FEDERAL REGISTER

Vol. 85 Wednesday,

No. 214 November 4, 2020

Pages 70027–70414

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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Presidential Documents

Title 3—

The President

Proclamation 10107 of October 30, 2020

To Modify Duty-Free Treatment Under the Generalized System of Preferences and for Other Purposes

By the President of the United States of America

A Proclamation

1. In Executive Order 11844 of March 24, 1975, the President designated Thailand as a beneficiary developing country for purposes of the Generalized System of Preferences (GSP) (19 U.S.C. 2461 *et seq.*).

2. Sections 502(d)(1) and 503(c)(1) of the Trade Act of 1974, as amended, (the ''1974 Act'') (19 U.S.C. 2462(d)(1) and 2463(c)(1)) provide that the President may withdraw, suspend, or limit the application of the duty-free treatment accorded under the GSP with respect to any beneficiary developing country and any article upon consideration of the factors set forth in sections 501 and 502(c) of the 1974 Act (19 U.S.C. 2461 and 2462(c)).

3. Section 502(c)(4) of the 1974 Act (19 U.S.C. 2462(c)(4)) provides that, in determining whether to designate any country as a beneficiary developing country under the GSP, the President shall take into account the extent to which such country has assured the United States that it will provide equitable and reasonable access to the markets and basic commodity resources of such country and the extent to which such country has assured the United States that it will refrain from engaging in unreasonable export practices.

4. Pursuant to sections 502(d)(1) and 503(c)(1) of the 1974 Act, and having considered the factors set forth in sections 501 and 502(c), including in particular section 502(c)(4), I have determined that Thailand has not assured the United States that Thailand will provide equitable and reasonable access to its markets. Accordingly, it is appropriate to suspend the duty-free treatment accorded under the GSP to certain eligible articles that are the product of Thailand, effective on December 30, 2020.

5. Pursuant to section 503(c)(1) of the 1974 Act, the President may withdraw, suspend, or limit the application of the duty-free treatment accorded to specified articles under the GSP when imported from designated beneficiary developing countries.

6. Section 503(c)(2)(A) of the 1974 Act (19 U.S.C. 2463(c)(2)(A)) subjects beneficiary developing countries, except those designated as least-developed beneficiary developing countries or beneficiary sub-Saharan African countries as provided in section 503(c)(2)(D) of the 1974 Act (19 U.S.C. 2463(c)(2)(D)), to competitive need limitations on the duty-free treatment afforded to eligible articles under the GSP.

7. Pursuant to section 503(c)(2)(A) of the 1974 Act, I have determined that in 2019 certain beneficiary developing countries exported eligible articles in quantities exceeding the applicable competitive need limitations. I hereby terminate the duty-free treatment for such articles from such beneficiary developing countries.

8. Pursuant to section 503(c)(1) of the 1974 Act, and having considered the factors set forth in sections 501 and 502(c) of the 1974 Act, I have determined to withdraw the application of the duty-free treatment accorded to a certain article.

9. Pursuant to sections 501 and 503(a)(1)(A) of the 1974 Act (19 U.S.C. 2461 and 2463(a)(1)(A)), the President may, after receiving the advice of the United States International Trade Commission (the ''Commission''), designate certain articles as eligible for preferential tariff treatment under the GSP when they are imported from designated beneficiary developing countries.

10. Pursuant to sections 501 and 503(a)(1)(A) of the 1974 Act, and having received advice from the Commission in accordance with section 503(e) of the 1974 Act (19 U.S.C. 2463(e)), I have determined to designate a certain article as an eligible article when it is imported from beneficiary developing countries.

11. Section 503(c)(2)(F)(i) of the 1974 Act (19 U.S.C. 2463(c)(2)(F)(i)) provides that the President may disregard the competitive need limitation provided in section 503(c)(2)(A)(i)(II) of the 1974 Act (19 U.S.C. 2463(c)(2)(A)(i)(II)) with respect to any eligible article from any beneficiary developing country if the aggregate appraised value of the imports of any such article into the United States during the preceding calendar year does not exceed the amount set forth in section 503(c)(2)(F)(ii) of the 1974 Act (19 U.S.C. 2463(c)(2)(F)(ii)).

12. Pursuant to section 503(c)(2)(F)(i) of the 1974 Act, I have determined that the competitive need limitation provided in section 503(c)(2)(A)(i)(II) of the 1974 Act should be disregarded with respect to certain eligible articles from certain beneficiary developing countries.

13. The short-form name of ''Macedonia'' has changed to ''North Macedonia,'' and I have determined that additional U.S. note 6 to Chapter 20 of the Harmonized Tariff Schedule of the United States (HTS) should be modified to reflect this change.

14. Section 604 of the 1974 Act (19 U.S.C. 2483) authorizes the President to embody in the HTS the substance of the relevant provisions of the 1974 Act, and of other Acts affecting import treatment, and actions thereunder, including removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States of America, including title V and section 604 of the 1974 Act, do hereby proclaim that:

(1) The duty-free treatment accorded under the GSP to certain eligible articles that are the product of Thailand is suspended, effective on December 30, 2020.

(2) In order to reflect in the HTS this suspension of certain benefits under the GSP with respect to Thailand, general note 4(d) and pertinent subheadings of the HTS are modified as set forth in Annex I to this proclamation.

(3) In order to provide that one or more countries should no longer be treated as beneficiary developing countries with respect to one or more eligible articles for purposes of the GSP, the Rates of Duty 1–Special subcolumn for the corresponding HTS subheadings and general note 4(d) to the HTS are modified as set forth in sections A, B, and C of Annex II to this proclamation.

(4) In order to withdraw the application of duty-free treatment accorded to one eligible article for purposes of the GSP, the Rates of Duty 1–Special subcolumn for the corresponding HTS subheading is modified as set forth in section D of Annex II to this proclamation.

(5) In order to designate a certain article as an eligible article when imported from a beneficiary developing country for purposes of the GSP, the Rates of Duty 1–Special column for the corresponding HTS subheading is modified as set forth in section E of Annex II to this proclamation.

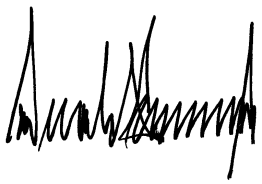
(6) The competitive need limitation provided in section 503(c)(2)(A)(i)(II) of the 1974 Act is disregarded with respect to the eligible articles in the HTS subheadings and to the beneficiary developing countries set forth in Annex III to this proclamation.

(7) In order to reflect the change in the name of Macedonia, U.S. note 6 to chapter 20 of the HTS is modified by deleting ''Macedonia'' and inserting ''North Macedonia'' in alphabetical order.

(8) The modifications to the HTS set forth in Annex II and Annex III of this proclamation shall be effective with respect to articles entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on November 1, 2020.

(9) Any provisions of previous proclamations and Executive Orders that are inconsistent with the actions taken in this proclamation are superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of October, in the year of our Lord two thousand twenty, and of the Independence of the United States of America the two hundred and forty-fifth.



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Annex I

To modify the Harmonized Tariff Schedule of the United States to remove certain articles that are the product of Thailand for the purposes of the Generalized System of Preferences

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. Eastern Standard Time on December 30, 2020, the Harmonized Tariff Schedule of the United States (HTS) is modified for the following subheadings:

1. General note 4(d) is modified:

A. By adding the following subheadings, in numerical sequence, and the country set out opposite them:

"0502.10.00	Thailand	0811.90.50	Thailand	2001.90.42	Thailand
0602.90.30	Thailand	0811.90.52	Thailand	2001.90.45	Thailand
0602.90.40	Thailand	0811.90.55	Thailand	2001.90.48	Thailand
0602.90.60	Thailand	0910.99.06	Thailand	2001.90.50	Thailand
0602.90.90	Thailand	0910.99.40	Thailand	2008.11.45	Thailand
0712.90.10	Thailand	0910.99.60	Thailand	2611.00.60	Thailand
0712.90.15	Thailand	1209.91.80	Thailand	2826.90.10	Thailand
0712.90.30	Thailand	1209.99.41	Thailand	2826.90.90	Thailand
0712.90.65	Thailand	1515.90.60	Thailand	2905.44.00	Thailand
0712.90.70	Thailand	1515.90.80	Thailand	2905.45.00	Thailand
0712.90.74	Thailand	1702.40.22	Thailand	2918.21.10	Thailand
0712.90.85	Thailand	1702.40.40	Thailand	3307.90.00	Thailand
0713.20.10	Thailand	2001.90.10	Thailand	3802.10.00	Thailand
0713.20.20	Thailand	2001.90.20	Thailand	3813.00.50	Thailand
0713.39.11	Thailand	2001.90.25	Thailand	3910.00.00	Thailand
0713.39.21	Thailand	2001.90.30	Thailand	3911.10.00	Thailand
0713.39.41	Thailand	2001.90.33	Thailand	3913.90.50	Thailand
0811.90.10	Thailand	2001.90.34	Thailand	3917.32.00	Thailand
0811.90.25	Thailand	2001.90.38	Thailand	3920.10.00	Thailand

3920.20.00	Thailand	7318.12.00	Thailand	8214.20.30	Thailand
4009.32.00	Thailand	7320.90.50	Thailand	8214.20.90	Thailand
4012.90.90	Thailand	7505.22.10	Thailand	8301.70.00	Thailand
4113.90.60	Thailand	7505.22.50	Thailand	8302.10.30	Thailand
4016.93.10	Thailand	7606.12.60	Thailand	8302.10.60	Thailand
4016.93.50	Thailand	7612.90.10	Thailand	8302.10.90	Thailand
4205.00.05	Thailand	7615.10.11	Thailand	8302.20.00	Thailand
4205.00.40	Thailand	7615.10.20	Thailand	8302.30.30	Thailand
4205.00.60	Thailand	7615.10.50	Thailand	8302.42.30	Thailand
4415.10.90	Thailand	7615.10.71	Thailand	8302.42.60	Thailand
5903.10.10	Thailand	7615.10.91	Thailand	8302.49.20	Thailand
6304.99.10	Thailand	7616.91.00	Thailand	8302.49.60	Thailand
6304.99.25	Thailand	7616.99.51	Thailand	8302.49.80	Thailand
6304.99.40	Thailand	8101.97.00	Thailand	8411.99.90	Thailand
6504.00.30	Thailand	8201.40.60	Thailand	8417.90.00	Thailand
6504.00.60	Thailand	8204.11.00	Thailand	8424.41.90	Thailand
6601.10.00	Thailand	8205.51.30	Thailand	8424.89.90	Thailand
6702.10.20	Thailand	8205.51.60	Thailand	8451.40.00	Thailand
6702.10.40	Thailand	8205.51.75	Thailand	8456.11.10	Thailand
6802.29.10	Thailand	8207.19.30	Thailand	8456.11.90	Thailand
6802.29.90	Thailand	8207.19.60	Thailand	8466.20.10	Thailand
7006.00.10	Thailand	8207.70.30	Thailand	8466.20.80	Thailand
7006.00.20	Thailand	8207.70.60	Thailand	8477.30.00	Thailand
7006.00.40	Thailand	8207.90.15	Thailand	8477.59.01	Thailand
7016.10.00	Thailand	8207.90.30	Thailand	8481.80.10	Thailand
7103.99.50	Thailand	8207.90.45	Thailand	8481.80.50	Thailand
7307.21.10	Thailand	8207.90.60	Thailand	8481.90.10	Thailand
7307.23.00	Thailand	8207.90.75	Thailand	8481.90.50	Thailand

8483.50.40	Thailand	8516.90.25	Thailand	9003.11.00	Thailand
8483.50.60	Thailand	8516.90.85	Thailand	9005.80.40	Thailand
8483.50.90	Thailand	8516.90.90	Thailand	9005.80.60	Thailand
8483.90.10	Thailand	8527.21.25	Thailand	9010.90.95	Thailand
8483.90.20	Thailand	8528.59.23	Thailand	9030.33.34	Thailand
8483.90.50	Thailand	8528.59.40	Thailand	9404.21.00	Thailand
8487.90.00	Thailand	8539.32.00	Thailand	9404.29.90	Thailand
8501.61.00	Thailand	8539.39.90	Thailand	9405.10.40	Thailand
8504.10.00	Thailand	8544.20.00	Thailand	9405.10.60	Thailand
8505.90.75	Thailand	8708.40.11	Thailand	9405.10.80	Thailand
8507.20.40	Thailand	8708.50.51	Thailand	9405.20.40	Thailand
8507.20.80	Thailand	8708.50.61	Thailand	9405.20.60	Thailand
8511.40.00	Thailand	8708.50.79	Thailand	9405.20.80	Thailand
8512.90.20	Thailand	8708.50.85	Thailand	9405.30.00	Thailand
8512.90.70	Thailand	8708.50.95	Thailand	9405.92.00	Thailand
8512.90.90	Thailand	8708.70.45	Thailand	9506.69.40	Thailand
8513.10.20	Thailand	8708.94.50	Thailand	9506.69.60	Thailand
8513.10.40	Thailand	8708.94.75	Thailand	9601.90.40	Thailand
8515.11.00	Thailand	8708.99.55	Thailand	9601.90.80	Thailand
8515.31.00	Thailand	8708.99.58	Thailand	9614.00.25	Thailand
8516.60.60	Thailand	8711.40.60	Thailand	9614.00.28	Thailand
8516.90.05	Thailand	8716.90.30	Thailand	9614.00.94	Thailand
8516.90.15	Thailand	9001.10.00	Thailand	9614.00.98	Thailand”

B. By adding the country “Thailand”, in alphabetical order, set out opposite the following HTS subheadings:

2008.11.25	3913.90.20	4418.79.01
2804.69.10	4011.10.50	7307.21.50
2918.21.50	4012.90.45	7606.12.30

8481.80.30	8708.50.65	8708.70.60
8481.80.90	8708.50.89	8708.99.81
8708.40.50	8708.50.91	8716.90.50
8708.40.75	8708.50.99	9614.00.26

2. The following HTS subheadings are modified by deleting from the Rates of Duty 1 – Special subcolumn, the symbol "A" and by inserting in lieu thereof "A*":

0502.10.00	0910.99.06	2826.90.10
0602.90.30	0910.99.40	2826.90.90
0602.90.40	0910.99.60	2905.44.00
0602.90.60	1209.91.80	2905.45.00
0602.90.90	1209.99.41	2918.21.10
0712.90.10	1515.90.60	3307.90.00
0712.90.15	1515.90.80	3802.10.00
0712.90.30	1702.40.22	3813.00.50
0712.90.65	1702.40.40	3910.00.00
0712.90.70	2001.90.10	3911.10.00
0712.90.74	2001.90.20	3913.90.50
0712.90.85	2001.90.25	3917.32.00
0713.20.10	2001.90.30	3920.10.00
0713.20.20	2001.90.33	3920.20.00
0713.39.11	2001.90.34	4009.32.00
0713.39.21	2001.90.38	4012.90.90
0713.39.41	2001.90.42	4016.93.10
0811.90.10	2001.90.45	4016.93.50
0811.90.25	2001.90.48	4113.90.60
0811.90.50	2001.90.50	4205.00.05
0811.90.52	2008.11.45	4205.00.40
0811.90.55	2611.00.60	4205.00.60

4415.10.90	7615.10.71	8302.42.60
5903.10.10	7615.10.91	8302.49.20
6304.99.10	7616.91.00	8302.49.60
6304.99.25	7616.99.51	8302.49.80
6304.99.40	8101.97.00	8411.99.90
6504.00.30	8201.40.60	8417.90.00
6504.00.60	8204.11.00	8424.41.90
6601.10.00	8205.51.30	8424.89.90
6702.10.20	8205.51.60	8451.40.00
6702.10.40	8205.51.75	8456.11.10
6802.29.10	8207.19.30	8456.11.90
6802.29.90	8207.19.60	8466.20.10
7006.00.10	8207.70.30	8466.20.80
7006.00.20	8207.70.60	8477.30.00
7006.00.40	8207.90.15	8477.59.01
7016.10.00	8207.90.30	8481.80.10
7103.99.50	8207.90.45	8481.80.50
7307.21.10	8207.90.60	8481.90.10
7307.23.00	8207.90.75	8481.90.50
7318.12.00	8214.20.30	8483.50.40
7320.90.50	8214.20.90	8483.50.60
7505.22.10	8301.70.00	8483.50.90
7505.22.50	8302.10.30	8483.90.10
7606.12.60	8302.10.60	8483.90.20
7612.90.10	8302.10.90	8483.90.50
7615.10.11	8302.20.00	8487.90.00
7615.10.20	8302.30.30	8501.61.00
7615.10.50	8302.42.30	8504.10.00

8505.90.75	8539.32.00	9010.90.95
8507.20.40	8539.39.90	9030.33.34
8507.20.80	8544.20.00	9404.21.00
8511.40.00	8708.40.11	9404.29.90
8512.90.20	8708.50.51	9405.10.40
8512.90.70	8708.50.61	9405.10.60
8512.90.90	8708.50.79	9405.10.80
8513.10.20	8708.50.85	9405.20.40
8513.10.40	8708.50.95	9405.20.60
8515.11.00	8708.70.45	9405.20.80
8515.31.00	8708.94.50	9405.30.00
8516.60.60	8708.94.75	9405.92.00
8516.90.05	8708.99.55	9506.69.40
8516.90.15	8708.99.58	9506.69.60
8516.90.25	8711.40.60	9601.90.40
8516.90.85	8716.90.30	9601.90.80
8516.90.90	9001.10.00	9614.00.25
8527.21.25	9003.11.00	9614.00.28
8528.59.23	9005.80.40	9614.00.94
8528.59.40	9005.80.60	9614.00.98

Annex II

To modify the Harmonized Tariff Schedule of the United States to reflect changes in products eligible for duty-free treatment under the Generalized System of Preferences

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. Eastern Daylight time on November 1, 2020, the Harmonized Tariff Schedule of the United States (HTS) is modified for the following subheadings:

Section A

For each of the following subheadings, the Rates of Duty 1-Special subcolumn is modified by deleting the symbol "A" and inserting the symbol "A*" in lieu thereof:

0714.40.10	3805.10.00	8502.12.00

Section B

General note 4(d) to the HTS is modified by adding in numerical sequence the following subheading numbers and the countries set out opposite such subheading numbers:

"0714.40.10	Ecuador	3805.10.00	Brazil	8502.12.00	Brazil"

Section C

General note 4(d) to the HTS is modified by adding, for the subheading number set out below, the country set out opposite in alphabetical order:

2909.19.14	"Argentina"	4412.34.32	"Ecuador"	7113.19.29	"Indonesia"

Section D

For subheading 1006.30.10, the Rates of Duty 1-Special subcolumn is modified by deleting the symbol "A".

Section E

For subheading 0603.11.00, the Rates of Duty 1-Special subcolumn is modified by inserting the symbol "A" in alphabetical order

Annex III

HTS subheadings and countries for which the Competitive Need Limitation provided in Section 503(c)(2)(A)(i)(ll) is disregarded

0406.10.04	Ecuador
0603.13.00	Thailand
0802.61.00	Brazil
0908.22.20	Indonesia
1601.00.40	Brazil
1604.13.90	Ecuador
1701.91.42	Brazil
1703.10.30	Brazil
2008.91.00	Ecuador
2106.90.03	Pakistan
2305.00.00	Brazil
2819.10.00	Kazakhstan
2849.10.00	Brazil
2912.19.40	Brazil
4104.41.40	Argentina
4106.22.00	Pakistan
4107.19.80	Argentina
4206.00.13	Brazil
4302.19.45	Thailand
4302.19.60	Brazil
4412.94.80	Brazil
4601.22.40	Indonesia
4601.94.05	Indonesia
9603.10.90	Sri Lanka

[FR Doc. 2020–24589
Filed 11–3–20; 8:45 am]
Billing code 7020–02–C

Presidential Documents

Memorandum of October 31, 2020

Protecting Jobs, Economic Opportunities, and National Security for All Americans by Ensuring Appropriate Support of Innovative Technologies for Using Our Domestic Natural Resources

Memorandum for the Secretary of State[,] the Secretary of the Treasury[,] the Secretary of Defense[,] the Attorney General[,] the Secretary of the Interior[,] the Secretary of Agriculture[,] the Secretary of Commerce[,] the Secretary of Labor[,] the Secretary of Transportation[,] the Secretary of Energy[,] the United States Trade Representative[,] the Administrator of the Environmental Protection Agency[,] the Director of the Office of Management and Budget[,] the Assistant to the President for National Security Affairs[,] the Assistant to the President for Economic Policy[,] the Chairman of the Council of Economic Advisers[,] the Director of the Office of Science and Technology Policy[,] the Chairman of the Council on Environmental Quality[, and] the Administrator of the Office of Information and Regulatory Affairs

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

Section 1. *Purpose.* This memorandum sets forth policies related to protecting American jobs, economic opportunities, and national security by ensuring appropriate support of hydraulic fracturing and other innovative technologies for the use of domestic natural resources, including energy resources. In support of these policies, this memorandum directs certain officials to assess the potential effects of efforts to ban or restrict the use of such technologies.

Sec. 2. *Background.* Our country has been favored with abundant land, wildlife, and natural resources. Americans have rightly seen this abundance as both an opportunity and a responsibility. Our blessings have rightly been a great source of national pride and gratitude. As we enjoy these bounties, we are also bound by a responsibility of stewardship to use, protect, and preserve them for future generations.

Among the greatest of our blessings are our energy resources, which all too often we take for granted. Our Nation has untold potential to deliver energy to provide us with the necessities—light, heat, cold, food, and water, to say nothing of modern telecommunications—for our daily lives at home and at work, and our travel from place to place. Reliable, affordable energy is essential for running our homes, businesses, farms, factories, health care facilities, and schools, and is critical to every sector of our economy, including our energy-intensive and trade-exposed industries. Access to dependable, inexpensive sources of energy is a cornerstone of our well-being, of our economic strength and global competitiveness, and of our national security.

One of the great success stories of our time has been the development of hydraulic fracturing (often known as ''fracking'') and other technologies to facilitate the extraction of natural resources from the earth. Hydraulic fracturing is a process that provides access to reservoirs of natural gas and petroleum by opening rocks deep underground. When coupled with horizontal drilling and other new technologies, fracking has opened up new sources of inexpensive, reliable, abundant energy for our country. It has also produced jobs and economic opportunities for many Americans.

In a report issued in October 2019, the Council of Economic Advisers (CEA) estimated that by lowering energy prices, the use of fracking and other innovations had saved United States consumers $203 billion per year, or $2,500 in annual savings for a family of four. These savings disproportionately benefit low-income households, which spend a larger share of their income on energy bills, representing 6.8 percent of income for the poorest fifth of households compared to 1.3 percent for the richest fifth of households. The CEA estimated that greater productivity had reduced the domestic price of natural gas by 63 percent as of 2018; had led to a 45 percent decrease in the wholesale price of electricity; and had reduced the global price of oil by 10 percent as of 2019.

The transformation wrought by technologies such as fracking is not only the result of America's natural abundance and Americans' capacity for scientific discovery and practical invention. It is also a testament to our Nation's greatest resource: our hardworking men and women. Energy workers have dedicated their lives to an industry that is essential to the modern world, and their labors have demonstrated their talent, perseverance, and courage. Even in the midst of this unprecedented pandemic, essential energy workers have continued to ensure that our Nation has the energy that it needs to survive and to flourish. We owe these workers our gratitude. We also owe them appropriate respect and support for their careers, their livelihoods, and their families.

It should be emphasized that technologies such as fracking—when used lawfully and responsibly, with appropriate attention to environmental, health, and safety protections—are vital not just to our domestic prosperity but also to our national security. Shortly after I entered office, I issued Executive Order 13783 of March 28, 2017 (Promoting Energy Independence and Economic Growth), which directed an immediate review of all agency actions that potentially burdened the development or use of domestic energy resources. That order also rescinded certain actions of the previous Administration that, in my judgment, were not consistent with the national interest and the Nation's geopolitical security. As a result of new technologies and my Administration's continued push for energy independence, our country recently became a net energy exporter for the first time since 1952, as well as the leading producer of oil and natural gas in the world. We are no longer beholden to foreign countries upon which we had depended for decades for the survival of our way of life. This achievement is a great accomplishment for our country, which should not be taken for granted.

Now that we have achieved a dominant position in energy production, powerful voices in the United States, echoed by countries such as China and Russia, are clamoring for policies that would undermine that position, forgetting the very real costs and risks of energy dependence. Some of these voices call for using legislative or regulatory mechanisms to ban, or sharply restrict, the use of fracking and other technologies. In my view, such proposals are not responsible and would be harmful to the economic and national security of the United States.

Sec. 3. *Policy*. It is the policy of the Federal Government to aggressively protect and enhance American jobs, economic opportunities, and national security for all Americans by ensuring appropriate support of innovative technologies for using our domestic natural resources more efficiently and responsibly, including environmental protection and restoration technologies. Before taking actions that may jeopardize such innovation, responsible officials should carefully consider the impacts on American citizens.

Sec. 4. *Assessing the Domestic and Economic Impacts of Undermining Hydraulic Fracturing and Other Technologies*. (a) Within 70 days of the date of this memorandum, the Secretary of Energy, in consultation with the United States Trade Representative, shall submit a report to the President, through the Assistant to the President for Economic Policy (who shall act in coordination with the Assistant to the President for National Security Affairs), assessing:

(i) the economic impacts of prohibiting, or sharply restricting, the use of hydraulic fracturing and other technologies, including the following:

(A) any loss of jobs, wages, benefits, and other economic opportunities by Americans who work in or are indirectly benefited by the energy industry and other industries (including mining for sand and other minerals);

(B) any increases in energy prices (including the prices of gasoline, electricity, heating, and air conditioning) for Americans (including senior citizens and other persons on fixed incomes) and businesses;

(C) any decreases in property values and in the royalties and other revenues that are currently available to private property owners; and

(D) any decreases in tax revenues, impact fees, royalties, and other revenues currently available to the Federal Government, to State and local governments, and to civic institutions (including public schools, trade and vocational schools, community colleges, and other educational and training institutions; hospitals; and medical clinics);

(ii) the trade impacts of prohibiting, or sharply restricting, the use of hydraulic fracturing and other technologies, including impacts on United States exports of liquefied natural gas (LNG) and other energy products, as well as exports of other commodities that may be affected by increases in transportation costs; and

(iii) such other domestic or economic impacts as the Secretary of Energy deems appropriate.

(b) In preparing the report described in subsection (a) of this section, the Secretary of Energy and the United States Trade Representative shall consult with the Secretary of the Treasury, the Secretary of the Interior, the Secretary of Agriculture, the Secretary of Commerce, the Secretary of Labor, the Secretary of Transportation, the Administrator of the Environmental Protection Agency, the Chairman of CEA, the Chairman of the Council on Environmental Quality, and such other officials as the Secretary of Energy and the United States Trade Representative deem appropriate.

Sec. 5. *Assessing the National Security Impacts of Undermining Hydraulic Fracturing and Other Technologies*. Within 70 days of the date of this memorandum, the Secretary of Energy shall submit a report to the President, through the Assistant to the President for National Security Affairs (who shall act in coordination with the Assistant to the President for Economic Policy), assessing the national security impacts of prohibiting, or sharply restricting, the use of hydraulic fracturing and other technologies. This report shall include an assessment of potential impacts on Russian and Chinese energy production, consumption, and trade activities, and on the energy security of United States allies, that may be attributable to changes in United States exports of LNG and other energy products. In preparing this report, the Secretary of Energy shall consult with the Secretary of State, the Secretary of Defense, the United States Trade Representative, and such other officials as the Secretary of Energy deems appropriate. This report may be combined, as appropriate, with the report required by section 4 of this memorandum, in which case the combined report shall be submitted to the President through the Assistant to the President for National Security Affairs and the Assistant to the President for Economic Policy.

Sec. 6. *Reinforcing Executive Order 13211.* (a) Executive Order 13211 of May 18, 2001 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) provides that agencies ''shall prepare'' detailed Statements of Energy Effects when undertaking certain agency actions that are likely to have a significant adverse impact on the supply, distribution, or use of energy. Such Statements ''shall describe'' ''any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies) should the proposal be implemented'' and ''reasonable alternatives to the action with adverse energy effects and the expected effects of such alternatives on energy supply,

distribution, and use.'' In order to enhance compliance with Executive Order 13211, I direct the Director of the Office of Management and Budget (OMB), through the Administrator of the Office of Information and Regulatory Affairs (OIRA), to review the record of compliance with that order by agencies (as defined in that order) and to provide new guidance, as appropriate, concerning the implementation of and compliance with that order.

(b) Within 30 days of the date of this memorandum, the Director of OMB shall, as appropriate, identify for the President, through the Assistant to the President for Economic Policy (who shall act in coordination with the Assistant to the President for National Security Affairs), agencies on which the Administrator of OIRA intends to focus attention to ensure robust compliance with Executive Order 13211.

Sec. 7. *Definition*. For purposes of this memorandum, the terms ''hydraulic fracturing'' and ''fracking'' shall have the meaning assigned to ''hydraulic fracturing'' in 40 C.F.R. 60.5430.

Sec. 8. *General Provisions*. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

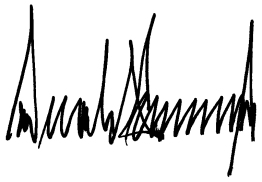
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary of Energy is hereby authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,

Washington, October 31, 2020

[FR Doc. 2020–24601

Filed 11–3–20; 8:45 am]

Billing code 6450–01–P

Rules and Regulations

Federal Register
Vol. 85, No. 214
Wednesday, November 4, 2020

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 284

[FNS–2020–0028]

RIN 0584–AE80

Supplemental Nutrition Assistance Program: Pandemic Electronic Benefits Transfer (P–EBT) Integrity

AGENCY: Food and Nutrition Service (FNS), Agriculture Department (USDA).

ACTION: Final rule.

SUMMARY: The Food and Nutrition Service (FNS or the Agency), an agency of the U.S Department of Agriculture (USDA or the Department), is issuing a final rule to add regulations that will ensure the integrity of the supplemental allotments created by Section 1101 of the Families First Coronavirus Response Act (FFCRA), as amended by the Continuing Appropriations Act, 2021 and Other Extensions Act (CR) for households with children who would have otherwise received free or reduced price school meals under the Richard B. Russell National School Lunch Act, but for school closures or reduction in the number of days or hours that students attend school in response to the ongoing and national Coronavirus Disease 2019 (COVID–19) Public Health Emergency. Such allotments are referred to as Pandemic Electronic Benefits Transfer (P–EBT) benefits. The CR extended the authority for P–EBT through Fiscal Year (FY) 2021, and also authorized P–EBT for households with at least one child enrolled in a covered child care facility (as defined by Section 1101(i)(1) of the FFCRA, as amended) and the supplemental nutrition assistance program (SNAP) when the covered child care facility is closed or has reduced attendance or hours or one or more schools in the area of the covered child care facility are closed or have reduced attendance or hours. This final rule would also safeguard the integrity of SNAP, as P–EBT operates within the SNAP infrastructure. USDA FNS is responsible for administering P–EBT and SNAP at the Federal level.

DATES: *Effective Date:* This final rule is effective on November 4, 2020.

Notice Date: Within 10 calendar days of November 4, 2020, SNAP authorized firms shall be notified of the contents of this final rule.

FOR FURTHER INFORMATION CONTACT: Andrea Gold, the SNAP Retailer Policy and Management Division, USDA FNS at *SM.FN.RPMDHQ-WEB@usda.gov;* 703.305.2434.

SUPPLEMENTARY INFORMATION:

Executive Summary

Background Information

Establishment of P–EBT

On January 31, 2020, Secretary Azar of the U.S. Department Health and Human Services (HHS) declared a public health emergency under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to the Coronavirus Disease 2019 (COVID–19). On March 13, 2020, President Trump declared the ongoing COVID–19 outbreak in the U.S. to be a national emergency. Due to COVID–19, many schools nationwide began closing in March 2020. In order to provide some financial relief to families, on March 18, 2020, President Trump signed into law the Families First Coronavirus Response Act (FFCRA; Pub. L. 116–127). Section 1101 of the FFCRA, as originally enacted, authorized USDA to approve State plans to provide federally funded food assistance to each household containing at least one child who would have received free or reduced price school meals, but for school closures lasting at least five consecutive days during a public health emergency declaration. The U.S. Department of Agriculture (USDA or the Department) refers to these benefits created by Section 1101 of the FFCRA as Pandemic Electronic Benefits Transfer (P–EBT) benefits. The Continuing Appropriations Act, 2021 and Other Extensions Act (CR; Pub. L. 116–159) amended Section 1101 of the FFCRA to extend the authority for P–EBT through FY 2021 (which would cover portions of School Years 2020/2021 and 2021/2022) and expanded P–EBT to include: (1) Households with children whose schools reduce the number of days or hours that students attend school for at least five consecutive days during a public health emergency, (2) households with at least one child enrolled in a covered childcare facility and SNAP when the covered child care facility is closed or has reduced attendance or hours for at least five consecutive days during a public health emergency, and (3) households with at least one child enrolled in a covered childcare facility and SNAP when one or more schools in the area of the covered child care facility are closed or have reduced attendance or hours for at least five consecutive days during a public health emergency.

The USDA's Food and Nutrition Service (FNS or the Agency) works to end hunger and obesity through the Federal administration of 15 Federal nutrition assistance programs including the National School Lunch Program (NSLP), which provides free and reduced price lunches to eligible children, and the Supplemental Nutrition Assistance Program (SNAP), which provides nutrition benefits to supplement the food budgets of needy families so they can purchase healthy food and move towards self-sufficiency. FNS was, therefore, charged by Congress with the implementation of P–EBT at the Federal level. As of November 4, 2020, 52 States [1] have been approved by USDA to administer P–EBT. Collectively, these States have been approved to provide over 30.1 million eligible children with about $10.1 billion in food assistance benefits.

Section 1101(d) of the FFCRA provided States the option to deliver P–EBT benefits via the Electronic Benefit Transfer (EBT) system established for SNAP benefits by Section 7 of the Food and Nutrition Act of 2008 (FNA; 7 U.S.C. 2016). All States, as defined by

[1] All 50 states, the District of Columbia, the U.S. Virgin Islands, and Guam are referred to as ''States'' for this rule, and all 53 States (as defined in section 3(r) of the Food and Nutrition Act) were eligible to administer P–EBT under section 1101 of FFCRA as originally enacted. Of those 53, only 52 have requested P–EBT. While the CR extended the option to receive P–EBT benefits to other State Agencies not covered by the original FFCRA—Puerto Rico, American Samoa, and the Northern Mariana Islands—these territories manage retailer participation as a part of their block grants. Retailers in these territories are not currently subject to 7 CFR part 278 and would not be subject to 7 CFR part 284. As such, for purposes of this rule, they are not included in any reference to States or State Agencies.

this rule, that have implemented P–EBT have opted to use the EBT system for such delivery.

Routine Operation of SNAP Benefit Issuance and Redemption

SNAP benefits are issued and redeemed using the EBT system. Each SNAP household has an account into which SNAP benefits are issued on a monthly basis. The SNAP benefits are accessed by a household using an EBT card and a personal identification number (PIN), and may only be used to purchase SNAP eligible food as defined in 7 CFR 271.2.

In addition, SNAP benefits may only be redeemed at firms [2] authorized by USDA to accept SNAP benefits. Per Section 9 of the FNA (7 U.S.C. 2018) and 7 CFR 278.1(a), firms must apply to and be authorized by the Department to accept SNAP benefits as a form of payment. The Department is responsible for policy and oversight related to firm eligibility, authorization, and compliance. USDA oversight includes integrity efforts such as findings of violations on the basis of evidence obtained through on-site investigations, inconsistent SNAP redemption data, and evidence obtained through a transaction report under the EBT system. Per 7 CFR 278.1, 278.6, and 278.7, firms that violate SNAP rules may face the following:

Adverse Administrative Actions

- Denial (a firm applying for SNAP authorization is found ineligible and may not reapply for a specific period)
- Withdrawal (an authorized firm is found ineligible, removed from the program, and may not reapply for a specific period)
- *Penalties (imposed after an investigation revealed violations):*
  - ➢ Warning Letter (the violations found at the firm do not rise to the level of a sanction, so the firm is only warned)
  - ➢ *Sanctions (the violations found at the firm are serious, so the firm is subject to a sanction):*
    - ○ Claim (the firm must repay illicitly obtained benefits)
    - ○ Disqualification (the firm may not participate in the program for a specific period)
    - ○ *Civil Money Penalty* (CMP; the firm must pay a fine)
      - ▪ Hardship CMP (a firm facing a term disqualification in a low food access area may pay a fine and continue to participate in the program)
      - ▪ Transfer of Ownership CMP (a firm is sold while serving a period of disqualification and must pay a fine)
      - ▪ Trafficking CMP (a firm meeting certain criteria may pay a fine in lieu of permanent disqualification for trafficking)

One of the most serious violations of SNAP rules for firms is *trafficking.* SNAP regulations at 7 CFR 271.2 currently define the violation of *trafficking. Trafficking* usually means the exchange of SNAP benefits for cash or other consideration and carries more serious sanctions for firms. The Department monitors and takes appropriate administrative action, including sanctions, against firms that engage in trafficking and other violations. USDA cannot fulfill its primary purpose of helping individuals and families in need afford a basic diet without maintaining strong program integrity. USDA takes its role as a steward of public funds seriously and emphasizes program integrity throughout all program operations, including the use of a fraud detection system to analyze data on EBT transactions conducted at firms.

Implementation of P–EBT and Interaction With SNAP

Per Section 1101(d) of the FFCRA, P–EBT benefits may be issued through the same EBT system established by Section 7 of the FNA (7 U.S.C. 2016) which is used to issue SNAP benefits. To accelerate the implementation of P–EBT, ease administrative burden for States, and more rapidly provide emergency financial relief to families, States generally issued P–EBT benefits onto a household's existing EBT card if the household was already receiving SNAP benefits (and therefore already possessed an EBT card).

