosures	$2.2	$0.2
Policies and Procedures	4.4	-
Rollover Documentation	65.3	65.3
Annual Report of Retrospective Review	15.9	13.3
Total	87.8	78.9

Note: Totals in table may not sum precisely due to rounding.

Regulatory Alternatives

The Department considered various alternative approaches in developing this exemption that are discussed below.

No New Exemption

The Department considered merely leaving in place the existing exemptions that provide prohibited transaction relief for investment advice transactions. However, the existing exemptions generally apply to more limited categories of transactions and investment products, and they include conditions that are tailored to the particular transactions or products covered under each exemption. Therefore, under the existing exemptions, Financial Institutions may find it inefficient to implement advice programs for all the different products and services they offer. By providing a single set of conditions for a wide variety of investment advice transactions, this exemption allows the use and availability of investment advice for a variety of types of transactions in a manner that aligns with the conduct standards of other regulators, such as the SEC.

Keeping FAB 2018–02

Similarly, the Department considered keeping FAB 2018–02 in effect without finalizing this exemption. However, the Department rejected this alternative, because FAB 2018–02 was intended to be a temporary policy. Furthermore, replacing the relief provided in FAB 2018–02 with a permanent exemption will provide certainty and stability to Financial Institutions and Investment Professionals that may currently be relying on the temporary enforcement policy. The final exemption includes conditions designed to support investment advice that meets the Impartial Conduct Standards.

To provide a transition period for Financial Institutions relying on FAB 2018–02 to comply with the final exemption, the Department has announced that FAB 2018–02 will remain in effect place for one year after the final exemption is published. This will allow some Financial Institutions to defer incurring compliance costs associated with this exemption for a limited period. The cost estimates discussed in this regulatory impact analysis are overstated to the extent such costs are deferred. On the other hand, the benefits discussed in this analysis will not be fully realized to the extent that some Financial Institutions rely on FAB 2018–02 during the transition period. However, the Department believes that most Financial Institutions will begin complying with all the conditions of the final exemption before the end of the transition period, because it provides protection from private litigation and Financial Institutions will be better positioned in an extremely competitive market.

Including an Independent Audit Requirement in the Exemption

This exemption will require Financial Institutions to conduct a retrospective review, at least annually, designed to detect and prevent violations of the Impartial Conduct Standards and to ensure compliance with the policies and procedures governing the exemption. The exemption does not require that the review be conducted by an independent party, allowing Financial Institutions to self-review.

As an alternative to this approach, the Department considered requiring independent audits to ensure compliance under the exemption. The Department decided against this approach, because it is not convinced that an independent, external audit would yield sufficient benefits in addition to the results of the retrospective review to justify the increased cost, especially in the case of smaller Financial Institutions. This exemption instead requires that Financial Institutions provide a written report documenting the retrospective review, and supporting information, to the Department and within 10 business days of a request. The Department believes this requirement compels Financial Institutions to take the review obligation seriously, regardless of whether they choose to hire an independent auditor to conduct the review.

While the proposal stated that the Financial Institution's chief executive officer (or equivalent) must certify the retrospective review, the final exemption provides, instead, that the retrospective review may be certified by any of the Financial Institution's Senior Executive Officers. The exemption defines a ''Senior Executive Officer'' as any of the following: The chief compliance officer, the chief executive officer, president, chief financial officer, or one of the three most senior officers of the Financial Institution. In making this change, the Department accepts the views of a number of commenters that stated that the CEO should not be the only person who can provide a certification regarding the retrospective review.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Department solicited comments concerning the information collection request (ICR) included in the proposed exemption entitled ''Improving Investment Advice for Workers & Retirees'' (85 FR 40834). At the same time, the Department also submitted an information collection request (ICR) to the Office of Management and Budget (OMB), in accordance with 44 U.S.C. 3507(d). OMB filed a comment on the proposed rule with the Department on September 21, 2020, requesting the Department to provide a summary of comments received on the ICR and identify changes to the ICR made in response to the comments. OMB did not approve the ICR and requested the Department to file future submissions of the ICR under OMB control number 1210–0163.

The Department received no comments that specifically addressed the paperwork burden analysis of the

information collections. Additionally, comments were submitted which contained information relevant to the costs and administrative burdens attendant to the proposed exemption. The Department considered such public comments in connection with making changes to the final exemption, analyzing the economic impact of the proposal, and developing the revised paperwork burden analysis summarized below.

In connection with publication of this final exemption, the Department is submitting an ICR to OMB requesting approval of a new collection of information under OMB Control Number 1210–0163. The Department will notify the public when OMB approves the ICR.

A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *www.RegInfo.gov.*

PRA Addressee: Address requests for copies of the ICR to G. Christopher Cosby, Office of Regulations and Interpretations, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC, 20210. Telephone (202) 693–8425; Fax: (202) 219–5333; (*cosby.chris@dol.gov*). These are not toll-free numbers. ICRs submitted to OMB also are available at *www.RegInfo.gov.*

As discussed in detail below, the exemption requires Financial Institutions and/or their Investment Professionals to (1) make certain disclosures to Retirement Investors, (2) adopt written policies and procedures, (3) document the basis for rollover recommendations, (4) prepare a written report of the retrospective review, and (5) maintain records showing that the conditions have been met to receive relief under the exemption. These requirements are ICRs subject to the Paperwork Reduction Act. The Department has made the following assumptions in order to establish a reasonable estimate of the paperwork burden associated with these ICRs:

- Disclosures distributed electronically will be distributed via means already used by respondents in the normal course of business, and the costs arising from electronic distribution will be negligible;
- Financial Institutions will use existing in-house resources to prepare the disclosures, policies and procedures, rollover documentations, and retrospective reviews, and to maintain the recordkeeping systems necessary to meet the requirements of the exemption;
- A combination of personnel will perform the tasks associated with the ICRs at an hourly wage rate of $194.77 for a personal financial advisor, $64.11 for mailing clerical personnel, and $365.39 for a legal professional;[214]
- Approximately 11,782 Financial Institutions will take advantage of the exemption and they will use the exemption in conjunction with transactions involving nearly all their clients that are defined benefit plans, defined contribution plans, and IRA holders.[215]

The exemption's impact on the hour and cost burden associated with the Department's information collections are discussed in more detail below.

Disclosures, Documentation, Retrospective Review, and Recordkeeping

Section II(b) of the exemption requires Financial Institutions to furnish Retirement Investors with a disclosure prior to engaging in a covered transaction. Section II(b)(1) requires Financial Institutions to acknowledge in writing that the Financial Institution and its Investment Professionals are fiduciaries under Title I and the Code, as applicable, with respect to any investment advice provided to the Retirement Investors. Section II(b)(2) requires Financial Institutions to provide a written description of the services they provide and any material conflicts of interest. The written description must be accurate in all material respects. Financial Institutions will generally be required to provide the disclosure to each Retirement Investor once, but Financial Institutions may need to provide updated disclosures to ensure accuracy. Section II(b)(3) requires Financial Institutions to provide the documentation of specific reasons for the rollover recommendation to the Retirement Investor.

Section II(c)(1) of the exemption requires Financial Institutions to establish, maintain, and enforce written policies and procedures prudently designed to ensure that they and their Investment Professionals comply with the Impartial Conduct Standards. Section II(c)(2) further requires that the Financial Institutions design the policies and procedures to mitigate conflicts of interest. Section II(c)(3) of the exemption requires Financial Institutions to document the specific reasons for any rollover recommendation and show that the rollover is in the best interest of the Retirement Investor.

Under Section II(d) of the exemption, Financial Institutions are required to conduct an annual retrospective review that is reasonably designed to prevent violations of the exemption's Impartial Conduct Standards and the institution's own policies and procedures. The methodology and results of the retrospective review are reduced to a written report that is certified by a Senior Executive Officer of the Financial Institution. The certifying officer will be required to verify that (1) the officer has reviewed the report of the retrospective review, (2) the Financial Institution has in place policies and procedures prudently designed to achieve compliance with the conditions of the exemption, and (3) the Financial Institution has a prudent process for modifying such policies and procedures. The process for modifying policies and procedures will need to be responsive to business, regulatory, and legislative changes and events, and the Financial Institution will be required to periodically test their effectiveness. The review, report, and certification must be completed no later than six months following the end of the period covered by the review. The Financial Institution will be required to retain the report, certification, and supporting data for at least six years, and to make these items available to the Department within 10 business days of the request.

Section IV sets forth the recordkeeping requirements in the exemption.

Production and Distribution of Required Disclosures

The Department assumes that 11,782 Financial Institutions, comprising 1,957

[214] The Department's 2018 hourly wage rate estimates include wages, benefits, and overhead, and are calculated as follows: Mean wage (from the 2018 National Occupational Employment Survey, May 2018, *www.bls.gov/news.release/archives/ocwage_03292019.pdf*), wages as a percent of total compensation (from the Employer Cost for Employee Compensation, December 2018, *www.bls.gov/news.release/archives/ecec_03192019.pdf*), and overhead cost corresponding to each 2-digit NAICS code (from the Annual Survey of Manufacturers, December 2017, *www.census.gov/data/Tables/2016/econ/asm/2016-asm.html*) multiplied by the percent of each occupation within that NAICS industry code based on a matrix of detailed occupation employment for each NAICS industry (from the BLS Office of Employment projections, 2016, *www.bls.gov/emp/data/occupational-data.htm*).

[215] For this analysis, ''IRA holders'' include rollovers from Title I Plans.

BDs,[216] 6,729 SEC-registered IAs,[217] 2,710 state-registered IAs,[218] and 386 insurance companies,[219] are likely to engage in transactions covered under this exemption. Each will need to provide disclosures that (1) acknowledge its fiduciary status, and (2) identify the services it provides and any material conflicts of interest. The Department estimates that preparing a disclosure indicating fiduciary status would take a legal professional between five and 30 minutes, depending on the nature of the business,[220] resulting in an hour burden of 1,599[221] and a cost burden of $584,130.[222] Preparing a disclosure identifying services provided and conflicts of interest would take a legal professional an estimated five minutes to five hours, depending on the nature of the business,[223] resulting in an hour burden of 3,691[224] and an equivalent cost burden of $1,348,628.[225]

The Department estimates that approximately 1.8 million Retirement Investors[226] have relationships with Financial Institutions and are likely to engage in transactions covered under this exemption. Of these 1.8 million Retirement Investors, it is assumed that 8.1 percent[227] or 141,636 Retirement Investors, will receive paper disclosures. Distributing paper disclosures is estimated to take a clerical professional one minute per disclosure, resulting in an hourly burden of 2,361[228] and an equivalent cost burden of $151,341.[229] Assuming the disclosures will require two sheets of paper at a cost $0.05 each, the estimated material cost for the paper disclosures is $14,164. Postage for each paper disclosure is expected to cost $0.55, resulting in a printing and mailing cost of $92,063.

Written Policies and Procedures Requirement

The Department assumes that 11,782 Financial Institutions, comprising 1,957 BDs,[230] 6,729 SEC-registered IAs,[231] 2,710 state registered IAs,[232] and 386 insurance companies,[233] are likely to engage in transactions covered under this exemption. The Department estimates that establishing, maintaining, and enforcing written policies and procedures prudently designed to ensure compliance with the Impartial Conduct Standards will take a legal professional between 15 minutes and 10 hours, depending on the nature of the business.[234] This results in an hour burden of 12,023[235] and an equivalent cost burden of $4,393,011.[236]

Rollover Documentation Requirement

To meet the requirement of the rollover documentation, Financial Institutions must document the specific reasons that any recommendation to roll over assets is in the best interest of the Retirement Investor. The Department

[216] The SEC estimated that there were 3,764 BDs as of December 2018 (*see* Form CRS Relationship Summary Release). The IAA Compliance 2019 Survey estimates that 52 percent of IAs have a pension consulting business. The estimated number of BDs affected by this exemption is the product of the SEC's estimate of total BDs in 2018 and IAA's estimate of the percent of IAs with a pension consulting business.

[217] The SEC estimated that there were 12,940 SEC-registered IAs that were not dually registered as BDs as of December 2018 (*see* Form CRS Relationship Summary Release). The IAA Compliance 2019 Survey estimates that 52 percent of IAs have a pension consulting business. The estimated number of IAs affected by this exemption is the product of the SEC's estimate of SEC-registered IAs in 2018 and the IAA's estimate of the percent of IAs with a pension consulting business.

[218] The SEC estimated that there were 16,939 state-registered IAs that were not dually registered as BDs as of December 2018 (*see* Form CRS Relationship Summary Release). The NASAA 2019 estimates that 16 percent of state-registered IAs have a pension consulting business. The estimated number of state-registered IAs affected by this exemption is the product of the SEC's estimate of state-registered IAs in 2018 and NASAA's estimate of the percent of state-registered IAs with a pension consulting business.

[219] NAIC estimates that the number of insurers directly writing annuities as of 2018 is 386.

[220] The Department assumes that it will take each retail BD firm 15 minutes, each nonretail BD or insurance firm 30 minutes, and each registered IA five minutes to prepare a disclosure conveying fiduciary status.

[221] Burden hours are calculated by multiplying the estimated number of each firm type by the estimated time it will take each firm to prepare the disclosure.

[222] The hourly cost burden is calculated by multiplying the burden hour of each firm associated with preparation of the disclosure by the hourly wage of a legal professional.

[223] The Department assumes that it will take each retail BD or IA firm five minutes, each small nonretail BD or small insurer 60 minutes, and each large nonretail BDs or large insurer five hours to prepare a disclosure conveying services provided and conflicts of interest.

[224] Burden hours are calculated by multiplying the estimated number of each firm type by the estimated time it will take each firm to prepare the disclosure.

[225] The hourly cost burden is calculated by multiplying the burden hour of each firm associated with preparation of the disclosure by the hourly wage of a legal professional.

[226] The Department estimates the number of affected Plans and IRAs be approximately equal to 49 percent of rollovers from defined contribution plans to IRAs. Cerulli has estimated the number of accounts in defined contribution plans rolled into IRAs to be 3,593,592 (*see* U.S. Retirement-End Investor 2020, *supra* note 178).