Initially, the Department planned to implement P–EBT using a model similar to that used for certain Child Nutrition Summer EBT demonstration projects (Summer EBT for Children or SEBTC) as authorized by the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010 (Pub. L. 111–80). In this SEBTC model, benefits are issued to a participant's existing EBT card into an account distinct from SNAP, and the SEBTC benefits remain separate from SNAP benefits throughout the issuance and redemption process. However, because this SEBTC model was only ever implemented as a demonstration project in 7 States, most States were not already equipped with the infrastructure needed to implement P–EBT in the same manner.

Due to the experience administering these SEBTC demonstration projects, USDA determined that it would take several months to modify SNAP State Agency eligibility and issuance systems to accommodate this type of model for P–EBT. In addition, due to the ongoing and national COVID–19 Public Health Emergency, SNAP State Agencies found themselves extremely short-staffed and unable implement this type of major system modification.

After consultation with SNAP State Agencies, and in light of the urgency of the ongoing and national COVID–19 Public Health Emergency, USDA permitted States to issue SNAP and P–EBT benefits using essentially the same existing SNAP EBT mechanism every State already had in place. As a result of this, however, P–EBT and SNAP benefits are generally indistinguishable throughout the issuance and redemption process.

Under the process implemented by States, P–EBT benefits were generally issued onto a household's existing EBT card if the household was already receiving SNAP benefits (and therefore already possessed an EBT card). Such SNAP households would have received P–EBT benefit issuances into their existing SNAP accounts. Once P–EBT benefits were issued into households' existing SNAP accounts, P–EBT benefits and SNAP benefits became comingled, and neither SNAP households receiving P–EBT benefits nor firms accepting P–EBT benefits were able to tell the difference between these two types of benefits. In at least one State, new cards were sent to all P–EBT recipient households, regardless as to their participation in SNAP.

Non-SNAP households that were eligible for P–EBT benefits generally received EBT cards in the mail that were loaded with only P–EBT benefits. These cards issued to non-SNAP households functioned identically to the EBT cards provided to SNAP households.

Despite using the same delivery and funding mechanism, P–EBT benefits are not SNAP benefits. SNAP was authorized and is governed by the FNA, while P–EBT was separately created and is governed by the FFCRA with separate appropriations for a different purpose—to provide supplemental allotments to households with children who would have otherwise received free or reduced school meals, but for school closures related to the ongoing and national COVID–19 Public Health Emergency. *See* Section 1101 of the FFCRA. Nevertheless, the aforementioned implementation mechanisms rendered P–EBT and SNAP benefits essentially

[2] As defined at 7 CFR 271.2.

indistinguishable for benefit issuance and redemption purposes.

Purpose of the Final Rule

Because P–EBT and SNAP benefits are essentially indistinguishable for benefit issuance and redemption purposes when the benefits are loaded onto the same EBT card, neither SNAP households receiving P–EBT benefits nor firms accepting P–EBT benefits are able to tell the difference between these two types of benefits. At the same time, the Department's SNAP fraud detection system also cannot distinguish between these two types of benefits.

In addition, as discussed earlier, 7 CFR parts 271 and 278 provide for adverse administrative actions against firms for SNAP violations, such as trafficking, but those regulations govern violations involving SNAP benefits, not P–EBT benefits. Since P–EBT benefits are not SNAP benefits, existing regulations regarding the appropriate use of SNAP benefits and the consequences for misusing those benefits do not apply to P–EBT benefits, and there are currently no such provisions for the misuse of P–EBT benefits. However, USDA finds it appropriate and necessary to impose certain restrictions on the use of P–EBT benefits for several reasons described below.

Congress initially authorized P–EBT as food assistance for households with children who lost free or reduced price school meals and since then, as mentioned previously, has greatly expanded P–EBT's scope. P–EBT benefits are not cash assistance, nor are they intended for misuse such as trafficking. As a type of replacement for the value of meals at schools or covered child care facilities,[3] P–EBT is not intended for certain incongruous uses, including the purchase of nonfood items such as alcohol and tobacco. To safeguard the integrity of P–EBT (as well as SNAP), this final rule will ensure that the Department can hold firms accountable by aligning P–EBT with certain existing SNAP integrity regulations. The Department believes that providing an integrity scheme for P–EBT helps ensure that P–EBT benefits are used for their intended purpose, upholding the Congressional intent of both the FFCRA and the CR.

The inability to impose penalties on all firms for misuse of P–EBT benefits undermines USDA's oversight and integrity efforts, and would also adversely affect SNAP oversight and integrity. For example, in FY 2019, USDA identified and sanctioned more than one thousand firms engaged in the trafficking of SNAP benefits.[4] The overwhelming majority of these cases were built, at least in part, using the Department's SNAP fraud detection system's transaction data. Since the Department's SNAP fraud detection system cannot distinguish between SNAP and P–EBT benefits in transaction data, USDA would be unable to use this vital data in program integrity work without considerable time-consuming modifications and resources, or the promulgation of this final rule.

Without this final rule, USDA's ability to hold violators accountable would be adversely impacted. To illustrate the impact on USDA's oversight efforts, a 2017 report regarding trafficking activities from 2012 through 2014 revealed that approximately 12 percent, or about 36,000 firms, engaged in trafficking, totaling approximately $1.1 billion a year or about 1.5% of all benefits redeemed. If USDA were unable to use EBT transaction data as is typically done for detecting trafficking and sanctioning trafficking firms, then as many as a thousand fewer firms engaging in trafficking would be identified and sanctioned in a year.[5] This would mean that such firms would be able to continue to commit trafficking violations without consequence, resulting in as much as $31 million in fraud a year that would remain unchecked.[6]

The purpose of P–EBT was to provide financial relief to families in the midst of the ongoing national COVID–19 Public Health Emergency. USDA prioritized expediting the implementation of P–EBT in States that applied. However, while making expeditious implementation possible, the co-mingling of SNAP and P–EBT benefits inadvertently introduced this anomaly into FNS integrity efforts.

If USDA did not promulgate this final rule, then USDA would not be able to efficiently and effectively address misuse by firms of P–EBT benefits or SNAP benefits, and both P–EBT and SNAP program integrity would be adversely impacted. Assuming that P–EBT benefits are trafficked at a rate similar to SNAP benefits, USDA estimates that $151 million in P–EBT benefits could be trafficked.[7] Currently, USDA estimates that about 3 percent of actual EBT fraud is detected through investigations that utilize EBT transaction data. The limited ability to use this data would potentially cause this fraud to go unchecked, which would constitute a serious integrity issue. Furthermore, because P–EBT benefits may remain in a household's account for months or even years before being expunged, USDA must address these integrity problems; otherwise, they could persist for months or even years after the issuance of P–EBT benefits.[8] This final rule is crucial in allowing USDA to address trafficking in a timely manner and ensuring P–EBT benefits, as well as SNAP benefits, are used in a manner consistent with Congressional intent.

This final rule allows USDA to immediately address the integrity issues, instead of prolonging them and allowing for bad actors to discover the anomaly and take advantage of it. If USDA were to notify the public of these integrity issues without implementing a comprehensive solution, then such a notice would subvert program integrity. By promulgating this final rule, USDA is ensuring that traditional mechanisms of ongoing and robust firm oversight

[3] As authorized by the originally enacted Section 1101(b) of FFCRA and explained in *Pandemic EBT (P–EBT) Questions and Answers* (April 15, 2020) (available at: *https://fns-prod.azureedge.net/sites/default/files/resource-files/SNAP-COVID-PEBTQA.pdf),* the guidelines for P–EBT benefit amounts were based on the value of the rates for free school meals. All States that issued P–EBT benefits after the original enactment of the FFCRA did so in amounts corresponding to the value of the rates for free school meals. The CR subsequently amended Section 1101(i) of the FFCRA to define ''free rate'' separately for breakfast and lunch, based on the rates of those free meals under Section 4 of the Child Nutrition Act of 1966 and the Richard B. Russell National School Lunch Act, respectively.

[4] Data drawn from USDA's ''Fiscal Year 2019 Year End Summary'' (*https://fns-prod.azureedge.net/sites/default/files/resource-files/2019-SNAP-Retailer-Management-Year-End-Summary.pdf*).

[5] Data drawn from USDA's ''Fiscal Year 2019 Year End Summary'' (*https://fns-prod.azureedge.net/sites/default/files/resource-files/2019-SNAP-Retailer-Management-Year-End-Summary.pdf*).

[6] The 2012–2014 retailer trafficking study estimated that about 36,000 retailers engage in trafficking totaling about $1.1 billion a year (reflecting about 1.5% of benefits redeemed). Using an arithmetic mean, the average trafficking retailer traffics about $31,000 in a year. USDA identified and sanctioned about 1,000 firms for trafficking in FY 2019 using EBT transaction data analysis as an investigative tool. If this USDA work were hampered, then these firms could continue trafficking activities at the same or a greater rate, resulting in as much as $31 million in trafficking being unchecked.

[7] Total P–EBT benefit issuance is about $10.1 billion and the estimated 2012–2014 SNAP retailer trafficking rate is 1.5% of benefits redeemed.

[8] For administrative ease, most States chose to issue P–EBT benefits such that these benefits would only be expunged from beneficiaries' SNAP accounts after a continuous 365-day period of inactivity per SNAP standards at 7 CFR 274.2(h)(2) as they were when P–EBT State Plans were submitted. Every time a beneficiary accesses their benefits, this 365-day expungement clock is reset. Some beneficiaries may choose to conserve their P–EBT benefits, using them sparingly over a protracted period. Therefore, although P–EBT is currently authorized through September 30, 2020, P–EBT benefits could remain on EBT cards years after that date.

and enforcement are maintained to protect the integrity of both P–EBT and SNAP and that the current lack of P–EBT integrity regulations is addressed without further unnecessary and harmful delay. This will allow USDA to continue detecting and pursuing administrative remedies to ensure there is no increase in trafficking and other violations.

Importantly, given the urgency of the issue, it is most efficient for P–EBT regulations to adopt the structure and meaning of SNAP regulations instead of crafting an entirely new regulatory scheme and implementing massive system changes that would accompany such a new regulatory scheme. Such separate undertakings solely for P–EBT are impractical and potentially ineffective because of the time, cost, and effort involved.

For the reasons discussed, this final rule establishes integrity regulations (as enumerated in this final rule) for P–EBT benefits as detailed further below in the ''Summary of P–EBT Regulations'' section.

Summary of P–EBT Regulations

This final rule establishes that P–EBT benefits issued pursuant to Section 1101 of the FFCRA, as amended by the Continuing Appropriations Act, 2021 and Other Extensions Act (CR; Pub. L. 116–159) or any subsequent legislation, are subject to integrity regulations, as enumerated below. This change will ensure that P–EBT (as well as SNAP) is administered in a manner that safeguards against fraud and abuse. This final rule renames the previously reserved part 284 as ''Miscellaneous'' and creates § 284.1, titled ''Pandemic Electronic Benefits Transfer (P–EBT),'' therein.

The following crosswalk summarizes the provisions of this new § 284.1. The left column lists the citation for each final rule provision, the center column summarizes the effect of the provision, and the right column indicates the preexisting SNAP integrity regulation to which the final rule provision refers. In using phrases such as ''involving P–EBT benefits'', the Department means that the activity at issue involves P–EBT benefits as well as SNAP benefits, or only P–EBT benefits. Under 7 CFR 278.6, a firm that commits serious violations may be subject to a period of disqualification or a civil money penalty. Under this final rule, if a firm commits violations involving P–EBT benefits (*e.g.,* trafficking only P–EBT benefits or trafficking a combination of P–EBT and SNAP benefits), then that firm shall be subject to the appropriate sanction (*e.g.,* permanent disqualification or a civil money penalty in lieu of permanent disqualification). Firms shall not be subject to multiple sanctions for a single investigation that involves both P–EBT and SNAP benefits (*i.e.,* firms shall not be subject to one sanction for misuse of P–EBT benefits and a separate sanction for misuse of SNAP benefits based on a single investigation).

While this final rule promulgates provisions for P–EBT benefits that generally track the corresponding SNAP benefit provisions, one exception is the P–EBT benefits provision concerning judicial review. As P–EBT benefits arise from FFCRA, as amended regulations at § 284.1(g) will provide for judicial appeal rights pursuant the Administrative Procedure Act (5 U.S.C. 702 through 706) as opposed to section 14 of the FNA. Currently, judicial review requests for civil cases filed pursuant to the Administrative Procedure Act have a six-year statute of limitations. *See* 28 U.S.C. 2401(a).

Citation in this final rule	Purpose of final rule provision	Reference to preexisting regulation
7 CFR 284.1(a)	background on P–EBT and the function of this section	n/a.
7 CFR 284.1(b)(1)	definition of *trafficking* applies to activities described in such definition involving P–EBT benefits.	7 CFR 271.2.
7 CFR 284.1(b)(2)	definition of *firm's practice* applies to activities described in such definition involving P–EBT benefits.	7 CFR 271.2.
7 CFR 284.1(b)(3)	definition of *involving P–EBT benefits* or *involve P–EBT benefits* means activities involving P–EBT benefits as well as SNAP benefits, or only P–EBT benefits.	n/a.
7 CFR 284.1(c)	requirements and restrictions on the participation of retail food stores and wholesale food concerns and the redemption of coupons apply to activities involving P–EBT benefits, including the restriction that P–EBT benefits may only be accepted by an authorized firm and only in exchange for eligible food.	7 CFR 278.2, 278.3, and 278.4.
7 CFR 284.1(d)	a firm may be subject to denial or withdrawal for any violations involving P–EBT benefits as specified in the subparagraphs.	7 CFR 278.1.
7 CFR 284.1(d)(1)	firms with certain sanctions for violations involving P–EBT benefits must submit a collateral bond or irrevocable letter or credit as a condition of authorization; the calculation of the value of such collateral bonds or irrevocable letters or credit shall also include the amount of P–EBT redemptions.	7 CFR 278.1(b)(4).
7 CFR 284.1(d)(2)	authorization will be denied or withdrawn for activities indicating a lack of necessary business integrity and reputation, including activities involving P–EBT benefits.	7 CFR 278.1(b)(3), (k)(3) and (6), and (l)(1)(iv).
7 CFR 284.1(d)(3)	authorization will be denied or withdrawn for failure to pay fines, penalties, and claims imposed for violations involving P–EBT benefits.	7 CFR 278.1(k)(7) and (l)(1)(v) and (vi).
7 CFR 284.1(e)	a firm may be subject to disqualification, monetary penalties, and/or fines for any violations that include activities involving P–EBT benefits as specified in the subparagraphs.	7 CFR 278.6.
7 CFR 284.1(e)(1)	permanent disqualification or civil monetary penalty in lieu of permanent disqualification for trafficking applies to trafficking that involves P–EBT benefits.	7 CFR 278.6(e)(1)(i) and (i).
7 CFR 284.1(e)(2)	permanent disqualification for violations involving P–EBT benefits, such as the sale of ineligible items, when the firm had already been sanctioned at least twice.	7 CFR 278.6(e)(1)(ii).
7 CFR 284.1(e)(3)	sanctions for unauthorized acceptance apply to transactions involving P–EBT benefits.	7 CFR 278.6(e)(2)(v), (e)(3)(iv), and (m).

Citation in this final rule	Purpose of final rule provision	Reference to preexisting regulation
7 CFR 284.1(e)(4)	5-year disqualification for certain firms when collective redemptions exceed food sales in a certain time period; the amount of redemptions shall also include the amount of P–EBT redemptions.	7 CFR 278.6(e)(2)(ii), (iii), and (iv).
7 CFR 284.1(e)(5)	3-year disqualification for any of the violations described in § 278.6(e)(2) when FNS had not previously advised the firm of the possibility that violations were occurring and of the possible consequences of violating the regulations, when those violations involve P–EBT benefits.	7 CFR 278.6(e)(3)(ii).
7 CFR 284.1(e)(6)	1-year disqualification for transactions involving P–EBT benefits where retailer accepted benefits in payment for items sold on credit.	7 CFR 278.6(e)(4)(ii) and 278.2(f).
7 CFR 284.1(e)(7)	disqualifications for sale of ineligible foods applies to transactions involving P–EBT benefits.	7 CFR 278.6(e)(2)(i), (e)(3)(i), (e)(4)(i), and (e)(5).
7 CFR 284.1(e)(8)	periods of disqualification imposed against firms will be doubled when such firms have been sanctioned for committing violations involving P–EBT benefits.	7 CFR 278.6(e)(6).
7 CFR 284.1(e)(9)	warning letters shall be issued to firms when such firms commit violations involving P–EBT benefits, which are too limited to warrant a period of disqualification.	7 CFR 278.6(e)(7).
7 CFR 284.1(e)(10)	calculation of hardship and transfer of ownership civil money penalties includes consideration of the firm's average monthly redemption of P–EBT benefits.	7 CFR 278.6(g).
7 CFR 284.1(e)(11)	calculation of trafficking civil money penalties includes consideration of the firm's average monthly redemption of P–EBT benefits.	7 CFR 278.6(j).
7 CFR 284.1(f)	standards regarding the determination and disposition of claims apply to claims based on P–EBT benefits.	7 CFR 278.7.
7 CFR 284.1(g)	firms aggrieved by administrative action under § 284.1(d), (e), and (f) may request administrative review in accordance with part 279, subpart A. Firms aggrieved by the determination of such an administrative review may seek judicial review under 5 U.S.C. 702 through 706.	7 CFR part 279.

Procedural Matters

Administrative Procedure Act (APA) Statement

The Administrative Procedure Act of 1946, as amended (APA; 5 U.S.C. 553), generally requires that agencies go through notice-and-comment rulemaking before finalizing regulations and have a 30-day delayed effective date for final rules. The APA, however, allows for exemptions to these requirements. This final rule is being promulgated under one of these exemptions, as described below.

APA Exemption for Rules Pertaining to Benefits

The APA provides that the notice-and-comment and 30-day delay in the effective date provisions do not apply when a rule concerns ''a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.'' 5 U.S.C. 553(a)(2). P–EBT is a food assistance benefit created by the FFCRA and, therefore, USDA has the authority under FFCRA to issue a final rule pertaining to P–EBT without notice-and-comment or a delayed effective date.[9]

[9] Previously, USDA utilized APA notice-and-comment rulemaking procedures regardless of the APA exemption for benefits, pursuant to the ''Public Participation in Rule Marking: Statement of Policy'' (Statement of Policy), published on July 24, 1971 (36 FR 13804). However, this Statement of Policy was rescinded in 2013. 78 FR 64194 (Oct. 28, 2013). Additionally, while Section 4(c) of the FNA (7 U.S.C. 2013(c)) generally requires USDA FNS to comply with the APA requirements when promulgating SNAP regulations under the FNA, this final rule is promulgated under the FFCRA, not the FNA. Therefore, this final rule regarding P–EBT benefits is exempt from the APA notice-and-comment and 30-day delay in the effective date provisions under 5 U.S.C. 553(a)(2). Furthermore, while notice-and-comment rulemaking remains an option for matters involving benefits, USDA is choosing to promulgate a final rule for P–EBT benefits under the authority in 5 U.S.C. 553(a)(2) because the additional time to undergo notice-and-comment would further undermine integrity. Firms are already subject to certain requirements regarding the redemption of SNAP benefits on EBT cards; therefore, carrying over those requirements to P–EBT benefits that are often comingled with SNAP benefits on the same EBT cards does not warrant departure from 5 U.S.C. 553(a)(2).

Executive Order 12866 and Executive Order 13563

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 quantifying both cost and benefits, of reducing cost, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) has reviewed this final rule and determined that it is not significant under Executive Order 12866 (E.O. 12866). E.O. 12866 defines a ''significant regulatory action'' as one that is likely to: (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 E.O. 12866. This final rule does not meet any of these criteria.

The Department does not anticipate that this final rule will impose any additional costs on firms, beneficiary households, SNAP State Agencies, or any other stakeholders. USDA estimates that failure to promulgate and implement this final rule would significantly hamper the agency's ability to enforce regulation and law in maintaining SNAP integrity. USDA considered the regulatory alternatives of taking no action or promulgating this final rule instead as a notice of proposed rulemaking, but these approaches were rejected for the reasons provided in the preamble. As this rule was designated not significant, no additional regulatory impact analysis has been performed for this rule.

Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (RFA) generally requires that agencies must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such an analysis in the **Federal Register**. Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such an analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. Except for such small government jurisdictions, neither State nor local governments are ''small entities.'' Similarly, for purposes of the RFA, individual persons are not small entities. The requirement to conduct a regulatory impact analysis does not apply if the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' The Department hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Congressional Review Act

Pursuant to the Congressional Review Act (CRA; Pub. L. 104–121), OMB has designated this action as not a major rule, as defined by 5 U.S.C. 804(2). The CRA defines a ''major rule'' as any rule that has resulted in or is likely to result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or, significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Executive Order 13771

Executive Order 13771 directs agencies to reduce regulation and control regulatory costs and provides that the cost of planned regulations be prudently managed and controlled through a budgeting process. This rule is not an E.O. 13771 regulatory action because it is not significant under E.O. 12866.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988 (E.O. 12988), Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations, or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This final rule is not intended to have retroactive effect. Prior to any judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted.

Executive Order 12372, Intergovernmental Review

Executive Order 12372 (E.O. 12372) requires intergovernmental consultation with State and local governments that would provide non-Federal funds for, or that would be directly affected by, proposed Federal financial assistance or direct Federal development. This is a final rule regarding benefits fully funded by the Federal Government and is therefore excluded from the scope of E.O. 12372.

Executive Order 13132, Federalism

Executive Order 13132 (E.O. 13132) requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, imposes substantial direct compliance costs on State and local government, and are not required by statute, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under Section (6)(b)(2)(B) of E.O. 13132.

The Department has considered the impact of this final rule on State and local governments and has determined that this rule does not have federalism implications. Therefore, a federalism impact summary is not required.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (E.O. 13175) requires Federal agencies to consult and coordinate With Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions 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. The Department has considered the impact of this final rule on Indian Tribes and has determined that this rule does not have Tribal implications. Although Tribal consultation and coordination is not required under E.O. 13175, USDA commits to review of this rule at the Department's next scheduled Tribal listening session in case unexpected Tribal government issues or concerns emerge during implementation.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; 5 CFR part 1320) requires the Office of Management and Budget (OMB) approve collections of information by a Federal agency before they can be implemented.

In accordance with 44 U.S.C. 3518(c)(1)(B)(ii), any information requests or requirements in this rule are not subject to the requirements of the Paperwork Reduction Act because such collections of information are pursuant to an administrative action or investigation by an agency of the United States against specific individuals or entities. The Secretary hereby certifies that this rule does not impose reporting or recordkeeping requirements subject to the approval by the Office of Management and Budget under the requirements of the Paperwork Reduction Act.

E-Government Act Compliance

USDA is committed to the E-Government Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. An electronic copy of this final rule will be made available through the agency's website.

Unfunded Mandates Reform Act

This final rule contains no Federal mandates (under the regulatory provision of title II of the Unfunded Mandates Reform Act of 1995) for State, local, and Tribal governments or the private sector. Therefore, this final rule is not subject to the requirements of section 202 and 205 of the Unfunded Mandates Reform Act.

Civil Rights Impact Analysis

USDA FNS has reviewed this final rule in accordance with USDA Regulation 4300–4, ''Civil Rights Impact Analysis,'' to identify any major civil rights impacts this final rule might have on SNAP or P–EBT participants on the basis of age, race, color, national origin, sex or disability. After review and

analysis of the final rule and available data, it has been determined that this final rule will neither adversely nor disproportionately impact any protected group. As this final rule has not been designated a ''significant regulatory action,'' a separate Civil Rights Impact Analysis (CRIA) is not required per Section 7(a) of USDA Regulation 4300–4, ''Civil Rights Impact Analysis.''

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and USDA civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *http://www.ascr.usda.gov/complaint_filing_cust.html* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

List of Subjects in 7 CFR Part 284

Administrative practice and procedure, Food stamps, Grant programs-social programs, Pandemic, Penalties.

■ For the reasons set out in the preamble, 7 CFR part 284 is added to read as follows:

PART 284—MISCELLANEOUS

Sec.
284.1 Pandemic Electronic Benefits Transfer (P–EBT).
284.2 [Reserved]

Authority: Pub. L. 116–127, 134 Stat. 178.

§ 284.1 Pandemic Electronic Benefits Transfer (P–EBT).

(a) *Overview.* Section 1101 of the Families First Coronavirus Response Act (FFCRA; Pub. L. 116–127), as amended, authorized supplemental allotments to certain households. These benefits shall be referred to as Pandemic Electronic Benefits Transfer (P–EBT) benefits throughout this section. This section establishes the retailer integrity regulations for P–EBT for retailers in any State as defined in Section 3(r) of the Food and Nutrition Act.

(b) *Definitions.* For this section:

(1) *Trafficking* means the activities described in the definition of trafficking at § 271.2 of this chapter when such activities involve P–EBT benefits.

(2) *Firm's practice* means the activities described in the definition of firm's practice at § 271.2 of this chapter when such activities involve P–EBT benefits.

(3) *Involving P–EBT benefits* or *involve P–EBT benefits* means activities involving P–EBT benefits as well as supplemental nutrition assistance program (SNAP) benefits, or only P–EBT benefits.

(c) *Participation of retail food stores and wholesale food concerns, and redemption of P–EBT benefits.* Requirements and restrictions on the participation of retail food stores and wholesale food concerns and the redemption of coupons described at §§ 278.2, 278.3 and 278.4 of this chapter, including the acceptance of coupons for eligible food at authorized firms, also apply to activities involving P–EBT benefits.

(d) *Firm eligibility standards.* A firm may be subject to the following actions described at § 278.1 of this chapter for noncompliance or violations involving P–EBT benefits:

(1) The requirements described at § 278.1(b)(4) of this chapter regarding a collateral bond or irrevocable letter of credit for applicant firms with certain sanctions apply to applicant firms with sanctions imposed for violations involving P–EBT benefits. The amount of the collateral bond or irrevocable letter of credit shall be calculated in accordance with § 278.1(b)(4)(i)(D) and shall also include the amount of P–EBT benefit redemptions when calculating the average monthly benefit redemption volume.

(2) Authorization shall be denied or withdrawn based on a determination by the Food and Nutrition Service (FNS) that a firm lacks or fails to maintain necessary business integrity and reputation, in accordance with the standards and time periods described at § 278.1(b)(3), (k)(3), and (l)(1)(iv) of this chapter. When making such determinations, FNS shall consider the criteria referred to in § 278.1(b)(3), (k)(3), and (l)(1)(iv) where the underlying activities involve P–EBT benefits.

(3) Firm authorization shall be denied or withdrawn for failure to pay any claims, fines, or civil money penalties in the manner described at § 278.1(k)(7) and (l)(1)(v) and (vi) of this chapter where such sanctions were imposed for violations involving P–EBT benefits.

(e) *Penalties.* For firms that commit certain violations described at §§ 278.6 and 278.2 of this chapter where such violations involve P–EBT benefits, FNS shall take the corresponding action prescribed at § 278.6 or § 278.2 for that violation. For the purposes of assigning a period of disqualification, a warning letter shall not be considered to be a sanction. Specifically, FNS shall:

(1) Disqualify a firm permanently, as described at § 278.6(e)(1)(i) of this chapter, for trafficking, as defined at § 284.1(b)(1) of this chapter, or impose a civil money penalty in lieu of permanent disqualification, as described at § 278.6(i) of this chapter, where such compliance policy and program is designed to prevent violations of regulations of this section;

(2) Disqualify a firm permanently, as described at § 278.6(e)(1)(ii) of this chapter, for any violation involving P–EBT benefits committed by a firm that had already been sanctioned at least twice before under this section or part 278 of this chapter;

(3) Disqualify the firm for 5 years, as described at § 278.6(e)(2)(v) of this chapter, or for 3 years, as described at § 278.6(e)(3)(iv) of this chapter, for unauthorized acceptance violations involving P–EBT benefits, and impose fines, as described at § 278.6(m) of this chapter, for unauthorized acceptance violations involving P–EBT benefits;

(4) Disqualify the firm for 5 years in circumstances described at § 278.6(e)(2) of this chapter when the amount of redemptions, which shall also include the amount of P–EBT redemptions, exceed food sales for the same period of time, as described at § 278.6(e)(2)(ii), (iii), and (iv);

(5) Disqualify the firm for 3 years as described at § 278.6(e)(3)(ii) of this chapter for situations described at § 278.6(e)(2) of this chapter involving P–EBT benefits;

(6) Disqualify the firm for 1 year for credit account violations as described at §§ 278.6(e)(4)(ii) and 278.2(f) of this chapter, where such violations involve P–EBT benefits;

(7) Disqualify the firm for ineligibles violations for such circumstances and corresponding time periods as described at § 278.6(e)(2)(i), (e)(3)(i), (e)(4)(i), and (e)(5) of this chapter, where such violations involve P–EBT benefits;

(8) Double the appropriate period of disqualification for a violation, as described at § 278.6(e)(6) of this chapter, where such violation involves P–EBT benefits, when the firm has once before been assigned a sanction under this section or part 278 of this chapter;

(9) Issue a warning letter to the violative firm when violations are too limited to warrant a period of disqualification, as described at § 278.6(e)(7) of this chapter, where such violations involve P–EBT benefits;

(10) Impose a civil money penalty for hardship or transfer of ownership, as described at § 278.6(g) of this chapter, in amounts calculated using the described formula at § 278.6(g), which shall also include the relevant amount of P–EBT redemptions when calculating the average monthly benefit redemptions; and

(11) Impose a civil money penalty in lieu of permanent disqualification for trafficking as described at § 278.6(j) of this chapter in an amount calculated using the described formula at § 278.6(j), which shall also include the relevant amount of P–EBT redemptions when calculating the average monthly benefit redemptions.

(f) *Claims.* The standards for determination and disposition of claims described at § 278.7 of this chapter apply to P–EBT benefits.

(g) *Administrative and Judicial review.* Firms aggrieved by administrative action under paragraphs (d), (e), and (f) of this section may request administrative review of the administrative action with FNS in accordance with part 279, subpart A, of this chapter. Firms aggrieved by the determination of such an administrative review may seek judicial review of the determination under 5 U.S.C. 702 through 706.

§ 284.2 [Reserved]

Pamilyn Miller,

Administrator, Food and Nutrition Service.

[FR Doc. 2020–24303 Filed 11–3–20; 8:45 am]

BILLING CODE 3410–30–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 125

RIN 3245–AH14

Regulatory Reform Initiative: Government Contracting Programs

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: With this deregulatory action, the U.S. Small Business Administration (SBA) is removing from the Code of Federal Regulations (CFR) four regulations in the Service-Disabled Veteran-Owned (SDVO) Small Business Concern (SBC) Program that are no longer necessary because they are unnecessary or redundant. The removal of these regulations assists the public by simplifying SBA's regulations in the CFR.

DATES: This rule is effective December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Khem Sharma, Chief, Office of Size Standards, (202) 205–7189 or *khem.sharma@sba.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

On February 4, 2020, SBA published a proposed rule with request for comments in the **Federal Register** to remove four regulations from the SDVO SBC program. 85 FR 6106. This program allows agencies to set aside contracts for SDVO SBCs. Under this program, Federal Agencies may also award sole source contracts to SDVO SBCs so long as the award can be made at a fair and reasonable price and the anticipated total value of the contract, including any options, is below $4 million ($6.5 million for manufacturing contracts). For purposes of this program, veterans and service-related disabilities are defined as they are under the statutes governing veterans' affairs, 38 U.S.C. 101.

SBA received no comments to the proposed rule. As such, SBA is finalizing the rule by removing four regulations that are unnecessary or covered elsewhere in the CFR.

II. Section-by-Section Analysis

§ 125.15 May an SDVO SBC have affiliates?

Section 125.15 provides that an SDVO SBC may have affiliates. This rule is redundant because whether an SDVO SBC can have an affiliate is addressed in 13 CFR 121.103, the general rules of affiliation.

§ 125.16 May 8(a) program participants, HUBZone SBCs, small and disadvantaged businesses, or women-owned small businesses qualify as SDVO SBCs?

Section 125.16 states that an SDVO SBC may qualify for other SBA contracting programs. This regulation is unnecessary because the requirements for an SDVO SBC to qualify for other programs are addressed in the rules on eligibility for those specific programs.

§ 125.19 Does SDVO SBC status guarantee receipt of a contract?

Section 125.19 states that an SDVO SBC is not guaranteed receipt of a contract. This provision is unnecessary because nothing in SBA's regulations indicates that qualifying as an SDVO SBC entitles a firm to a contract.

§ 125.20 Who decides if a contract opportunity for SDVO competition exists?

Section 125.20 is redundant because 13 CFR 125.22 and 125.23 already provide that contracting officers make SDVO SBC competition decisions.

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

A. Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule does not constitute a significant regulatory action for purposes of Executive Order 12866 and is not a major rule under the Congressional Review Act, 5 U.S.C. 801, *et seq.*

B. Executive Order 13771

This rule is expected to be an Executive Order 13771 deregulatory action with an annualized net savings of $33,669 and a net present value of $480,986, both in 2016 dollars.

The four regulations in the SDVO program are either unnecessary or redundant. Their removal will assist the public by simplifying the SBA's regulations in the CFR and reduce the time spent reviewing them. The cost saving calculation assumes 2 percent of the 21,750 SDVO small businesses per

year (or about 435) will save 30 minutes from not reading this removed information. This time is valued at a rate of $118.22 per hour—the median hourly wage of $59.11 for an attorney according to 2019 Bureau of Labor Statistics (BLS) data [1] plus 100 percent more for benefits and overhead. This produces savings to SDVO small businesses per year of $25,713 in current dollars.

The cost savings also includes a savings to the government, assuming that 2 percent of the 38,000 Federal contracting officers per year (or about 760) will save 30 minutes from not reading this removed information. This time is valued at a rate of $82.74—assuming the average Federal contracting officer is a GS–12 step 1 (DC locality in 2020 of $41.37) [2] and adding 100 percent more for benefits and overhead, for annual savings of $31,441. This produces total savings per year of $57,287 in current dollars.

The annual savings to SDVO small businesses and to the government totals to $57,154 in current dollars.

In the first year, it is assumed that 5 percent of SDVO small businesses (about 1,088) and 5 percent of Federal contracting officers (about 1,900) would read this **Federal Register** notice which is estimated to take 30 minutes per SDVO small business at $118.22 per hour and $82.74 per hour per Federal contracting officer, producing cost in the first year of $142,915 ($64,312 for SDVO small businesses and $78,603 for the Federal Government). This cost is not expected to continue in subsequent years.

Table 1 displays the costs and savings of this rule over the first 2 years it is published, with the savings and costs in the second year expected to continue into perpetuity. Table 2 presents the annualized net savings in 2016 dollars.

TABLE 1—SCHEDULE OF COSTS/(SAVINGS) OVER 2 YEAR HORIZON, CURRENT DOLLARS

	Savings	Costs
Year 1	598 hours, ($57,154).	1,494 hours, $142,915.
Year 2	598 hours, ($57,154).	0 hours, $0.

[1] *https://www.bls.gov/ooh/legal/lawyers.htm,* retrieved July 31, 2020.

[2] *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB_h.pdf,* retrieved July 31, 2020.

TABLE 2—ANNUALIZED SAVINGS IN PERPETUITY WITH 7% DISCOUNT RATE, 2016 DOLLARS

	Estimate
Annualized Savings	($40,254)
Annualized Costs	$6,585
Annualized Net Savings	($33,669)

C. Executive Order 12988

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

D. Executive Order 13132

This rule does not have federalism implications as defined in Executive Order 13132. 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, as specified in the Executive Order. As such, it does not warrant the preparation of a Federalism Assessment.

E. Paperwork Reduction Act, (5 U.S.C. 601–612)

SBA has determined that this final rule will not impose new, or modify existing, recordkeeping or reporting requirements under the Paperwork Reduction Act.

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

The Regulatory Flexibility Act (RFA) requires administrative agencies to consider the effect of their actions on small entities, small non-profit businesses, and small local governments. Pursuant to the RFA, when an agency issues a rule, the agency must prepare an analysis that describes whether the impact of the rule will have a significant economic impact on a substantial number of small entities. If not, the RFA permits agencies to certify to that effect.

There are approximately 21,750 SDVO small businesses and all can be affected by this rule. However, this rule removes regulations that are unnecessary or redundant, saving these entities time in reading the regulations. The annualized net savings to SDVO small businesses [3] is $15,147 in current dollars, or less than a dollar per SDVO small business, as detailed in the Executive Order 13771 discussion above.

SBA certified this rule at the proposed rule stage and received no comments on the certification. Accordingly, SBA therefore certifies that this rule has ''no significant impact upon a substantial number of small entities'' within the meaning of the RFA.

[3] From annualized savings of $18,110 per SDVO small businesses minus the one-time cost to SDVO small businesses annualized to $2,963, both in 2016 dollars.

List of Subjects in 13 CFR Part 125

Government contracts, Government procurement, Reporting and recordkeeping requirements, Small businesses, Technical assistance, Veterans.

Accordingly, for the reasons stated in the preamble, SBA is amending 13 CFR part 125 as follows:

PART 125—GOVERNMENT CONTRACTING PROGRAMS

■ 1. The authority citation for part 125 is revised to read as follows:

Authority: 15 U.S.C. 632(p), (q), 634(b)(6), 637, 644, 657f, 657q, 657r, and 657s; 38 U.S.C. 501 and 8127.

§§ 125.15, 125.16, 125.19, and 125.20 [Removed and Reserved]

■ 2. Remove and reserve §§ 125.15, 125.16, 125.19, and 125.20.

Jovita Carranza,

Administrator.

[FR Doc. 2020–23121 Filed 11–3–20; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0968; Project Identifier MCAI–2020–00974–T; Amendment 39–21304; AD 2020–22–08]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus SAS Model A320–251N and –271N airplanes; Model A321–251N, –271N, –272N, –252NX, and –271NX airplanes; Model A330–243, –343, and –941 airplanes; and Model A350–941 and –1041 airplanes. This AD was prompted by reports of removable

display units (RDUs) found undocked from the hosting display docking stations (DDSs). This AD requires removal of the RDUs or implementation of an operational restriction, and a one-time inspection of the RDU installation onto the DDS and, depending on findings, accomplishment of applicable corrective actions, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective November 19, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 19, 2020.

The FAA must receive comments on this AD by December 21, 2020.

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; phone: +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–2020–0968.

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–2020–0968; 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: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3225; email: *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0155, dated July 14, 2020 (''EASA AD 2020–0155'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A320–251N and –271N airplanes; Model A321–251N, –271N, –272N, –252NX, and –271NX airplanes; Model A330–243 airplanes; Model A330–343 airplanes; Model A330–941 airplanes; and Model A350–941 and –1041 airplanes.

This AD was prompted by reports of RDUs found undocked from the hosting DDSs caused by incorrect RDU installation or damage to the DDS. The FAA is issuing this AD to address undocked RDUs, which could lead to detachment of an RDU, possibly resulting in injury to airplane occupants. See the MCAI for additional background information.

Related IBR Material Under 1 CFR Part 51

EASA AD 2020–0155 describes procedures for removal of the RDUs or implementation of an operational restriction, and a one-time inspection of the RDU installation onto the DDS and, depending on findings, accomplishment of applicable corrective actions. Corrective actions include repair or replacement of the DDS, reinstallation or replacement of the RDU, and realignment of the RDU and DDS. 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 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 2020–0155 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 2020–0155 is incorporated by reference in this final rule. This AD, therefore, requires compliance with EASA AD 2020–0155 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 2020–0155 that is required for compliance with EASA AD 2020–0155 is available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0968.

FAA's Justification and Determination of the Effective Date

There are currently no domestic operators of these products. Therefore, the FAA finds that notice and opportunity for prior public comment are unnecessary and that good cause exists 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 the FAA did not precede it by notice and opportunity for public comment. 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–2020–0968; Project Identifier MCAI–2020–00974–T'' 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. 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 consider all comments received by the closing date and may amend this AD based on those comments.

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

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 the person identified in the **FOR FURTHER INFORMATION CONTACT** section. 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

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product
1 work-hour × $85 per hour = $85 per RDU	$0	$85 per RDU.

The FAA has received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

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 adding the following new airworthiness directive (AD):

2020–22–08 Airbus SAS: Amendment 39–21304; Docket No. FAA–2020–0968; Project Identifier MCAI–2020–00974–T.

(a) Effective Date

This AD becomes effective November 19, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS airplanes identified in paragraphs (c)(1) through (6) of this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2020–0155, dated July 14, 2020 (''EASA AD 2020–0155'').

(1) Model A320–251N and –271N airplanes.

(2) Model A321–251N, –271N, –272N, –252NX, and –271NX airplanes.

(3) Model A330–243 airplanes.

(4) Model A330–343 airplanes.

(5) Model A330–941 airplanes.

(6) Model A350–941 and –1041 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 23, Communications; 44, Cabin systems.

(e) Reason

This AD was prompted by reports of removable display units (RDUs) found undocked from the hosting display docking stations (DDS). The FAA is issuing this AD to address undocked RDUs, which could lead to detachment of an RDU, possibly resulting in injury to airplane 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 2020–0155.

(h) Exceptions to EASA AD 2020–0155

(1) Where EASA AD 2020–0155 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2020–0155 does not apply to this AD.

(3) Where the EASA AD specifies ''any discrepancies,'' those discrepancies include damage or deformity to the DDS tab, a jammed butterfly latch, a RDU that does not engage easily, and a RDU that does not latch.

(4) Where paragraph (3) of the EASA AD specifies a compliance time of ''before next flight,'' that compliance time does not apply to this AD.

(5) Where AOT A44P001–20–00 and A23L001–20–00, as specified in EASA AD 2020–0155, specify the gap must be equal to or greater than 4.2mm, for this AD, the gap must be greater than 4.0mm.

(i) 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 local Flight Standards District 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 (j) 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 local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, 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):* For any service information referenced in EASA AD 2020–0155 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3225; email: *dan.rodina@faa.gov.*

(k) 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.

(i) European Union Aviation Safety Agency (EASA) AD 2020–0155, dated July 14, 2020.

(ii) [Reserved]

(3) For information about EASA AD 2020–0155, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +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.*

(4) 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–2020–0968.

(5) 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 October 16, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–24345 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

32 CFR Part 2402

Implementing the Freedom of Information Act

AGENCY: Office of Science and Technology Policy.

ACTION: Final rule.

SUMMARY: The White House Office of Science and Technology Policy (OSTP), after consideration of the public comments submitted in response to its Notice of Proposed Rulemaking published on October 31, 2018, is amending its regulations to implement the FOIA Improvement Act of 2016. The regulations reflect OSTP's policy and practices and reaffirm its commitment to providing the fullest possible disclosure of records to the public.

DATES: Effective December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Nick Wittenberg, Legal Counsel, OSTP, (202) 456–4444. Questions about the content of this notice may also be sent to *ostpfoia@ostp.eop.gov.*

SUPPLEMENTARY INFORMATION: OSTP is amending its regulations governing its implementation of the Freedom of Information Act (FOIA). In 2013, OSTP implemented its FOIA regulations, currently codified at 32 CFR part 2402. The FOIA Improvement Act of 2016, Public Law 114–185, requires each agency to review and update its FOIA regulations in accordance with its provisions. Among other things, the FOIA Improvement Act makes changes that require agencies to (1) withhold information only when it is reasonably foreseeable that disclosure would harm an interest protected by an exemption; (2) allow a minimum of ninety (90) days to file an appeal following an adverse determination; and (3) inform requestors of their right to seek dispute resolution services.

In connection with OSTP's review of its FOIA regulations, OSTP is updating these regulations to clarify OSTP's process for responding to requests for information, incorporate new language on partial disclosures of information, increase the period of time for a requestor to appeal an adverse determination from thirty (30) days to ninety (90) days, and require OSTP to notify requestors of their right to seek dispute resolution services. Due to the scope of the proposed revisions, the new rules will replace OSTP's current FOIA regulations in their entirety. The new rules will reflect statutory changes to the FOIA and improve FOIA-related service and performance, thereby strengthening OSTP's compliance with the FOIA.

On October 31, 2018, OSTP issued a Notice of Proposed Rulemaking seeking comments on the proposed changes to its FOIA regulations. In response, OSTP received one public comment about the proposed rule. The commenter did not suggest any changes to the rule. OSTP, however, decided to make one minor additional change in order to clarify the calculation of fees. In the definition of ''direct cost'' in § 2402.3(c)(5), OSTP is changing the phrase, ''employee or

employees'' to ''personnel'' to more accurately reflect the fact that paid, contract, and other staff are used to search for, duplicate, and respond to FOIA requests. For this same reason, OSTP is revising § 2402.9(b) regarding calculation of fees to change the use of the word, ''employee(s),'' to ''personnel.''

Statutory and Executive Order Reviews

Executive Orders 12866 and 13563—Regulatory Review

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, section 1(b), Principles of Regulation, and in accordance with Executive Order 13563, Improving Regulation and Regulatory Review, section 1(b), General Principles of Regulation. This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866; accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB). Further, both 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 quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. OSTP has assessed the costs and benefits of this regulation and believes that the regulatory approach selected maximizes net benefits.

Paperwork Reduction Act

OSTP has determined that the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* does not apply because these regulations do not contain any information collection requirements subject to OMB's approval.

Executive Order 12988—Civil Justice Reform

These regulations meet the applicable standards set forth in sections 3(a) and 3(b) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132—Federalism

These regulations 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. Therefore, in accordance with Executive Order 13132, OSTP has determined that this regulation does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Regulatory Flexibility Act

This regulation finalizes the amendments to OSTP's FOIA regulations to incorporate certain changes made by the FOIA Improvement Act of 2016, to reflect developments in case law, and to streamline its procedures. OSTP, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this regulation and certifies that it will not have a significant economic impact on a substantial number of small entities because it pertains to administrative matters affecting the agency.

Unfunded Mandates Reform Act of 1995

This regulation 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 are necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501, *et seq.*

Small Business Regulatory Enforcement Fairness Act of 1996

This regulation is not a major regulation as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804. It will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

National Environmental Policy Act of 1969

OSTP has reviewed this regulation under the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321–4347, and has determined that it will not have a significant effect on the human environment.

List of Subjects in 32 CFR Part 2402

Freedom of information, Administrative practice and procedure.

■ For the reasons set forth in the preamble, OSTP revises 32 CFR part 2402 to read as follows:

PART 2402—REGULATIONS IMPLEMENTING THE FREEDOM OF INFORMATION ACT

Authority: 5 U.S.C. 552; E.O. 13392, 70 FR 75373, 3 CFR, 2005 Comp., p. 216.

§ 2402.1 Purpose and scope.

The regulations in this part prescribe procedures by which individuals may obtain access to the Office of Science and Technology Policy's (OSTP) agency records under the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, as well as the procedures OSTP must follow in response to requests for records under the FOIA. The regulations should be read together with the FOIA and the Office of Management and Budget's (OMB's) ''Uniform Freedom of Information Fee Schedule and Guidelines,'' which provides information about access to records. All requests for access to information contained within a system of records pursuant to the Privacy Act of 1974, 5 U.S.C. 552a, shall be processed in accordance with these regulations as well as those contained in 32 CFR part 2403.

§ 2402.2 Delegation of authority and responsibilities.

(a) The Director of OSTP designates the OSTP General Counsel as the Chief FOIA Officer and hereby delegates to the Chief FOIA Officer the authority to act upon all requests for agency records and to re-delegate such authority at his or her discretion.

(b) The Chief FOIA Officer shall designate a FOIA Public Liaison, who shall serve as the supervisory official to whom a FOIA requester can raise concerns about the service the FOIA requestor has received following an initial request. The FOIA Public Liaison will be listed on the OSTP website (*https://www.whitehouse.gov/ostp/foia*) and may re-delegate the FOIA Public Liaison's authority at his or her discretion.

(c) The Director establishes a FOIA Requester Service Center that shall be staffed by the Chief FOIA Officer and the FOIA Public Liaison. The contact

information for the FOIA Requester Service Center is: Address: Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue NW, Washington, DC 20504; Telephone: (202) 456–4444; Fax: (202) 395–1224; Email: *ostpfoia@ostp.eop.gov.* Updates to this contact information will be made on the OSTP website.

§ 2402.3 General policy and definitions.

(a) *Non-exempt records available to public.* Except for records exempt from disclosure by 5 U.S.C. 552(b) or published in the **Federal Register** under 5 U.S.C. 552(a)(1), OSTP's agency records subject to the FOIA are available to any requester who requests them in accordance with these regulations.

(b) *Record availability on the OSTP website.* OSTP shall make records available on its website in accordance with 5 U.S.C. 552(a)(2), as amended, and other documents that, because of the nature of their subject matter, are likely to be the subject of FOIA requests. To save both time and money, OSTP strongly urges requesters to review documents available on the OSTP website before submitting a request.

(c) *Definitions.* For purposes of this part:

(1) All of the terms defined in the FOIA and the definitions included in OMB's ''Uniform Freedom of Information Act Fee Schedule and Guidelines'' apply unless otherwise defined in this subpart.

(2) The term *agency record* means a record that is:

(i) Either created or obtained by OSTP; and

(ii) Under OSTP's control at the time the FOIA request is received.

(3) The term *commercial use request* means a request from or on behalf of a person who seeks information for a use or purpose that furthers his or her commercial, trade, or profit interests, which can include furthering those interests through litigation. OSTP shall determine, whenever reasonably possible, the use to which a requester will put the requested records. When it appears that the requester will put the records to a commercial use, either because of the nature of the request itself or because OSTP has reasonable cause to doubt a requester's stated use, OSTP shall provide the requester a reasonable opportunity to submit further clarification.

(4) The terms *disclose* and *disclosure* refer to making records available, upon request, for examination and copying, or furnishing a copy of records.

(5) The term *direct cost* means those expenditures OSTP actually incurred in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in response to a FOIA request. Direct costs include the salary of the personnel performing the work (*i.e.,* the basic rate of pay for the employee plus 16 percent of that rate to cover benefits) and the cost of operating computers and other electronic equipment, such as photocopiers and scanners. Direct costs do not include overhead expenses, such as the cost of space, heating, or lighting of the facility in which the records are stored.

(6) The term *duplication* means the making of a copy of a record, or of the information contained in it, necessary to respond to a FOIA request. Copies can take the form of paper, microform, audiovisual materials, or electronic records (*e.g.,* magnetic tape or disk), among others.

(7) The term *educational institution* means a preschool, a public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate higher education, an institution of professional education, or an institution of vocational education that operates a program of scholarly research. To fall within this category, a requester must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are not sought for a commercial use, but rather are sought to further scholarly research.

(8) The term *fee waiver* means the waiver or reduction of processing fees if a requester can demonstrate that certain statutory standards are satisfied.

(9) The term *FOIA Public Liaison* means an agency official who is responsible for assisting requesters in defining the scope of their request to reduce processing time, increasing transparency and understanding of the status of requests, and assisting in the resolution of disputes.

(10) The term *non-commercial scientific institution* means an institution that is not operated on a commercial basis, as that term is defined in these regulations, and that is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry. To fall within this category, a requester must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are not sought for a commercial use, but rather are sought to further scientific research.

(11) The term *perfected request* means a FOIA request for records that reasonably describes the records sought and has been received by OSTP in accordance with the requirements set forth in § 2402.4.

(12) The terms *representative of the news media* and *news media requester* mean any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. In this clause, the term *news* means information that is about current events or that would be of current interest to the public. Examples of news media entities are television or radio stations broadcasting to the public at large and publishers of periodicals (but only if such entities qualify as disseminators of news) who make their products available for purchase by, subscription by, or through free distribution to the general public. These examples are not all-inclusive. Moreover, as methods of news delivery evolve, such as through electronic or digital means, such news sources shall be considered to be news media entities. A freelance journalist shall be regarded as working for a news media entity if the journalist can demonstrate a solid basis for expecting publication through that entity, whether or not the journalist is actually employed by the entity. A publication contract would present a solid basis for such an expectation; the Government may also consider the past publication record of the requester in making such a determination.

(13) The term *requester* means any person, including an individual, partnership, corporation, association, Native American tribe, or other public or private organization, other than a Federal agency that requests access to records.

(14) The term *review* means the process of examining documents located in response to a request that is for a commercial use to determine whether any portion of any document located is permitted to be withheld. It includes the processing of any documents for disclosure—*i.e.,* doing all that is necessary to excise exempt information and otherwise prepare them for release. Review does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(15) The term *search* refers to the process of looking for and retrieving records or information responsive to a request. It includes page-by-page or line-by-line identification of information within records and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format.

(16) The term *working day* means a regular Federal working day between

the hours of 9:00 a.m. and 5:00 p.m. It does not include Saturdays, Sundays, or legal Federal holidays. Any requests received after 5:00 p.m. on any given working day will be considered received on the next working day.

§ 2402.4 Procedure for requesting records.

(a) *Format of requests.*(1) *In general.* Requests for information must be made in writing and may be delivered by mail, fax, or electronic mail, as specified in § 2402.2(c). All requests must be made in English. Requests for information may specify the preferred format (including electronic formats) of the response. When a requester does not specify the preferred format of the response, OSTP shall produce scanned records to be delivered electronically.

(2) *Records in electronic formats.* (i) OSTP shall provide responsive records in the format requested if the record or records are readily reproducible by OSTP in that format. OSTP shall make reasonable efforts to maintain its records in formats that are reproducible for the purposes of disclosure. For purposes of this paragraph, the term *readily reproducible* means, with respect to electronic format, a record that can be downloaded or transferred intact to an electronic medium using equipment currently in use by the agency processing the request. Even though some records may initially be readily reproducible, the need to segregate exempt records from nonexempt records may cause the releasable material to be not readily reproducible.

(ii) In responding to a request for records, OSTP shall make reasonable efforts to search for the records in electronic format, except where such efforts would interfere with the operation of the agency's automated information system(s). For purposes of this paragraph, the term *search* means to locate, manually or by automated means, agency records for the purpose of identifying those records that are responsive to a request.

(iii) Searches for records maintained in electronic format may require the application of codes, queries, or other minor forms of programming to retrieve the requested records.

(3) *Attachment restrictions.* To protect OSTP's computer systems, OSTP will not accept files sent as email attachments or as web links. A requester may submit a request by postal mail, by fax, or in the body of the email text.

(b) *Contents.* A request must describe the records sought in sufficient detail to enable OSTP personnel to locate the records with a reasonable amount of effort. To the extent possible, a requester should include specific information that may assist OSTP personnel in identifying the requested records, such as the date, title or name, author, recipient, and subject matter of the record. In general, a requester should include as much detail as possible about the specific records or the types of records sought. Before submitting a request, a requester may contact the OSTP FOIA Public Liaison to discuss the records sought and to receive assistance in describing the records. If, after receiving a request, OSTP determines that it does not reasonably describe the records sought or that the request will be unduly burdensome to process, OSTP shall inform the requester of the additional information that is needed or how the request may be modified. A Requester attempting to reformulate or modify such a request may discuss their requests with OSTP's FOIA Public Liaison.

(c) *Date of receipt.* A request that complies with paragraphs (a) and (b) of this section is deemed a ''perfected request.'' A perfected request is deemed received on the actual date it is received by OSTP. A request that does not comply with paragraphs (a) and (b) of this section is deemed received when information sufficient to perfect the request is actually received by OSTP.

(d) *Contact information.* A request must contain contact information, such as the requester's phone number, email address, or mailing address, to enable OSTP to communicate with the requester about the request and provide released records. If OSTP cannot contact the requester, or the requester does not respond within 30 calendar days to OSTP's requests for clarification, OSTP will administratively close the request.

(e) *Types of records not available.* The FOIA does not require OSTP to:

(1) Compile or create records solely for the purpose of satisfying a request for records;

(2) Provide records not yet in existence, even if such records may be expected to come into existence at some future time; or

(3) Restore records destroyed or otherwise disposed of, except that OSTP must notify the requester of the destruction or disposal of the requested records.

§ 2402.5 Responses to requests.

(a) *In general.* In determining which records are responsive to a request, OSTP will ordinarily include only records in its possession as of the date it begins its search for records. If any other date is used, OSTP shall inform the requester of that date.

(b) *Authority to grant or deny requests.* OSTP shall make initial determinations to grant or deny, in whole or in part, a request for records.

(c) *Granting of requests.* When OSTP determines that any responsive records shall be made available, OSTP shall notify the requester in writing and provide copies of the requested records in whole or in part. Records disclosed in part shall be marked or annotated to show the exemption(s) applied to the withheld information and the amount of information withheld unless doing so would harm the interest protected by an applicable exemption. If a requested record contains exempted material along with nonexempt material, all reasonably segregable material shall be disclosed.

(d) *Adverse determinations.* If OSTP makes an adverse determination denying a request in any respect, it must notify the requester of that adverse determination in writing. Adverse determinations include decisions that: The requested record is exempt from disclosure, in whole or in part; the request does not reasonably describe the records sought, but only if, after discussion with the FOIA Public Liaison, the requester refuses to modify the terms of the request; the information requested is not a record subject to the FOIA; the requested record does not exist, cannot be located, or has been destroyed; or the requested record is not readily reproducible in the form or format sought by the requester; denials involving fees or fee waiver matters; and denials of requests for expedited processing.

(e) *Content of adverse determinations.* Any adverse determination issued by OSTP must include:

(1) A brief statement of the reason(s) for the adverse determination, including any FOIA exemption applied by the agency in denying access to a record unless such inclusion would harm the interest protected by an applicable exemption;

(2) An estimate of the volume of any records or information withheld, such as the number of pages or other reasonable form of estimation, although such an estimate is not required if the volume is otherwise indicated by deletions marked on records that are disclosed in part or if providing an estimate would harm an interest protected by an applicable exemption;

(3) A statement that the adverse determination may be appealed under § 2402.8 of this subpart and a description of the appeal requirements; and

(4) A statement notifying the requester of the assistance available from OSTP's FOIA Public Liaison and the dispute

resolution services offered by the Office of Government Information Services.

(f) *Consultations, referrals, and coordinations.* When OSTP receives a request for a record in its possession, it shall determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA and, if so, whether it should be disclosed as a matter of administrative discretion. If OSTP determines that it is best able to process the record in response to the request, then it shall do so. If OSTP determines that it is not best able to process the record, then it shall proceed in one of the following ways:

(1) *Consultation.* When records originating with OSTP contain information of interest to another Federal agency, OSTP should typically consult with that Federal agency prior to making a release determination.

(2) *Referral.* (i) When OSTP believes that a different Federal agency is best able to determine whether to disclose the record, OSTP should typically refer the responsibility for responding to the request regarding that record to that agency. Ordinarily, the agency creating the record is presumed to be the agency best able to determine whether the record should be disclosed. If OSTP and another Federal agency jointly agree that the agency processing the request is in the best position to respond regarding the record, then the record may be handled as a consultation.

(ii) Whenever OSTP refers any part of the responsibility for responding to a request to another agency, OSTP must document the referral, maintain a copy of the record that it refers, and notify the requester of the referral.

(iii) After OSTP refers a record to another Federal agency, the agency receiving the referral shall make a disclosure determination and respond directly to the requester. The referral of a record is not an adverse determination and no appeal rights accrue to the requester therefrom.

(3) *Coordination.* The standard referral procedure is not appropriate where disclosure of the identity of the Federal agency to which a referral would be made could harm an interest protected by an applicable exemption, such as an exemption that protects personal privacy or national security interests. For example, if a non-law enforcement agency responding to a request for records on a living third party locates within its files records originating with a law enforcement agency, and if the existence of that law enforcement interest in the third party is not publicly known, then to disclose that law enforcement interest could cause an unwarranted invasion into the personal privacy of the third party. Similarly, if an agency locates within its files material originating with an Intelligence Community agency, and the involvement of that agency in the matter is classified and not publicly acknowledged, then to disclose or give attribution to the involvement of that Intelligence Community agency could harm national security interests. In such instances, in order to avoid harm to an interest protected by an applicable exemption, OSTP will coordinate with the agency that created the record to seek its views on disclosure of the record. OSTP will then notify the requester of the disclosure determination for the record that is the subject of the coordination.

§ 2402.6 Timing of responses to requests.

(a) *In general.* OSTP shall ordinarily respond to requests in order of their receipt.

(b) *Initial determinations.* OSTP will exercise all reasonable efforts to make an initial determination acknowledging and granting, partially granting, or denying a request for records within twenty (20) working days after receiving a perfected request.

(c) *Extensions of response time in ''unusual circumstances.''* (1) The twenty (20)-working day period provided in paragraph (b) of this section may be extended if unusual circumstances arise. If an extension is necessary, OSTP shall promptly notify the requester of the extension, briefly state the reasons for the extension, and estimate when a response will be issued. Unusual circumstances warranting extension are:

(i) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(2) After OSTP notifies the requester of the reasons for the delay, the requester will have an opportunity to modify the request or arrange for an alternative time frame for completion of the request. To assist in this process, OSTP shall advise the requester of the availability of OSTP's FOIA Public Liaison to aid in the resolution of any disputes between the requester and OSTP, and notify the requester of his or her right to seek dispute resolution services from the Office of Government Information Services.

(3) If no initial determination is made at the end of the twenty-day period provided for in paragraph (b) of this section, including any extension provided for in paragraph (c)(1) of this section, the requester may appeal the action to the FOIA Appeals Officer.

(d) *Expedited processing of request.* (1) A requester may make a request for expedited processing at any time.

(2) When a request for expedited processing is received, OSTP must determine whether to grant the request for expedited processing within ten (10) calendar days of its receipt. Requests will receive expedited processing if one of the following compelling needs is met:

(i) The requester can establish that failure to receive the records quickly could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) The requester is primarily engaged in disseminating information and can demonstrate that an urgency to inform the public concerning actual or alleged Federal Government activity exists.

(3) A requester who seeks expedited processing must submit a statement, certified to be true and correct, explaining in detail the basis for making the request for expedited processing. As a matter of administrative discretion, OSTP may waive the formal certification requirement.

(4) Administrative appeals of denials of expedited processing will be given expeditious consideration. If the FOIA Appeals Officer upholds the denial of expedited processing, that decision is immediately subject to judicial review in the appropriate Federal district court.

(e) *Multi-track processing.* (1) OSTP may use multi-track processing in responding to requests. Multi-track processing means placing simple requests that require limited review in one processing track and placing more voluminous and complex requests in one or more other processing tracks. Requests in each track are processed on a first-in, first-out basis.

(i) *Track one—expedited requests.* Track one is made up of requests that sought and received expedited processing as provided for in paragraph (d)(2) of this section.

(ii) *Track two—simple requests.* Track two is for requests of simple to moderate complexity that do not require

consultations with other entities and do not involve voluminous records.

(iii) *Track three—complex requests.* Track three is for complex requests that involve voluminous records, require lengthy or numerous consultations, raise unique or novel legal questions, or require submitter review under § 2402.7.

(2) OSTP may provide requesters with requests in slower track(s) the opportunity to limit the scope of their requests in order to qualify for faster processing within the specified limits of faster track(s). OSTP will do so by contacting the requester by letter, telephone, email, or facsimile, whichever is more efficient in each case. When providing a requester with the opportunity to limit the scope of a request, OSTP shall also advise the requester of OSTP's FOIA Public Liaison to aid in the resolution of any dispute arising between the requester and OSTP as well as the requester's right to seek dispute resolution services from the Office of Government Information Services.

(f) *Aggregating requests.* OSTP may aggregate requests if it reasonably appears that multiple requests, submitted either by a single requester or by a group of requesters acting in concert, involve related matters and constitute a single request that otherwise would involve unusual circumstances. For example, OSTP may aggregate multiple requests for similar information filed by a single requester within a short period of time.

§ 2402.7 Confidential commercial information.

(a) *In general.* Business information obtained by OSTP from a submitter will be disclosed under the FOIA only under this section.

(b) *Definitions.* For purposes of this section:

(1) *Confidential commercial information* means records provided to the government by a submitter that arguably contain material exempt from release under 5 U.S.C. 552(b)(4).

(2) *Submitter* means any person or entity from whom OSTP directly or indirectly obtains confidential commercial information. The term includes corporations; State, local, and tribal governments; universities; non-profit organizations; associations; and foreign governments.

(c) *Designation of business information.* Either at the time of submission or at a reasonable time thereafter, a submitter of business information will use good-faith efforts to designate, by appropriate markings, any portions of its submission that it considers to be protected from disclosure under 5 U.S.C. 552(b)(4). These designations will expire ten years after the date of submission unless the submitter requests, and provides justification for, a longer designation period.

(d) *Notice to submitters.* OSTP shall provide a submitter with prompt written notice of a FOIA request or administrative appeal that seeks its business information in order to give the submitter an opportunity to object to disclosure of any specified portion of that information. The notice shall either describe the business information requested or include copies of the requested records or record portions containing the information. When notification of a voluminous number of submitters is required, notification may be made by posting or publishing the notice in a place reasonably likely to accomplish notification.

(e) *Where notice is required.* Notice shall be given to a submitter whenever:

(1) The information has been designated in good faith by the submitter as information considered protected from disclosure under 5 U.S.C. 552(b)(4); or

(2) OSTP has reason to believe that the information may be protected from disclosure under 5 U.S.C. 552(b)(4).

(f) *Opportunity to object to disclosure.* OSTP will allow a submitter reasonable time to respond to the notice described in paragraph (d) of this section and will specify that time period within the notice. If a submitter has any objection to disclosure, the submitter must provide a detailed written statement of objections. The statement must specify all grounds for withholding any portion of the information under any exemption of the FOIA and, in the case of information withheld under 5 U.S.C. 552(b)(4), the submitter must demonstrate the reasons the submitter believes the information is a trade secret or commercial or financial information that is privileged or confidential. In the event that a submitter fails to adequately respond to the notice within the time specified, the submitter will be considered to have no objection to disclosure of the information. Information provided by the submitter that OSTP does not receive within the time specified shall not be considered by OSTP. Information provided by a submitter under this paragraph may itself be subject to disclosure under the FOIA.

(g) *Notice of intent to disclose.* OSTP shall consider a submitter's objections and specific grounds for nondisclosure in deciding whether to disclose business information. Whenever OSTP determines that disclosure is appropriate over the objection of a submitter, OSTP shall, within a reasonable number of days prior to disclosure, provide the submitter with written notice of the intent to disclose, which shall include:

(1) A statement of the reason(s) why each of the submitter's objections to disclosure was not sustained;

(2) A description of the business information to be disclosed; and

(3) A specified disclosure date, which shall be a reasonable time subsequent to the notice.

(h) *Exceptions to notice requirements.* The notice requirements of paragraphs (d) and (g) of this section shall not apply if:

(1) OSTP determines that the information should not be disclosed;

(2) The information has been lawfully published or has been officially made available to the public;

(3) Disclosure of the information is required by statute (other than the FOIA) or by a regulation issued in accordance with the requirements of Executive Order 12600 of June 23, 1987;

(4) The designation made by the submitter under paragraph (c) of this section appears obviously frivolous. In such a case, OSTP shall, within a reasonable time prior to a specified disclosure date, give the submitter written notice of any final decision to disclose the information, but no opportunity to object will be offered; or

(5) The information requested was not designated by the submitter as exempt from disclosure in accordance with this part, when the submitter had an opportunity to do so at the time of submission of the information or a reasonable time thereafter, unless OSTP has substantial reason to believe that disclosure of the information would result in competitive harm.

(i) *Notice of FOIA lawsuit.* Whenever a requester files a lawsuit seeking to compel the disclosure of business information, OSTP shall promptly notify the submitter.

(j) *Notice to requesters.* Whenever OSTP provides a submitter with notice and an opportunity to object to disclosure under paragraph (d) of this section, OSTP shall also notify the requester(s). Whenever OSTP notifies a submitter of its intent to disclose requested information under paragraph (g) of this section, OSTP shall also notify the requester(s). Whenever a submitter files a lawsuit seeking to prevent the disclosure of business information, OSTP shall notify the requester(s).

§ 2402.8 Appeal of denials.

(a) *Right to administrative appeal.* A requester has the right to appeal to the FOIA Appeals Officer any adverse determination.

(b) *Notice of appeal.* (1) *Time for appeal.* To be considered timely, an appeal must be postmarked, or in the case of electronic submissions, transmitted no later than ninety (90) calendar days after the date of the initial adverse determination or after the time limit for response by OSTP has expired. Prior to submitting an appeal, the requester must pay in full any outstanding fees associated with the request.

(2) *Form of appeal.* An appeal shall be initiated by filing a written notice of appeal. The notice shall specify the tracking number assigned to the FOIA request by OSTP and be accompanied by copies of the original request and adverse determination. To expedite the appellate process and give the requester an opportunity to present his or her arguments, the notice should contain a brief statement of the reason(s) why the requester believes the adverse determination to be in error. Requesters may submit appeals by mail or electronically. If sent by regular mail, appeals shall be sent to: Chief FOIA Officer, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue NW, Washington, DC 20504. Appeals sent via electronic mail shall be submitted to *ostpfoia@ostp.eop.gov.* Updates to this contact information will be made on the OSTP website. To facilitate handling, the requester should mark both the appeal letter and envelope, if submitted by mail, or subject line of the transmission, if submitted electronically, with ''Freedom of Information Act Appeal.''

(c) *Decisions on appeals.* The FOIA Appeals Officer shall make a determination in writing on the appeal under 5 U.S.C. 552(a)(6)(A)(ii) within twenty (20) working days after the receipt of the appeal. If the denial is wholly or partially upheld, the Chief FOIA Officer shall:

(1) Notify the requester that judicial review is available pursuant to 5 U.S.C. 552(a)(4)(B)–(G); and

(2) Notify the requester that the Office of Government Information Services (OGIS) offers mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, MD 20740, Email: *ogis@nara.gov,* Telephone: 202–741–5770, Facsimile: 202–741–5769, Toll-free: 1–877–684–6448.

(d) *Dispute resolution services.* Dispute resolution is a voluntary process. If OSTP agrees to participate in the dispute resolution services provided by the Office of Government Information Services, it will actively engage as a partner to the process in an attempt to resolve the dispute.

(e) *When appeal is required.* Before seeking judicial review of OSTP's adverse determination in Federal district court, a requester generally must first submit a timely administrative appeal.

§ 2402.9 Fees.

(a) *Fees generally required.* OSTP shall use the most efficient and least costly methods to comply with requests for documents made under the FOIA. OSTP shall charge fees in accordance with paragraph (b) of this section unless fees are waived or reduced in accordance with § 2402.10.

(b) *Calculation of fees.* In general, fees for searching, reviewing, and duplication will be based on the direct costs of these services, including the average hourly salary (basic pay plus 16% for benefits) of the personnel conducting the search, reviewing the records for exemption, or duplicating the records. Charges for time less than a full hour will be in increments of quarter hours.

(1) *Search fees.* Search fees may be charged even if responsive documents are not located or are located but withheld on the basis of an exemption. However, search fees shall not be charged or shall be limited as follows:

(i) *Educational, scientific, or news media requests.* No search fee shall be charged if the request is not sought for a commercial use and is made by an educational or non-commercial scientific institution, whose purpose is scholarly or scientific research, or by a representative of the news media.

(ii) *Other non-commercial requests.* No search fee shall be charged for the first two hours of searching if the request is not for a commercial use and is submitted by an entity that is not an educational or scientific institution, whose purpose is scholarly or scientific research, or a representative of the news media.

(iii) *Requests for records about oneself.* No search fee shall be charged to search for records performed under the terms of the Privacy Act, 5 U.S.C. 552a(f)(5).

(2) *Review fees.* Review fees shall be assessed only with respect to those requesters who seek records for a commercial use. A review fee shall be charged for the initial examination of documents located in response to a request to determine whether the documents may be withheld from disclosure and for the redaction of document portions exempt from disclosure. Records or portions of records withheld under an exemption that is subsequently determined not to apply may be reviewed again to determine the applicability of other exemptions not previously considered. The costs for such subsequent review are also assessable.

(3) *Duplication fees.* Records will be photocopied at a rate of ten cents ($0.10) per page. For other methods of reproduction or duplication, OSTP will charge the actual direct costs of producing the document(s). Duplication fees shall not be charged for the first 100 pages of copies unless the copies are requested for a commercial use.

(c) *Aggregation of requests.* When OSTP determines that a requester, or a group of requesters acting in concert, is attempting to evade the assessment of fees by submitting multiple requests in place of a single, more complex request, OSTP may aggregate any such requests and assess fees accordingly.

(d) *Fees likely to exceed $25.* If total fee charges are likely to exceed $25, OSTP shall notify the requester of the estimated amount to be charged. The notification shall offer the requester an opportunity to confer with the FOIA Public Liaison to reformulate the request to meet the requester's needs at a lower cost. OSTP may administratively close a submitted FOIA request if the requester does not respond in writing within thirty (30) calendar days after the date on which OSTP notifies the requester of the fee estimate.

(e) *Advance payments.* Fees may be paid upon provision of the requested records, except that payment may be required prior to that time if the requester has previously failed to pay fees or if OSTP determines that the total fees will exceed $250. When payment is required in advance of the processing of a request, the time limits prescribed in § 2402.6 shall not be deemed to begin until OSTP has received payment of the assessed fees. If the requester has previously failed to pay fees or charges are likely to exceed $250, OSTP shall notify the requester of the estimated cost and:

(1) Obtain satisfactory assurance from the requester, in writing, of full payment; or

(2) OSTP may require the requester to pay the full amount of any fees owed or make an advance payment of the full amount of OSTP's estimated charges.

(3) If OSTP does not receive an adequate response, assurance, or advance payment within thirty (30) calendar days of a fee determination or notification issued under the authority of this section, OSTP will administratively close the corresponding request.

(f) *Other charges.* OSTP will recover the full costs of providing services, such as those enumerated below, when it elects to provide them:

(1) Certifying that records are true copies; and

(2) Sending records by special methods, such as express mail.

(g) *Remittances.* Remittances shall be made either via personal check or bank draft drawn on a bank in the United States, or by postal money order. Remittances shall be made payable to the order of the Treasury of the United States and mailed to the Chief FOIA Officer, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue NW, Washington, DC 20504. Updates to this contact information will be made on the OSTP website.

(h) *Receipts and refunds.* OSTP will provide a receipt for fees paid upon request. OSTP will not refund fees paid for services actually rendered.

§ 2402.10 Waiver of fees.

(a) *In general.* OSTP shall waive part or all of the fees assessed under § 2402.9 if, based upon information provided by a requester or otherwise made known to OSTP, the disclosure of the requested information is in the public interest. Disclosure is in the public interest if it is likely to contribute significantly to public understanding of government operations or activities and is not primarily for commercial purposes. Requests for a waiver or reduction of fees shall be considered on a case-by-case basis. To determine whether a fee waiver requirement is met, OSTP shall consider the following factors:

(1) Disclosure of the requested information would shed light on the operations or activities of the Federal Government. The subject of the request must concern identifiable operations or activities of the Federal Government with a connection that is direct and clear, not remote or attenuated.

(2) Disclosure of the requested information is likely to contribute significantly to public understanding of those operations or activities. This factor is satisfied when the following criteria are met:

(i) Disclosure of the requested records must be meaningfully informative about government operations or activities. The disclosure of information already in the public domain, in either the same or a substantially similar form, would not be meaningfully informative if nothing new would be added to the public's understanding.

(ii) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public must be considered. OSTP will presume that a representative of the news media will satisfy this consideration.

(3) The disclosure must not be primarily in the commercial interest of the requester. To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, OSTP will consider the following criteria:

(i) OSTP will identify whether the requester has any commercial interest that would be furthered by the requested disclosure. A commercial interest includes any commercial, trade, or profit interest. Requesters are encouraged to provide explanatory information regarding this consideration.