[227] According to data from the National Telecommunications and Information Agency (NTIA), 37.7 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure if automatically enrolled (for a total of 31.7 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.5 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 31.7 percent who receive electronic disclosure at work with the 24.7 percent who receive electronic disclosure outside of work produces a total of 56.4 percent who will receive electronic disclosure overall. In light of the 2019 Electronic Disclosure Regulation, the Department estimates that 81.5 percent of the remaining 43.6 percent of individuals will receive the disclosures electronically. In total, 91.9 percent of participants are expected to receive disclosures electronically.

[228] Burden hours are calculated by multiplying the estimated number of plans receiving the disclosures non-electronically by the estimated time it will take to prepare the physical disclosure.

[229] The hourly cost burden is calculated as the burden hours associated with the physical preparation of each non-electronic disclosure by the hourly wage of a clerical professional.

[230] The SEC estimated that there were 3,764 BDs as of December 2018 (*see* Form CRS Relationship Summary Release). The IAA Compliance 2019 Survey estimates that 52 percent of IAs have a pension consulting business. The estimated number of BDs affected by this exemption is the product of the SEC's estimate of total BDs in 2018 and IAA's estimate of the percent of IAs with a pension consulting business.

[231] The SEC estimated that there were 12,940 SEC-registered IAs, who were not dually registered as BDs, as of December 2018 (*see* Form CRS Relationship Summary Release). The IAA Compliance 2019 Survey estimates that 52 percent of IAs have a pension consulting business. The estimated number of IAs affected by this exemption is the product of the SEC's estimate of SEC-registered IAs in 2018 and IAA's estimate of the percent of IAs with a pension consulting business.

[232] The SEC estimated that there were 16,939 state-registered IAs who were not dually registered as BDs as of December 2018 (*see* Form CRS Relationship Summary Release). The NASAA 2019 estimates that 16 percent of state-registered IAs have a pension consulting business. The estimated number of state-registered IAs affected by this exemption is the product of the SEC's estimate of state-registered IAs in 2018 and NASAA's estimate of the percent of state-registered IAs with a pension consulting business.

[233] NAIC estimates that 386 insurers were directly writing annuities as of 2018.

[234] The Department assumes that it will take each small retail BD 22.5 minutes, each large retail BD 45 minutes, each small nonretail BD five hours, each large nonretail BD 10 hours, each small IA 15 minutes, each large IA 30 minutes, each small insurer five hours, and each large insurer 10 hours to meet the requirement.

[235] Burden hours are calculated by multiplying the estimated number of each firm type by the estimated time it will take each firm to establish, maintain, and enforce written policies and procedures.

[236] The hourly cost burden is calculated as the burden hour of each firm associated with meeting the written policies and procedures requirement multiplied by the hourly wage of a legal professional.

estimates that 1.8 million defined contribution plan accounts rolled into IRAs in accordance with advice from a financial services professional.[237] Facing uncertainty, the Department assumes that 67.4 percent of rollovers will be affected by the exemption.[238] Under this assumption, the Department estimates that the costs for documenting the basis for rollover decisions will come to $65 million per year.[239] This was based on the assumption that most financial services professionals already incorporate documenting the basis for rollover recommendations in their regular business practices and another assumption that 67.4 percent of rollovers are handled by financial services professionals who act in a fiduciary capacity.[240] The Department estimates that documenting each rollover recommendation will require 30 minutes for a personal financial advisor whose firms currently do not require rollover documentations and five minutes for financial advisors whose firms already require them to do so,[241] resulting in 335,330 [242] burden hours and an equivalent cost burden of $65,313,770.[243]

Annual Retrospective Review Requirement

Under the internal retrospective review requirement, a Financial Institution is required to (1) conduct an annual retrospective review reasonably designed to assist the Financial Institution in detecting and preventing violations of, and achieving compliance with the Impartial Conduct Standards and their policies and procedures; and (2) produce a written report that is certified by a Senior Executive Officer of the Financial Institution.

The Department understands that, as per FINRA Rule 3110,[244] FINRA Rule 3120,[245] and FINRA Rule 3130,[246] broker-dealers are already held to a standard functionally identical to that of the retrospective review requirements of this exemption. Accordingly, in this analysis, the Department assumes that broker-dealers will incur minimal costs to meet this requirement. In 2018, the Investment Adviser Association estimated that 92 percent of SEC-registered IAs voluntarily provide an annual compliance program review report to senior management.[247] The Department estimates that only eight percent, or 538,[248] of SEC-registered IAs advising retirement plans will incur costs associated with producing a retrospective review report. Due to lack of data, the Department assumes that state-registered IAs exhibit similar retrospective review patterns and estimates that eight percent, or 217,[249] of state-registered IAs will also incur costs associated with producing a retrospective review report.

As SEC-registered IAs are already subject to SEC Rule 206(4)–7, the Department assumes these IAs will incur minimal costs to satisfy the conditions related to this requirement. Insurance companies in many states are already subject state insurance law based on the NAIC's Model Regulation.[250] Thus, the Department assumes that insurance companies will incur negligible costs associated with producing a retrospective review report. This is estimated to take a legal professional five hours for small firms and 10 hours for large firms, depending on the nature of the business. This results in an hour burden of 7,032 [251] and an equivalent cost burden of $2,569,337.[252]

Financial Institutions that already produce retrospective review reports voluntarily or in accordance with other regulators' rules likely will spend additional time to fully comply with this exemption condition such as revising their current retrospective review reports. This is estimated to take a financial professional one hour for small firms and two hours for large firms, depending on the nature of the business. This results in an hour burden of 20,727 hours and an equivalent cost burden of $7,573,614.

In addition to conducting the audit and producing a report, Financial Institutions also will need to review the report and certify the exemption. The Department substantially increased the burden hours associated with this requirement in response to concerns raised by a commenter that this is a superficial process.[253] This is estimated to take the certifying officer two hours for small firms and four hours for large firms, depending on the nature of the business.[254] This results in an hour

[237] Cerulli has estimated the number of accounts in defined contribution plans rolled into IRAs to be 3,593,591 (*see* U.S. Retirement-End Investor 2020, *supra* note 178). The Department estimates that 49 percent of these rollovers will be handled by a financial professional.

[238] *See supra* note 206.

[239] *See supra* note 207.

[240] *See supra* note 206.

[241] *See supra* note 207.

[242] Burden hours are calculated by multiplying the estimated number of rollovers affected by this proposed exemption by the estimated hours needed to document each recommendation.

[243] The hourly cost burden is calculated as the burden hour of each firm associated with meeting the rollover documentation requirement multiplied by the hourly wage of a personal financial advisor.

[244] *Rule 3110. Supervision,* FINRA Manual, *www.finra.org/rules-guidance/rulebooks/finra-rules/3110.*

[245] *Rule 3120. Supervisory Control System,* FINRA Manual, *www.finra.org/rules-guidance/rulebooks/finra-rules/3120.*

[246] *Rule 3130. Annual Certification of Compliance and Supervisory Processes,* FINRA Manual, *www.finra.org/rules-guidance/rulebooks/finra-rules/3130.*

[247] *2018 Investment Management Compliance Testing Survey,* Investment Adviser Association (Jun. 14, 2018), *https://higherlogicdownload.s3.amazonaws.com/INVESTMENTADVISER/aa03843e-7981-46b2-aa49-c572f2ddb7e8/UploadedImages/publications/2018-Investment-Management_Compliance-Testing-Survey-Results-Webcast_pptx.pdf.*

[248] The SEC estimated that there were 12,940 SEC-registered IAs that were not dually registered as BDs as of December 2018 (*see* Form CRS Relationship Summary Release). The IAA Compliance 2019 Survey estimates that 52 percent of IAs have a pension consulting business. The IAA Investment Management Compliance Testing Survey estimates that 92 percent of SEC-registered IAs provide an annual compliance program review report to senior management. The estimated number of IAs affected by this exemption who do not meet the retrospective review requirement is the product of the SEC's estimate of SEC-registered IAs in 2018, the IAA's estimate of the percent of IAs with a pension consulting business, and IAA's estimate of the percent of IA's who do not provide an annual compliance program review report.