(ii) If there is an identified commercial interest, OSTP will determine whether that is the primary interest furthered by the request. OSTP will ordinarily presume that when a news media requester has satisfied the conditions in paragraphs (a)(1) and (2) of this section, the request is not primarily in the commercial interest of the requester. Data brokers or others who merely compile and market government information for direct economic return will not receive the benefit of this presumption.

(b) *Timing of fee waivers.* A request for a waiver or reduction of fees should be made when a request for records is first submitted to the agency and should address the criteria referenced in paragraph (a) of this section. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester must pay any costs incurred up to the date of the fee waiver request was received.

(c) *Clarification.* Where OSTP has reasonable cause to doubt the use to which a requester will put the records sought, or where that use is not clear from the request itself, OSTP may seek clarification from the requester before assigning the request to a specific category for fee assessment purposes.

(d) *Restrictions on charging fees.* Except as described in paragraphs (c)(1) through (3) of this section, if OSTP fails to comply with the FOIA's time limits for responding to a request, it may not charge search fees. In addition, subject to the exceptions set forth in paragraphs (c)(1) through (3) of this section, if OSTP does not comply with the FOIA's time limits for responding to a request, it may not charge duplication fees when records are not sought for a commercial use and the request is made by an educational institution, non-commercial scientific institution, or representative of the news media.

(1) If OSTP determines that unusual circumstances, as defined by the FOIA, apply and provides timely written notice to the requester in accordance with the FOIA, then a failure to comply with the statutory time limit shall be excused for an additional ten (10) days.

(2) If OSTP determines that unusual circumstances, as defined by the FOIA, apply and more than 5,000 pages are necessary to respond to the request, then OSTP may charge search fees and duplication fees, where applicable, if the following steps are taken. OSTP must:

(i) Provide timely written notice of unusual circumstances to the requester in accordance with the FOIA; and

(ii) Discuss with the requester via postal mail, email, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5 U.S.C. 552(a)(6)(B)(ii).

(3) If a court determines that exceptional circumstances exist, as defined by the FOIA, then a failure to comply with the statutory time limits shall be excused for the length of time provided by the court order.

§ 2402.11 Maintenance of statistics.

(a) OSTP shall maintain records sufficient to allow accurate reporting of FOIA processing statistics, as required under 5 U.S.C. 552(e) and all guidelines for the preparation of annual FOIA reports issued by the Department of Justice.

(b) OSTP shall annually, on or before February 1 of each year, prepare and submit to the Attorney General an annual report compiling the statistics maintained in accordance with paragraph (a) of this section for the previous fiscal year. A copy of the report will be available for public inspection on the OSTP website.

§ 2402.12 Disclaimer.

Nothing in this part shall be construed to entitle any person, as a right, to any service or to the disclosure of any record to which such person is not entitled under the FOIA.

Dated: October 5, 2020.

Stacy Lynn Murphy,

Operations Manager.

[FR Doc. 2020–22375 Filed 11–3–20; 8:45 am]

BILLING CODE 3270–F7–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0046; FRL–10012–51]

Trinexapac-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trinexapac-ethyl in or on sugarcane, cane and sugarcane, molasses. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 4, 2020. Objections and requests for hearings must be received on or before January 4, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0046, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. 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 OPP Docket is (703) 305–5805. Due to public health concerns related to COVID–19, the EPA Docket Center and Public Reading Room are closed for the time being, although EPA staff are continuing to provide remote assistance. Please review additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0046 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 4, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0046, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 3, 2020 (85 FR 12454) (FRL–10005–58), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8761) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180.662 be amended by establishing tolerances for residues of the herbicide trinexapac-ethyl, (4-(cyclopropyl-a-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester), and its primary metabolite CGA-179500 in or on sugarcane, cane at 1.5 parts per million (ppm) and sugarcane, molasses at 5.0 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is modifying the tolerance expression and the tolerance for sugarcane, molasses at a different level than petitioned-for. The reasons for these are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA

determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for Trinexapac-ethyl including exposure resulting from the tolerances established by this action.

EPA published a final rule in the **Federal Register** on May 20, 2015 (80 FR 28843) (FRL–9926–62) establishing tolerances for residues of trinexapac-ethyl in or on rice and rye commodities based on the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to trinexapac-ethyl to the general population, including infants and children. That document contains a summary of the toxicological profile, a reference to toxicological endpoints, a description of EPA's position on the potential for cumulative risk, as well as the rationale for the Agency's determination regarding the children's safety factor. As those sections continue to reflect the Agency's current position on those topics, those sections are incorporated here by reference.

EPA's exposure assessments have been updated to include the additional exposure from the increased tolerance of trinexapac-ethyl from use in or on sugarcane, cane and sugarcane, molasses. Those assessments rely on tolerance-level residues, 2019 default processing factors, and an assumption of 100% crop treated (PCT). EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure in drinking water and from residential sources, although those latter exposures are not impacted by the modified use on sugarcane and thus have not changed since the last assessment.

Acute dietary risks are below the Agency's level of concern: 2.5% of the acute population adjusted dose (aPAD) for females 13 to 49 years old, the population group of concern. Chronic dietary risks are below the Agency's level of concern: 6.6% of the chronic population adjusted dose (cPAD) for children 1 to 2 years old, the population group receiving the greatest exposure. Aggregating chronic (or background) dietary exposure with short- and intermediate-term exposures, EPA has concluded that the combined food, water, and short- and intermediate-term residential exposures result in aggregate margins of exposures above the level of concern for all scenarios assessed and are not of concern. Finally, EPA has concluded that trinexapac-ethyl is not expected to pose a cancer risk, given the lack of evidence of carcinogenicity in the database.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to trinexapac-ethyl residues. Further information about EPA's risk assessment and determination of safety can be found at *http://www.regulations.gov* in the document titled ''Trinexapac-ethyl. Human Health Risk Assessment for the Petition to Amend the Pre-Harvest Intervals on Sugarcane.'' dated July 13, 2020 in the docket ID number EPA–HQ–OPP–2020–0046.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method GRM020.01A), which utilizes high performance liquid chromatography with triple-quadrupole mass spectrometry (LC–MS/MS) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL for trinexapac-ethyl in or on sugarcane at 0.5 ppm. This MRL is different than the tolerances established for trinexapac-ethyl in the United States. The United States is not able to harmonize its sugarcane tolerance with the Codex MRL; based on the reduction of the preharvest interval (PHI) from 28 to 14 days on sugarcane, the field trial data indicate that use in accordance with the label results in residues may exceed tolerances if they were harmonized with Codex.

C. Response to Comments

Two comments were received in response to the Notice of Filing. Neither comment was accompanied by any substantiation nor data supporting a conclusion that the tolerances being established in this action do not meet the FFDCA safety standard. Although EPA recognizes that some individuals would oppose any use of pesticides on food, section 408 of the FFDCA authorizes EPA to set tolerances for residues of pesticide chemicals in or on food when it determines that the tolerance meets the safety standard imposed by that statute. Upon review of the available information, EPA concludes that these tolerances would be safe.

D. Revisions to Petitioned-For Tolerances

EPA is revising the tolerance expression to include the free and conjugated forms of the parent (trinexapac-ethyl) and acid. Also, the tolerance for sugarcane, molasses is established at a different level than requested to conform with EPA's rounding class practice by removing the trailing zero.

V. Conclusion

Therefore, EPA is increasing tolerances for residues of trinexapac-ethyl, ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate, including

its metabolites and degradates, in or on sugarcane, cane at 1.5 ppm, and sugarcane, molasses at 5 ppm.

VI. Statutory and Executive Order Reviews

This action modifies existing tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 16, 2020.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA amends 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.662, amend paragraph (a) by:

■ i. Revising the Introductory text.

■ ii. Revising the existing entries in the table for ''Sugarcane, cane'' and ''Sugarcane, molasses''.

The revisions read as follows:

§ 180.662 Trinexapac-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator, trinexapac-ethyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the free and conjugated forms of both trinexapac-ethyl, ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate and trinexapac, 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid, calculated as the stoichiometric equivalent of trinexapac-ethyl, in or on the commodity.

Commodity	Parts per million
* * * * *	
Sugarcane, cane	1.5
Sugarcane, molasses	5
* * * * *	

* * * * *

[FR Doc. 2020–23040 Filed 11–3–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171

RIN 0955–AA02

Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) gives health IT developers and health care providers flexibilities to effectively respond to the public health threats posed by the spread of the coronavirus disease 2019 (COVID–19). Recognizing the urgency of this situation, and understanding that caring for patients with COVID–19 is of utmost importance, ONC is issuing this IFC to extend certain compliance dates and timeframes adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule), including compliance and applicability dates for the information blocking provisions, certain 2015 Edition health IT certification criteria, and Conditions and Maintenance of Certification

requirements under the ONC Health IT Certification Program (Program). In this IFC, we are also making programmatic changes to the Program by updating standards. In addition, we are making corrections and clarifications to the ONC Cures Act Final Rule, which was published in the **Federal Register** on May 1, 2020.

DATES:

Effective date: This interim final rule is effective on December 4, 2020 except for 45 CFR 170.401, 170.402(a)(1), and the amendments to 45 CFR part 171 which are effective on November 4, 2020.

Incorporation by reference: The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of November 4, 2020. The incorporation by reference of certain other publications listed in the rule was approved by the Director of the Federal Register as of September 4, 2012.

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

ADDRESSES: You may submit comments, identified by RIN 0955–AA02, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *http://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.
- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 235 [1] countries internationally, and all 50 States and the District of Columbia. The virus has been named ''severe acute respiratory syndrome coronavirus 2'' (SARS–CoV–2) and the disease it causes has been named ''coronavirus disease 2019'' (COVID–19).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the

[1] *https://www.who.int/emergencies/diseases/novel-coronavirus-2019* (Accessed on 10/22/2020).

outbreak a ''Public Health Emergency of international concern.'' On January 31, 2020, pursuant to section 319 of the Public Health Service Act (PHSA), Health and Human Services Secretary, Alex M. Azar II, determined that a Public Health Emergency (PHE) exists for the United States to aid the nation's health care community in responding to COVID–19. On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President of the United States declared the COVID–19 pandemic a national emergency. Effective October 23, 2020, Secretary Azar renewed the January 31, 2020 determination that was previously renewed on April 21, 2020 and July 23, 2020 that a PHE for COVID–19 exists and has existed since January 27, 2020.

As the health care community establishes and implements recommended infection prevention and control practices, regulatory agencies—under appropriate waiver authority granted by the declaration of the COVID–19 PHE—are also working to revise regulations to allow the health care community to focus on the PHE. We believe that the ONC Cures Act Final Rule should be revised to offer the health care system additional flexibilities in furnishing services to combat the COVID–19 pandemic. On April 21, 2020, concurrent with Secretary Azar's first renewal of the determination of a PHE, ONC announced a policy of enforcement discretion to allow compliance flexibilities regarding the implementation of the ONC Cures Act Final Rule in response to the COVID–19 PHE.[2] We stated our intention to exercise enforcement discretion for three months at the end of certain ONC Health IT Certification Program (Program) compliance dates associated with the ONC Cures Act Final Rule to provide flexibility while ensuring the goals of the rule remain on track. In this IFC, we are extending the applicability date for the information blocking provisions and some compliance dates in the Program, including dates for certain updated 2015 Edition health IT certification criteria and Conditions and Maintenance of Certification requirements. The extensions in this IFC for information blocking and the Program are longer than the three month extension that was announced in the April 21, 2020 enforcement discretion statement for the Program. These additional flexibilities for development and implementation enable our health care system to focus on addressing the COVID–19 PHE, while still maintaining a trajectory that will advance patients' access to their health information, reduce the cost of care, and improve the quality of care. This IFC also updates certain standards in the Program, and makes necessary corrections and clarifications to the ONC Cures Act Final Rule, which was published in the **Federal Register** on May 1, 2020 (85 FR 25642), and became effective on June 30, 2020.

II. Provisions of the Interim Final Rule With Comment Period

A. Extension of Compliance Dates and Timeframes

The ONC Cures Act Final Rule fosters innovation in health care to deliver better information, more conveniently, to patients and their providers. It also promotes transparency through technology, providing opportunities for the American public to gain visibility into the services, quality, and costs of health care.

The ONC Cures Act Final Rule includes provisions that require support for modern computing standards and application programming interfaces (APIs). These technical provisions will inject competition into health care by promoting an entrepreneurial economy and new business models using smartphone apps to provide novel services and choices in care. The ONC Cures Act Final Rule will also make sure health information follows a patient by preventing industrywide information blocking practices and other anti-competitive behavior by those entrusted to hold patients' electronic health information (EHI).

In the ONC Cures Act Final Rule, we set applicability and compliance dates for certain provisions of the regulations. In light of the COVID–19 PHE, in this IFC, ONC is extending the applicability date for the information blocking provisions and compliance dates and timeframes for certain Program requirements, including compliance dates for certain 2015 Edition health IT certification criteria and Conditions and Maintenance of Certification requirements. These additional flexibilities for development and implementation will enable our health care system to focus on addressing the COVID–19 PHE, while continuing to advance policies that will promote patients' access to their EHI and enable greater data exchange.

We have also heard from stakeholders and organizations representing clinicians, hospitals, health systems and health information technology developers requesting an extension for the applicability and compliance dates. These stakeholders expressed concern over meeting the information blocking applicability date of November 2, 2020. They stated that the COVID–19 PHE continues to monopolize their time and attention, and has strained resources, drastically limiting their ability to prepare for the November 2nd information blocking date.

In an effort to minimize any burden or confusion for developers and providers, we have aligned the extensions around three distinct dates. For ease of comparison, in Table 1 below, we have added the dates from the ONC Cures Act Final Rule, the dates in the April 21, 2020 enforcement discretion announcement, and the dates in this IFC.

TABLE 1—APPLICABILITY AND COMPLIANCE DATES

Provision	Final rule	Enforcement discretion announcement	Interim final rule with comment period
Information Blocking Overall Applicability Date—(45 CFR part 171)[3].	November 2, 2020	N/A—No Change	April 5, 2021.
Condition of Certification (CoC)—Information Blocking—(§ 170.401).	November 2, 2020	3 months after the compliance timeframe.	

[2] *https://www.healthit.gov/curesrule/resources/enforcement-discretion.*

[3] Note that for the Content and Manner Exception, in § 171.301(a), for the period before October 6, 2022, the definition of EHI is limited to, at a minimum, the data elements represented in the USCDI standard; and, for the period on and after Oct 6, 2022, EHI is defined as it is in § 171.102. These dates reflect the extension from May 2, 2022, which was the compliance date included in the ONC Cures Act Final Rule. These dates are discussed in more detail in section II.A.1.

TABLE 1—APPLICABILITY AND COMPLIANCE DATES—Continued

Provision	Final rule	Enforcement discretion announcement	Interim final rule with comment period
CoC—Assurances—(§ 170.402(a)(1))—Will not take any action that constitutes information blocking or actions that inhibit access, exchange, and use of electronic health information (EHI).	November 2, 2020	3 months after the compliance timeframe.	
CoC—Assurances—(§ 170.402(a)(2) and (3), and (b)(1))—Other.	Effective date: June 30, 2020	Enforcement discretion expired 3 months after the effective date of the final rule.	
CoC—Communications—(§ 170.403)—Communications requirements, except for § 170.403(b)(1) where we removed the notice requirement for 2020.	Effective date: June 30, 2020	Enforcement discretion expired 3 months after the effective date of the final rule.	
CoC—API—(§ 170.404(b)(4))—Compliance for current API criteria.	November 2, 2020	3 months after the compliance timeframe.	
CoC—API—(§ 170.404(b)(3))—Rollout of new standardized API functionality.	May 2, 2022	3 months after the compliance timeframe.	December 31, 2022.
CoC—Real World Testing—2015 Edition health IT certification criteria with standards updates.	May 2, 2022	3 months after the compliance timeframe.	
CoC—Assurances—(§ 170.402(a)(4) and (b)(2))—EHI Export Rollout.	May 1, 2023	3 months after the compliance timeframe.	December 31, 2023.
CoC—Communications—(§ 170.403(b)(1))—Notice to all customers with which developer has contracts or agreements containing provisions that contravene Communications CoC.	Annually beginning in calendar year 2020.	Notice can be made until March 31, 2021, for the 2020 calendar year.	Begin annual cycle 1 year later. CY 2021.
CoC—*Initial* Attestations—(§ 170.406) ..	April 1–30, 2021 attestation window for attestation period running June 30, 2020, through March 31, 2021.	Generally remains the same except for the initial attestation, which will now be accepted through July 30, 2021.	Begin annual cycle 1 year later. CY 2022.
CoC—Real World Testing—(§ 170.405(b)(1) and (2)) Submit *initial* plan and *initial* results submission.	*Plan:* December 15, 2020 ..... *Results:* March 15, 2022.	*Initial Plan:* Initial RWT plans (*i.e.,* 2021 RWT plans) may be submitted through March 15, 2021. *Initial Results:* Initial RWT results from the 2021 performance year may be submitted up through June 2022.	Begin annual cycle 1 year later. *Initial Plan:* December 15, 2021. *Initial Results:* March 15, 2023.

In selecting these dates, we carefully considered a number of factors, including the possibility that health IT developers of certified health IT and other actors would divert resources needed to respond to the COVID–19 PHE in order to meet requirements of the ONC Cures Act Final Rule. In particular, we considered whether the requirements placed a current conflicting resource burden on developers and whether the ongoing PHE necessitates greater lead time prior to compliance. We considered whether affected parties' workforces would need more time for education and training due to the round-the-clock need to respond to the PHE. Further, we note that effective October 23, 2020, Secretary Azar renewed the determination that a PHE exists, demonstrating a Department-wide commitment to a unified effort against the COVID–19 PHE. Given these considerations, we concluded that the extensions and flexibilities finalized in this IFC are appropriate and necessary.

Once we concluded that the extensions were appropriate, we balanced those factors against the overall policy and purpose of the ONC Cures Act Final Rule. ONC takes seriously the responsibility to implement key provisions of the Cures Act and Executive Order 13813. In this IFC, we strived to ensure that our attention to the demands of the PHE is balanced with our commitment to advance interoperability and support the access, exchange, and use of EHI through implementation and enforcement of the information blocking provisions. Therefore, we sought to limit the extensions to no longer than reasonably necessary, given the concerns cited above.

Extensions can be shorter where fewer technological demands are placed on stakeholders. For example, in § 170.403(b), a health IT developer must not impose or enforce any contractual requirement that contravenes the requirements of the Communications Condition of Certification. Furthermore, if a health IT developer has contracts/agreements in existence that contravene the requirements of the Communications Condition of Certification, the developer must notify all affected customers, other persons, or entities that the prohibition or restriction within the contract/agreement will not be enforced by the health IT developer. In this IFC, we suspended the annual notice requirement in § 170.403(b)(1) for just the 2020 year. This limited suspension ensures that the users and customers of certified health IT will still be notified in a timely manner by health IT developers, while also relieving pressure on the developers to immediately devote portions of their workforce to review contracts. We believe the annual requirement will lessen compliance obligations for health IT developers of certified health IT

while still providing adequate notice in a reasonable amount of time. We have finalized the deadline for the notice requirement in § 170.403(b)(1) to be annually, beginning in calendar year 2021.

Other extensions are limited because of the positive outcomes we anticipate from certain provisions. For example, the information blocking provisions in 45 CFR 171 are critical to ensuring patients are able to access their EHI when and where they need it. Therefore, the extensions for most of the information blocking provisions are limited to April 5, 2021, for two reasons. First and foremost, we must balance the need to provide actors with more time to address the PHE with the ultimate goal of making EHI more accessible to improve the cost and quality of care. Second, unlike some of the 2015 Edition Cures Update certification criteria, the information blocking provisions do not explicitly require actors to purchase or update certified health IT, so there is less of a concern about technology resource allocations in the near term.

In other instances, a close review of the ONC Cures Act Final Rule in light of the PHE led us to conclude that some provisions would be better served by lengthier extensions. For example, we are extending until December 31, 2022, the compliance date for the 2015 Edition Cures Update certification criteria (85 FR 25666 through 25667). The updated certification criteria require health IT developers to upgrade their current technology in order to maintain or earn their certified status. Developers have been allocating resources to ensure their technology meets the new needs of their customers (*e.g.,* health care providers and health care systems) including, for example, the ability to collect and report COVID–19 data. However, health IT developers are also not currently in a situation to be able to successfully rollout and test the certification criteria with their customers because the health care system has been focused on fighting the COVID–19 PHE. Developers, therefore, should have greater leeway to ensure the costs of meeting the 2015 Edition Cures Update certification criteria compliance dates do not impair efforts to fight the COVID–19 PHE. Further, certified health IT serves an important public good: Hospitals, patients and public health networks rely on certified health IT. If ONC does not grant an appropriate extension for developers to comply with the 2015 Edition Cures Update, some health IT developers may decide not to seek re-certification, or forego certification altogether, if they determine they do not have the resources required to meet tight deadlines. While the new and revised certification criteria in the 2015 Edition Cures Update will further advance the policy goals of the Cures Act, we are confident the current certification criteria promote interoperability and support the access, exchange and use of EHI. Therefore, in balancing these interests, we concluded it would be contrary to the public interest if we did not extend the compliance date for the 2015 Edition Cures Update certification criteria.

Finally, some of the extensions are related to the actions of other components of HHS. For example, the Centers for Medicare & Medicaid Services (CMS) works closely with ONC because some CMS programs require technology to be certified under the Program. As discussed in the ONC Cures Act Final Rule, ONC considers these impacts when establishing policies for health IT developers that may also affect health care providers participating in CMS programs (85 FR 25665). Because of the cyclical nature of CMS reporting requirements each calendar year, including the 90-day reporting period that is self-selected by CMS Promoting Interoperability Program participants, ONC regularly works to ensure that our own certification timelines complement the schedules inherent to this program and other CMS programs. In the interest of clarity and cohesion among HHS components, we have aligned some of our dates to the calendar year for instances that may impact CMS program participants. Aligning these related compliance dates to the calendar year also aligns them to the CMS program annual cycle. This approach will avoid confusion and best serve the public interest. This approach also extends existing flexibility, rather than creating a new restriction or requirement, and minimizes the impact on health care providers. While we are finalizing more flexible compliance dates, we continue to encourage developers to implement these updates and make them available to customers as soon as practicable under the circumstances.

1. Information Blocking Provisions and Related Condition and Maintenance of Certification Requirements

In the ONC Cures Act Final Rule, the compliance date for 45 CFR part 171, which contains the information blocking provisions of the final rule, is November 2, 2020 (85 FR 25642). This is six months after the publication date of the final rule in the **Federal Register**. Section 171.101(b) provides that health care providers, health IT developers of certified health IT, health information exchanges, and health information networks must comply with 45 CFR part 171 on and after November 2, 2020. We established the six-month-delayed compliance date to provide actors with time to thoroughly read and understand the final rule and educate their workforces in order to apply the exceptions in an appropriate manner (85 FR 25792). We also noted that the finalized definition of information blocking (§ 171.103) and the Content and Manner Exception (§ 171.301(a)) narrowed the scope of the EHI definition to include only the EHI identified by the data elements represented in the United States Core Data for Interoperability (USCDI) for the first 18 months after the compliance date for 45 CFR part 171. Therefore, in addition to the six-month post-publication compliance date for 45 CFR part 171, the ONC Cures Act Final Rule granted actors an additional 18 months to gain experience applying the exceptions with only the EHI identified by the data elements represented in the USCDI, as compared to the full scope of EHI, which would apply thereafter (85 FR 25792).

In the ONC Cures Act Final Rule, we encouraged actors, during this combined period of 24 months, to apply the exceptions to *all* EHI as if the scope was not limited to EHI identified by the data elements represented in the USCDI. However, given the initial scope of EHI identified in the information blocking definition in § 171.103 and the Content and Manner Exception in § 171.301(a), if an actor did not, in the first 24 months after the ONC Cures Act Final Rule's publication date, enable access, exchange, or use of data outside the USCDI, or did not appropriately apply an exception to data outside the USCDI, such practice or ''error'' would not be considered information blocking because that data would not be considered ''EHI'' during that time period (85 FR 25792).

We also stated that the compliance dates for the Information Blocking Condition of Certification requirement in § 170.401 and the Assurances Condition of Certification requirement in § 170.402(a)(1) would be six months after the publication date of the final rule in the **Federal Register**, *i.e.,* November 2, 2020.

In light of the PHE, we believe it is necessary to offer additional flexibilities. Therefore, in this IFC, we are extending the date for 45 CFR part 171 from November 2, 2020, to April 5, 2021. We also believe it is more precise to refer to this date as the applicability date for 45 CFR part 171 instead of the

compliance date. Accordingly, in section II.C.7 of this IFC, we are revising § 171.101(b) to state that actors ''are subject to'' 45 CFR part 171 on and after April 5, 2021. We believe the additional five months will enable actors to focus on the PHE, provide sufficient additional time to thoroughly read and understand the ONC Cures Act Final Rule, and educate their workforce about information blocking and the exceptions contained in the final rule. However, at this time, we do not believe the applicability date for 45 CFR part 171 should extend beyond April 5, 2021. We believe this timeframe appropriately balances the additional flexibility necessary due to the PHE with ONC's sense of urgency in addressing information blocking. We emphasized the urgency of addressing information blocking in the ONC Cures Act Final Rule. We explained that, based on our findings from our 2015 Report to Congress,[4] we concluded that information blocking is a serious problem and recommended that Congress prohibit information blocking and provide penalties and enforcement mechanisms to deter these harmful practices (85 FR 25652). Congress responded by enacting the Cures Act on December 13, 2016, with many provisions specifying a need for swift implementation. Implementation of the information blocking provisions in the ONC Cures Act Final Rule will increase information sharing, improve patient care, and ensure that a patient's health information follows the patient—all of which are urgent goals, particularly during a PHE. In addition, we also believe the applicability date should not extend beyond April 5, 2021, because the information blocking provisions do not contain any technical upgrade requirements that necessitate a longer extension.

We have revised § 171.101(b) to codify the extended applicability date for 45 CFR part 171. Section 171.101(b) now states that health care providers, health IT developers of certified health IT, health information exchanges, and health information networks are subject to this part on and after April 5, 2021. Because we are extending the applicability date for 45 CFR part 171 generally, we are also updating the date by which actors must provide *all* EHI in response to a request, rather than responding with only the data elements represented in the USCDI. Consistent with our original intent to narrow the scope of the EHI definition to just the data elements represented in the USCDI for the first 18 months after the applicability date for 45 CFR part 171, in this IFC, we are also extending the end date for this narrowed definition by 5 months. Therefore, for the 18-month period on and after the April 5, 2021, applicability date and before October 6, 2022, the EHI required in § 171.101(b) will be limited to the data represented in the USCDI. Thus actors will have additional time to gain experience applying the exceptions with the narrower definition of EHI, as compared to the full scope of EHI, which will apply on and after October 6, 2022.

Therefore, we have revised § 171.103(b) of the information blocking definition to extend the period of time for which the EHI is limited to the data elements represented in the USCDI. We state in § 171.103(b) that for the period before October 6, 2022, at a minimum, the EHI identified for the purposes of the information blocking definition in § 171.103(a) is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213. Similarly, we revised and finalized the same date in two paragraphs of the Content and Manner exception (§ 171.301(a)(1) and (2)). We find good cause to waive the notice and comment procedures and delayed effective date requirements of the APA as impracticable and contrary to the public interest due to the COVID–19 PHE (5 U.S.C. 553(b)(B), (d)(3)). Please see sections II.C and III of this IFC for further discussions of our good cause finding.

We have also revised § 170.401 and § 170.402. The ONC Cures Act Final Rule required health IT developers of certified health IT to comply with the Information Blocking Condition of Certification requirement in § 170.401, and the Assurances Condition of Certification requirement related to information blocking in § 170.402(a)(1), beginning on November 2, 2020. For the reasons stated above, we have also provided an extension to these compliance dates. Now, health IT developers must comply with the Condition of Certification requirements in § 170.401 and § 170.402(a)(1) beginning on April 5, 2021. We find good cause to waive the notice and comment procedures and delayed effective date requirements of the APA as impracticable and contrary to the public interest due to the COVID–19 PHE (5 U.S.C. 553(b)(B), (d)(3)). Please see section III of this IFC for further discussion of our good cause finding. This IFC finalizes the extensions and we seek comment on the information blocking dates and extensions that we adopt in this IFC.

2. Certain 2015 Edition Health IT Certification Criteria Updates

In light of the COVID–19 PHE, we are extending compliance dates and timeframes for certain 2015 Edition certification criteria under 45 CFR part 170. In the ONC Cures Act Final Rule, in general, we provided that health IT developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to the updated criteria available to their customers. We noted that, during this time, developers could continue supporting technology certified to the prior version of certification criteria for use by their customers (85 FR 25666).

To allow the health care system time to focus on the COVID–19 PHE, we are extending the timeline for certain 2015 Edition certification criteria (please see Table 2 below) until December 31, 2022, and until December 31, 2023, for § 170.315(b)(10), ''EHI export''. This represents an extension of nearly eight months beyond the original compliance dates finalized in the ONC Cures Act Final Rule and nearly an additional five months beyond the period of enforcement discretion ONC announced on April 21, 2020.[5] As discussed above, we considered several factors as we determined the appropriate date to which to extend the compliance dates.

To determine that December 31, 2022, as well as December 31, 2023, for ''EHI Export'' (§ 170.315(b)(10)), are appropriate compliance dates for updating certain 2015 Edition Cures Update certification criteria, we considered a number of factors. The updated certification criteria require health IT developers to upgrade their current technology in order to maintain or earn their certified status. Some of the upgrades may require training staff or providers on how to operationalize the updated certification criteria. We want to provide additional flexibilities for the health care system to respond to the public health threats posed by the COVID–19 PHE, and to reduce the burden in administrative efforts associated with staff attending any necessary trainings or with incorporating the updated technology into their operations. Accordingly, we are delaying the compliance date for developers to transition to the updated standards in the 2015 Edition Cures Update certification criteria. This extension will delay the burden that health IT developers would incur from being required to make the updated health IT available to their customers. This delay will enable these providers

[4] *https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf.*

[5] *https://www.healthit.gov/curesrule/resources/enforcement-discretion.*

and developers to continue using technology certified to the current versions of the certification criteria with which they are already familiar for an extended period, allowing for greater flexibility in choosing when to implement updated technology. Developers should have greater leeway to ensure the costs of meeting the 2015 Edition Cures Update certification criteria compliance dates do not impair efforts to fight the COVID–19 PHE.

We have included in Table 2 (below) the 2015 Edition Cures Update certification criteria with new compliance dates. Note that ''ONC–ACBs'' refers to ONC-Authorized Certification Bodies.

TABLE 2—2015 EDITION CURES UPDATE

Certification criteria	Reference	2015 Edition cures update—timing	Impact on CMS Promoting Interoperability (PI) programs
Transitions of Care	§ 170.315(b)(1)	Update to adopted USCDI/C–CDA companion guide by December 31, 2022.	PI Measures: —Support Electronic Referral Loops by Sending Health Information. —Support Electronic Referral Loops by Receiving and Incorporating Health Information.
Clinical information reconciliation and incorporation.	§ 170.315(b)(2)	Update to adopted USCDI/C–CDA companion guide by December 31, 2022.	PI Measures: Support Electronic Referral Loops by Receiving and Incorporating Health Information.
Electronic prescribing	§ 170.315(b)(3)	Update to adopted NCPDP SCRIPT standard version 2017071 by December 31, 2022.	PI Measures: —e-Prescribing. —Query of PDMP.
Data Export	§ 170.315(b)(6)	ONC–ACBs may only issue certificates for this criterion for the period before December 31, 2023.	Removed from 2015 Edition Base EHR definition effective date of the final rule (60 days after publication).
Security tags—summary of care—send	§ 170.315(b)(7)	Document, section, and entry (data element) level; or Document level for the period before December 31, 2022.	
Security tags—summary of care—receive.	§ 170.315(b)(8)	Document, section, and entry (data element) level; or Document level for the period before December 31, 2022.	
Care plan	§ 170.315(b)(9)	Update to C–CDA companion guide referenced in § 170.205(a)(4) and § 170.205(a)(5) by December 31, 2022.	
EHI export	§ 170.315(b)(10)	Certify to new criterion by December 31, 2023.	
Clinical quality measures (CQMs)—report.	§ 170.315(c)(3)	Update to CMS QRDA Category I/III IG by December 31, 2022.	PI Programs.
Auditable events and tamper-resistance.	§ 170.315(d)(2)	Update to ASTM 2147–18 standard by December 31, 2022.	
Audit report(s)	§ 170.315(d)(3)	Update to ASTM 2147–18 standard by December 31, 2022.	
Auditing actions on health information	§ 170.315(d)(10)	Update to ASTM 2147–18 standard by December 31, 2022.	
View, Download, and Transmit to 3rd Party.	§ 170.315(e)(1)	Update to USCDI referenced in § 170.213 and C–CDA companion guide referenced in § 170.205(a)(4) and § 170.205(a)(5) by December 31, 2022.	PI Measure: Provide Patients Electronic Access to Their Health Information.
Transmission to public health agencies—electronic case reporting.	§ 170.315(f)(5)	Update to USCDI referenced in § 170.213 by December 31, 2022.	PI Measure: Electronic Case Reporting.
Consolidated CDA creation performance.	§ 170.315(g)(6)	Update to USCDI referenced in § 170.213 and C–CDA companion guide referenced in § 170.205(a)(4) and § 170.205(a)(5) by December 31, 2022.	
Application Access—Data Category Request.	§ 170.315(g)(8)	ONC–ACBs may only issue certificates for this criterion for the period before December 31, 2022.	PI Measure: Provide Patients Electronic Access to Their Health Information.
Application Access—All Data Request	§ 170.315(g)(9)	Update to USCDI referenced in § 170.213 and C–CDA companion guide referenced in § 170.205(a)(4) and § 170.205(a)(5) by December 31, 2022.	PI Measure: Provide Patients Electronic Access to Their Health Information.

TABLE 2—2015 EDITION CURES UPDATE—Continued

Certification criteria	Reference	2015 Edition cures update—timing	Impact on CMS Promoting Interoperability (PI) programs
Standardized API for patient and population services.	§ 170.315(g)(10)	Certify to new criterion by December 31, 2022.	Added to the 2015 Edition Base EHR definition. PI Measure: Provide Patients Electronic Access to Their Health Information.

3. Conditions and Maintenance of Certification Requirements Under the ONC Health IT Certification Program

We have also extended compliance dates and timeframes for other Conditions and Maintenance of Certification requirements in the ONC Cures Act Final Rule to allow adequate time for our health care system to address the COVID–19 PHE.

a. Assurances

Section 4002 of the Cures Act requires that a health IT developer, as a Condition of Certification requirement under the Program, provide assurances to the Secretary that, unless for legitimate purpose(s) as specified by the Secretary, the developer will not take any action that constitutes information blocking as defined in section 3022(a) of the PHSA or any other action that may inhibit the appropriate exchange, access, and use of EHI. In the ONC Cures Act Final Rule, we finalized implementation of this provision through several Conditions of Certification in § 170.402(a) and accompanying Maintenance of Certification requirements, which are set forth in § 170.402(b). We stated in the final rule that the Assurances Condition and Maintenance of Certification requirements had an effective date of June 30, 2020. We exercised enforcement discretion on April 21, 2020, to extend the compliance date an additional three months to September 30, 2020.[6] While we have not made a public announcement that we would be extending our enforcement discretion for an additional period of time, we have not taken any actions to enforce the Assurance Condition and Maintenance of Certification requirements since September 30, 2020. In this IFC, we are extending the compliance date and timeframe for the Assurances Condition and Maintenance of Certification requirements until April 5, 2021, to provide maximum flexibilities for our health care system to respond to the public health threats posed by the COVID–19 PHE. We find good cause to waive the notice and comment procedures of the APA due to the COVID–19 PHE (as discussed in section III of this IFC) (5 U.S.C. 553(b)(B)). Additionally, because affected parties are best served by reducing the uncertainty that could result from different compliance and applicability dates (information blocking-related Conditions of Certification requirements and the information blocking provisions (45 CFR part 171)) and because an immediate effective date serves to reduce a burden on the regulated party by allowing developers of health technology to immediately certify their technology without meeting this new requirement, we find good cause to waive the delayed effective date requirements (5 U.S.C. 553(d)). We are also announcing that any actions or omissions of developers of certified health IT that may have not been in compliance with these Condition and Maintenance of Certification requirements since either the effective date of the final rule or since the expiration of the prior enforcement discretion period would not be subject to non-compliance enforcement for those actions and omissions that occurred during those time periods. In other words, we do not intend to engage in Program enforcement for non-compliance between June 30, 2020, and April 5, 2021.