[249] The SEC estimated that there were 16,939 state-registered IAs that were not dually registered as BDs as of December 2018 (*see* Form CRS Relationship Summary Release). The NASAA 2019 estimates that 16 percent of state-registered IAs have a pension consulting business. The IAA Investment Management Compliance Testing Survey estimates that 92 percent of SEC-registered IAs provide an annual compliance program review report to senior management. The Department assumes state-registered IAs exhibit similar retrospective review patterns as SEC-registered IAs. The estimated number of state-registered IAs affected by this exemption is the product of the SEC's estimate of state-registered IAs in 2018, NASAA's estimate of the percent of state-registered IAs with a pension consulting business, and IAA's estimate of the percent of IA's who do not provide an annual compliance program review report.

[250] NAIC Model Regulation, Section 6.C.(2)(i) (The same requirement is found in the NAIC Suitability in Annuity Transactions Model Regulation (2010), Section 6.F.(1)(f).)

[251] Burden hours are calculated by multiplying the estimated number of each firm type by the estimated time it will take each firm to review the report and certify the exemption.

[252] The hourly cost burden is calculated by multiplying the burden hours for reviewing the report and certifying the exemption requirement by the hourly wage of a legal professional.

[253] For more detailed discussion, see the corresponding Cost section of the Regulatory Impact Analysis above.

[254] Due to lack of data, the Department estimates the hourly labor cost of a certifying officer to be that of a Financial Manager, as outlined on the Employee Benefits Security Administration's 2018 labor rate estimates. See *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculation,* Employee Benefits Security Administration (June 2019), *www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-*

Continued

burden of 34,718[255] and an equivalent cost burden of $5,750,451.[256]

Overall Summary

Overall, the Department estimates that in order to satisfy the exemption, 11,782 Financial Institutions will produce 1.8 million disclosures and notices annually. These disclosures and notices will result in 417,480 burden hours during the first year and 393,136 burden hours in subsequent years, at an equivalent cost of $87.7 million and $78.8 million respectively. The disclosures and notices in this exemption will also result in a total cost burden for materials and postage of $92,063 annually.

These paperwork burden estimates are summarized as follows:

- *Type of Review:* New collection.
- *Agency:* Employee Benefits Security Administration, Department of Labor.
- *Title:* Improving Investment Advice for Workers & Retirees.
- *OMB Control Number:* 1210–0163.
- *Affected Public:* Business or other for-profit institution.
- *Estimated Number of Respondents:* 11,782.
- *Estimated Number of Annual Responses:* 1,755,959.
- *Frequency of Response:* Initially, Annually, and when engaging in exempted transaction.
- *Estimated Total Annual Burden Hours:* 417,480 during the first year and 393,136 in subsequent years.
- *Estimated Total Annual Burden Cost:* $92,063 during the first year and $92,063 in subsequent years.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[257] imposes certain requirements on rules subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act or any other law.[258] Under section 604 of the RFA, agencies must submit a final regulatory flexibility analysis (FRFA) of a proposal that is likely to have a significant economic impact on a substantial number of small entities, such as small businesses, organizations, and governmental jurisdictions.

The Department has determined that this final class exemption will likely have a significant economic impact on a substantial number of small entities. Therefore, the Department has prepared the FRFA presented below.

Need for and Objectives of the Rule

As discussed earlier in this preamble, the final class exemption will allow investment advice fiduciaries to receive compensation and engage in transactions that would otherwise violate the prohibited transaction provisions of Title I and the Code. As such, the final exemption will provide Financial Institutions and Investment Professionals with flexibility to address different business models and would lessen their overall regulatory burden by coordinating potentially overlapping regulatory requirements. The exemption conditions, including the Impartial Conduct Standards and other conditions supporting the standards, are expected to provide protections to Retirement Investors. Therefore, the Department expects that the final exemption will benefit Retirement Investors that are small entities and provide efficiencies to small Financial Institutions.

Significant Issues Raised by Public Comments

In response to the Department's Initial Regulatory Flexibility Analysis (IRFA), no significant issue was raised by public comments. In the preamble to the proposed class exemption, the Department solicited comments regarding whether the proposed exemption would have a significant economic impact on a substantial number of small entities and received no comments in response. Moreover, the Department received no public comments from the Small Business Administration. As a result, the Department made no major changes to the IFRA.

Affected Small Entities

The Small Business Administration (SBA),[259] pursuant to the Small Business Act,[260] defines small businesses and issues size standards by industry. The SBA defines a small business in the Financial Investments and Related Activities Sector as a business with up to $41.5 million in annual receipts. Due to a lack of data and shared jurisdiction, for purpose of performing Regulatory Flexibility Analyses pursuant to section 601(3) of the Regulatory Flexibility Act, the Department, after consultation with SBA's Office of Advocacy, defines small entities included in this analysis differently from the SBA definitions.[261] For instance, in this analysis, the small-business definitions for BDs and SEC-registered IAs are consistent with the SEC's definitions, as these entities are subject to the SEC's rules as well as the Act.[262] As with SEC-registered IAs, the size of state-registered IAs is determined based on total value of the assets they manage.[263] The size of insurance companies is based on annual sales of annuities. The Department requested comments on the appropriateness of the size standard used to evaluate the impact of the proposed exemption on small entities and received no comments in response. In particular, the Department received no comments asserting that it is inappropriate for the Department to use size standards that are different from those promulgated by the SBA.

In December 2018, there were 985 small-business BDs and 528 SEC-registered, small-business IAs.[264] The Department estimates that approximately 52 percent of these small-businesses will be affected by the final class exemption.[265] In December 2018, the Department estimates there were approximately 10,840 small state-registered IAs,[266] of which about 1,700 are estimated to be affected by the final exemption.[267] There were

june-2019.pdf. The Department assumes that it will take the certifying officer two hours for small firms and four hours for large firms. If we assume that an average person reads 250 words per minute, the certifying officer can read 30,000 words in two hours or 60,000 words in four hours. This implies a retrospective review report would be approximately 125 pages to 250 pages if this report is double-spaced with a with 12 point font size.

[255] Burden hours are calculated by multiplying the estimated number of each firm type by the estimated time it will take each firm to review the report and certify the exemption.

[256] The hourly cost burden is calculated by multiplying the burden hours for reviewing the report and certifying the exemption requirement by the hourly wage of a financial professional.

[257] 5 U.S.C. 601 *et seq.*

[258] 5 U.S.C. 601(2), 603(a); *see also* 5 U.S.C. 551.

[259] 13 CFR 121.201.

[260] 15 U.S.C. 631 *et seq.*

[261] The Department consulted with the Small Business Administration Office of Advocacy in making this determination as required by 5 U.S.C. 603(c).