As we noted above, we have also extended the compliance date related to § 170.402 until April 5, 2021, except for § 170.402(b)(2). In § 170.402(b)(2), we extended the compliance date to meet the requirement that a health IT developer must provide all of its customers of certified health IT with health IT certified to the ''EHI export'' certification criterion in § 170.315(b)(10) to December 31, 2023.

b. Communications

In the ONC Cures Act Final Rule, we finalized in § 170.403 provisions that permit developers to impose on communications certain types of limited prohibitions and restrictions that strike a balance between the need to promote open communication about certified health IT and related developer business practices, and the need to protect the legitimate business interests of health IT developers and others. The provisions identify certain narrowly-defined types of communications, such as communications required by law, made to a government agency, or made to a defined category of safety organization, which will receive ''unqualified protection'' under our Program. Under this policy, developers will be prohibited from imposing any prohibitions or restrictions on such protected communications. We also finalized provisions that allow health IT developers certified under the Program to place limitations on certain types of communications, including screenshots and video. In the ONC Cures Act Final Rule, the compliance date for the Communications Condition of Certification requirements was the effective date of the final rule, June 30, 2020. We exercised enforcement discretion on April 21, 2020, to extend compliance for an additional three months to September 30, 2020.[7] While we have not made a public announcement that we would be extending our enforcement discretion for an additional period of time, we have not taken any actions to enforce the Communications Condition and Maintenance of Certification requirements since September 30, 2020. In this IFC, we are extending the compliance date until April 5, 2021, to allow additional time for the health care system to respond to public health threats posed by the COVID–19 PHE. We find good cause to waive the notice and comment procedures of the APA due to the COVID–19 PHE (as discussed in section III of this IFC) (5 U.S.C. 553(b)(B)). Additionally, because affected parties are best served by reducing the uncertainty that could result from different compliance and applicability dates (information

[6] *https://www.healthit.gov/curesrule/resources/enforcement-discretion.*

[7] *https://www.healthit.gov/curesrule/resources/enforcement-discretion.*

blocking-related Conditions of Certification requirements and the information blocking provisions (45 CFR part 171)) and because an immediate effective date serves to reduce a burden on the regulated party by allowing developers of health technology to immediately certify their technology without meeting this new requirement, we find good cause to waive the delayed effective date requirements (5 U.S.C. 553(d)). We are also announcing that any actions or omissions of developers of certified health IT that may have not been in compliance with these Condition and Maintenance of Certification requirements since either the effective date of the final rule or since the expiration of the prior enforcement discretion period would not be subject to non-compliance enforcement for those actions and omissions that occurred during those time periods. In other words, we do not intend to engage in Program enforcement for non-compliance between June 30, 2020, and April 5, 2021.

In the ONC Cures Act Final Rule, we also adopted Maintenance of Certification requirements for health IT developers of certified health IT in § 170.403(b). Section 170.403(b)(2) states that a health IT developer must not impose or enforce any contractual requirement that contravenes the requirements of paragraph (a) of § 170.403, the Communications Condition of Certification. Furthermore, if a health IT developer has contracts or agreements in existence that contravene the requirements of the Condition of Certification, the developer must notify all affected customers, other persons, or entities that the prohibition or restriction within the contract or agreement will not be enforced by the health IT developer (§ 170.403(b)(1)). In the ONC Cures Act Final Rule, we stated that the developer must notify all affected customers annually, beginning in 2020. Due to the COVID–19 PHE, we are suspending the notice requirement in § 170.403(b)(1) for 2020 *only.* Health IT developers of certified health IT with such contracts or agreements must provide notice to all customers beginning in 2021 and annually thereafter so long as those contracts or agreements remain in place.

This limited suspension ensures that health IT developers will still notify the users and customers of certified health IT in a timely manner, and also relieves pressure on the developers to immediately devote portions of their workforce to review contracts. We believe the annual requirement, beginning with notification in calendar year 2021, will simplify compliance for health IT developers while still providing adequate notice in a reasonable amount of time. We have finalized the deadline for the notice requirement in § 170.403(b)(1) to be annually, beginning in calendar year 2021.

c. Application Programming Interfaces

A Condition of Certification requirement in section 4002 of the Cures Act requires health IT developers to publish APIs that allow ''health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law.'' The Cures Act's API Condition of Certification requirement also states that a developer must, through an API, ''provide access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws.'' The Cures Act's API Condition of Certification requirement in section 4002 includes several key phrases and requirements for health IT developers that go beyond the technical functionality of the Health IT Modules they present for certification. The ONC Cures Act Final Rule captures both the technical functionality and behaviors necessary to implement the Cures Act API Condition of Certification requirement. Specifically, we adopted new standards, new implementation specifications, a new certification criterion, and modified the Base EHR definition. In addition, we finalized detailed Condition and Maintenance of Certification requirements for health IT developers.

For instance, in the ONC Cures Act Final Rule, we adopted a requirement in § 170.404(b)(4) that a Certified API Developer with Health IT Module(s) certified to the certification criteria in § 170.315(g)(7), (8), or (9) (ONC Certification Program API criteria) must comply with § 170.404(a) (API Condition of Certification requirements) by no later than November 2, 2020 (85 FR 25765). We exercised enforcement discretion on April 21, 2020, to extend compliance for an additional three months.[8] In this IFC, we are extending the compliance date until April 5, 2021, so that the health care system can focus on addressing the COVID–19 PHE. We align the new compliance date for this provision with other dates that had a November 2, 2020 compliance date in the ONC Cures Act Final Rule. Setting a more delayed compliance date would have unreasonably delayed and ultimately diminished the benefits of the Program requirements we have finalized in the ONC Cures Act Final Rule.

We also stated in the ONC Cures Act Final Rule in § 170.404(b)(3) that Certified API Developers with API technology previously certified to the criterion in § 170.315(g)(8) must provide API technology certified to § 170.315(g)(10) to all API Information Sources deployed with certified API technology by no later than May 1, 2022 (85 FR 25765). In this IFC, we are extending the compliance timeline for that rollout of new standardized API functionality under § 170.404(b)(3) to December 31, 2022. We are also revising the dates in § 170.102, in the definition of 2015 Edition Base EHR, to be consistent with this extension.

As stated above, we believe extending the compliance date for this requirement by eight months is appropriate so that health IT developers and health care providers may adequately allocate time and resources to address the COVID–19 PHE.

d. Real World Testing

The Cures Act also added a new Condition and Maintenance of Certification requirement that health IT developers must successfully test the real world use of health IT for interoperability in the type(s) of setting(s) in which such technology would be marketed. This provision is critical to advancing transparency regarding Health IT Modules' performance and to users having information that could be crucial to their decisions to acquire certified health IT.

In the ONC Cures Act Final Rule, we established in § 170.405 real world testing requirements that include Maintenance of Certification requirements to update Health IT Modules certified to certain certification criteria (see § 170.405(b)(3) through (7) and (10)) to ensure the technology meets its users' needs for widespread and continued interoperability. We provide details on the 2015 Edition Cures Update certification criteria in section II.A.2 above. We are extending the compliance dates for updating these criteria until December 31, 2022 (and until December 31, 2023, for § 170.315(b)(10), ''EHI export'').

Under real world testing Condition and Maintenance of Certification requirements, health IT developers must also submit publicly available annual real world testing plans and results for health IT certified to the criteria identified in § 170.405(a). In the ONC

[8] *https://www.healthit.gov/curesrule/resources/enforcement-discretion.*

Cures Act Final Rule, we stated that developers must submit plans by December 15 of each calendar year and results by March 15 of each calendar year to ONC for public availability (85 FR 25773 and 25774). Due to the COVID–19 PHE, developers are modifying their technology in ways that are needed to support the health care system in this country. Rather than taking resources from that essential work, in this IFC, we are extending the compliance dates for submitting initial real world testing plans to December 15, 2021, and initial real world testing results to March 15, 2023.

e. Attestations

In the ONC Cures Act Final Rule, in § 170.406, we stated that health IT developers must attest twice a year to compliance with the Conditions and Maintenance of Certification requirements (except for the EHR reporting criteria submission requirement) (85 FR 25648). We believe requiring attestations every six months under § 170.406(b) will properly balance the need to support appropriate enforcement with our desire to minimize the burden on health IT developers. In light of the COVID–19 PHE and extensions provided for other Conditions and Maintenance of Certification requirements, in this IFC, we are extending our annual cycle for attestations by one year, to calendar year 2022. To clarify, due to the extensions provided for other Conditions and Maintenance of Certification requirements in this IFC, the first attestation window will continue to cover an irregular time period from the effective date of the final rule through the extended date of March 31, 2022. Subsequently, a regular six-month period will commence with the next attestation window.

We believe that delaying the implementation of these Condition and Maintenance of Certification requirements will allow health IT developers additional time to comply with the requirements and provides appropriate flexibility so that our health care system may adequately respond to the current COVID–19 PHE.

4. Updates to ONC–ACB Dates and Timeframes

In the ONC Cures Act Final Rule, we finalized several certification criteria changes that were accompanied by compliance dates and timeframes. As we stated previously, due to the COVID–19 PHE, this IFC extends certain compliance dates and timeframes for those new and updated certification criteria and Condition and Maintenance of Certification Requirements. Consequently, for purposes of coordination, we are also extending compliance dates and timeframes for the appropriate provisions applicable to the ONC—Authorized Certification Bodies (ACBs).

In the ONC Cures Act Final Rule, we finalized in § 170.523(p)(3) that ONC–ACBs must submit real world testing plans by December 15 of each calendar year and results by March 15 of each calendar year to ONC for public availability. Because we are now extending those dates for health IT developers, we are also extending the dates by which ONC–ACBs must submit the real world testing plans and results to ONC for public availability. ONC–ACBs must now submit initial plans to ONC by December 15, 2021, and initial results by March 15, 2023.

We had also finalized in § 170.550(m)(2) and (3) a time-limited certification status for certain 2015 Edition certification criteria. We finalized that an ONC–ACB may only issue a certification to a Health IT Module and permit continued certified status for § 170.315(b)(6) and (g)(8) until May 1, 2023, and May 2, 2022, respectively. To reflect the extension of compliance dates and timeframes, we are now finalizing in § 170.550(m)(2) and (3) that an ONC–ACB may only issue a certification to a Health IT Module and permit continued certified status for § 170.315(b)(6) and (g)(8) until December 31, 2023, and December 31, 2022, respectively.

Lastly, in the ONC Cures Act Final Rule, we finalized that for criteria being updated from the Common Clinical Data Set (CCDS) to the USCDI, a transition from the CCDS to the USCDI must occur no later than 24 months after the publication date of the final rule. We stated that for the period up to 24 months after the publication date of the ONC Cures Act Final Rule, the CCDS remains permissible for certified Health IT Modules until such Health IT Modules are updated to the USCDI. Due to the extension of compliance dates for certain 2015 Edition Cures Update certification criteria (we refer readers to section II.A.2), we are also providing an extension such that for certified Health IT Modules, the CCDS may remain applicable up to December 31, 2022, when such Health IT Modules are updated to the USCDI.

We believe these revisions are appropriate and align with the extended compliance dates and timelines for related certification criteria and Program requirements.

B. Standards Updates

1. USCDI

In the ONC Cures Act Final Rule, we published the USCDI version 1 (v1) to replace the CCDS as the standard patient data set in several ONC certification criteria.[9] Through the USCDI v1 we added new data classes, including Allergies and Intolerances, Clinical Notes, and Provenance; and added data elements to Patient Demographics and Vital Signs. In USCDI v1, we also defined applicable terminology standards to represent respective data elements, where appropriate. In the ONC Cures Act Final Rule, we adopted into the USCDI additional data classes and data elements, with the applicable standards thus replacing CCDS. With the exception of the Medication class and Medication Allergies data element, we neither proposed nor intended to change applicable standards relevant to the CCDS data elements. However, we included in the USCDI v1 [10] new applicable terminology standards that were neither previously required for the CCDS nor presented for addition or change through the rulemaking process. Several stakeholders commented on and objected to these unexpected changes to the applicable standards, and ONC concurred with these comments. Therefore, we published the USCDI v1 (July 2020 Errata) [11] to address these concerns, to make the necessary corrections to the standards, and to describe the changes over the original USCDI v1. We are adopting and incorporating by reference the updated standard USCDI v1 (July 2020 Errata) in this IFC.

2. US Core Implementation Guide

We adopted the HL7® FHIR® US Core Implementation Guide STU3 Release 3.1.0 (US Core IG 3.1.0) as part of the ONC Cures Act Final Rule testing and certification requirements for the § 170.315(g)(10) standardized API for patient and population services certification criterion. Since publication of the ONC Cures Act Final Rule, the health IT standards community has identified and resolved several technical issues, editorial copy/paste errors, omissions, and places in need of minor clarification in the US Core IG 3.1.0. The health IT standards community has also published a revised HL7 FHIR US

[9] *https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf.*

[10] *https://www.healthit.gov/isa/sites/isa/files/2020-03/USCDI-Version1-2020-Final-Standard.pdf.*

[11] *https://www.healthit.gov/isa/sites/isa/files/2020-07/USCDI-Version-1-July-2020-Errata-Final.pdf.*

Core Implementation Guide STU3 Release 3.1.1 (US Core IG 3.1.1) with technical errata to address these updates. We are adopting the US Core IG 3.1.1 in § 170.215(a)(2) in order to support industry standardization around the latest version of the US Core IG.

C. Corrections and Clarifications to the ONC Cures Act Final Rule

In **Federal Register** document 2020–07419 (85 FR 25642), the ONC Cures Act Final Rule, we identified certain inadvertent errors following publication in the **Federal Register** on May 1, 2020. In this IFC, we are correcting these errors and providing clarification. As we discuss in further detail below, we find good cause to waive the notice and comment (and, for certain corrections, the delayed effective date) requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553(b) and (d). We believe adherence to these APA requirements would be impracticable, unnecessary, or contrary to the public interest for these corrections and clarifications, and explain below our reasoning for each.

It is important for our final rules to be written clearly and accurately, and to reflect the final policies we adopted after considering the public comments we received on our proposals. Inadvertent errors such as these could be confusing to regulated individuals and entities that are subject to the ONC Cures Act Final Rule. Failure to correct these errors and provide clarifications could place unnecessary burden on regulated parties as they attempt to comply with the final rule. We summarize and correct these errors and offer the necessary clarifications below.

1. General Applicability and Applicability of Standards and Implementation Specifications for Health Information Technology

As noted in the ONC Cures Act Final Rule, the Cures Act amended title XXX of the PHSA to establish the ''Communications'' condition of certification, which applies to ''health information technology'' (85 FR 25733). Title XXX of the PHSA was previously added by the HITECH Act, which included the definition of ''health information technology.'' Section 3000(5) of the PHSA defines health information technology to mean hardware, software, integrated technologies or related licenses, IP, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information. We adopted this definition of ''health information technology'' in § 170.102 in the ONC Cures Act Final Rule (85 FR 25733). However, in § 170.101 and § 170.200, we neglected to update the language to say ''health information technology.'' Instead, we erroneously kept the reference to ''Health IT Modules.'' We, therefore, are updating this language in this IFC. As these are clarifications and not substantive corrections, we find good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. 553(b)(B)).

2. Standards for Health Information Technology To Protect Electronic Health Information Created, Maintained, and Exchanged

a. Record Actions Related to Electronic Health Information, Audit Log Status, and Encryption of End-User Devices

In the ONC Cures Act Final Rule (85 FR 25708), we inadvertently referred to the auditable events and tamper-resistance standard as ''ASTM E1247–18''. The error occurs twice on that page. The correct standard is ASTM E2147–18, which is what we included in the relevant regulatory text.

We also inadvertently omitted amendatory text for § 170.210(e)(2)(i) and (e)(3) (85 FR 25940). Because we updated the standard in § 170.210(h) to ASTM E2147–18, we have also updated the requirements in § 170.210(e) to align with the new numbering sequence of the updated standard. However, we inadvertently neglected to update the same reference language for the ASTM data elements in § 170.210(e)(2)(i) and (e)(3). Therefore, we are correcting § 170.210(e)(2)(i) and (e)(3) by replacing ''7.2 and 7.4,'' which referred to the previous ASTM standard, with ''7.1.1 and 7.1.7,'' which refers to the updated ASTM E2147–18 standard. This does not constitute a change in requirements, but simply a change to where those requirements are referenced within the updated ASTM E2147–18 standard. The correction of typographic errors does not constitute a substantive change, and we, therefore, find good cause to waive the public notice and comment procedures of the APA as unnecessary (5 U.S.C. 553(b)(B)).

In addition, the new numbering of the ASTM data elements led to another error. The ONC Cures Act Final Rule included the requirement for Health IT Modules to support 7.1.3 Duration of Access in the ASTM E2147–18 standard. However, we have determined this will not be a requirement for testing and certifying to 2015 Edition Cures Update certification and we are removing it from the regulatory text. The requirement added a significant burden for health IT developers and it was not our intent to add burden beyond the requirements to update to the new ASTM E2147–18 standard. Our intent, as proposed and stated in the preamble, was simply to update the standards' numbering in our Program for certification and testing to conform with the new numbering set by the standards organization itself (''. . . the updated standard reinforces what we have previously required and maintained with previous certification requirements and note that there is no substantial change to the standard'' 85 FR 25708). After publication of the ONC Cures Act Final Rule, we heard from health IT developers who noted that we had errantly included 7.1.3 Duration of Access, a requirement we did not intend to include as part of the Program at this time. In fact, requiring developers of certified health IT to certify to 7.1.3 would substantially increase the development costs and time. While the other related requirements for auditable events and tamper resistance require basic data like ''date and time of access,'' the duration of access certification criteria would require substantial updates to all health technology to record and preserve more data than previously required. In response, we immediately clarified in sub-regulatory guidance (the certification companion guide for auditable events and tamper-resistance) that this requirement will not be in scope for certification or testing. Since our intent, as proposed and discussed, was to incorporate requirements similar to those previously required, 7.1.3 Duration of Access in the ASTM E2147–18 was errantly included. The correction of typographic errors does not constitute a substantive change, and we, therefore, find that there is good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. § 553(b)(B)).

b. Synchronized Clocks

Section 170.210(g) (Synchronized clocks) included a reference to Request for Comment (RFC) 1305 Network Time Protocol, a standard maintained by the Internet Engineering Task Force (IETF). However, prior to the release of the ONC Cures Act NPRM, IETF obsoleted RFC 1305 and replaced it with RFC 5905, which is backward compatible with RFC 1305. In this IFC, we removed the reference to RFC 1305 in § 170.210(g). Because the obsolete standard is no longer maintained by its standard organization and is therefore no longer publically recognized as the current

standard for common internet protocols, and because the removal of the RFC 1305 standard and the replacement with the current RFC 5905 standard were both previously available for public input through IETF's open standards process, we find good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. § 553(b)(B)). To note, RFC 5905 Network Time Protocol Version 4 (incorporated by reference in § 170.299) was already approved for § 170.210 on September 4, 2012.

3. Applicability of Certification Criteria for Health Information Technology

In the ONC Cures Act Final Rule, we removed the 2014 Edition from the CFR (85 FR 25656). We also finalized removal of terms and definitions specific to the 2014 Edition from § 170.102, including the ''2014 Edition Base EHR,'' ''2014 Edition EHR certification criteria,'' and ''Complete EHR, 2014 Edition'' definitions (85 FR 25655). As explained in the 2015 Edition final rule (80 FR 62719), the ''Complete EHR'' concept was discontinued for the 2015 Edition. Therefore, in conjunction with the removal of the 2014 Edition, we also removed references to ''Complete EHR'' from the regulation text. In the ONC Cures Act Final Rule, consistent with our intent to remove all terms specific to the 2014 Edition, we neglected to include the removal of the term ''EHR Module.'' The term should have been corrected to say ''Health IT Module.'' We, therefore, now correct this error in § 170.300(a) and (c). The correction of typographic errors does not constitute a substantive change, and we, therefore, find that there is good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. § 553(b)(B)).

Consistent with our intent above to remove the 2014 Edition, in § 170.300(d), we neglected to remove the reference to § 170.314. We corrected this error in this IFC by only referencing § 170.315 in § 170.300(d). Since we removed and reserved § 170.314, referring to § 170.314 in this section is misleading and meaningless. The correction of typographic errors does not constitute a substantive change, and we, therefore, find that there is good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. § 553(b)(B)).

4. Electronic Prescribing

As discussed in the ONC Cures Act Final Rule, an RxFillIndicatorChange is sent by a prescriber to a pharmacy to indicate to the pharmacy that the prescriber is changing the types of RxFill transactions that were previously requested, modifying their status, or canceling future transactions (85 FR 25682). We requested comment on this transaction in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule (84 FR 7444) and ultimately adopted it as optional in the ONC Cures Act Final Rule. However, in the regulation text, we inadvertently used the transaction ''RxFillIndicator'' (85 FR 25942). Therefore, in § 170.315(b)(3)(ii)(B)(*2*), we are correcting the transaction to ''RxFillIndicatorChange.'' The correction of typographic errors does not constitute a substantive change, and we, therefore, find that there is good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. § 553(b)(B)).

5. Clinical Quality Measures—Report Criterion

In the ''Updates to the 2015 Edition Certification Criteria'' section of the ONC Cures Act Final Rule, we noted that we only adopted two new technical certification criteria in § 170.315(b)(10) (EHI export) and § 170.315(g)(10) (Standardized API for patient and population services) to which health IT developers seeking to upgrade their products will need to present Health IT Modules for certification (85 FR 25665). We also included § 170.315(c)(3) (Clinical quality measures—report) in the list of criteria that currently apply to certified Health IT Modules that CMS program participants use. We stated that, in general, health IT developers of certified health IT have 24 months from the publication date of the ONC Cures Act Final Rule to make technology certified to *these* updated certification criteria available to their customers, and during this time developers may continue supporting technology certified to the prior version of the ONC certification criteria for use by their customers (85 FR 25666). We intended for § 170.315(c)(3) to also have a compliance timeline of 24 months, but we erroneously omitted it from the ''clinical quality measures—report'' criterion section of the preamble and the real world testing regulatory text.

For all of the other criteria we revised due to standards updates, we allowed a 24-month compliance timeline. In Table 1—2015 Edition Cures Update of the ONC Cures Act Final Rule (85 FR 25667), we incorrectly included the timing for the revised criterion ''clinical quality measures—report'' to be the effective date of the final rule, which was 60 days after it was published in the **Federal Register**. Our intent, as evidenced above in our description of the overarching approach for all of the standards updates to the 2015 Edition criteria, was to make the compliance timelines consistent for all of the revised criteria and allow health IT developers 24 months from the date of publication to update to the new standards. Therefore, to align with the other revised criteria to relieve an impractical burden on stakeholders and to allow for the extension that we discuss in section II.A.2, the correct compliance timeline for the ''clinical quality measures—report'' criterion is December 31, 2022. We reflect this change in § 170.405(b)(10) of the real world testing Maintenance of Certification requirements, stating that health IT developers with health IT certified to § 170.315(c)(3) as of June 30, 2020, would have to update such certified health IT to the revisions by December 31, 2022. The correction of typographic errors does not constitute a substantive change, and we, therefore, find that there is good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. 553(b)(B)). Even if this change constituted a substantive rulemaking subject to notice and comment procedures or delayed effective date requirements, because it would be impractical and unnecessary to request comment on such a change, we find good cause to waive notice and comment procedures and delayed effective date requirements of the APA (5 U.S.C. 553(b)(B), (d)).

CMS Quality Reporting Document Architecture Implementation Guides

In the ONC Cures Act Final Rule, we also failed to adopt the latest versions of the CMS Quality Reporting Document Architecture (QRDA) Implementation Guides (IGs) as we stated we would do in the Proposed Rule (84 FR 7446). In the Proposed Rule, we stated at 85 FR 25687 that ''we propose to incorporate by reference in § 170.299 the latest annual CMS QRDA IGs'' and in the Cures Act Final Rule we stated at 85 FR 25689 that ''We thank commenters for their input and have adopted the latest CMS QRDA IG versions available at the time of publication of this final rule.'' In order to align with our proposals and requirements in the ONC Cures Act Final Rule, in this IFC, we are adopting the standards for CMS clinical quality measure reporting in § 170.205(h)(3) and § 170.205(k)(3) to the latest CMS QRDA standards available at the time of the ONC Cures Act Final Rule publication (May 1, 2020), which are included in the certification criterion at

§ 170.315(c)(3). The 2020 CMS QRDA IGs we are adopting for testing and certification align with changes CMS already requires health care providers to use. We incorporate by reference at § 170.299 the CMS QRDA IGs, specifically the 2020 CMS QRDA I IG for Hospital Quality Reporting,[12] which published on December 3, 2019, and the 2020 CMS QRDA III IG for Eligible Clinicians and Eligible Professionals,[13] which published on April 30, 2020. These IGs were available prior to the publication of the ONC Cures Act Final Rule, but we erroneously included prior QRDA IGs. Specifically, in this IFC, we are adopting the 2020 CMS QRDA category I for inpatient measures at § 170.205(h)(3) and 2020 CMS QRDA category III for ambulatory measures at § 170.205(k)(3). We waive the notice and comment period for this change as it is unnecessary, because the change ensures that the regulations accurately reflect the policies we proposed, the public commented on, and that we then finalized in the ONC Cures Act Final Rule. We note that CMS programs may independently require the implementation and use of the most up-to-date CMS QRDA specifications prior to the December 31, 2022 deadline.

6. Multi-Factor Authentication

In § 170.315(d)(13)(ii), we mistakenly used the word ''identify'' in the regulatory text related to multi-factor authentication (85 FR 25943). We are correcting § 170.315(d)(13)(ii) by replacing ''identify'' with the word ''identity.'' The correction of typographic errors does not constitute a substantive change, and we therefore find that there is good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. § 553(b)(B)).

7. Transmission to Public Health Agencies—Electronic Case Reporting

We erroneously included a requirement in the ONC Cures Act Final Rule that health IT developers certifying to § 170.315(f)(5) were required to conform to the HL7 Clinical Document Architecture standard and companion guide adopted in § 170.205(a)(4) and (5). We did not propose this change for § 170.315(f)(5) in the ONC Cures Act Proposed Rule (84 FR 7443 and 7591), and intended only to finalize a requirement that health IT developers certifying to § 170.315(f)(5) are required to conform to data classes expressed in the standards in § 170.213 or the Common Clinical Data Set for the period before December 31, 2022 (see 84 FR 7441). Because the application of these standards would completely change the certification requirements to the ''electronic case reporting'' criterion and impose a significant development burden for developers, and because the standards were not proposed, we are revising the regulation text in § 170.315(f)(5) and § 170.405(b)(3) to correct this clear error. Specifically, we have removed the words ''and in accordance with § 170.205(a)(4) and (5),'' from § 170.315(f)(5)(iii)(B)(*1*) and ''in accordance with § 170.205(a)(4)'' from § 170.315(f)(5)(iii)(B)(*2*), and corrected the real world testing regulation text in § 170.405(b)(3) by removing the words ''for C–CDA'' from the title of the paragraph to accommodate the corrections to § 170.315(f)(5). As these revisions do not constitute substantive changes to what we proposed, received comment on, and intended to finalize, we find good cause to waive the public notice and comment procedures of the APA as unnecessary.

8. Conditions and Maintenance of Certification Requirements for Health IT Developers

a. Assurances

In § 170.402(a)(4) of the ONC Cures Act Final Rule, there was a typo: ''heath IT product'' (85 FR 25946). We are correcting the typo ''heath IT product'' to ''health IT product.'' The correction of typographic errors does not constitute a substantive change, and we, therefore, find that there is good cause to waive the notice and commend procedures of the APA as unnecessary (5 U.S.C. § 553(b)(B)).

b. Application Programming Interfaces—Clarification for Native Applications and Refresh Tokens

In the ONC Cures Act Final Rule, we established an approach that required Health IT Modules to issue refresh tokens to applications that are ''capable of storing a client secret'' (85 FR 25945). We based our approach on the standards and implementation specifications we adopted for the § 170.315(g)(10) certification criterion. After the publication of the Cures Act Final Rule, health IT developers preparing for testing and certification to the § 170.315(g)(10) certification criterion, as well as third-party application developers, requested that we clarify this requirement.

Stakeholders identified that we had not fully explained how our policy would apply to ''native applications,'' which, according to IETF RFC 6749, are ''clients installed and executed on the device used by the resource owner (*i.e.,* desktop application, native mobile application)'' and their interactions with OAuth 2.0 authorization servers.[14] These stakeholders noted that a strict interpretation of the final rule could exclude native applications that use or are capable of using additional technology that make them ''capable of storing a client secret,'' or native applications that are capable of securely handling a refresh token without needing a client secret. Consequently, stakeholders indicated that the technical ambiguity around native applications would negatively impact testing and certification. Further, stakeholders contended that without timely and explicit clarifications to native applications, health IT developers' support for native applications would vary widely.

We agree with these concerns and that timely and additional clarification is necessary. In our assessment, if such variation were to occur, it would greatly affect the types of applications supported by certified API technology in the next two years as compliance timelines come into effect. Moreover, such a result would be contrary to the public interest because it would contradict the intent of the Cures Act and our implementation of the API Condition of Certification, would negatively impact market competition, and would especially disadvantage and limit patients' ability to access their electronic health information without special effort. In the ONC Cures Act Proposed Rule (84 FR 7481), we stated, ''The SMART Guide specifies the use of 'refresh tokens' as optional. We believe that this requirement is necessary in order to enable persistent access by apps, especially in a patient access context. Thus, we propose to make their use mandatory with a minimum refresh token life of three months . . . we wish to emphasize that implementing refresh token support is directly intended to enable a patient's 'persistent access' to their electronic health information without special effort (*i.e.,* without having to frequently re-authenticate and re-authorize while using their preferred app).'' Recognizing that patients will largely use smartphone applications (native applications) to access their health information, we would substantially limit patients' ability to access their electronic health information without special effort if native applications were categorically

[12] *https://ecqi.healthit.gov/sites/default/files/QRDA-HQR-2020-CMS-IG-v1.1-508.pdf.*

[13] *https://ecqi.healthit.gov/sites/default/files/2020-CMS-QRDA-III-Eligible-Clinicians-and-EP-IG-v1.2.1-508.pdf.*

[14] IETF RFC 6749: *https://tools.ietf.org/html/rfc6749.*

excluded from enabling ''persistent access.'' By making this clarification and revising the regulation text, we are ensuring that the regulation best matches the policies commented on and then finalized in the ONC Cures Act Final Rule. For these reasons, we find good cause to waive the notice and comment procedures of the APA as contrary to the public interest and unnecessary (5 U.S.C. 553(b)(B)).

Based on our analysis of the applicable standards and industry practices,[15] including the HL7® SMART Application Launch Framework Implementation Guide Release 1.0.0 (SMART IG) (adopted in § 170.215(a)(3)), we identified that it is possible for native applications to use secure storage capabilities and technologies on mobile platforms to secure a refresh token, a client secret, or both. Indeed, section 3.0.1 of the SMART IG provides examples of native applications that can meet either the ''confidential app profile'' or the ''public app profile.'' Examples of technologies native applications can use to secure a refresh token, a client secret, or both include operating system-specific features to register application-claimed, private-use Uniform Resource Identifier (URI) schemes as OAuth 2.0 redirect URIs,[16] and technologies that enable applications to securely store credentials through on-device storage.[17]

In response to these concerns, we have clarified and made the regulation text consistent by adding a new paragraph in § 170.315(g)(10)(v)(A)(*1*)(*iii*) and revising paragraphs § 170.315(g)(10)(v)(A)(*1*)(*ii*) and § 170.315(g)(10)(v)(A)(*2*)(*ii*). In the new paragraph in § 170.315(g)(10)(v)(A)(*1*)(*iii*), we have specified that Health IT Modules' authorization servers must issue a refresh token to native applications that are capable of securing a refresh token. In § 170.315(g)(10)(v)(A)(*1*)(*ii*) and § 170.315(g)(10)(v)(A)(*2*)(*ii*), we have updated the regulation text to be consistent with the paragraph we have added in § 170.315(g)(10)(v)(A)(*1*)(*iii*) by specifying that a ''Health IT Module's authorization server'' must issue a refresh token to applications that are capable of storing a client secret. And in § 170.315(g)(10)(v)(A)(*2*)(*ii*) we have updated the regulation text by removing the word ''new'' preceding ''refresh token''. These updates make the certification criterion clear and consistent, and disambiguate the implications for native applications.

The requirement we have finalized in § 170.315(g)(10)(v)(A)(*1*)(*iii*) addresses the technical ambiguity regarding native applications that we discussed previously and clarifies that Health IT Modules must support the issuance of an initial refresh token to native applications that are capable of securing a refresh token. As part of the requirements in § 170.315(g)(10)(v)(A)(*1*)(*iii*), health IT developers must publish the method(s) by which their Health IT Modules support the secure issuance of an initial refresh token to native applications according to the technical documentation requirements in § 170.315(g)(10)(viii) and transparency conditions in § 170.404(a)(2). Additionally, application developer attestations to health IT developers regarding the ability of their applications to secure a refresh token, a client secret, or both, must be treated in a good faith manner consistent with the provisions established in the openness and pro-competitive conditions in § 170.404(a)(4).

We emphasize that health IT developers can determine the method(s) they use to support interactions with native applications and we clarify that health IT developers are not required to support all methods that third-party application developers seek to use. Moreover, while we have not specified that health IT developers use a standards-based approach with respect to interactions with native applications, we encourage the industry to coalesce around a single set of requirements across all health IT developers.

In order to support the ability of end-users to persistently access health information, we required in the ONC Cures Act Final Rule in § 170.315(g)(10)(v)(A)(*2*)(*ii*) that for subsequent connections, ''an application capable of storing a client secret must be issued a new refresh token valid for a new period of no less than three months.'' According to stakeholder feedback, the double use of ''new'' in the regulation text has caused confusion and unintended over-interpretation of the regulation text. As a result, we have removed the first ''new'' preceding ''refresh token,'' and clarify that the remaining ''new'' applies to the extended or renewed duration of the ''refreshed'' refresh token. The additional revisions we have made in § 170.315(g)(10)(v)(A)(*2*)(*ii*) are simply stylistic changes to match the language in our revisions in § 170.315(g)(10)(v)(A)(*1*)(*ii*) and § 170.315(g)(10)(v)(A)(*1*)(*iii*). Such corrections are not substantive, therefore, we find good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. 553(b)(B)).

Additionally, we clarify that the paragraph focused on ''First time connections'' in § 170.315(g)(10)(v)(A)(*1*) and the paragraph focused on ''Subsequent connections'' in § 170.315(g)(10)(v)(A)(*2*) are aligned and that our policy for subsequent connections remains unchanged. That is, Health IT Modules must issue a refresh token that is valid for a new period of no less than three months to only applications that are capable of storing a client secret. While the new paragraph in § 170.315(g)(10)(v)(A)(*1*)(*iii*) requires Health IT Modules to issue an initial refresh token to native applications, Health IT Modules may require native applications that can secure a refresh token without a client secret to re-authenticate and re-authorize after the initial refresh token expires. As this is a clarification and not a substantive correction, we find good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. 553(b)(B)).

[15] RFC 6749 (*https://tools.ietf.org/html/rfc6749*) describes native applications as ''clients installed and executed on the device used by the resource owner (*i.e.,* desktop applications, and native mobile applications).'' IETF RFC 8252 (*https://tools.ietf.org/html/rfc8252*), referenced by the HL7® SMART Application Launch Framework Implementation Guide Release 1.0.0 (SMART IG) (adopted in § 170.215(a)(3)), updates RFC 6749 and provides guidance for OAuth 2.0 authorization requests from native applications. RFC 8252 describes technology and security practices that can be used to enable native applications to securely authenticate their identity and prevent well-documented security threats. Notable examples include Dynamic Client Registration Protocol (IETF RFC 7591) (*https://tools.ietf.org/html/rfc7591*) to enable native applications to receive per-instance client secrets, private-use URI scheme redirect URIs to support native apps to verify their identity, and Proof Key for Code Exchange (PKCE) (IETF RFC 7636) (*https://tools.ietf.org/html/rfc7636*) to secure the authorization code during the authorization process.

[16] For example, Android makes available ''App Links'' (*https://developer.android.com/training/app-links*) and iOS makes available ''Universal Links,'' (*https://developer.apple.com/documentation/xcode/allowing_apps_and_websites_to_link_to_your_content*) which applications can use to register application-claimed, private URI schemes as OAuth 2.0 redirect URIs.

[17] For example, Android enables third-party application developers to use technologies like the ''Keystore'' (*https://developer.android.com/training/articles/keystore.html*) for secure storage on supported devices, and newer Apple devices contain a ''Secure Enclave'' (*https://developer.apple.com/documentation/security/certificate_key_and_trust_services/keys/storing_keys_in_the_secure_enclave)* within their processors, which third-party application developers can use for secure storage.

9. Principles of Proper Conduct for ONC–ACBs

In the ONC Cures Act Final Rule, we discussed removing § 170.523(k)(2) (85 FR 25663). In the regulatory text, we removed § 170.523(k)(2) to further reduce administrative burden for health IT developers and ONC–ACBs, and included the instructions to do so (85 FR 25951). Because we removed § 170.523(k)(2), the requirement in § 170.523(f)(1)(xxi) that the ONC–ACB include the attestation from that section in its certified product listing should also have been removed. We inadvertently omitted that removal from the amendatory instructions for § 170.523(f) (85 FR 25950). We are correcting the error by removing the requirement in § 170.523(f)(1)(xxi) because the Principles of Proper Conduct for ONC–ACBs should accurately reflect the policies we proposed, the public commented on, and that we then finalized in the ONC Cures Act Final Rule. Further, because the remnant has no meaning in the absence of the other provision, and can impose no benefit or obligation, the correction of such errors does not constitute a substantive change. As such, we therefore find that there is good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. § 553(b)(B)).

Additionally in the ONC Cures Act Final Rule, in the amendatory instructions for § 170.523, we instructed in step h that the phrase ''Complete EHR or'' be removed from paragraph (k)(1), but the phrase specifically appeared in (k)(1)(i) (85 FR 25950). We corrected the error and removed the phrase ''Complete EHR or'' from § 170.523(k)(1)(i) in this IFC. Section 170.523(k)(1)(i) is also further revised to remove the brackets before ''Complete EHR or'' and after ''Health IT Module'' (85 FR 25950). We have made this correction. The correction of typographic errors does not constitute a substantive change, and we therefore find that there is good cause to waive the notice and comment procedures of the APA as unnecessary (5 U.S.C. 553(b)(B)).

10. Applicability of the Information Blocking Provisions

In the ONC Cures Act Final Rule preamble, we inadvertently stated that health care providers, health IT developers of certified health IT, health information exchanges, and health information networks ''must comply'' with 45 CFR part 171 by a particular date (85 FR 25793). We unintentionally used the same language in the regulation text § 171.101(b) (85 FR 25955). Because part 171 defines information blocking and provides a series of voluntary exceptions to that definition, it is more precise to say such actors ''are subject to'' this part. We corrected § 171.101(b) to replace ''must comply'' with ''are subject to.'' Because this is primarily a correction to an inadvertent use of language, and not a substantive change, we, therefore, find that there is good cause to waive the notice and comment procedures and delayed effective date requirements of the APA as unnecessary (5 U.S.C. 553(b)(B), (d)(3)). Further, even if this constituted a substantive change, for the reasons we stated previously in this section II.C, we find good cause to waive the notice and comment rulemaking process and delayed effective date for this correction, because these requirements would be impracticable and contrary to the public interest.

11. Information Blocking Definition and Security Exception

In the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule (Proposed Rule), we considered a definition of information blocking that included actions that ''interfere with, prevent or materially discourage'' access, exchange or use of EHI, but ultimately we proposed that the term ''interfere with'' was already inclusive of ''prevent'' and ''materially discourage'' (84 FR 7516). Similarly, in the preamble to the ONC Cures Act Final Rule, in discussing the information blocking definition, we determined that the terms ''interfere with'' and ''interference'' are themselves inclusive of both prevention and material discouragement of access, exchange or use of EHI (85 FR 25809). Further, in § 171.102, we defined ''*Interfere with* or *interference*'' to include both ''prevent'' and ''materially discourage'' (85 FR 25956). The definition of information blocking in § 171.103, therefore, should not include ''prevent, or materially discourage.'' It is redundant and could confuse stakeholders who read and commented on the Proposed Rule and read in the preamble of the ONC Cures Act Final Rule that ''interfere with'' is inclusive of those terms. We also failed to remove the words from the regulatory text for the ''Security exception'' in § 171.203(e)(2). Therefore, we have corrected the definition of ''information blocking'' in § 171.103 by removing the redundant phrase ''prevent, or materially discourage'' in two instances—§ 171.103(a)(2) and (a)(3) (85 FR 25956). Further, in order to eliminate the same redundancy and to promote clarity, we have corrected § 171.203(e)(2) by removing the phrase ''prevent, or materially discourage'' (85 FR 25958). These corrections are necessary to ensure the policies we discussed in the Proposed Rule and finalized in the preamble of the ONC Cures Act Final Rule are accurately and clearly reflected in the regulatory framework we established. This correction imposes no further burden or obligation on any party, and does not constitute a substantive change. For these reasons, we find good cause to waive the notice and comment procedures and delayed effective date requirements of the APA as unnecessary (5 U.S.C. 553(b)(B), (d)(3)).

When defining the actors to whom the definition of information blocking would apply in the ONC Cures Act Final Rule, we finalized a policy to use the term ''health IT developer of certified health IT.'' In doing so, we considered the many comments we received in response to our proposed definition for that specific term in the Proposed Rule. We extensively discussed the term ''health IT developer of certified health IT,'' as well as the comments we received regarding the proposed term and definition, in the preamble of the ONC Cures Act Final Rule (85 FR 25795 through 25797). We finalized the definition of the term ''health IT developer of certified health IT'' itself, in § 171.102 (85 FR 25956). We referred to ''health IT developers of certified health IT'' in 45 CFR 171.101(a) and (b) in stating the applicability of 45 CFR part 171. Thus, we made clear our explicit intent that the definition of information blocking would only apply to developers *of certified health IT,* not *all* health IT developers.

In the definition of information blocking itself in § 171.103, however, we erroneously used only the term ''health IT developer'' and omitted the rest of the phrase (''of certified health IT''). We proposed, received comment on, discussed and finalized specific policies in regards to the regulatory definition of information blocking and the meaning of ''health IT developer'' found in the statutory information blocking definition. We finalized the policy for the narrower definition ''health IT developer of certified health IT'' based on comments we received and for reasons we extensively discussed in the preamble of the ONC Cures Act Final Rule. Therefore, we have corrected § 171.103(a)(2) to include the full phrase ''health IT developer *of certified health IT.*'' By erroneously omitting the full

phrase, the regulation could have caused confusion and been read as creating a burden on *all* developers of health IT, an expansion we explicitly decided not to include in the ONC Cures Act Final Rule. For the reasons we stated previously in this section II.C; and because this error does not correctly reflect any policy proposed, commented on, or finalized; and because it could be read to impose an immediate, unnecessary burden on a large number of entities without notice, we find good cause to waive the notice and comment rulemaking process and delayed effective date requirements of the APA as unnecessary (5 U.S.C. 553(b)(B), (d)(3)).

12. Content and Manner Exception

In the ONC Cures Act Final Rule, we discussed the manner in which actors must fulfill a request to access, exchange or use EHI. The action is best characterized as ''fulfilling a request,'' which is how we described it throughout the ONC Cures Act Final Rule, except for one instance in the preamble when we erroneously used the word ''response'' instead (85 FR 25877). For the purpose of consistency, we clarify that when an actor fulfills a request in any manner requested, any fees charged by the actor in relation to fulfilling the request are not required to satisfy the Fees Exception in § 171.302. We also made an error in the regulation text in § 171.301(b)(1)(ii)(A), where we inadvertently referred to an actor's practice of fulfilling a request for EHI as ''fulfilling a response'' which is incorrect and an obvious error (85 FR 25959). Therefore, we have corrected this phrase to read ''fulfilling a request.''

In addition, we clarify a typographical error in the ONC Cures Act Final Rule preamble. At 85 FR 25877, we erroneously refer to § 171.301(b)(2)(i)(a); the correct citation has a capitalized (A) instead of lowercase (a).

The correction of these typographic errors does not constitute a substantive change, and we, therefore, find that there is good cause to waive the notice and comment procedures and delayed effective date requirements of the APA as unnecessary (5 U.S.C. 553(b)(B), (d)(3)).

13. Licensing Exception

In § 171.303(b)(2)(i), we erroneously cross-referenced paragraph (c)(3) instead of the correct paragraph, (b)(3) (85 FR 25960). We have corrected the error. The correction of typographic errors does not constitute a substantive change, and we therefore find that there is good cause to waive the notice and comment procedures and delayed effective date requirements of the APA as unnecessary (5 U.S.C. 553(b)(B), (d)(3)).

III. Waiver of Proposed Rulemaking, Comment Period, and Delay in Effective Date

Under the Administrative Procedure Act (APA), 5 U.S.C. 553(b), an agency is required to publish a notice of proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. In addition, § 553(d) mandates a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) provide for exceptions from the notice and comment and delay in effective date requirements. Section 553(b)(B) authorizes an agency to dispense with normal rulemaking requirements when the agency for good cause finds that the notice and comment processes are impracticable, unnecessary, or contrary to the public interest. In addition, § 553(d)(3) allows the agency to waive the 30-day delay in effective date for ''otherwise provided by the agency for good cause found and published with the rule.''

The nation is experiencing an emergency of unprecedented magnitude. This IFC directly supports that goal by offering regulated individuals and entities flexibilities in complying with the ONC Cures Act Final Rule while they are combating the COVID–19 pandemic. The IFC also helps to ensure that sufficient health IT products and services are available to meet the needs of affected health care systems, health care providers, and individuals.

On January 30, 2020, the International Health Regulations Emergency Committee of the WHO declared the outbreak of COVID–19 to be a Public Health Emergency of International Concern.[18] On January 31, 2020, Secretary Azar declared a PHE [19] under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID–19. On March 11, 2020, the WHO publicly declared COVID–19 to be a pandemic.[20] On March 13, 2020, the President declared that the COVID–19 outbreak in the United States constitutes a national emergency,[21] beginning March 1, 2020. Effective October 23, 2020, Secretary Azar renewed the January 31, 2020 determination that was previously renewed on April 21, 2020 and July 23, 2020 that a PHE for COVID–19 exists and has existed since January 27, 2020.

As we discussed in section II.A above, it is critical that we extend our support to the health care community, specifically those who are affected by the ONC Cures Act Final Rule. In support of the imperative to contain and combat the virus in the United States, developers of health technology have raced to update their technology, for example, to create new codes for COVID–19 and its associated illnesses. Many developers are working to ensure that critical data about infection rates, testing outcomes, and hospitalization rates are accurate and are transmitted accurately to local, State and Federal authorities. Further, health IT developers of certified health IT are responding to requests from public health entities, health care providers, and health care systems, asking for updates to, or information about, the technology to help them better track, respond and treat illnesses caused by COVID–19. Developers of certified health IT are also exploring novel methods to help address the PHE using time and resources that might otherwise have been used to upgrade their technology. It is in the best interest of the public to ensure that developers of certified health IT are able to respond in a dynamic and rapid manner in order to assist the nation in confronting the PHE.

If these developers of certified health IT were required to update their technology according to the timeline and deadlines in the ONC Cures Act Final Rule, they would likely devote more time and resources to ensuring their technology was upgraded and certified to avoid losing customers and users. In doing so, they would have less time and fewer resources to address the urgent and constantly changing technological needs of health care providers, public health entities, and health care systems dealing with the COVID–19 PHE. Further, even if the developers of certified health IT were able to upgrade their technology to the 2015 Edition Cures Update by the original compliance dates, their customers may require training and time to adapt to the new technology. This is especially true for health care providers, who may not have control over updates to the technology used in their care settings. It is in the best interest of the

[18] *https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).*

[19] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[20] *https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-11-march-2020.*

[21] *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

public that health care providers are able to combat COVID–19 PHE without also having to manage the potential disruption that such updates at this time could entail. Delaying the enforcement deadlines and extending certain timelines ensures that the technology will be updated at a time when the threat from the PHE has lessened and both developers and health care providers would have the time and resources to devote to these technology updates.

It is imperative that the health care community, including developers of certified health IT, remain focused on addressing the grave threat to public health posed by COVID–19. Therefore, we find good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures. Furthermore, because we cannot afford any delay in effectuating this IFC and do not want to create unnecessary burdens on stakeholders who would otherwise try to meet the November 2, 2020 compliance and applicability date for various provisions of the ONC Cures Act Final Rule, we find good cause to waive the 30-day delayed effective date for the information blocking provisions and the Conditions and Maintenance of Certification requirements related to information blocking, communications, and assurances.

We are providing a 60-day public comment period for this IFC as specified in the **DATES** section of this document.

IV. Incorporation by Reference

The Office of the Federal Register has established requirements for materials (*e.g.,* standards and implementation specifications) that agencies incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5). Specifically, § 51.5(b) requires agencies to discuss, in the preamble of a final rule, the ways that the materials they incorporate by reference are reasonably available to interested parties and how interested parties can obtain the materials, and to summarize, in the preamble of the final rule, the material they incorporate by reference.

To make the materials we are incorporating by reference reasonably available, we provide a uniform resource locator (URL) for the standards. These standards are directly accessible through the URLs provided. As an alternative, a copy of the standards may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201. Please call (202) 690–7151 in advance to arrange inspection.

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 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 selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. As stated in the ONC Cures Final Rule (85 FR 25668), we have followed the NTTAA and OMB Circular A–119 in adopting standards and implementation specifications for adoption, including describing any exceptions in the adoption of standards and implementation specifications.

As required by 1 CFR 51.5(b), we provide a summary of the standards we have adopted and incorporate by reference in the Code of Federal Regulations (CFR). We also provide relevant information about the standards throughout the preamble. We previously adopted IETF's Network Time Protocol Version 4 (approved for incorporation by reference as of September 4, 2012), which we continue to use without change.

We have organized the standards we have adopted through this rulemaking according to the sections of the CFR in which they will be codified and cross-referenced for associated certification criteria and requirements that we have adopted.

Content Exchange Standards and Implementation Specifications for Exchanging Electronic Health Information—45 CFR 170.205

- *CMS Implementation Guide for Quality Reporting Document Architecture Category I Hospital Quality Reporting Implementation Guide for 2020, December 3, 2019*

URL: https://ecqi.healthit.gov/sites/default/files/QRDA-HQR-2020-CMS-IG-v1.1-508.pdf.

This is a direct access link.

Summary: This guide is a CMS Quality Reporting Document Architecture Category I (QRDA I) implementation guide to the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, Standards for Trial Use (STU) Release 5 (published December 2017), and referred to as the HL7 QRDA IG STU R5 in this guide. This guide describes additional conformance statements and constraints for electronic health record (EHR) data submissions that are required for reporting information to the CMS for the Hospital Inpatient Quality Reporting Program 2020 Reporting Period. The purpose of this guide is to serve as a companion to the base HL7 QRDA I STU R5 for entities such as Eligible Hospitals (EHs), CAHs, and developers to submit QRDA I data for consumption by CMS systems including for Hospital Quality Reporting (HQR).

- *CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020, April 30, 2020*

URL: https://ecqi.healthit.gov/sites/default/files/2020-CMS-QRDA-III-Eligible-Clinicians-and-EP-IG-v1.2-508.pdf.

This is a direct access link.

Summary: The Health Level Seven International (HL7) Quality Reporting Document Architecture (QRDA) defines constraints on the HL7 Clinical Document Architecture Release 2 (CDA R2). QRDA is a standard document format for the exchange of electronic clinical quality measure (eCQM) data. QRDA reports contain data extracted from EHRs and other information technology systems. The reports are used for the exchange of eCQM data between systems for quality measurement and reporting programs. This QRDA guide contains the CMS supplemental implementation guide to the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture, Category III, STU Release 2.1 (June, 2017) for the 2020 performance period. This HL7 base standard is referred to as the HL7 QRDA–III STU R2.1.

United States Core Data for Interoperability—45 CFR 170.213

- *The United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1)*

URL: https://www.healthit.gov/USCDI.

This is a direct access link.

Summary: The United States Core Data for Interoperability (USCDI) establishes a minimum set of data classes that are required to be interoperable nationwide and is designed to be expanded in an iterative and predictable way over time. Data classes listed in the USCDI are

represented in a technically agnostic manner.

Application Programming Interface Standards—45 CFR 170.215

- HL7 FHIR US Core Implementation Guide STU Release 3.1.1, August 28, 2020

URL: http://hl7.org/fhir/us/core/STU3.1.1/.

This is a direct access link.

Summary: The US Core Implementation Guide is based on FHIR Version R4 and defines the minimum conformance requirements for accessing patient data. The Argonaut pilot implementations, ONC 2015 Edition Common Clinical Data Set (CCDS), and ONC U.S. Core Data for Interoperability (USCDI) v1 provided the requirements for this guide. The prior Argonaut search and vocabulary requirements, based on FHIR DSTU2, are updated in this guide to support FHIR Version R4. This guide was used as the basis for further testing and guidance by the Argonaut Project Team to provide additional content and guidance specific to Data Query Access for purpose of ONC Certification testing. These profiles are the foundation for future US Realm FHIR implementation guides. In addition to Argonaut, they are used by DAF-Research, QI-Core, and CIMI. Under the guidance of HL7 and the HL7 US Realm Steering Committee, the content will expand in future versions to meet the needs specific to the US Realm.

V. 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.

VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

VII. Regulatory Impact Analysis

A. Executive Orders 12866 and 13563

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, and public health and safety effects; distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

To determine the impact of this rule, we reviewed the costs and benefits in the ONC Cures Act Final Rule associated with the provisions in this IFC. We did this to determine if adjustments to the ONC Cures Act Final Rule's RIA were needed and should be accounted for in this rule. We also explored whether there are new quantifiable and unquantifiable costs and benefits as a direct result of the delays proposed in the IFC.

The provisions in this IFC are limited in nature: Applicability and compliance date extensions, standards updates, and regulatory clarifications and corrections. Except as noted below, we were unable to identify any new quantifiable costs or benefits as a result of the provisions in this IFC. However, we welcome comments on the additional impacts developers or other entities might experience as a result of the delays noted in this IFC.

There are unquantifiable costs and benefits of this rule. The extensions in this IFC are in response to developers' need for additional time to meet the deadlines due, in part, to external factors, such as COVID–19. However, we are unable to quantify the extent to which such external factors including but not limited to, temporary changes in labor and other supply chain costs/shortages due to the pandemic—would affect the cost differential between compliance according to the timeline set forth in this IFC and (hypothetically) according to the timeline set forth in the ONC Cures Act Final Rule. We acknowledge that we do not have any evidence or information from the regulated community that they have been working to meet the applicability and compliance dates identified in the ONC Cures Act Final Rule. On April 21, 2020, we announced that we would exercise our discretion in enforcing all new requirements under 45 CFR part 170 that have compliance dates until 3 months after each initial compliance date identified in the ONC Cures Act Final Rule. In addition, we noted in the ONC Cures Act Final Rule that enforcement of information blocking civil monetary penalties in section 3022(b)(2)(A) of the PHSA would not begin until a final rule was issued by the Office of the Inspector General (OIG), which has not occurred as of the publication of this interim final rule. We also acknowledged in the Proposed Rule that any health care provider determined by OIG to have committed information blocking would, per the Cures Act, be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking. In the Proposed Rule, we requested comment on potential disincentives (84 FR 7553). HHS has not, however, issued a proposed rule to begin the process of establishing such disincentives. Since the publication of the ONC Cures Act Final Rule, we are not aware of any negative consequences that health IT developers of certified health IT or other types of actors have experienced for not complying with 45 parts 170 or 171, respectively. We request comment on whether stakeholders did incur costs for trying to meet the compliance dates in the ONC Cures Act Final Rule. We also invite feedback on whether the COVID–19 PHE may have an impact on costs of complying with 45 parts 170 and 171 in the future—taking into account the new compliance and applicability dates established by this interim final rule.

Additionally, we explored whether the delays in the IFC will have a significant impact on the 10 year cost/benefit projections described in the ONC Cures Act Final Rule. We note that several IFC provisions implement a delay of less than one year from its original deadline. However, the following IFC provisions have delays that are one year or more:

- Submission of initial Attestations (§ 170.406)
- Submission of initial plans and results of real world testing (§ 170.405(b)(1) and (2))

We previously estimated that the Year 1 quantifiable costs for these provisions are $47,686,943 and the quantifiable benefits are $310,450,000. Both the cost and benefit estimates were estimated to be perpetual. Because this impact is over $100 million, it is sufficient to make this IFC economically significant under E.O. 12866. The IFC's changes have implications for the distribution of the costs and benefits over time found in the ONC Cures Act Final Rule as described above.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a

substantial number of small entities. We do not believe that the changes in this IFC alter any of the prior analyses we performed for the ONC Cures Act Final Rule; and therefore, the Secretary certifies that this IFC will not have a significant impact on a substantial number of small entities.

C. Executive Order 13771

The White House issued Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs on January 30, 2017. This rule's designation under 13771 will be informed by comments received.

D. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule (including an interim final rule with comment period) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Because this IFC does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), 2 U.S.C. 1532, requires that covered agencies prepare a budgetary impact statement before promulgating a 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 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $156 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. This IFC is not expected to result in expenditures by state, local, and tribal governments, or by the private sector, of $156 million or more in any one year.

List of Subjects

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

45 CFR Part 171

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health care provider, Health information exchange, Health information technology, Health information network, Health insurance, Health records, Hospitals, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, is amended as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14

■ 2. Revise § 170.101 to read as follows:

§ 170.101 Applicability.

The standards, implementation specifications, and certification criteria adopted in this part apply to health information technology and the testing and certification of Health IT Modules.

■ 3. Amend § 170.102 by revising paragraphs (3)(ii) and (iii) in the definition of ''2015 Edition Base EHR'' to read as follows:

§ 170.102 Definitions.

* * * * *

2015 Edition Base EHR * * *

(3) * * *

(ii) Section 170.315(g)(8) or (10) for the period before December 31, 2022; and

(iii) Section 170.315(g)(10) on and after December 31, 2022.

* * * * *

■ 4. Revise § 170.200 to read as follows:

§ 170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Health Information technology.

■ 5. Amend § 170.205 by revising paragraphs (h)(3) and (k)(3) to read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * * *

(h) * * *

(3) *Standard.* CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020 (incorporated by reference in § 170.299).

* * * * *

(k) * * *

(3) *Standard.* CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020 (incorporated by reference in § 170.299).

* * * * *

■ 6. Amend § 170.210:

■ a. In paragraph (e)(1)(i), by removing the words ''through 7.1.3'' and adding in its place the words ''and 7.1.2'';

■ b. In paragraphs (e)(2)(i) and (e)(3), by removing the words ''7.2 and 7.4,'' and adding in their place the words ''7.1.1 and 7.1.7''; and

■ c. By revising paragraph (g).

The revision reads as follows:

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

* * * * *

(g) *Synchronized clocks.* The date and time recorded utilize a system clock that has been synchronized following (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).

* * * * *

■ 7. Revise § 170.213 to read as follows:

§ 170.213 United States Core Data for Interoperability.

Standard. United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (incorporated by reference in § 170.299).

■ 8. Amend § 170.215 by revising (a)(2) to read as follows:

§ 170.215 Application Programming Interface Standards.

* * * * *

(a) * * *

(2) *Implementation specification.* HL7 FHIR® US Core Implementation Guide STU 3.1.1 (incorporated by reference in § 170.299).

■ 9. Amend § 170.299 by revising paragraphs (e)(4) and (5), (f)(34), and (m)(5) to read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(e) * * *

(4) CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting Implementation Guide for 2020; published December 3, 2019, IBR approved for § 170.205(h).

(5) CMS Implementation Guide for Quality Reporting Document

Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs Implementation Guide for 2020; published April 30, 2020, IBR approved for § 170.205(k).

* * * * *

(f) * * *

(34) HL7 FHIR® US Core Implementation Guide STU3 Release 3.1.1, August 28, 2020, IBR approved for § 170.215(a).

* * * * *

(m) * * *

(5) United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata, IBR approved for § 170.213; available at *https://www.healthit.gov/USCDI.*

* * * * *

■ 10. Amend § 170.300 by revising paragraphs (a), (c), and (d) to read as follows:

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Health IT Modules.

* * * * *

(c) Health Modules are not required to be compliant with certification criteria or capabilities specified within a certification criterion that are designated as optional.

(d) In § 170.315, all certification criteria and all capabilities specified within a certification criterion have general applicability (*i.e.,* apply to any health care setting) unless designated as ''inpatient setting only'' or ''ambulatory setting only.''

* * * * *

■ 11. Amend § 170.315 by:

■ a. Revising paragraphs (b)(1)(iii)(A)(*2*), (b)(2)(i), (b)(2)(iii)(D) introductory text, (b)(2)(iv), (b)(3)(ii)(B)(*2*), (b)(7)(ii), (b)(8)(i)(B), (b)(9)(ii), (c)(3), (d)(13)(ii), (e)(1)(i)(A)(*2*), (f)(5)(iii)(B)(*1*) and (*2*), (g)(6)(i)(B), (g)(9)(i)(A)(*2*), (g)(10)(v)(A)(*1*)(ii), and (g)(10)(v)(A)(*2*)(ii); and

■ b. Adding paragraph (g)(10)(iv)(A)(*1*)(iii).

The revisions and addition read as follows:

§ 170.315 2015 Edition health IT certification criteria.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(A) * * *

(*2*) The Common Clinical Data Set in accordance with § 170.205(a)(4) and paragraph (b)(1)(iii)(A)(*3*)(*i*) through (*iv*) of this section for the period before December 31, 2022, and

* * * * *

(2) * * *

(i) *General requirements.* Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) through (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates on and after December 31, 2022.

* * * * *

(iii) * * *

(D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s) on and after December 31, 2022:

* * * * *

(iv) *System verification.* Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template and the standard specified in § 170.205(a)(5) on and after December 31, 2022.

(3) * * *

(ii) * * *

(B) * * *

(*2*) Send fill status notifications (RxFillIndicatorChange).

* * * * *

(7) * * *

(ii) Document level for the period before December 31, 2022.

(8) * * *

(i) * * *

(B) Document level for the period before December 31, 2022; and

* * * * *

(9) * * *

(ii) The standard in § 170.205(a)(5) on and after December 31, 2022.

* * * * *

(c) * * *

(3) *Clinical quality measures—report.* Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the applicable implementation specifications specified by the CMS implementation guides for Quality Reporting Document Architecture (QRDA), category I, for inpatient measures in § 170.205(h)(3) and CMS implementation guide for QRDA, category III for ambulatory measures in § 170.205 (k)(3); or

(ii) In accordance with the standards specified in § 170.205(h)(2) and § 170.205(k)(1) and (2) for the period before December 31, 2022.

* * * * *

(d) * * *

(13) * * *

(ii) No—the Health IT Module does not support authentication, through multiple elements, of the user's identity with the use of industry-recognized standards. When attesting ''no,'' the health IT developer may explain why the Health IT Module does not support authentication, through multiple elements, of the user's identity with the use of industry-recognized standards.

(e) * * *

(1) * * *

(i) * * *

(A) * * *

(*2*) The Common Clinical Data Set in accordance with § 170.205(a)(4) and paragraphs (e)(1)(i)(A)(*3*)(*i*) through (*iv*) of this section for the period before December 31, 2022.

* * * * *

(f) * * *

(5) * * *

(iii) * * *

(B) * * *

(*1*) The data classes expressed in the standard in § 170.213, or

(*2*) The Common Clinical Data Set for the period before December 31, 2022.

* * * * *

(g) * * *

(6) * * *

(i) * * *

(B) The Common Clinical Data Set in accordance with § 170.205(a)(4) and paragraphs (g)(6)(i)(C)(*1*) through (*4*) of this section for the period before December 31, 2022.

* * * * *

(9) * * *

(i) * * *

(A) * * *

(*2*) The Common Clinical Data Set in accordance with paragraphs (g)(9)(i)(A)(*3*)(*i*) through (*iv*) of this section for the period before December 31, 2022, and

* * * * *

(10) * * *

(v) * * *

(A) * * *

(*1*) * * *

(*ii*) A Health IT Module's authorization server must issue a refresh token valid for a period of no less than three months to applications capable of storing a client secret.

(*iii*) A Health IT Module's authorization server must issue a refresh token for a period of no less than three months to native applications capable of securing a refresh token.

(*2*) * * *

(*ii*) A Health IT Module's authorization server must issue a refresh token valid for a new period of no less

than three months to applications capable of storing a client secret.

* * * * *

■ 12. Amend § 170.401 by revising paragraph (a) to read as follows:

§ 170.401 Information blocking.

(a) *Condition of Certification requirement.* A health IT developer must not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj–52 and § 171.103 on or after April 5, 2021.

* * * * *

■ 13. Amend by revising § 170.402 by revising paragraphs (a)(1), (4) and (b)(2) to read as follows:

§ 170.402 Assurances.

(a) * * *

(1) A health IT developer must provide assurances satisfactory to the Secretary that the health IT developer will not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj–52 and § 171.103 of this chapter on and after April 5, 2021, unless for legitimate purposes as specified by the Secretary; or any other action that may inhibit the appropriate exchange, access, and use of electronic health information.

* * * * *

(4) A health IT developer of a certified Health IT Module that is part of a health IT product which electronically stores EHI must certify to the certification criterion in § 170.315(b)(10).

(b) * * *

(2)(i) By December 31, 2023, a health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10).

(ii) On and after December 31, 2023, a health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10).

■ 14. Amend § 170.403 by revising (b)(1) to read as follows:

§ 170.403 Communications.

* * * * *

(b) * * *

(1) *Notice.* Health IT developers must issue a written notice to all customers and those with which it has contracts or agreements containing provisions that contravene paragraph (a) of this section annually, beginning in calendar year 2021, until paragraph (b)(2)(ii) of this section is fulfilled, stating that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer.

* * * * *

■ 15. Amend § 170.404 by revising (b)(3) and (4) to read as follows:

§ 170.404 Application programming interfaces.

* * * * *

(b) * * *

(3) *Rollout of (g)(10)-certified APIs.* A Certified API Developer with certified API technology previously certified to the certification criterion in § 170.315(g)(8) must provide all API Information Sources with such certified API technology deployed with certified API technology certified to the certification criterion in § 170.315(g)(10) by no later than December 31, 2022.

(4) *Compliance for existing certified API technology.* By no later than April 5, 2021, a Certified API Developer with Health IT Module(s) certified to the certification criteria in § 170.315(g)(7), (8), or (9) must comply with paragraph (a) of this section, including revisions to their existing business and technical API documentation and make such documentation available via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

* * * * *

■ 16. Amend § 170.405 by:

■ a. Revising paragraphs (b)(1) introductory text, (b)(2)(ii) introductory text, (b)(3) introductory text, (b)(4)(ii), (b)(5)(ii), (b)(6)(ii), and (b)(7)(ii); and

■ b. Adding paragraph (b)(10).

The revisions and addition read as follows:

§ 170.405 Real world testing.

* * * * *

(b) * * *

(1) *Real world testing plan submission.* A health IT developer with Health IT Module(s) certified to any one or more of the criteria referenced in paragraph (a) of this section must submit to its ONC–ACB an annual real world testing plan addressing each of those certified Health IT Modules by a date determined by the ONC–ACB that enables the ONC–ACB to publish a publicly available hyperlink to the plan on CHPL no later than December 15 of each calendar year, beginning in 2021.

* * * * *

(2) * * *

(ii) For real world testing activities conducted during the immediately preceding calendar year, a health IT developer must submit to its ONC–ACB an annual real world testing results report addressing each of its certified Health IT Modules that include certification criteria referenced in paragraph (a) of this section by a date determined by the ONC–ACB that enables the ONC–ACB to publish a publicly available hyperlink to the results report on CHPL no later than March 15 of each calendar year, beginning in 2023. The real world testing results must report the following for each of the certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

* * * * *

(3) *USCDI Updates.* A health IT developer with health IT certified to § 170.315(b)(1), (b)(2), (e)(1), (g)(6) and/or (g)(9) on May 1, 2020, must:

* * * * *

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(3)(i) of this section by December 31, 2022.

(4) * * *

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(4)(i) of this section by December 31, 2022.

(5) * * *

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(5)(i) of this section by December 31, 2022.

(6) * * *

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(6)(i) of this section by December 31, 2022.

(7) * * *

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(7)(i) of this section by December 31, 2022.

* * * * *

(10) *Clinical quality measures—report.* A health IT developer with health IT certified to § 170.315(c)(3) prior to June 30, 2020, must:

(i) Update their certified health IT to be compliant with the revised versions of this criteria adopted in § 170.315(c)(3); and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(10)(i) of this section by December 31, 2022.

■ 17. Amend § 170.523 by:

■ a. Removing and reserving paragraph (f)(1)(xxi); and

■ b. Revising paragraphs (k)(1) introductory text and (k)(1)(i).

The revisions read as follows:

§ 170.523 Principles of proper conduct for ONC–ACBs.

* * * * *

(k) * * *

(1) *Mandatory Disclosures.* A health IT developer must conspicuously include the following on its website and in all marketing materials, communications statements, and other assertions related to the Health IT Module's certification:

(i) The disclaimer ''This Health IT Module is [specify Edition of health IT certification criteria] compliant and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services.''

* * * * *

■ 18. Amend § 170.550 by revising paragraphs (m)(1), (2), and (3) to read as follows:

§ 170.550 Health IT Module certification.

* * * * *

(m) * * *

(1) Section 170.315(a)(10) and (13) and § 170.315(e)(2) for the period before January 1, 2022.

(2) Section 170.315(b)(6) for the period before December 31, 2023.

(3) Section 170.315(g)(8) for the period before December 31, 2022.

PART 171—INFORMATION BLOCKING

■ 19. The authority citation for part 171 continues to read as follows:

Authority: 42 U.S.C. 300jj–52

■ 20. Amend § 171.101 by revising paragraph (b) to read as follows:

§ 171.101 Applicability.

* * * * *

(b) Health care providers, health IT developers of certified health IT, health information exchanges, and health information networks are subject to this part on and after April 5, 2021.

■ 21. Amend § 171.103 by revising paragraphs (a)(2), (a)(3) and (b) to read as follows:

§ 171.103 Information blocking.

(a) * * *

(2) If conducted by a health IT developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information; or

(3) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.

* * * * *

(b) For the period before October 6, 2022, electronic health information for the purposes of paragraph (a) of this section is limited to the electronic health information identified by the data elements represented in the USCDI standard adopted in § 170.213.

* * * * *

■ 22. Amend § 171.203 by revising paragraph (e)(2) to read as follows:

§ 171.203 Security exception—When will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to protect the security of electronic health information not be considered information blocking?

* * * * *

(e) * * *

(2) There are no reasonable and appropriate alternatives to the practice that address the security risk that are less likely to interfere with access, exchange or use of electronic health information.

■ 23. Amend § 171.301 by revising paragraphs (a)(1), (a)(2) and (b)(1)(ii)(A) to read as follows:

§ 171.301 Content and manner exception—When will an actor's practice of limiting the content of its response to or the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

* * * * *

(a) * * *

(1) *USCDI.* For the period before October 6, 2022, at a minimum, the electronic health information identified by the data elements represented in the USCDI standard adopted in § 170.213.

(2) *All electronic health information.* On and after October 6, 2022, electronic health information as defined in § 171.102.

(b) * * *

(1) * * *

(ii) * * *

(A) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and

* * * * *

■ 24. Amend § 171.303 by revising paragraph (b)(2)(i) to read as follows:

§ 171.303 Licensing exception—When will an actor's practice to license interoperability elements in order for electronic health information to be accessed, exchanged, or used not be considered information blocking?

* * * * *

(b) * * *

(2) * * *

(i) The royalty must be nondiscriminatory, consistent with paragraph (b)(3) of this section.

* * * * *

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–24376 Filed 11–2–20; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 181009921–8999–02; RTID 0648–XA604]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2020 Commercial Closure for Atlantic Migratory Group Cobia

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements a closure for Atlantic migratory group cobia (Atlantic cobia) that are sold (commercial) and harvested from Atlantic Federal waters off Georgia through New York. NMFS projects that commercial landings of Atlantic cobia will reach the commercial quota on November 6, 2020. Therefore, NMFS closes the commercial sector for Atlantic cobia in Federal waters from November 6, 2020, until the start of the next fishing year on January 1, 2021. This closure is necessary to protect the Atlantic cobia resource.

DATES: This temporary rule is effective at 12:01 a.m. eastern time on November 6, 2020, until 12:01 a.m. eastern time on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for Atlantic cobia in Federal waters is managed under the authority of the Atlantic Coastal Fisheries Cooperative Management Act (Atlantic

Coastal Act) by regulations at 50 CFR part 697.

Separate migratory groups of cobia are managed in the Gulf of Mexico and Atlantic. Atlantic cobia is managed from Georgia through New York. The southern boundary for Atlantic cobia is a line that extends due east of the Florida and Georgia state border at 30°42′45.6″ N latitude. The northern boundary for Atlantic cobia is the jurisdictional boundary between the Mid-Atlantic and New England Fishery Management Councils, as specified in 50 CFR 600.105(a).

Amendment 31 to the Fishery Management Plan (FMP) for Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region (Amendment 31) and the implementing final rule removed Atlantic cobia from Federal management under the Magnuson-Stevens Fishery Conservation and Management Act, while also implementing comparable regulations in Federal waters under the Atlantic Coastal Act (84 FR 4733, February 19, 2019).

Atlantic cobia are unique among federally managed species in the U.S. southeast region, because no commercial permit is required to harvest and sell them, and so the distinction between the commercial and recreational sectors is not as clear as with other federally managed species. However, for purposes of this temporary rule, Atlantic cobia that are sold are considered commercially caught, and those that are not sold are considered recreationally caught.

As specified in 50 CFR 697.28(f)(1), the commercial quota for Atlantic cobia is 50,000 pounds (lb) (22,680 kilograms (kg)) in round or gutted weight for the 2020 fishing year, which runs from January 1 through December 31.

Regulations for the commercial sector of Atlantic cobia at 50 CFR 697.28(f)(1) require that NMFS file a notification with the Office of the Federal Register to prohibit the sale and purchase of Atlantic cobia for the remainder of the fishing year if commercial landings reach or are projected to reach the commercial quota specified in 50 CFR 697.28(f)(1). NMFS projects that commercial landings of Atlantic cobia will reach the commercial quota on November 6, 2020. Accordingly, the commercial sector for Atlantic cobia is closed in Federal waters beginning on November 6, 2020, and will remain closed until the start of the next fishing year on January 1, 2021.

During the commercial closure, the sale and purchase of Atlantic cobia is prohibited. The recreational bag and possession limits for Atlantic cobia apply while the recreational sector is open (50 CFR 697.28(e)). The prohibition on sale and purchase does not apply to Atlantic cobia that were harvested, landed ashore, and sold before November 6, 2020, and were held in cold storage by a dealer or processor.

Classification

NMFS issues this action pursuant to the Atlantic Coastal Act. This action is required by 50 CFR 697.28(f)(1) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the regulations associated with the commercial quota for Atlantic cobia have already been subject to notice and comment, and all that remains is to notify the public of the commercial closure for the remainder of the 2020 fishing year. Prior notice and opportunity for public comment on this action is contrary to the public interest because of the need to immediately implement the commercial closure to protect Atlantic cobia, since the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment would require time and would potentially result in a harvest that exceeds the commercial quota.

For the aforementioned reasons, there is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the effective date of this action.

Authority: 16 U.S.C. 5101 *et seq.*

Dated: October 30, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–24431 Filed 11–3–20; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 85, No. 214
Wednesday, November 4, 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.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0983; Project Identifier MCAI–2020–00542–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2018–05–09, which applies to all Airbus Helicopters Model AS332C, AS332C1, AS332L, and AS332L1 helicopters. AD 2018–05–09 requires inspecting the tail rotor (T/R) flapping hinge link (hinge) and reporting the results. Since the FAA issued AD 2018–05–09, the FAA has determined that repetitive inspections of the spindle bolts and the inner ring and needle bearings of each flapping hinge and repetitive replacements of affected flapping hinge components must be done in order to address the unsafe condition. Replacement of all affected flapping hinge components on each flapping hinge is terminating action for the repetitive inspections. This proposed AD would require repetitive inspections of the spindle bolts and the inner ring and needle bearings of each flapping hinge, corrective actions if necessary, and repetitive replacements of affected flapping hinge components, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. This proposed AD would also expand the applicability. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 21, 2020.

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 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, 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. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0983.