[262] 17 CFR parts 230, 240, 270, and 275, *www.sec.gov/rules/final/33-7548.txt.*

[263] Due to lack of available data, the Department includes state-registered IAs managing assets less than $30 million as small entities in this analysis.

[264] *See Form CRS Relationship Summary; Amendments to Form ADV,* 84 FR 33492 (Jul. 12, 2019).

[265] *2019 Investment Management Compliance Testing Survey,* Investment Adviser Association (Jun. 18, 2019), *https://higherlogicdownload.s3.amazonaws.com/INVESTMENTADVISER/aa03843e-7981-46b2-aa49-c572f2ddb7e8/UploadedImages/about/190618_IMCTS_slides_after_webcast_edits.pdf.*

[266] The SEC estimates there were approximately 17,000 state-registered IAs (*see Form CRS Relationship Summary; Amendments to Form ADV,* 84 FR 33492 (Jul. 12, 2019)). The Department estimates that about 64 percent of state-registered IAs manage assets less than $30 million, and it considers such entities small businesses. (*See 2018 Investment Adviser Section Annual Report,* North American Securities Administrators Association (May 2018), *www.nasaa.org/wp-content/uploads/2018/05/2018-NASAA-IA-Report-Online.pdf.*) Therefore, the Department estimates there were about 10,840 small, state-registered IAs.

[267] Of the small, state-registered IAs, the Department estimates that 16 percent provide

approximately 386 insurers directly writing annuities in 2018,[268] 316 of which the Department estimates are small entities.[269] Table 1 summarizes the distribution of affected entities by size.

TABLE 2—DISTRIBUTION OF AFFECTED ENTITIES BY SIZE

	BDs		SEC-registered IAs		State-registered IAs		Insurers	
Small	985	26%	528	4%	10,840	64%	316	82%
Large	2,779	74%	12,412	96%	6,099	36%	70	18%
Total	3,764	100%	12,940	100%	16,939	100%	386	100%

Projected Reporting, Recordkeeping, and Other Compliance Requirements

As discussed above, the final exemption provides Financial Institutions and Investment Professionals with flexibility to choose between the new final exemption or the Department's existing exemptions, depending on their individual needs and business models. Furthermore, the final exemption provides Financial Institutions and Investment Professionals broader, more flexible prohibited transaction relief than is currently available, while safeguarding the interests of Retirement Investors. In this regard, this final exemption could present a less burdensome compliance alternative for some Financial Institutions because it would allow them to streamline compliance rather than rely on multiple exemptions with multiple sets of conditions.

This final exemption simply provides an additional alternative pathway for Financial Institutions and Investment Professionals to receive compensation and engage in certain transactions that would otherwise be prohibited under Title I and the Code. Financial Institutions would incur costs to comply with conditions set forth in the final exemption. However, the Department believes the costs associated with those conditions are modest because the final exemption was developed in consideration of other regulatory conduct standards. The Department believes that many Financial Institutions and Investment Professionals have already developed compliance structures for similar regulatory standards. Therefore, the Department does not expect that the final exemption will impose a significant compliance burden on small entities. For example, the Department estimates that a small entity would incur, on average, an additional $3,034 in compliance costs to meet the conditions of this final exemption. These additional costs represent 0.6 percent of the net capital of BD with $500,000. A BD with less than $500,000 in net capital is generally considered small, according to the SEC.

Steps Taken To Minimize Impacts and Significant Alternatives Considered

Section 604 of the RFA requires the Department to consider significant alternatives that would accomplish the stated objective, while minimizing any significant adverse impact on small entities. Title I and the Code rules governing advice on the investment of retirement assets overlap with SEC rules that govern the conduct of IAs and BDs who advise retail investors. The Department considered conduct standards set by other regulators, such as SEC, state insurance regulators, and FINRA, in developing the final exemption, with the goal of avoiding overlapping or duplicative requirements. To the extent the requirements overlap, compliance with the other disclosure or recordkeeping requirements can be used to satisfy the exemption, provided the conditions are satisfied. This will lead to overall regulatory efficiency.

The Department describes below additional steps it has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternatives adopted in the final exemption.

Revisions to Annual Retrospective Review Requirement: Under section II(d) of the final exemption, Financial Institutions are required to conduct an annual retrospective review that is reasonably designed to detect and prevent violations of, and achieve compliance with, the Impartial Conduct Standards and the institution's own policies and procedures. The Department considered the alternative of requiring a Financial Institution to engage an independent party to provide an external audit. The Department elected not to require this condition to avoid the increased costs this approach would impose. Smaller Financial Institutions may have been disproportionately impacted by such costs, which would have been contrary to the Department's goals of promoting access to investment advice for Retirement Investors. Further, the Department is not convinced that an independent, external audit would yield useful information commensurate with the cost, particularly to small entities. Instead, the final exemption requires that Financial Institutions to document their retrospective review, and provide it, and supporting information, to the Department, within 10 business days of request, to the extent permitted by law.

Addition of Self-Correction Provision: The Department has added a new Section II(e) to the exemption, under which Financial Institutions will be able to correct certain violations of the exemption. Under the new Section II(e), the Department will not consider a non-exempt prohibited transaction to have occurred due to a violation of the exemption's conditions, provided: (1) Either the violation did not result in investment losses to the Retirement Investor or the Financial Institution made the Retirement Investor whole for any resulting losses; (2) the Financial Institution corrects the violation and notifies the Department via email to *IIAWR@dol.gov* within 30 days of correction; (3) the correction occurs no later than 90 days after the Financial Institution learned of the violation or reasonably should have learned of the violation; and (4) the Financial Institution notifies the persons responsible for conducting the retrospective review during the applicable review cycle, and the violation and correction is specifically set forth in the written report of the retrospective review.

advice or services to retirement plans (*see 2019 Investment Adviser Section Annual Report,* North American Securities Administrators Association, (May 2019)).

[268] NAIC estimates that the number of insurers directly writing annuities as of 2018 is 386.

[269] LIMRA estimates in 2016, 70 insurers had more than $38.5 million in sales. (*See U.S. Individual Annuity Yearbook: 2016 Data,* LIMRA Secure Retirement Institute (2017)).

While this section was not a part of the proposal, several commenters requested that the Department provide a means for Financial Institutions, acting in good faith, to avoid loss of the exemption for violations of the conditions. One commenter specified that there should be a correction process in connection with the retrospective review, because failure to include this could put Financial Institutions in a difficult position of having discovered technical violations but not being able to cure them without being subject to an excise tax for the prohibited transaction.

Upon consideration of the comments, the Department determined to provide this self-correction procedure. Accordingly, the section allows for correction even if a Retirement Investor has suffered investment losses, provided that the Retirement Investor is made whole. The Department believes that the self-correction provision will provide Financial Institutions with an additional incentive to take the retrospective review process seriously, timely identify and correct violations, and use the process to correct deficiencies in their policies and procedures, so as to avoid potential future penalties and lawsuits.

Revision to Recordkeeping Requirements: Under Section IV of the exemption, Financial Institutions must maintain records for six years demonstrating compliance with the exemption. The Department generally includes a recordkeeping requirement in its administrative exemptions to ensure that parties relying on an exemption can demonstrate, and the Department can verify, compliance with the conditions of the exemption. The proposal provided that records should be available for review by the following parties in addition to the Department: Any fiduciary of a Plan that engaged in an investment transaction pursuant to this exemption; any contributing employer and any employee organization whose members are covered by a Plan that engaged in an investment transaction pursuant to this exemption; or any participant or beneficiary of a Plan, or IRA owner that engaged in an investment transaction pursuant to this exemption. Several commenters stated that allowing parties other than the Department to review records would increase the burden placed on Financial Institutions. In particular, they expressed the view that parties might overwhelm Financial Institutions with requests for information in order to generate claims for use in litigation. Fear of potential litigation, could in turn, they argued, lead to a ''culture of quiet'' in which employees of Financial Institutions elect not to address compliance issues because of the fear of this disclosure. In response to these comments, the Department has revised the final exemption's recordkeeping provisions so that access is limited to the Department and the Department of the Treasury.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 [270] requires each federal agency to prepare a written statement assessing the effects of any federal mandate in a proposed or final rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by state, local, and tribal governments, in the aggregate, or by the private sector. For purposes of the Unfunded Mandates Reform Act, as well as Executive Order 12875, this exemption does not include any Federal mandate that will result in such expenditures.

Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism. It also requires federal agencies to adhere to specific criteria in formulating and implementing policies that have ''substantial direct effects'' on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the final regulation. The Department does not believe this class exemption has federalism implications because it has no substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under ERISA section 408(a) and Code section 4975(c)(2) does not relieve a fiduciary, or other party in interest or disqualified person with respect to a Plan or an IRA, from certain other provisions of Title I and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404 which require, among other things, that a fiduciary act prudently and discharge his or her duties respecting the Plan solely in the interests of the participants and beneficiaries of the Plan. Additionally, the fact that a transaction is the subject of an exemption does not affect the requirement of Code section 401(a) that the Plan must operate for the exclusive benefit of the employees of the employer maintaining the Plan and its beneficiaries;

(2) In accordance with section 408(a) of ERISA and section 4975(c)(2) of the Code, and based on the entire record, the Department finds that this exemption is administratively feasible, in the interests of Plans and their participants and beneficiaries and IRA owners, and protective of the rights of participants and beneficiaries of the Plan and IRA owners;

(3) The exemption is applicable to a particular transaction only if the transaction satisfies the conditions specified in the exemption; and

(4) The exemption is supplemental to, and not in derogation of, any other provisions of Title I and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Improving Investment Advice for Workers & Retirees

Section I—Transactions

(a) In general. ERISA Title I (Title I) and the Internal Revenue Code (the Code) prohibit fiduciaries, as defined, that provide investment advice to Plans and individual retirement accounts (IRAs) from receiving compensation that varies based on their investment advice and compensation that is paid from third parties. Title I and the Code also prohibit fiduciaries from engaging in purchases and sales with Plans or IRAs on behalf of their own accounts (principal transactions). This exemption permits Financial Institutions and Investment Professionals who provide fiduciary investment advice to Retirement Investors to receive otherwise prohibited compensation and engage in riskless principal transactions and certain other principal transactions (Covered Principal Transactions) as described below. The exemption provides relief from the prohibitions of ERISA section 406(a)(1)(A), (D), and 406(b), and the sanctions imposed by

[270] Public Law 104–4, 109 Stat. 48 (1995).

Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A), (D), (E), and (F), if the Financial Institutions and Investment Professionals provide fiduciary investment advice in accordance with the conditions set forth in Section II and are eligible pursuant to Section III, subject to the definitional terms and recordkeeping requirements in Sections IV and V.

(b) Covered transactions. This exemption permits Financial Institutions and Investment Professionals, and their Affiliates and Related Entities, to engage in the following transactions, including as part of a rollover from a Plan to an IRA as defined in Code section 4975(e)(1)(B) or (C), as a result of the provision of investment advice within the meaning of ERISA section 3(21)(A)(ii) and Code section 4975(e)(3)(B):

(1) The receipt of reasonable compensation; and

(2) The purchase or sale of an asset in a riskless principal transaction or a Covered Principal Transaction, and the receipt of a mark-up, mark-down, or other payment.

(c) Exclusions. This exemption does not apply if:

(1) The Plan is covered by Title I of ERISA and the Investment Professional, Financial Institution or any Affiliate is (A) the employer of employees covered by the Plan, or (B) a named fiduciary or plan administrator with respect to the Plan that was selected to provide advice to the Plan by a fiduciary who is not independent of the Financial Institution, Investment Professional, and their Affiliates;

(2) The transaction is a result of investment advice generated solely by an interactive website in which computer software-based models or applications provide investment advice based on personal information each investor supplies through the website, without any personal interaction or advice with an Investment Professional (*i.e.,* robo-advice); or

(3) The transaction involves the Investment Professional acting in a fiduciary capacity other than as an investment advice fiduciary within the meaning of the regulations at 29 CFR 2510.3–21(c)(1)(i) and (ii)(B) or 26 CFR 54.4975–9(c)(1)(i) and (ii)(B) setting forth the test for fiduciary investment advice.

Section II—Investment Advice Arrangement

Section II requires Investment Professionals and Financial Institutions to comply with Impartial Conduct Standards, including a best interest standard, when providing fiduciary investment advice to Retirement Investors. In addition, the exemption requires Financial Institutions to acknowledge fiduciary status under Title I and/or the Code, and describe in writing the services they will provide and their material Conflicts of Interest. Finally, Financial Institutions must adopt policies and procedures prudently designed to ensure compliance with the Impartial Conduct Standards when providing fiduciary investment advice to Retirement Investors and conduct a retrospective review of compliance.

(a) *Impartial Conduct Standards.* The Financial Institution and Investment Professional comply with the following ''Impartial Conduct Standards'':

(1) Investment advice is, at the time it is provided, in the Best Interest of the Retirement Investor. As defined in Section V(b), such advice reflects the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, and does not place the financial or other interests of the Investment Professional, Financial Institution or any Affiliate, Related Entity, or other party ahead of the interests of the Retirement Investor, or subordinate the Retirement Investor's interests to their own;

(2)(A) The compensation received, directly or indirectly, by the Financial Institution, Investment Professional, their Affiliates and Related Entities for their services does not exceed reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2); and (B) as required by the federal securities laws, the Financial Institution and Investment Professional seek to obtain the best execution of the investment transaction reasonably available under the circumstances; and

(3) The Financial Institution's and its Investment Professionals' statements to the Retirement Investor about the recommended transaction and other relevant matters are not, at the time statements are made, materially misleading.

(b) *Disclosure.* Prior to engaging in a transaction pursuant to this exemption, the Financial Institution provides the disclosures set forth in (1) and (2) to the Retirement Investor:

(1) A written acknowledgment that the Financial Institution and its Investment Professionals are fiduciaries under Title I and the Code, as applicable, with respect to any fiduciary investment advice provided by the Financial Institution or Investment Professional to the Retirement Investor;

(2) A written description of the services to be provided and the Financial Institution's and Investment Professional's material Conflicts of Interest that is accurate and not misleading in all material respects; and

(3) Prior to engaging in a rollover recommended pursuant to the exemption, the Financial Institution provides the documentation of specific reasons for the rollover recommendation, required by Section II(c)(3), to the Retirement Investor.