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–2020–0983; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, 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: Daniel E. Moore, Aviation Safety Engineer, Regulations & Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *daniel.e.moore@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one copy of the comments. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA 2020–0983; Project Identifier MCAI–2020–00542–R'' at the beginning of your 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, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

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 NPRM 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 NPRM, 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 NPRM. Submissions containing CBI should be sent to Daniel E. Moore, Aviation Safety Engineer, Regulations & Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *daniel.e.moore@faa.gov.* Any commentary that the FAA receives that is not specifically

designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA issued AD 2018–05–09, Amendment 39–19218 (83 FR 10360, March 9, 2018) (AD 2018–05–09), which applies to all Airbus Helicopters Model AS332C, AS332C1, AS332L, and AS332L1 helicopters. AD 2018–05–09 requires inspecting the T/R flapping hinge and reporting the results. The FAA issued AD 2018–05–09 to address failure of a T/R flapping hinge. This condition could result in unbalance of the T/R, detachment of the T/R gearbox and hub, and subsequent loss of control of the helicopter.

Actions Since AD 2018–05–09 Was Issued

Since the FAA issued AD 2018–05–09, the FAA has determined repetitive inspections of the spindle bolts and the inner ring and needle bearings of each flapping hinge and repetitive replacements of affected flapping hinge components must be done in order to address the unsafe condition. Replacement of all affected flapping hinge components on each flapping hinge is terminating action for the repetitive inspections of the spindle bolts and the inner ring and needle bearings of each flapping hinge. In addition, the applicability has been expanded to include Model SA330J helicopters.

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0086, dated April 14, 2020 (EASA AD 2020–0086) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, and SA330J helicopters.

This proposed AD was prompted by a report of a damaged flapping hinge on a T/R blade. The FAA is proposing this AD to address failure of a T/R flapping hinge. This condition could result in unbalance of the T/R, detachment of the T/R gearbox and hub, and subsequent loss of control of the helicopter. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0086 describes procedures for repetitive replacement of the flapping hinge components and repetitive inspections of the spindle bolts, inner ring, and needle bearings of each flapping hinge, and corrective action. The inspection procedures include repetitive inspections of the spindle bolts for cracking; repetitive inspections of the inner ring for spalling, brinelling, and cracking; and repetitive inspections of the needle bearings for spalling. The corrective actions include replacement of any affected component with a serviceable part. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

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

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2020–0086 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD and except as discussed under ''Differences Between this Proposed AD and the MCAI.''

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 2020–0086 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2020–0086 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD. Service information specified in EASA AD 2020–0086 that is required for compliance with EASA AD 2020–0086 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0983 after the FAA final rule is published.

Differences Between This Proposed AD and the MCAI

Although the service information referenced in EASA AD 2020–0086 specifies to return affected parts and submit a form to the manufacturer, this proposed AD does not include those requirements.

Where paragraph (1) of EASA AD 2020–0086 refers to a compliance time of ''within 25 flight hours or during the next scheduled 50 FH inspection, whichever occurs later . . . ,'' for the initial replacement, this proposed AD requires completion within 25 hours time-in-service after the effective date of this proposed AD.

Costs of Compliance

The FAA estimates that this proposed AD affects 26 helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
8 work-hours × $85 per hour = $680	$11,630	$12,310	$320,060

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2018–05–09, Amendment 39–19218 (83 FR 10360, March 9, 2018), and adding the following new AD:

Airbus Helicopters: Docket No. FAA–2020–0983; Project Identifier MCAI–2020–00542–R.

(a) Comments Due Date

The FAA must receive comments by December 21, 2020.

(b) Affected Airworthiness Directives (ADs)

This AD removes AD 2018–05–09, Amendment 39–19218 (83 FR 10360, March 9, 2018) (AD 2018–05–09).

(c) Applicability

This AD applies to all Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, and SA330J helicopters, certificated in any category, all manufacturer serial numbers.

(d) Subject

Joint Aircraft System Component (JASC) Codes 6420, Tail Rotor Head; 6720, Tail Rotor Control System.

(e) Reason

This AD was prompted by a report of a damaged flapping hinge link (hinge) on a tail rotor (T/R) blade. The FAA is issuing this AD to address failure of a T/R flapping hinge. This condition could result in unbalance of the T/R, detachment of the T/R gearbox and hub, and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0086, dated April 14, 2020 (EASA AD 2020–0086).

(h) Exceptions to EASA AD 2020–0086

(1) Where EASA AD 2020–0086 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2020–0086 does not apply to this AD.

(3) Although the service information referenced in EASA AD 2020–0086 specifies to return affected parts and submit a form to the manufacturer, this AD does not include those requirements.

(4) Where paragraph (9) of EASA AD 2020–0086 refers to ''any discrepancy,'' for the purposes of this AD, discrepancies include spalling, brinelling, and cracking on the inner ring, and spalling on the bearing needles.

(5) Where EASA AD 2020–0086 refers to flight hours (FH), this AD requires using hours time-in-service.

(6) Where paragraph (1) of EASA AD 2020–0086 refers to a compliance time of ''within 25 flight hours or during the next scheduled 50 FH inspection, whichever occurs later . . . ,'' for the initial replacement, this AD requires completion within 25 hours time-in-service after the effective date of this AD.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Manager, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(j) Related Information

(1) For EASA AD 2020–0086, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, 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. 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–2020–0983.

(2) For more information about this AD, contact Daniel E. Moore, Aviation Safety Engineer, Regulations & Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *daniel.e.moore@faa.gov.*

Issued on October 29, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–24394 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0937; Airspace Docket No. 20–AEA–11]

RIN 2120–AA66

Proposed Amendment of the Class D and Class E Airspace and Establishment of Class E Airspace; Niagara Falls and Buffalo, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class D airspace and Class E airspace at Niagara Falls International Airport, Niagara Falls, NY, and amend and establish Class E airspace extending upward from 700 feet above the surface at Buffalo, NY. The FAA is proposing this action as the result of airspace

reviews due to new instrument procedures being implemented at Buffalo-Lancaster Regional Airport, Lancaster, NY. The names and geographic coordinates of airports and navigational aids would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before December 21, 2020.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2020–0937/Airspace Docket No. 20–AEA–11, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class D airspace, Class E surface area, and Class E airspace extending upward from 700 feet above the surface at Niagara Falls International Airport, Niagara Falls, NY; amend the Class E airspace extending upward from 700 feet above the surface at Buffalo Niagara International Airport, Buffalo, NY, and Akron Airport/Jesson Field, Akron, NY, contained within the Buffalo, NY, airspace legal description; and establish Class E airspace extending upward from 700 feet above the surface at Buffalo-Lancaster Regional Airport, Lancaster, NY, which will be contained within the Buffalo, NY, airspace legal description, to support instrument flight rule operations at these airports.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–0937/Airspace Docket No. 20–AEA–11.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by:

Amending the Class D airspace to within a 4.6-mile (increased from a 4.5-mile) radius of Niagara Falls International Airport, Niagara Falls, NY; amending the extension to 1 mile (decreased from 1.8 miles) each side of the 090° bearing from the Niagara Falls Intl: RWY 28R–LOC (previously KATHI LOM) extending from the 4.6-mile radius of the airport to 4.8 miles east of the airport; and replacing the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

Amending the Class E surface area airspace to within a 4.6-mile (increased from a 4.5-mile) radius of Niagara Falls International Airport, Niagara Falls, NY; amending the extension to 1 mile (decreased from 1.8 miles) each side of the 090° bearing from the Niagara Falls Intl: RWY 28R–LOC (previously KATHI LOM) extending from the 4.6-mile radius of the airport to 4.8 miles east of the airport; and replacing the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

And amending the Class E airspace extending upward from 700 feet above the surface to within a 7.5-mile (increased from a 6.7-mile) radius of Buffalo Niagara International Airport, Buffalo, NY; removing the extensions

associated with Buffalo Niagara International Airport as they are no longer needed; updating the name and geographic coordinates of Buffalo Niagara International Airport (previously Greater Buffalo International Airport) to coincide with the FAA's aeronautical database; removing the Buffalo VORTAC from the airspace legal description as it is no longer needed; removing ''and within the arc of a 10.5-mile radius circle from 052° to 112° clockwise, centered on a point, lat. 42°56′26″ N, long. 78°44′10″ W'' as it is no longer needed; amending the Class E airspace extending upward from 700 feet above the surface to within a 7.1-mile (increased from a 7-mile) radius of Niagara Falls International Airport, contained within the Buffalo, NY, airspace legal description; amending the extension from Niagara Falls International Airport to within 8.2 miles north (increased from 7 miles) and 7 miles (increased from 5.2 miles) south of the 090° bearing from the KATHI NDB (previously Niagara Falls International Airport east localizer course) extending from the KATHI NDB (previously OM) to 16.8 miles (increased from 10.5 miles) east of the KATHI NDB (previously OM); removing the Niagara Falls International Airport East Localizer Course OM as it is no longer needed; updating the geographic coordinates of Niagara Falls International Airport to coincide with the FAA's aeronautical database; amending the Class E airspace extending upward from 700 feet above the surface to within a 6.3-mile (decreased from a 6.4-mile) radius of Akron Airport/Jesson Field, Akron, NY, contained within the Buffalo, NY, airspace legal description; removing the extension associated with Akron Airport/Jesson Field as it is no longer needed; and updating the name and geographic coordinate of Akron Airport/Jesson Field (previously Akron Airport) to coincide with the FAA's aeronautical database; and establishing Class E airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Buffalo-Lancaster Regional Airport, Lancaster, NY, which will be contained within the Buffalo, NY, airspace legal description.

This action is the result of airspace reviews caused by the establishment of new instrument procedures at Buffalo-Lancaster Regional Airport.

Class D and E airspace designations are published in paragraph 5000, 6002, and 6005, respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AEA NY D Niagara Falls, NY [Amended]

Niagara Falls International Airport, NY
(Lat. 43°06′27″ N, long. 78°56′45″ W)
Niagara Falls Intl: RWY 28R–LOC
(Lat. 43°01′16″ N, long. 78°58′19″ W)

That airspace extending upward from the surface to and including 3,100 feet MSL within a 4.6-mile radius of Niagara Falls International Airport, and within 1 mile each side of the 090° bearing from the Niagara Falls Intl: RWY 28R–LOC extending from the 4.6-mile radius to 4.8 miles east of the airport, excluding the portion outside the United States and that airspace which coincides with the Buffalo, NY, Class C airspace. This Class D airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published continuously in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

AEA NY E2 Niagara Falls, NY [Amended]

Niagara Falls International Airport, NY
(Lat. 43°06′27″ N, long. 78°56′45″ W)
Niagara Falls Intl: RWY 28R–LOC
(Lat. 43°01′16″ N, long. 78°58′19″ W)

That airspace extending upward from the surface within a 4.6-mile radius of Niagara Falls International Airport, and within 1 mile each side of the 090° bearing from the Niagara Falls Intl: RWY 28R–LOC extending from the 4.6-mile radius to 4.8 miles east of the airport, excluding the portion outside the United States and that airspace which coincides with the Buffalo, NY, Class C airspace. This Class E airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published continuously in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA NY E5 Buffalo, NY [Amended]

Buffalo Niagara International Airport, NY
(Lat. 42°56′26″ N, long. 78°43′50″ W)
Niagara Falls International Airport, NY
(Lat. 43°06′27″ N, long. 78°56′45″ W)
KATHI NDB
(Lat. 43°06′33″ N, long. 78°50′18″ W)
Akron Airport/Jesson Field, NY
(Lat. 43°01′16″ N, long. 78°28′57″ W)
Buffalo-Lancaster Regional Airport, NY
(Lat. 42°55′19″ N, long. 78°36′43″ W)
Buffalo Airfield, NY
(Lat. 42°51′43″ N, long. 78°43′00″ W)

That airspace extending upward from 700 feet above the surface within a 7.5-mile radius of the Buffalo Niagara International Airport, and within a 7.1-mile radius of Niagara Falls International Airport, and within 8.2 miles north and 7 miles south of the 090° bearing from the KATHI NDB extending from the KATHI NDB to 16.8 miles

east of the KATHI NDB, and within a 6.3-mile radius of Akron Airport/Jesson Field, and within a 6.3-mile radius of Buffalo-Lancaster Regional Airport, and within a 6.3-mile radius of Buffalo Airfield.

Issued in Fort Worth, Texas, on October 29, 2020.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2020–24336 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0935; Airspace Docket No. 20–ANE–4]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Calais, ME

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface for Calais Regional Heliport, Calais, ME, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this heliport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before December 21, 2020.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2020–0935; Airspace Docket No. 20–ANE–4, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class E airspace in Calais, ME, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2020–0935 and Airspace Docket No. 20–ANE–4) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–0935; Airspace Docket No. 20–ANE–4.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to establish Class E airspace extending upward from 700 feet above the surface in Calais, ME, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for IFR operations at Calais Regional Heliport.

Class E airspace designations are published in Paragraph 6005, of FAA

Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'', prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE ME E5 Calais, ME [New]

Calais Regional Heliport, ME
(Lat. 45°10′37″ N, long. 67°16′5″ W)

That airspace extending upward from 700 feet above the surface of the earth within a 6-mile radius of Calais Regional Heliport.

Issued in College Park, Georgia, on October 29, 2020.

Matthew N. Cathcart,

Manager, Airspace & Procedures Team North, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2020–24383 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0923; Airspace Docket No. 20–AEA–18]

RIN 2120–AA66

Proposed Amendment, Establishment, and Revocation of Multiple Air Traffic Service (ATS) Routes in the Vicinity of Henderson, WV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Jet Route J–134, Area Navigation (RNAV) route Q–67, and VHF Omnidirectional Range (VOR) Federal airways V–45 and V–119; establish RNAV route Q–176; and remove Jet Route J–91 and VOR Federal airway V–174 in the vicinity of Henderson, WV. The Air Traffic Service (ATS) route modifications are necessary due to the planned decommissioning of the VOR portion of the Henderson, WV, VOR/Tactical Air Navigation (VORTAC) navigation aid (NAVAID). The NAVAID provides navigation guidance for portions of the affected air traffic service (ATS) routes. The VOR is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before December 21, 2020.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–0923; Airspace Docket No. 20–AEA–18 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall

regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2020–0923; Airspace Docket No. 20–AEA–18) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–0923; Airspace Docket No. 20–AEA–18.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX, 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning decommissioning activities for the VOR portion of the Henderson, WV, VORTAC in June 2021. The VOR portion of the Henderson, WV, VORTAC is a candidate VOR identified for discontinuance by the FAA's VOR MON program and listed in the final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Henderson VORTAC is planned for decommissioning, the co-located DME portion of the NAVAID is being retained.

The existing ATS route dependencies to the Henderson, WV, VORTAC NAVAID are Jet Routes J–91 and J–134, and VOR Federal airways V–45, V–119, and V–174.

With the planned decommissioning of the VOR portion of the Henderson, WV, VORTAC, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected Jet Routes and VOR Federal airways. As such, proposed modifications to the affected Jet Routes would result in the removal of a route segment at the end of one of the routes (J–134) and in the removal of the other route (J–91). The proposed modifications to the affected VOR Federal airways would result in an increased gap in one of the airways (V–45), the removal of an affected airway segment at the beginning of another airway (V–119), and the removal of the remaining airway (V–174).

To overcome the loss of two ATS routes, the increased gap in another route, and the loss of route segments at the beginning and end of the other ATS routes, instrument flight rules (IFR) traffic could use adjacent ATS routes, including Jet Routes J–6, J–24, J–85, and J–145; RNAV routes Q–67, Q–68, Q–71, Q–80, and Q–145; and VOR Federal airways V–4, V–35, V–38, V–44, V–115, V–128, V–133, and V–309, or receive air traffic control (ATC) radar vectors to fly through or circumnavigate the affected area. Additionally, IFR pilots equipped with RNAV PBN capabilities could also navigate point to point using the existing fixes that will remain in place to support continued operations though the affected area. Visual flight rules (VFR) pilots who elect to navigate via the airways through the affected area could also take advantage of the adjacent VOR Federal airways or ATC services listed previously.

Further, the FAA proposes to retain RNAV route Q–67 as it is charted today, but change the ending route point from the DARYN, WV, waypoint (WP) to the Henderson, WV, DME. The Henderson DME is located approximately 1 nautical mile southwest and just short of the DARYN WP on Q–67. Changing the ending route point from the DARYN WP to the Henderson DME would overlay the Q–67 route segment between the TONIO, KY, FIX and the Henderson DME on the J–91 routing proposed to be removed.

Lastly, the FAA proposes to establish RNAV route Q–176 between the Cimarron, NM, VORTAC and the OTTTO, VA, WP. This Q-route would be a direct overlay of Jet Route J–134 and mitigate the loss of the J–134 route segment affected by the planned decommissioning of the VOR portion of the Henderson, WV, VORTAC. Additionally, establishing Q–176 would provide RNAV routing capability from the Cimarron, NM, area eastward to the Front Royal, VA, area; as well as, support ongoing FAA NextGen efforts to transition the NAS to performance-based navigation.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Jet Route J–134, RNAV route Q–67, and VOR Federal airways V–45 and V–119; establishing RNAV route Q–176; and removing Jet Route J–91 and VOR Federal airway V–174. The planned decommissioning of the VOR portion of the Henderson, WV, VORTAC has made this action necessary.

The proposed Jet Route changes are outlined below.

J–91: J–91 currently extends between the Volunteer, TN, VORTAC and the Henderson, KY, VORTAC. The FAA proposes to remove the route in its entirety.

J–134: J–134 currently extends between the Los Angeles, CA, VORTAC and the Linden, VA, VORTAC. The FAA proposes to remove the airway segment overlying the Henderson, KY, VORTAC between the Falmouth, KY, VOR/Distance Measuring Equipment (VOR/DME) and the Linden, VA, VORTAC. The unaffected portions of the existing route would remain as charted.

The proposed RNAV route changes are outlined below.

Q–67: Q–67 currently extends between the SMTTH, TN, WP and the DARYN, WV, WP. The FAA proposes to change the route end point from the DARYN, WV, WP to the Henderson, WV, DME (located approximately 1 nautical mile southwest of the DARYN WP), and reduce the number of route points listed in the description while retaining the route as charted. The route would continue to provide RNAV routing capability from the Knoxville, TN, area northeastward to the Henderson, WV, area.

The proposed new RNAV route is outlined below.

Q–176: Q–176 is a proposed new route that would extend between the Cimarron, NM, VORTAC and the OTTTO, VA, WP. This RNAV route would mitigate the loss of the J–134 route segment proposed to be removed between the Falmouth, KY, VOR/DME and the Linden, VA, VORTAC and would be a direct overlay of the existing J–134. Additionally, it would provide RNAV routing capability from the Cimarron, NM, area eastward to the Front Royal, VA, area.

The proposed VOR Federal airway changes are outlined below.

V–45: V–45 currently extends between the New Bern, NC, VOR/DME and the Appleton, OH, VORTAC; and between the Saginaw, MI, VOR/DME and the Sault Ste Marie, MI, VOR/DME. The FAA proposes to remove the airway segment overlying the Henderson, WV, VORTAC between the Charleston, WV, VOR/DME and the Appleton, OH, VORTAC. The unaffected portions of the existing airway would remain as charted.

V–119: V–119 currently extends between the Henderson, WV, VORTAC and the Clarion, PA, VOR/DME. The FAA proposes to remove the airway segment overlying the Henderson, WV, VORTAC between the Henderson, WV, VORTAC and the Parkersburg, WV, VOR/DME. Additional changes to other portions of the airway have been proposed in a separate NPRM. The unaffected portions of the existing airway would remain as charted.

V–174: V–174 currently extends between the York, KY, VORTAC and the Elkins, WV, VORTAC. The FAA proposes to remove the airway in its entirety.

All NAVAID radials in the VOR Federal airway descriptions below are unchanged and stated in True degrees.

Jet Routes are published in paragraph 2004, United States RNAV Q-routes are published in paragraph 2006, and VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11E dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The ATS routes listed in this document would be subsequently published in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed 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 Department of Transportation (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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–91 [Removed]

* * * * *

J–134 [Amended]

From Los Angeles, CA; Seal Beach, CA; Thermal, CA; Parker, CA; Drake, AZ; Gallup, NM; Cimarron, NM; Liberal, KS; Wichita, KS; Butler, MO; St Louis, MO; to Falmouth, KY.

* * * * *

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–67 SMTTH, TN to Henderson, WV (HNN) [Amended]

SMTTH, TN	WP	(Lat. 35°54′41.57″ N, long. 084°00′19.74″ W)
TONIO, KY	FIX	(Lat. 37°15′15.20″ N, long. 083°01′47.53″ W)
Henderson, WV (HNN)	DME	(Lat. 38°45′14.85″ N, long. 082°01′34.20″ W)

* * * * *

* *

Q–176 Cimarron, NM (CIM) to OTTTO, VA [New]

Cimarron, NM (CIM)	VORTAC	(Lat. 36°29′29.03″ N, long. 104°52′19.20″ W)
KENTO, NM	WP	(Lat. 36°44′19.10″ N, long. 103°05′57.13″ W)
Liberal, KS (LBL)	VORTAC	(Lat. 37°02′39.82″ N, long. 100°58′16.31″ W)

Wichita, KS (ICT)	VORTAC	(Lat. 37°44′42.92″ N, long. 097°35′01.79″ W)
Butler, MO (BUM)	VORTAC	(Lat. 38°16′19.49″ N, long. 094°29′17.74″ W)
St Louis, MO (STL)	VORTAC	(Lat. 38°51′38.48″ N, long. 090°28′56.52″ W)
GBEES, IN	FIX	(Lat. 38°41′54.72″ N, long. 085°10′13.03″ W)
BICKS, KY	WP	(Lat. 38°38′29.92″ N, long. 084°25′20.82″ W)
Henderson, WV (HNN)	DME	(Lat. 38°45′14.85″ N, long. 082°01′34.20″ W)
OTTTO, VA	WP	(Lat. 38°51′15.81″ N, long. 078°12′20.01″ W)

* * * * *

* * * * *

V–45 [Amended]

From New Bern, NC; Kinston, NC; Raleigh-Durham, NC; INT Raleigh-Durham 275° and Greensboro, NC, 105° radials; Greensboro; INT Greensboro 334° and Pulaski, VA, 147° radials; Pulaski; Bluefield, WV; to Charleston, WV. From Saginaw, MI; Alpena, MI; to Sault Ste Marie, MI.

* * * * *

V–119 [Amended]

From Parkersburg, WV; INT Parkersburg 067° and Indian Head, PA, 254°radials; Indian Head; to Clarion, PA.

* * * * *

V–174 [Removed]

* * * * *

Issued in Washington, DC, on October 29, 2020.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–24288 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0500; Airspace Docket No. 20–AGL–9]

RIN 2120–AA66

Proposed Amendment of V–221 and V–305 in the Vicinity of Bloomington, IN

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice of proposed rulemaking (NPRM); withdrawal.

SUMMARY: The FAA is withdrawing the NPRM published in the **Federal Register** on June 26, 2020, proposing to amend VHF Omnidirectional Range (VOR) Federal airways V–221 and V–305 due to the planned decommissioning of the VOR portion of the Hoosier, IN, VOR/Tactical Air Navigation (VORTAC) in support of the FAA's VOR Minimum Operational Network (MON) program. Subsequent to the NPRM, the FAA reviewed the Hoosier VOR decommissioning project and determined additional planning meetings are necessary to ensure a more efficient implementation and integration with other ongoing program activities, and determined that withdrawal of the proposed rule is warranted.

DATES: Effective as of 0901 UTC, November 4, 2020, the proposed rule published June 26, 2020 (85 FR 38343), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Rules and Regulations, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a NPRM in the **Federal Register** for Docket No. FAA–2020–0500 (85 FR 38343; June 26, 2020). The NPRM proposed to amend VOR Federal airways V–221 and V–305 in the vicinity of Bloomington, IN, due to the planned decommissioning of the VOR portion of the Hoosier, IN, VORTAC navigation aid which provides navigation guidance for portions of the affected airways.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

FAA's Conclusions

The FAA has reviewed the Hoosier VOR decommissioning project and determined that additional planning meetings are warranted to ensure a more efficient implementation and integration with other ongoing program activities; therefore, the NPRM is withdrawn.

List of Subjects in 14 CFR part 71

Airspace, Incorporation by reference, Navigation (air).

The Withdrawal

Accordingly, pursuant to the authority delegated to me, the NPRM published in the **Federal Register** on June 26, 2020 (85 FR 38343), FR Doc. 2020–13657, is hereby withdrawn.

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

Issued in Washington, DC, on October 29, 2020.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–24356 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 6

42 CFR Parts 1 and 404

45 CFR Part 6

[Docket No. HHS–OS–2020–0012]

RIN 0991–AC24

Securing Updated and Necessary Statutory Evaluations Timely

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Regulatory Flexibility Act (RFA) requires agencies to publish plans to conduct periodic reviews of certain of their regulations. Multiple Executive Orders also require agencies to submit plans for periodic reviews of certain regulations. To further comply with the RFA and Executive Orders, and to ensure the Department's regulations have appropriate impacts, the U.S. Department of Health and Human Services (HHS) issues this notice of proposed rulemaking to set expiration dates for its regulations (subject to certain exceptions), unless the Department periodically assesses the regulations to determine if they are subject to the RFA, and if they are, performs a review that satisfies the criteria in the RFA.

DATES: Submit either electronic or written comments on the proposed rule by December 4, 2020, except that electronic or written comments on the portion of the proposed rule amending

42 CFR parts 400–429 and parts 475–499 are due January 4, 2021.

ADDRESSES: You may submit comments, identified by Docket No. HHS–OS–2020–0012, by the following method:

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

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Comments must be identified by RIN *0991–AC24.* Because of staff and resource limitations, all comments must be submitted electronically to *www.regulations.gov.* Follow the ''Submit a comment'' instructions.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to comments received.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Follow the search instructions on that website to view the public comments.

A public hearing on this proposed rule will be held before the end of the public comment period. A separate notice will be published in the **Federal Register** providing details of this hearing. Subject to consideration of the comments received, the Secretary intends to publish a final regulation.

FOR FURTHER INFORMATION CONTACT: James Lawrence, 200 Independence Avenue SW, Washington, DC 20201; or by email at *reviewnprm@hhs.gov;* or by telephone at 1–877–696–6775.

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking is organized as follows:

Table of Contents

I. Summary

The U.S. Department of Health and Human Services (HHS or the Department) issues this notice of proposed rulemaking to enhance the Department's implementation of section 3(a) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 610, and various executive orders, and improve accountability and the performance of its regulations.[1] The RFA requires federal agencies to publish in the **Federal Register** ''a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities'' in order ''to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant impact of the rules upon a substantial number of small entities.'' 5 U.S.C. 610(a). In conducting this retrospective review, agencies must consider a variety of factors, including the continued need for the rule, legal issues, public input, overlap and duplication with other federal or State and local governmental rules, and technological, economic, or other changes. 5 U.S.C. 610(b). Agency compliance with 5 U.S.C. 610 may be subject to judicial review. *See* 5 U.S.C. 611(a).

Several Executive Orders have also directed agencies to submit plans for the periodic review of certain of their regulations. *See, e.g.,* Executive Orders 12866 and 13563.

The Department has tried to carry out the evidence-based approach to regulation prescribed by Congress and the executive orders, but HHS' efforts have met varying levels of success. Several States, as well as jurisdictions outside the United States, have experimented with different ways of ensuring agencies engage in retrospective regulatory reviews so that legal requirements are updated in view of emerging evidence and changed circumstances. Among the lessons that have emerged is that while statutory mandates are helpful, one of the most important factors for ensuring agencies conduct retrospective reviews of their regulations is to provide for the sunset or automatic expiration of certain regulatory requirements after a period of time unless a retrospective review determines that the regulations should be maintained.

Therefore, in order to ensure evidence-based regulation that does not become outdated as conditions change, HHS proposes that, subject to certain exceptions, all regulations issued by the Secretary or his delegates or sub-delegates in Titles 21, 42, and 45 of the CFR shall expire at the end of (1) two calendar years after the year that this proposed rule first becomes effective, (2) ten calendar years after the year of the regulation's promulgation, or (3) ten calendar years after the last year in which the Department Assessed and, if required, Reviewed the regulation, whichever is latest.[2] The RFA and executive orders have only resulted in limited retrospective review by the Department. The Department believes this proposed rule would effectuate the desire for periodic retrospective reviews expressed in the RFA and Executive Orders, as well as ensure the Department's regulations are having appropriate impacts and have not become outdated.

II. Background

A. The Regulatory Flexibility Act

In 1980, Congress enacted the Regulatory Flexibility Act (RFA), Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980). Congress stated that ''the purpose of this Act [is] to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' 94 Stat. at 1165. Consistent with this purpose, section 3(a) of the RFA requires agencies to publish in the **Federal Register** a ''plan for the periodic review of rules which have or will have a significant economic impact upon a substantial number of small entities.'' 5 U.S.C. 610(a). The ''purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded . . . to minimize any significant economic impact of the rules upon a substantial number of small entities.'' *Id.* In conducting this review,

[1] Unless otherwise indicated, all references to HHS in this proposed rule include HHS' constituent agencies and other components.

[2] As ''Assessed'' and ''Reviewed'' are defined herein.

Congress provided that agencies ''shall consider the following factors'':

(a) The continued need for the rule;

(b) The nature of complaints or comments received concerning the rule from the public;

(c) The complexity of the rule;

(d) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

(e) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

5 U.S.C. 610(b)(1)–(5). Congress required agencies to conduct an initial review within ten years of the effective date of the RFA, as well as subsequent reviews ''within ten years of the publication of'' future final rules. 5 U.S.C. 610(a).

The retrospective review provided for in 5 U.S.C. 610 is a congressional mandate. Under the plain terms of the Act, having a plan for such reviews is not optional. Congress fashioned a private right of action for small entities to ensure agencies satisfy 5 U.S.C. 610. *See* 5 U.S.C. 611(a)(1) (for ''any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7''). Originally, as one commentator explained, the RFA ''contain[ed] an extremely qualified and ambiguous provision for judicial review.'' [3] In 1996, Congress amended the RFA to more clearly provide for judicial review of violations of 5 U.S.C. 610.[4] As one House Committee report explained, the lack of judicial review made ''agencies completely unaccountable for their failure to comply with its requirements,'' a problem the amendment attempted to solve.[5]

B. Executive Orders Directing Agencies To Review Existing Regulations

Other efforts to conduct retrospective regulatory review both predate and have continued after passage of the RFA. In 1978, President Carter issued an executive order on improving federal regulations.[6] The order directed agencies to ''periodically review their existing regulations.'' [7] In determining which existing regulations to review, the order required agencies to consider, among other things, whether ''technology, economic conditions or other factors have changed in the area affected by the regulation.'' [8] The Executive Order considered suggestions from the public that all regulations be reviewed, usually 3–5 years after issuance. But the Carter Administration instead instructed that, due to agency resource limitations, agencies should concentrate their reviews on those regulations which no longer serve their intended purpose, which have caused administrative difficulties, or which have been affected by new developments.[9] The executive order also considered, but rejected, the idea of including a sunset provision in regulations on the ground that agencies cannot entirely eliminate regulations unless the law which authorized the regulations allows it.[10] However, the Department believes that executive order did not consider that the authorizing statutes for many regulations permit those regulations to be rescinded. Moreover, as discussed below, experience since 1978 has shown it is difficult to adequately conduct retrospective regulatory review if regulations do not contain sunset provisions.

Like the Carter Administration, every subsequent administration has directed agencies to engage in retrospective review of existing regulations. In 1981, President Reagan ordered agencies to ''review[ ] existing regulations'' in view of cost-benefit principles and potential alternatives.[11] In 1992, President George H.W. Bush issued a memorandum instructing agencies to conduct a 90-day review ''to evaluate existing regulations and programs and to identify and accelerate action on initiatives that will eliminate any unnecessary regulatory burden or otherwise promote economic growth.'' [12] President Clinton similarly called for review of existing regulations to determine whether they have become ''unjustified or unnecessary as a result of changed circumstances,'' and ''to confirm that regulations are both compatible with each other and [are] not duplicative or inappropriately burdensome in the aggregate.'' [13] Specifically, that Executive Order required agencies to submit to the Office of Information and Regulatory Affairs (OIRA) a program under which the agency ''will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive Order.'' [14] The George W. Bush Administration's Acting OIRA Administrator noted that the Bush Administration was ''in the process of reviewing a variety of existing regulations and regulatory programs in an effort to identify areas where sensible changes will yield greater benefits for the public at lower costs.'' [15]

President Obama also instructed agencies to engage in retrospective regulatory review. In 2011, President Obama issued an executive order ordering agencies ''[t]o facilitate the periodic review of existing significant regulations . . . to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' [16] Similarly, in 2012, President Obama noted that retrospective review has particular relevance ''[d]uring challenging economic times,'' and that agencies should consider whether regulations ''should be modified or streamlined in

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[3] Paul R. Verkuil, *A Critical Guide to the Regulatory Flexibility Act,* 1982 Duke L.J. 213, 259 (1982).

[4] Contract with America Advancement Act of 1996, Public Law 104–121, 110 Stat. 847, 865–66 (1996).

[5] H.R. Rep. No. 104–500, at 3 (1996).

[6] Exec. Order No. 12044 of Mar. 23, 1978, 43 FR 12661 (Mar. 24, 1978) (revoked by Exec. Order No. 12291 of Feb. 17, 1981, 46 FR 13193 (Feb. 19, 1981)).

[7] 43 FR at 12663.

[8] *Id.*

[9] *Id.* at 12669. As discussed below, the Department is proposing to review a different subset of its regulations than was directed by Exec. Order No. 12044, in part because the RFA's directive to review regulations that have a significant economic impact upon a substantial number of small entities had not yet been enacted at the time of Exec. Order No. 12044. Moreover, Exec. Order No. 12044 was responding to suggestions that the review be performed every three to five years. The Department is proposing that its reviews be performed every ten years (except for regulations that have already been in effect for ten years), which should lessen the burden on the Department's resources.

[10] *Id.* at 12669.

[11] Exec. Order No. 12291 of Feb. 17, 1981, 46 FR 13193, 13193 (Feb. 19, 1981) (revoked by Exec. Order 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993)); *see also* Exec. Order 12498 of Jan. 4, 1985, 50 FR 1036 (Jan. 8, 1985) (creating annual regulatory planning program), revoked by Exec. Order 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993)).

[12] Memorandum on Reducing the Burden of Government Regulation (Jan. 28, 1992).

[13] Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993).

[14] *Id.*

[15] Draft Report to Congress on the Costs and Benefits of Federal Regulations Introduction, 66 FR 22041, 22054 (May 2, 2001).

[16] Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821, 3822 (Jan. 21, 2011); *see also* Exec. Order No. 13579 of July 11, 2011, 76 FR 41587, 41587 (July 14, 2011) (applying the same requirement to independent regulatory agencies).

light of changed circumstances, including the rise of new technologies.'' [17]

President Trump has attempted to identify existing undue regulatory burdens and facilitate retrospective review of regulations. For example, in January 2017, President Trump issued an executive order requiring agencies to identify at least two regulations to be repealed for every one regulation proposed or otherwise promulgated.[18] Similarly, a 2017 OIRA report to Congress explained, ''Rules should be written and designed to facilitate retrospective analysis of their effects, including consideration of the data that will be needed for future evaluation of the rules' ex post costs and benefits.'' [19] In May 2020, in response to the COVID–19 pandemic, President Trump ordered agencies to ''identify regulatory standards that may inhibit economic recovery'' and to ''consider taking appropriate action, consistent with applicable law,'' including modifying, waiving, or rescinding those regulatory requirements.[20]

In addition to the executive orders, other executive branch actions have sought to spur agencies to conduct the reviews called for by 5 U.S.C. 610. One example was the Regulatory Review and Reform (r3) initiative, which the Small Business Administration launched in part to improve compliance with 5 U.S.C. 610 and further the goals of periodic reviews. The r3 initiative was a long-term project to help agencies pinpoint existing federal rules that warrant review—and to revise those rules if they are found to be ineffective, duplicative, out of date, or otherwise deficient.[21]

Consistent with these actions, HHS has conducted retrospective reviews of some of its regulations. For example, pursuant to Executive Order 13563, HHS published a list of regulations the Department identified as candidates for retrospective review.[22] The Department also took action. For example, HHS, citing Executive Order 13563, eliminated certain restrictions on the use of telemedicine in rural areas.[23]

Nonetheless, the Department has only conducted retrospective review of regulations to a very limited extent. One academic analysis determined that, in response to Executive Order 13563, the Department planned 83 retrospective analyses in 2012 and completed 33 analyses with final action by August 31, 2013.[24] By contrast, the Department issued 247 rules between the date Executive Order 13563 was issued and August 31, 2013.[25] As of July 2016, the Department had 40 planned retrospective analyses and by April 2017 had completed analyses with final action on 19 of them.[26] These findings are consistent with government assessments that the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking.[27]

Scholars have posited reasons why agencies may be reluctant to perform retrospective reviews. One administrative law expert has written:

> [E]ven with sufficient resources, agencies may not be properly incentivized. They are less likely to be found at fault for not conducting rigorous periodic reviews. Many rules, even those with significant effects, are often not on the public's radar once adopted. Challenging agency regulation under the RFA is more difficult than under the Administrative Procedure Act (APA) because there is no comment process and standing is granted to more limited parties. The harm to the public resulting from a cursory analysis is also much less clear. If sufficient interests exist to modify the rule, strong interest groups will directly lobby the agency to modify the rule. But in this case, a brand new rulemaking effort emerges.
>
> There are also political reasons and moral hazard concerns associated with performing retrospective analyses. In most cases, retrospective analyses of existing regulations are routine business matters left to be handled by staff members, rather than political appointees. Political appointees, such as agency heads, tend to come with specific regulatory agendas of their own. By contrast, staff members at regulatory agencies are best viewed as career members who have a vested interest in seeing their agencies continue to exist and thrive. All else equal, they are not inclined to acknowledge that the work of their agency is inefficient or unnecessary, and even less inclined to conduct analyses that may lead to a curtailing of the agency's authority. Whatever the reasons may be, serious ex post reviews are few and far between. A majority of rules, once adopted, will likely persist without significant ex post modification. As to how many agency rules currently implemented may be costing more resources than yielding benefits is anyone's guess.[28]

Thus, the Department proposes that it needs to impose a strong incentive on itself to perform retrospective review, given these countervailing incentives to not perform such reviews and the limited number of retrospective reviews that the Department has performed over the last 40 years. As discussed in more detail in the regulatory impact analysis *infra,* the Department has the resources to periodically review the impacts of its regulations. Only a handful of Department employees are needed to perform the periodic reviews.