(c) *Policies and Procedures.*

(1) The Financial Institution establishes, maintains, and enforces written policies and procedures prudently designed to ensure that the Financial Institution and its Investment Professionals comply with the Impartial Conduct Standards in connection with covered fiduciary advice and transactions.

(2) Financial Institutions' policies and procedures mitigate Conflicts of Interest to the extent that a reasonable person reviewing the policies and procedures and incentive practices as a whole would conclude that they do not create an incentive for a Financial Institution or Investment Professional to place their interests ahead of the interest of the Retirement Investor.

(3) The Financial Institution documents the specific reasons that any recommendation to roll over assets from a Plan to another Plan or an IRA as defined in Code section 4975(e)(1)(B) or (C), from an IRA as defined in Code section 4975(e)(1)(B) or (C) to a Plan, from an IRA to another IRA, or from one type of account to another (*e.g.,* from a commission-based account to a fee-based account) is in the Best Interest of the Retirement Investor.

(d) *Retrospective Review.*

(1) The Financial Institution conducts a retrospective review, at least annually, that is reasonably designed to assist the Financial Institution in detecting and preventing violations of, and achieving compliance with, the Impartial Conduct Standards and the policies and procedures governing compliance with the exemption.

(2) The methodology and results of the retrospective review are reduced to a written report that is provided to a Senior Executive Officer.

(3) A Senior Executive Officer of the Financial Institution certifies, annually, that:

(A) The officer has reviewed the report of the retrospective review;

(B) The Financial Institution has in place policies and procedures prudently designed to achieve compliance with the conditions of this exemption; and

(C) The Financial Institution has in place a prudent process to modify such policies and procedures as business, regulatory, and legislative changes and events dictate, and to test the effectiveness of such policies and procedures on a periodic basis, the timing and extent of which is reasonably designed to ensure continuing compliance with the conditions of this exemption.

(4) The review, report and certification are completed no later than six months following the end of the period covered by the review.

(5) The Financial Institution retains the report, certification, and supporting data for a period of six years and makes the report, certification, and supporting data available to the Department, within 10 business days of request, to the extent permitted by law including 12 U.S.C. 484.

(e) *Self-Correction.* A non-exempt prohibited transaction will not occur due to a violation of the exemption's conditions with respect to a transaction, provided:

(1) Either the violation did not result in investment losses to the Retirement Investor or the Financial Institution made the Retirement Investor whole for any resulting losses;

(2) The Financial Institution corrects the violation and notifies the Department of Labor of the violation and the correction via email to *IIAWR@dol.gov* within 30 days of correction;

(3) The correction occurs no later than 90 days after the Financial Institution learned of the violation or reasonably should have learned of the violation; and

(4) The Financial Institution notifies the person(s) responsible for conducting the retrospective review during the applicable review cycle and the violation and correction is specifically set forth in the written report of the retrospective review required under subsection II(d)(2).

Section III—Eligibility

(a) General. Subject to the timing and scope provisions set forth in subsection (b), an Investment Professional or Financial Institution will be ineligible to rely on the exemption for 10 years following:

(1) A conviction of any crime described in ERISA section 411 arising out of such person's provision of investment advice to Retirement Investors, unless, in the case of a Financial Institution, the Department grants a petition pursuant to subsection (c)(1) below that the Financial Institution's continued reliance on the exemption would not be contrary to the purposes of the exemption; or

(2) Receipt of a written ineligibility notice issued by the Department for (A) engaging in a systematic pattern or practice of violating the conditions of this exemption in connection with otherwise non-exempt prohibited transactions; (B) intentionally violating the conditions of this exemption in connection with otherwise non-exempt prohibited transactions; or (C) providing materially misleading information to the Department in connection with the Financial Institution's or Investment Professional's conduct under the exemption; in each case, as determined by the Department pursuant to the process described in subsection (c).

(b) Timing and Scope of Ineligibility.

(1) An Investment Professional shall become ineligible immediately upon (A) the date of the trial court's conviction of the Investment Professional of a crime described in subsection (a)(1), regardless of whether that judgment remains under appeal; or (B) the date of the written ineligibility notice described in subsection (a)(2), issued to the Investment Professional.

(2) A Financial Institution shall become ineligible following (A) the 10th business day after the conviction of the Financial Institution or another Financial Institution in the same Controlled Group of a crime described in subsection (a)(1) regardless of whether that judgment remains under appeal, or, if the Financial Institution timely submits a petition described in subsection (c)(1) during that period, 21 days after the date of the Department's written denial of the petition; or (B) 21 days after the date of the written ineligibility notice, described in subsection (a)(2), issued to the Financial Institution or another Financial Institution in the same Controlled Group.

(3) Controlled Group. A Financial Institution is in the same Controlled Group with another Financial Institution if it would be considered in the same ''controlled group of corporations'' or ''under common control'' with the Financial Institution, as those terms are defined in Code section 414(b) and (c), in each case including the accompanying regulations.

(4) Winding Down Period. Any Financial Institution that is ineligible will have a one-year winding down period during which relief is available under the exemption subject to the conditions of the exemption other than eligibility. After the one-year period expires, the Financial Institution may not rely on the relief provided in this exemption for any additional transactions.

(c) *Opportunity to be heard.*

(1) Petitions under subsection (a)(1).

(A) A Financial Institution that has been convicted of a crime described under subsection (a)(1) or another Financial Institution in the same Controlled Group may submit a petition to the Department informing the Department of the conviction and seeking a determination that the Financial Institution's continued reliance on the exemption would not be contrary to the purposes of the exemption. Petitions must be submitted, within 10 business days after the date of the conviction, to the Department by email at *IIAWR@dol.gov.*

(B) Following receipt of the petition, the Department will provide the Financial Institution with the opportunity to be heard, in person or in writing or both. The opportunity to be heard in person will be limited to one in-person conference unless the Department determines in its sole discretion to allow additional conferences.

(C) The Department's determination as to whether to grant the petition will be based solely on its discretion. In determining whether to grant the petition, the Department will consider the gravity of the offense; the relationship between the conduct underlying the conviction and the Financial Institution's system and practices in its retirement investment business as a whole; the degree to which the underlying conduct concerned individual misconduct, or, alternately, corporate managers or policy; how recent was the underlying lawsuit; remedial measures taken by the Financial Institution upon learning of the underlying conduct; and such other factors as the Department determines in its discretion are reasonable in light of the nature and purposes of the exemption. The Department will provide a written determination to the Financial Institution that articulates the basis for the determination.

(2) Written ineligibility notice under subsection (a)(2). Prior to issuing a written ineligibility notice, the Department will issue a written warning to the Investment Professional or Financial Institution, as applicable, identifying specific conduct implicating subsection (a)(2), and providing a six-month opportunity to cure. At the end of the six-month period, if the Department determines that the conduct persists, it will provide the Investment

Professional or Financial Institution with the opportunity to be heard, in person or in writing or both, before the Department issues the written ineligibility notice. The opportunity to be heard in person will be limited to one in-person conference unless the Department determines in its sole discretion to allow additional conferences. The written ineligibility notice will articulate the basis for the determination that the Investment Professional or Financial Institution engaged in conduct described in subsection (a)(2).

(d) A Financial Institution or Investment Professional that is ineligible to rely on this exemption may rely on a statutory or separate administrative prohibited transaction exemption if one is available or seek an individual prohibited transaction exemption from the Department. To the extent an applicant seeks retroactive relief in connection with an exemption application, the Department will consider the application in accordance with its retroactive exemption policy as set forth in 29 CFR 2570.35(d). The Department may require additional prospective compliance conditions as a condition of retroactive relief.

Section IV—Recordkeeping

The Financial Institution maintains for a period of six years records demonstrating compliance with this exemption and makes such records available, to the extent permitted by law including 12 U.S.C. 484, to any authorized employee of the Department or the Department of the Treasury.

Section V—Definitions

(a) ''Affiliate'' means:

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the Investment Professional or Financial Institution. (For this purpose, ''control'' would mean the power to exercise a controlling influence over the management or policies of a person other than an individual);

(2) Any officer, director, partner, employee, or relative (as defined in ERISA section 3(15)), of the Investment Professional or Financial Institution; and

(3) Any corporation or partnership of which the Investment Professional or Financial Institution is an officer, director, or partner.

(b) Advice is in a Retirement Investor's ''Best Interest'' if such advice reflects the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, and does not place the financial or other interests of the Investment Professional, Financial Institution or any Affiliate, Related Entity, or other party ahead of the interests of the Retirement Investor, or subordinate the Retirement Investor's interests to their own.

(c) A ''Conflict of Interest'' is an interest that might incline a Financial Institution or Investment Professional—consciously or unconsciously—to make a recommendation that is not in the Best Interest of the Retirement Investor.

(d) A ''Covered Principal Transaction'' is a principal transaction that:

(1) For sales to a Plan or an IRA:

(A) Involves a U.S. dollar denominated debt security issued by a U.S. corporation and offered pursuant to a registration statement under the Securities Act of 1933, a U.S. Treasury Security, a debt security issued or guaranteed by a U.S. federal government agency other than the U.S. Department of Treasury, a debt security issued or guaranteed by a government-sponsored enterprise, a municipal security, a certificate of deposit, an interest in a Unit Investment Trust, or any investment permitted to be sold by an investment advice fiduciary to a Retirement Investor under an individual exemption granted by the Department after the effective date of this exemption that includes the same conditions as this exemption; and

(B) If the recommended investment is a debt security, the security is recommended pursuant to written policies and procedures adopted by the Financial Institution that are reasonably designed to ensure that the security, at the time of the recommendation, has no greater than moderate credit risk and sufficient liquidity that it could be sold at or near carrying value within a reasonably short period of time; and

(2) For purchases from a Plan or an IRA, involves any securities or investment property.

(e) ''Financial Institution'' means an entity that is not disqualified or barred from making investment recommendations by any insurance, banking, or securities law or regulatory authority (including any self-regulatory organization), that employs the Investment Professional or otherwise retains such individual as an independent contractor, agent or registered representative, and that is:

(1) Registered as an investment adviser under the Investment Advisers Act of 1940 (15 U.S.C. 80b-1 *et seq.*) or under the laws of the state in which the adviser maintains its principal office and place of business;

(2) A bank or similar financial institution supervised by the United States or a state, or a savings association (as defined in section 3(b)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1813(b)(1)));

(3) An insurance company qualified to do business under the laws of a state, that: (A) Has obtained a Certificate of Authority from the insurance commissioner of its domiciliary state which has neither been revoked nor suspended; (B) has undergone and shall continue to undergo an examination by an independent certified public accountant for its last completed taxable year or has undergone a financial examination (within the meaning of the law of its domiciliary state) by the state's insurance commissioner within the preceding five years, and (C) is domiciled in a state whose law requires that an actuarial review of reserves be conducted annually and reported to the appropriate regulatory authority;

(4) A broker or dealer registered under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*); or

(5) An entity that is described in the definition of Financial Institution in an individual exemption granted by the Department after the date of this exemption that provides relief for the receipt of compensation in connection with investment advice provided by an investment advice fiduciary under the same conditions as this class exemption.

(f) For purposes of subsection I(c)(1), a fiduciary is ''independent'' of the Financial Institution and Investment Professional if: (i) The fiduciary is not the Financial Institution, Investment Professional, or an Affiliate; (ii) the fiduciary does not have a relationship to or an interest in the Financial Institution, Investment Professional, or any Affiliate that might affect the exercise of the fiduciary's best judgment in connection with transactions covered by the exemption; and (iii) the fiduciary does not receive and is not projected to receive within the current federal income tax year, compensation or other consideration for his or her own account from the Financial Institution, Investment Professional, or an Affiliate, in excess of 2% of the fiduciary's annual revenues based upon its prior income tax year.

(g) ''Individual Retirement Account'' or ''IRA'' means any plan that is an account or annuity described in Code section 4975(e)(1)(B) through (F).

(h) ''Investment Professional'' means an individual who:

(1) Is a fiduciary of a Plan or an IRA by reason of the provision of investment advice described in ERISA section 3(21)(A)(ii) or Code section 4975(e)(3)(B), or both, and the applicable regulations, with respect to the assets of the Plan or IRA involved in the recommended transaction;

(2) Is an employee, independent contractor, agent, or representative of a Financial Institution; and

(3) Satisfies the federal and state regulatory and licensing requirements of insurance, banking, and securities laws (including self-regulatory organizations) with respect to the covered transaction, as applicable, and is not disqualified or barred from making investment recommendations by any insurance, banking, or securities law or regulatory authority (including any self-regulatory organization).

(i) ''Plan'' means any employee benefit plan described in ERISA section 3(3) and any plan described in Code section 4975(e)(1)(A).

(j) A ''Related Entity'' is any party that is not an Affiliate, but in which the Investment Professional or Financial Institution has an interest that may affect the exercise of its best judgment as a fiduciary.

(k) ''Retirement Investor'' means:

(1) A participant or beneficiary of a Plan with authority to direct the investment of assets in his or her account or to take a distribution;

(2) The beneficial owner of an IRA acting on behalf of the IRA; or

(3) A fiduciary of a Plan or an IRA.

(l) A ''Senior Executive Officer'' is any of the following: The chief compliance officer, the chief executive officer, president, chief financial officer, or one of the three most senior officers of the Financial Institution.

Jeanne Klinefelter Wilson,

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

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No. 244 December 18, 2020

Part VI

The President

Notice of December 16, 2020—Continuation of the National Emergency With Respect to Serious Human Rights Abuse and Corruption

Federal Register
Vol. 85, No. 244
Friday, December 18, 2020

Presidential Documents

Title 3—

The President

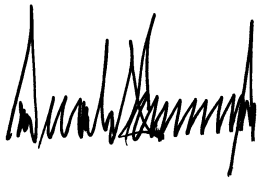
Notice of December 16, 2020

Continuation of the National Emergency With Respect to Serious Human Rights Abuse and Corruption

On December 20, 2017, by Executive Order 13818, the President declared a national emergency with respect to serious human rights abuse and corruption around the world and, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), took related steps to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States.

The prevalence and severity of human rights abuse and corruption that have their source, in whole or in substantial part, outside the United States, continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared on December 20, 2017, must continue in effect beyond December 20, 2020. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13818 with respect to serious human rights abuse and corruption.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
December 16, 2020.

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