C. Limitations in Government Projections Counsel in Favor of Retrospective Regulatory Review

The Congressional and Presidential directives to periodically review existing regulations are sound policy. When the Department first issues a regulation, it makes an educated guess about the regulation's impact. Several years after the regulation is promulgated, the Department has a somewhat greater basis for assessing its real-world impacts and can refine the regulation or agency enforcement practices, as appropriate. This would

[17] Exec. Order No. 13610 of May 10, 2012, 77 FR 28469, 28469 (May 14, 2012).

[18] Exec. Order No. 13771 of Jan. 30, 2017, 82 FR 9339, 9339 (Feb. 3, 2017).

[19] Office of Mgmt. & Budget, 2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act at 5 (2017), *https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf; see also id.* at 16 (''[I]t is important to consider retrospective, as opposed to ex ante, estimates of both benefits and costs.'').

[20] Exec. Order No. 13924 of May 19, 2020, 85 FR 31353, 31354 (May 22, 2020).

[21] Testimony of The Hon. Thomas M. Sullivan, Chief Counsel for Advocacy, U.S. SBA, U.S. House of Representatives Comm. on Small Bus. Subcomm. on Reg.'s, Health Care and Trade (July 30, 2008), *https://www.sba.gov/sites/default/files/files/test08_0730.pdf* (''Historically, federal agency compliance with section 610 has been limited.'') (last visited Oct. 19, 2020).

[22] *See also Retrospective Review of Existing Rules,* U.S. Dept. of Health & Human Servs., *https://www.hhs.gov/open/retrospective-review/index.html* (last visited Oct. 19, 2020).

[23] *See* Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging, 76 FR 25550 (May 5, 2011); *see also* Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II, 79 FR 27106 (May 12, 2014) (finalizing several rules to remove unnecessary regulatory and reporting requirements previously imposed on hospitals and other health care providers).

[24] Connor Raso, *Assessing regulatory retrospective review under the Obama administration,* Brookings Inst., (Jun. 15, 2017) *https://www.brookings.edu/research/assessing-regulatory-retrospective-review-under-the-obama-administration/.*

[25] *Id.*

[26] *Id.*

[27] *See, e.g.,* Curtis W. Copeland, Cong. Research Serv., RL32801, Reexamining Rules: Section 610 of the Regulatory Flexibility Act 7–8 (2008); U.S. Gov't Accountability Off., GAO/GGD–94–105, Regulatory Flexibility Act: Status of Agencies' Compliance 12 (1994) (quoting a 1983 Small Business Administration report that stated that the Department's section 610 review plan was '' 'very general,' and, as a result, 'it is difficult to measure progress and to make recommendations with respect to future review' ''); *see also* Testimony of The Hon. Thomas M. Sullivan, Chief Counsel for Advocacy, U.S. SBA, U.S. House of Representatives Comm. on Small Bus. Subcomm. on Reg.'s, Health Care and Trade (July 30, 2008), *https://www.sba.gov/sites/default/files/files/test08_0730.pdf* (''Historically, federal agency compliance with section 610 has been limited.'') (last visited Oct. 19, 2020).

[28] Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 895–96 (2013).

further democratic values such as accountability, administrative simplification, transparency, and performance measurement and evaluation.

Indeed, the literature indicates that government projections of regulatory impacts would benefit from refinement based on experience after the regulations are implemented. In 2005, the Office of Management and Budget (OMB) provided an overview of a sample of retrospective analyses based on an examination of forty-seven case studies.[29] OMB considered a pre-regulation estimate to be accurate if the post-regulation estimate was within +/−25 percent of the pre-regulation estimate.[30] This measure of accuracy reveals the difficulty and uncertainty inherent in prospective cost-benefit analysis. OMB found that agencies often inaccurately estimated the benefits of regulations in its sample of regulations, and agencies were more likely to overestimate benefits than to underestimate them, where benefits were estimated.[31] Agencies overestimated benefits in 19 of 39 sampled regulations, whereas they underestimated benefits in only two of the 39 regulations.[32] In two cases, agencies overestimated benefits by a factor of 10.[33] Second, agencies sometimes overestimated the benefit-cost ratio, and in that sense were a bit too optimistic about the consequences of their rules. Agency estimates were accurate in only 11 rules, while the ratio was overestimated in 22 rules and underestimated in 14 rules.[34] Third, agencies also overestimated and, less frequently, underestimated costs in the sampled regulations. Agency cost estimates were accurate for only 12 rules, overestimated for 16 rules, underestimated for 12 rules, and not estimated for seven rules.[35]

Academic studies have also identified inaccuracies in agency estimates, relative to an ex post re-estimation. For example, one study of sixty-one rules for which benefit-cost ratios could be compared before and after the fact (including some not included in the OMB review) found that in only sixteen of the sixty-one cases were the estimated ratios essentially accurate, though the study found no bias in estimates of benefit-cost ratios.[36] In this analysis, Dr. Harrington criticized certain aspects of the OMB analysis. But it is notable that, even though OMB and Dr. Harrington used somewhat differing methods and reviewed samples of regulations that did not completely overlap, they both found ex ante estimates to be in many cases lacking. Dr. Harrington concluded his analysis by noting that ''the results demonstrate the value of *ex post* analysis. It is frustrating that there is so little of it, especially when so many close observers, from all points of view, claim to be in favor of it.'' [37]

A more recent study of a sample of federal regulations found that of the eight regulations for which the author was able to make ex ante and ex post cost comparisons, six regulations involved overestimates of costs, two involved underestimates of costs, and none were deemed accurate.[38] A regulation was deemed accurate if the regulation's regulatory impact analysis fell roughly within +/−25% of the ex post observation.[39] Of the 18 regulatory requirements for which the author was able to compare benefits (also referred to as ''effectiveness'' in the study) estimates on an ex ante and ex post basis, he found that 10 involved overestimates, six were underestimates, and two were relatively accurate.[40]

Inaccurate estimates are not always the result of poor analysis by the agency. Sometimes changes in the legal landscape can cause government projections to become obsolete. For example, in February 2010, officials in the Centers for Medicare and Medicaid Services' Office of the Actuary (OACT) issued health spending and coverage projections through 2019.[41] A month later, Congress enacted the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119, and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, 124 Stat. 1029 (''ACA''). Largely as a result of the ACA's passage, in October 2010 OACT issued revised projections forecasting that by 2019 the insured share of the population would be 92.7 percent—roughly ten percentage points higher than OACT projected nine months earlier.[42]

Changes in technology can also render projections inaccurate. One study has noted that even when an agency's benefit-cost analysis uses sound science and the best available information to estimate the costs associated with a rule, technological innovation can result in an ex post assessment of costs differing from the agency's cost estimates at the time it promulgated the rule.[43] As an example of technology's impact on regulations, in 2019 the Food and Drug Administration (FDA) issued a rule amending requirements for medical device premarket submissions to remove requirements for paper and multiple copies, and replace these requirements with requirements for a single submission in electronic format.[44] Changes in technology had rendered the requirement for multiple

[29] Office of Mgmt. & Budget, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, at 46–47 (2005) *http://perma.cc/R8LX–BQMJ* (collecting studies comparing ex ante and ex post analyses of regulations' costs and benefits, including examples where cost and benefit estimates were off by more than a factor of ten).

[30] *Id.* at 42.

[31] *Id.* at 43–46.

[32] *Id.* at 47.

[33] *Id.* at 43.

[34] *Id.* at 47.

[35] *Id.*

[36] Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation,* Res. for the Future, Discussion Paper 06–39, 2006, at 33, *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=937357.* Dr. Harrington used the same measure of accuracy as OMB. While both OMB and Dr. Harrington noted that using +/−25% as the measure of accuracy could be arbitrary, it is nonetheless informative that in many cases the ex ante estimates in the sampled regulations differed from ex post estimates by more than +/−25%.

[37] *Id.* at 34.

[38] Richard Morgenstern, *Retrospective Analysis of U.S. Federal Environmental Regulation,* 9 J. of Benefit Cost Anal., no. 2, 2018, at 294 *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/891E36D3DBCEB79C969278488E5E1897/S2194588817000173a.pdf/retrospective_analysis_of_us_federal_environmental_regulation.pdf.*

[39] *Id.*

[40] *Id.; see also* Cynthia Morgan & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs*, 5 J. Benefit Cost Anal. no. 2, 2014, at 259–84 *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf* (finding that the EPA methodology overestimated predicted capital costs from its arsenic rule in most studied cases, especially as the size of the system increases (as measured by the design flow rate)).

[41] *See* Truffer CJ, et al. *Health Spending Projections Through 2019: The Recession's Impact Continues,* 29 Health Aff. no. 3, 2010, at 522–29, *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.1074.*

[42] *See* Sisko, et al., *National Health Spending Projections: The Estimated Impact Of Reforms Through 2019,* 29 Health Aff. no. 10, at 1936, *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2010.0788.*

[43] Cynthia Morgan & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs*, 5 J. Benefit Cost Anal. no. 2, 2014, at 259–84, *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf.* One example referred to in this study is that technological innovation or regulatory or technical constraints could result in water systems using different treatment technologies for arsenic removal than assumed by the agency when it promulgated a regulation.

[44] Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Required in Electronic Format, 84 FR 68334 (Dec. 16, 2019).

copies, whether in electronic format or paper form, no longer necessary.[45] Had the Department reviewed more of its regulations, it might have learned of additional instances where technological changes counsel in favor of amendment. In addition, some scholars have suggested that in some cases changes in technology can reduce the costs of complying with regulatory mandates.[46] If retrospective reviews conclude that technology has reduced compliance costs, that can inform the Department's decision about if or how to amend a regulation.

Yet another reason for potential divergence between prospective and retrospective regulatory impact estimates is non-compliance with the regulation being assessed. One study found differing accuracy for prospective per-unit cost estimates and prospective aggregate cost estimates; where there is substantial non-compliance with the regulation being analyzed, the study claimed, cost estimates per unit can sometimes be reasonably accurate while aggregates are simultaneously overestimated.[47] (Non-compliance would, of course, also affect the accuracy of benefits estimates.[48]) As such, ex post analysis has the potential to inform not just decisions about codified regulatory requirements but also about agency enforcement practices.

While the prospective cost-benefit analyses performed in connection with the promulgation of rules are quite useful, former OIRA Administrator Cass Sunstein has explained that '' [w]hen agencies issue rules, they have to speculate about benefits and costs.'' [49] Therefore, ''[a]fter rules are in place, [agencies] should test those speculations, and they should use what they learn when revisiting a regulation or issuing a new one.'' [50] Professor Sunstein described this as ''one of the most important steps imaginable'' for regulatory reform, ''not least because it can reduce cumulative burdens and promote the goal of simplification.'' [51] He has noted that agencies' failure ''until very recently . . . to gather, let alone act on'' retrospective reviews is ''an astonishing fact.'' [52]

Michael Greenstone, who served as Chief Economist on the Council of Economic Advisors between 2009 and 2010, similarly concluded that the ''single greatest problem with the current system is that most regulations are subject to a cost-benefit analysis only in advance of their implementation. This is the point when the least is known and any analysis must rest on many unverifiable and potentially controversial assumptions.'' [53] According to Professor Greenstone, the lack of a regulatory lookback created a system ''largely based on faith, rather than evidence,'' where the agency ''all too frequently takes shots in the dark and we all too infrequently fail to find out if we have hit anything—or even worse, we only find out when things have gone horribly wrong.'' [54] As he explained, ''it is nearly impossible to imagine'' only prospective, and not retrospective, evaluations ''being used in other contexts where people's lives are on the line. For example, I am confident that there would be a deafening uproar of protest if the FDA announced that it would approve drugs without testing them in advance. Yet, this is largely what we do with regulations that affect our health and well-being.'' [55]

If retrospective analysis ''could be firmly institutionalized,'' Professor Sunstein observed, then it ''would count as the most important structural change in regulatory policy since the original requirement of prospective analysis during the Reagan Administration.'' [56]

Other administrative law experts have also urged agencies to more robustly institutionalize retrospective review of regulations. The Administrative Conference of the United States (ACUS) has ''urge[d] agencies to remain mindful of their existing body of regulations and the ever-present possibility that those regulations may need to be modified, strengthened, or eliminated in order to achieve statutory goals while minimizing regulatory burdens.'' [57] More recently, the American Bar Association Section of Administrative Law and Regulatory Practice, has ''*urge[d]* [*the Administration*] *to build on the efforts of previous administration[s] and take steps to institutionalize careful, in-depth retrospective review of existing rules.*'' (Emphasis in original).[58]

Yet, despite these many calls for retrospective review, as noted in section II.B., the Department has had limited success in implementing retrospective review in practice.[59] In 2019, the Department piloted an approach to augment expert policy insights with artificial intelligence-driven data analysis of its regulations, which showed the need to more firmly institutionalize retrospective review. The artificial intelligence review found that 85% of Department regulations created before 1990 have not been

[45] *Id.* at 68334.

[46] *See, e.g.,* Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 599 (2014).

[47] Winston Harrington, Richard D. Morgenstern and Peter Nelson, *On the Accuracy of Regulatory Cost Estimates,* J. Policy Anal. & Management 2000, 19(2): 297–322.

[48] *See, e.g.,* Si Kyung Seong and John Mendeloff, *Assessing the Accuracy of OSHA's Projections of the Benefits of New Safety Standards*, Am. J. Industrial Medicine 2004, 45(4): 313–328.

[49] Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 591 (2014).

[50] *Id.*

[51] *Id.*

[52] *Id.* at 588.

[53] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 113 (David Moss & John Cisternino eds., 2009). It should not be inferred, however, that retrospective analysis is free of assumptions (including potentially controversial assumptions) or is generally without challenges, especially with respect to establishing relevant counterfactuals. For discussion and recent examples related to just two of the many areas of Department regulatory activity, see Trinided Beleche *et al., Are Graphic Warning Labels Stopping Millions of Smokers? A Comment on Huang, Chaloupka, and Fong,* 15 Econ Journal Watch 129 (2018) and Aaron Kearsley *et al., A Retrospective and Commentary on FDA's Bar Code Rule,* 9 J. Benefit-Cost Analysis 496 (2018). Moreover, to the extent that retrospective analysis is used to inform policy choices going forward, it becomes, or is at least being used as, prospective analysis and thus relies on assumptions about the future, including as regards technology and the legal and regulatory landscape. But since retrospective analysis is conducted after some real-world experience living under the regulation, it can in many cases be an improvement over earlier prospective analysis.

[54] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 111–12 (David Moss & John Cisternino eds., 2009); *see also* Office of Mgmt. & Budget, 2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act at 5 (2017), *https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf* (''The aim of retrospective analysis is to understand and improve the accuracy of prospective analysis and to provide a basis for potentially modifying rules as a result of *ex post* evaluations.'').

[55] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 114 (David Moss & John Cisternino eds., 2009).

[56] Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 589 (2014).

[57] Administrative Conference of the United States, Recommendation 2014–5, Appendix—Recommendations of the Administrative Conference of the United States, 79 FR 75114, 75114 (Dec. 17, 2014); *see also* ABA Sec. of Admin. Law & Reg. Prac., Improving the Administrative Process: A Report to the President-Elect of the United States (2016), 69 Admin. L. Rev. 205 (2017).

[58] ABA Sec. of Admin. Law & Reg. Prac., *Improving the Administrative Process: A Report to the President-Elect of the United States (2016),* 69 Admin. L. Rev. 205, 219 (2017) (emphasis in original).

[59] *See also* Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 894 (2013), (''one might think that agencies would faithfully take advantage of [] opportunities to conduct rigorous retrospective [cost-benefit analyses] of their existing regulations and test their effectiveness and efficiency. This would be the surest way of incorporating ex post learning in rule implementation. This is far from the truth in practice, however.'').

edited; the Department has nearly 300 broken citation references in the CFR (*i.e.,* CFR sections that reference other CFR sections that no longer exist); more than 50 instances of regulatory requirements to submit paper documents in triplicate or quadruplicate; and 114 parts in the CFR with no regulatory entity listed, 17 of which may be misplaced.[60] The Department concluded that some good governance stewardship recommendations ''were deprioritized and relegated to rainy day activities that [Department operating divisions] would get around to when they could.''[61] Unfortunately, in many cases the Department has for years not gotten around to addressing these issues.

For the reasons discussed in this section, the Department believes a stronger incentive is needed to achieve the benefits of retrospective review.[62] This proposed rule proposes a mechanism to more firmly institutionalize the retrospective reviews that Professors Sunstein and Greenstone, as well as ACUS and others, have called for.

D. The Experiences of States and Other Jurisdictions With Automatic Expiration or ''Sunset'' Provisions

The proposed mechanism is based in part on the experiences of States and other jurisdictions. Several States incorporate retrospective regulatory review into their laws. New York, for example, requires retrospective review of regulations ''no later than in the fifth calendar year after the year in which the rule is adopted,'' and requires that rules be ''re-reviewed at five-year intervals'' thereafter. N.Y. A.P.A. Law sec. 207. Similarly, Texas requires State agencies to review rules four years after they go into effect and then subsequently at four-year intervals. Tex. Gov't Code sec. 2001.039. In addition to New York and Texas, State law requires some form of retrospective regulatory review in at least Alabama, Arizona, Illinois, Iowa, Michigan, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, and Washington.[63]

Some States with retrospective review requirements allow regulations to automatically expire or sunset after a period of time, unless reviewed or readopted. In New Jersey, regulations automatically expire ''seven years following the effective date of the rule'' unless extended by the agency. N.J. Stat. Ann. sec. 52:14B–5.1(b).[64] Indiana allows regulations to expire on January 1 following the seven-year anniversary of their effective dates. Ind. Code sec. 4–22–2.5–2. The Governor of Florida recently instructed Florida government agencies to ''include a sunset provision in all proposed or amended rules,'' which ''may not exceed five years unless otherwise required by existing statute.''[65]

Experience in the States suggests that sunset provisions can be an important tool to ensure reviews take place. An analysis of regulation in all 50 States found that for a reduction in both regulatory creation and enforcement, ''[t]he single most important policy in a state is the presence of a sunset provision.''[66] On the other hand, one report stated that, despite their initial popularity in the States,[67] sunset provisions fell out of favor, not because they did not produce more cost-effective, cost-justified regulation, but because sunset requirements did not provide sufficient legislative control over executive agencies.[68] That observation is inapplicable to the Department, because this proposed rule concerns the Department's review of its own regulations. Noting the benefits of sunset provisions, the report added that sunset ''provisions have been responsible for the analysis of thousands of state regulations and, on average, the repeal of twenty to thirty percent of existing regulations and the modification of another forty percent.''[69]

Experience outside the United States also suggests the utility of sunset provisions. The Office for Economic Co-Operation and Development (OECD) analyzed regulatory practices in the European Union. In a 2010 report, the OECD recommended, for ''[t]he management and rationalization of existing regulations,'' that Germany ''[k]eep up the 'spring cleaning' of legislation at regular intervals'' and ''consider the inclusion of a review mechanism in individual draft regulations, or even [include] a sunset clause (beyond which the law automatically expires) where appropriate.''[70] With respect to the United Kingdom's regulatory program, the OECD noted ''sunset clauses are also helpful'' in order ''to remove unnecessary burdens in legislation.''[71] Throughout the 2010 report, the OECD repeatedly noted the value of retrospective regulatory review.[72]

In 2019, the OECD published an additional survey regarding regulatory review practices in the European Union. The OECD again noted the utility of

[60] Regulatory Streamlining & Analysis (Mar. 2019).

[61] *Id.* at 18

[62] *Id.* (it ''appears the current set of governance structures, incentives and processes to promulgate regulatory reform need strengthening to be more effective'').

[63] Ala. Code 41–22–5.2; Ariz. Rev. Stat. 41–1056; 5 Ill. Comp. Stat. Ann. 100/5–130; Iowa Code Ann. 17A.33; Mich. Comp. Laws 10.151; N.J. Stat. Ann. 52:14B–5.1; N.M. Stat. 14–4A–6; N.C. Gen. Stat. 150B–21.3A; N.D. Cent. Code 28–32–18.1; Ohio Rev. Code Ann. 106.03; Okla. Stat. Ann. tit. 75, 307.1; 71 Pa. Stat. Ann. 745.2; R.I. Gen. Laws Ann. tit. 42, ch. 64.13; Tenn. Code Ann. 4–56–102; Wash Rev. Code Ann. 43.70.041, 43.22.052.

[64] Although the New Jersey law permits the Governor, within five days of the expiration of a rule, to restore it, the Department does not include a similar provision in this proposed rule. That is because the RFA contains no such similar provision and the Department is giving itself ten years, as opposed to seven years, to perform Assessments and (when required) Reviews of Regulations.

[65] Letter from Gov. Ron DeSantis to Florida Agency Heads (Nov. 11, 2019) *https://www.floridahasarighttoknow.myflorida.com/content/download/147113/980326/FINAL_Directive_to_Agencies_11.19.pdf.*

[66] Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* (Mercatus Ctr., Working Paper No. 12–18, at 36 (2012), *https://www.mercatus.org/system/files/State-Regulatory-Review-50-State-Analysis-Effectiveness.pdf.*

[67] Jason A. Schwartz, *52 Experiments with Regulatory Review: The Political and Economic Inputs into State Rulemakings,* Inst. for Policy Integrity, Rep. No. 6, at 33 (Nov. 2010), *https://policyintegrity.org/files/publications/52_Experiments_with_Regulatory_Review.pdf.*

[68] *See id.* (noting that ''North Carolina was first to repeal its sunset law, and many other states quickly followed suit'' after concluding that ''sunset provisions quickly proved to be an expensive, cumbersome, and disappointing method for enhancing legislative control'').

[69] *Id.* at 23–24. The report added, without citing a great deal of empirical evidence, that ''sunset requirements produce perfunctory reviews and waste resources.'' This appears to be based on a law review article that noted, not that retrospective reviews were per se perfunctory, but that ''unless adequate resources are provided, the reviews *may be* relatively perfunctory and meaningless, wasting whatever resources are expended.'' *See* Neil R. Eisner & Judith S. Kaleta, *Federal Agency Reviews of Existing Regulations,* 48 Admin. L. Rev. 139, 160 (1996) (emphasis added). But this law review article noted that adding ''sunset'' dates to regulations unless they are reviewed was ''likely to ensure that a review is done.'' *Id.* As explained herein, the Department intends to commit adequate resources to its reviews if this proposed rule were to be finalized. The law review article said that sunset provisions should be used only in narrowly focused situations where it is determined that it is necessary to apply some ''pressure'' and only where assessments are made of the available resources and the benefits to be derived from the review. *Id.* But the article was written in 1996. As discussed herein, subsequent experience with efforts short of a forcing mechanism suggest that forcing mechanisms are needed to ensure review of a wide array of Department regulations, and that the benefits from these retrospective reviews would be substantial.

[70] OECD, *Better Regulation in Europe: Executive Summaries,* GOV/RPC(2010)13, at 113 *http://www.oecd.org/gov/regulatory-policy/45079126.pdf.*

[71] *Id.* at 46.

[72] *See, e.g., id.* at 107 (''The *ex post* evaluation of regulations which is provided for in the impact assessment process provides a framework in principle for checking what really happens, and whether regulations have actually achieved the objectives originally set.'').

sunset provisions, describing them as a ''useful 'failsafe' mechanism to ensure the entire stock of subordinate regulation remains fit for purpose over time.'' [73] The report noted as of its 2019 date that sunset provisions are in place for at least some regulations in nine different countries, including the United Kingdom, France, and Germany.[74]

In 2009, the Republic of Korea (ROK) enacted a law under which about 20% of the existing regulations are to be reviewed on a regular basis (about every 3 to 5 years) and become invalid if they are found to lack feasibility.[75] Under the ROK's ''review and sunset,'' there is a duty to carry out a review of a regulation on a specified schedule. This sunset clause was established upon the idea that even a rational regulation needs to be examined periodically to determine its grounds for remaining in force, as its validity may be compromised under any change in circumstances or its characteristics.[76] An OECD report stated that ''[g]iven such rationale, the sunset clause is considered as a critical component of efforts in regulatory quality improvement.'' [77]

These authorities indicate an emerging awareness that sunset provisions are useful in ensuring retrospective regulatory review. This is consistent with the Department's experience over the last 40 years, which suggests that, absent a sunset provision or automatic expiration date, Congressional and Presidential directives to perform periodic retrospective reviews of regulations have limited success.

Indeed, previous Administrations have recognized the benefits of sunset provisions. In a June 2015 report, the Department of Treasury's Office of Economic Policy, the Obama Administration's Council of Economic Advisors, and the Department of Labor discussed sunset provisions as applied to occupational licensing.[78] That report found evidence that sunset reviews that automatically terminate regulatory boards and agencies absent legislative action assist with ''removing unnecessary licensing.'' [79] The report explained that sunset review can be ''useful because, even if licensing was justified when first introduced, technological and economic changes may have rendered it unnecessary or overly restrictive.'' [80] The report found ''[p]eriodic examination of existing rules is thus helpful in maintaining the quality of occupational regulation.'' [81] Professor Greenstone has similarly recommended the automatic repeal of regulations if their benefits and costs are not periodically assessed:

> [Another] step in reforming our regulatory system is to require that all regulations contain rules specifying the date by which the regulatory review board has to assess their costs and benefits. If the regulatory review board fails to meet one of these deadlines, then the regulation should be repealed by default. The purpose of this sunset provision is to ensure that all regulations are evaluated carefully and do not stay on the books just because they have been on the books in the past.[82]

Professor Greenstone suggested that this review could cause the regulation to be expanded if supported by evidence.[83] According to Professor Greenstone, this would ''ensure that ineffective regulations are removed and that society fully benefits from the effective ones.'' [84]

This proposed rule seeks to advance democratic values and apply the lessons learned from States, foreign jurisdictions, and the academic community. This proposed rule would apply the benefits of automatic-expiration-absent-periodic-review to a broader array of regulations than is currently being reviewed by the Department.

III. Statutory Authority

The statutory authorities supporting this rulemaking are the statutory authorities for the Department's existing regulations. The Department proposes herein to amend its regulations to add expiration dates unless the Department periodically conducts the required review of the regulations or an exception applies. Some of the Department's primary rulemaking authorities include:

- Section 701(a) of the Federal Food Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 371(a) which authorizes the Secretary to ''promulgate regulations for the efficient enforcement of [the FD&C Act], except as otherwise provided in this section'';
- Section 1102 of the Social Security Act, 42 U.S.C. 1302, which provides that the Secretary ''shall make and publish such rules and regulations, not inconsistent with this Act, as may be

[73] OECD, *Better Regulation Practices across the European Union,* at ch. 4, Box 4.1 (2019), *https://www.oecd-ilibrary.org/sites/9789264311732-en/1/2/4/index.html?itemId=/content/publication/9789264311732-en&_csp_=07701faff9659027b81a5b5ae2ff041c&itemIGO=oecd&itemContentType=book.*

[74] *Id.* at ch. 4, Table 4.1.

[75] OECD, *Latest Developments on Korea's Regulatory Policy,* at 2, *https://www.oecd.org/gov/regulatory-policy/45347364.pdf.*

[76] OECD Reviews of Regulatory Reform, Regulatory Policy in Korea, Toward Better Regulation, at 86 (2017), *https://publicadministration.un.org/unpsa/Portals/0/UNPSA_Submitted_Docs/2019/4cd3e219-c819-40f3-8246-7a024d9a82a9/2020%20UNPSA_the%20Regulatory%20Reform%20Sinmungo_Evaluation%20Report_27112019_032807_e4d166a9-f6ef-4a6c-9aaf-99748fa94284.pdf?ver=2019-11-27-032807-637.*

[77] *Id.*

[78] *Occupational Licensing: A Framework for Policymakers,* The White House, at 48–50 (July 2015), *https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf.*

[79] *Id.* at 48.

[80] *Id.* at 49.

[81] *Id.* The report also suggests that to strengthen sunset provisions in the States, sunset commissions responsible for conducting the cost-benefit analysis should be provided adequate resources; the cost-benefit review process should be insulated against political interference; a minimum number of votes should be required to overrule the sunrise agency's recommendation; and specialized committees within legislatures be appointed to work with the agency in charge of conducting the review. *See id.* at 42. As discussed herein, the Department believes it has adequate resources to conduct the required reviews. As discussed in footnote 84, it is not clear that a federal agency can legally completely insulate its reviews from supervision by the agency's leadership, but the Department believes that its retrospective reviews will generally be performed by career civil servants. Lastly, the Department cannot require Congress to appoint committees to work with the Department officials performing the retrospective reviews, but the Department would welcome the opportunity to discuss reviews with Congressional staff if Congress so chose. The report also suggested ''sunrise'' reviews can be more effective than sunset reviews. But for already-existing regulations, the Department cannot perform sunrise reviews, so the Department is proposing to take advantage of the benefits of sunset reviews. Moreover, the Department already engages in ''sunrise review'' to some extent when it develops regulatory flexibility analyses, *see* 5 U.S.C. 603, 604, and regulatory impact analyses (notably, such reviews did not occur for regulations that preceded the RFA, many of which still remain in effect).

[82] Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 121 (David Moss & John Cisternino eds., 2009).

[83] *Id.*

[84] *Id.* at 123. Professor Greenstone made a separate suggestion that a regulatory review board be created with the authority to assess the effectiveness of regulations and repeal regulations deemed ineffective. The Department considered this, but has decided not to include this proposal in this notice of proposed rulemaking. First, the Department is concerned that such a board raises legal concerns, since many Department regulations can only be repealed by the Secretary, not by an independent board. Second, Professor Greenstone proposed the independent review board on the grounds that (1) it would remove the board's functions as much as possible from political control, and (2) those most deeply involved in implementing a regulation are likely to see the benefits more clearly than the costs. *Id.* at 119–121. While these concerns are understandable, the Department believes it is capable of performing the Review. As an initial matter, those who conduct the Review would not necessarily be those in the Department who implement the Regulation. Moreover, as described herein, Reviews must be performed in such a manner that they can withstand judicial review under the arbitrary and capricious standard. This would require the Reviews to meet a minimum standard of rigor and require them to consider relevant factors. Moreover, many regulations legally cannot be amended or repealed without authorization by a political appointee.

necessary to the efficient administration of the functions with which [he] is charged under this Act'';

• Section 1871 of the Social Security Act, 42 U.S.C. 1395hh, which provides that ''the Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title''; and

• 5 U.S.C. 301, which provides that ''[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public.''

It complies with the Administrative Procedure Act (APA) to amend regulations to add dates by which the regulations expire unless a review of the regulation is timely performed. An agency can, through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date.[85] An agency can also provide that its regulations expire when an event occurs or ceases to occur.[86] That is what the Department is proposing in this proposed rule. This is discussed in more detail in the description of section [XX](c) in Section IV *infra*.

The Department also notes the text of 5 U.S.C. 610 indicates Congress believed agencies had the authority to periodically review at least those regulations that have a significant economic impact upon a substantial number of small entities (and that the agency had the authority to assess which of its regulations have such an impact).

IV. Provisions of Proposed Rule[87]

Section 3(a) of the RFA, 5 U.S.C. 610, and Executive Orders 12866 and 13563 direct agencies to devise plans to periodically review certain of their regulations using certain criteria. By requiring the Department to periodically perform such reviews, this proposed rule would implement Congress' and the President's desires for retrospective review of regulations. This proposed rule would lead to the amendment or rescission, where appropriate, of Department regulations that have a significant economic impact upon a substantial number of small entities. The proposed rule would also further democratic values such as accountability, administrative simplification, transparency, and performance measurement and evaluation. Below the Department discusses each provision of this proposed rule.

Section [XX](a)

Section [XX](a) provides that this section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in this title.

Section [XX](b)

Section [XX](b) defines several terms used in the proposed rule.

Section [XX](b)(1)

Section [XX](b)(1) defines ''Assess''[88] as ''a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.''

5 U.S.C. 610 directs agencies to have plans to periodically review those regulations that have or will have a significant economic impact upon a substantial number of small entities. Accordingly, in order to determine which regulations to periodically review using 5 U.S.C. 610's criteria, the Department must first determine which rules have a significant economic impact upon a substantial number of small entities. When promulgating regulations, the Department is required to determine whether a rule will have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).[89] The Assessment refers to an essentially identical determination. In making the Assessment, the Department can look to the determination of the regulation's impact on small entities made at the time of promulgation, as well as experience since promulgation.

Section [XX](b)(2)

Section [XX](b)(2) defines ''Review'' as a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether the Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Regulations upon a substantial number of small entities. The Department discusses the Reviews in more detail in the discussion of section [XX](d) below.

Section [XX](b)(3)

Section [XX](b)(2) defines ''Regulation'' for purposes of this proposed rule as ''a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.'' This definition makes clear that a section of the CFR, as opposed to a part, subpart, or paragraph within a section, is the unit that must be assessed and (if required) reviewed, or will otherwise expire. Defining ''Regulation'' in this objective way makes it easier for the Department and the public to know what exactly has to be reviewed by the dates listed in this proposed rule. Had

[85] *See, e.g.,* Amendment to the Interim Final Regulation for Mental Health Parity, 70 FR 42276, 42277 (July 22, 2005) (amending interim final rule, to provide that ''the requirements of the MHPA interim final regulation apply to group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan during the period commencing August 22, 2005 through December 31, 2005. Under the extended sunset date, MHPA requirements do not apply to benefits for services furnished after December 31, 2005.''); *see generally Clean Air Council* v. *Pruitt,* 862 F.3d 1, 9 (D.C. Cir. 2017) (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking).

[86] *See, e.g.,* Control of Communicable Diseases; Foreign Quarantine, 85 FR 7874, 7874 (Feb. 12, 2020) (providing that, unless extended, interim final rule ''will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of 2019–nCoV, or (2) when the Secretary determines there is no longer a need for this interim final rule''); Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 54820, 54820 (Sept. 2, 2020) (providing that an interim final rule applies ''for the duration of the [public health emergency] for COVID–19'').

[87] The Department proposes to add substantively identical provisions to Titles 21, 42, and 45. For concision, in this section the Department describes these provisions once, rather than repeating the same substantive provisions several times. The Department uses the phrase ''[XX]'' to refer to the fact that substantively identical provisions will be added to Titles 21, 42, and 45. Because certain regulations in Title 42 cannot be amended without a 60-day comment period, *see* 42 U.S.C. 1395hh(b), the Department has written two proposed regulations for Title 42. One applies to the parts of that title that require a 60-day comment period, and the other applies to the remainder of the Department's regulations in Title 42.

[88] ''Assess,'' ''Review,'' and ''Regulation'' are capitalized in this preamble where those terms have the definitions ascribed to them in the text of this proposed rule.

[89] 5 U.S.C. 605(b) refers to rules that have a ''significant economic impact *on* a substantial number of small entities,'' whereas 5 U.S.C. 610 refers to rules that have ''significant economic impact *upon* a substantial number of small entities.'' This does not appear to be a material difference.

the Department used the Administrative Procedure Act's (APA's) definition of ''rule,'' [90] it could be unclear in certain circumstances what precisely needed to be reviewed.

Section [XX](b)(4)

Third, this proposed rule defines ''Year of the Regulation's Promulgation'' to mean the calendar year the Regulation first became effective, irrespective of whether it was subsequently amended. The purpose of this definition is to provide clarity to the Department and the public. If a Regulation were amended, questions could arise whether the clock for re-reviewing a Regulation begins on the date the Regulation was first promulgated; the date it was last amended; or whether the clock for reviewing the amended portion begins on a different date than the portion that was initially enacted. This definition creates simplicity for the Department and the public, because this definition, in conjunction with section [XX](c), makes clear that the clock starts for the retrospective review of an entire Regulation on the date that the Regulation was first promulgated, even if it is subsequently amended.

If, for example, the Department issues a Regulation and amends it nine years later, the Department may wish to conduct the Review at the time of amendment, particularly since the Department is presumably already performing a regulatory impact analysis with regard to the amendment. Since the Department is already conducting a regulatory impact analysis, performing the Review at that time may save Department resources and spare the Department from having to perform the Review on the Regulation the next year. In fact, any time the Department amends a Regulation, it could perform the Review of the Regulation at that time, thereby restarting the Regulation's ten-year clock.

Section [XX](b)(5)

Section [XX](b)(5) provides that ''[s]ignificant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

Section [XX](c)

Section [XX](c) provides that unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title shall expire at the end of either (1) two calendar years after the year that this proposed rule first becomes effective, (2) ten calendar years after the Year of the Regulation's Promulgation, or (3) ten calendar years after the last year in which the Department Assessed and (if Review of the Regulation is required pursuant to paragraph (d)) Reviewed the Regulation, whichever is latest. The last year in which the Department Assessed and (if Review of the Regulation is required) Reviewed the Regulation shall be the year during which the findings of the Assessment and, if required, the Review of the Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

In other words, the Department must Review all its Regulations (subject to the exceptions listed below) that have a significant economic impact upon a substantial number of small entities every ten years, or such Regulations shall expire. To determine which Regulations have a significant economic impact upon a substantial number of small entities, the Department must Assess all its Regulations (subject to the exceptions listed below) every ten years, or such Regulations shall expire if not Assessed. For Regulations that have already been in effect at the time this proposed rule goes into effect, the Department would have two years from this proposed rule's effective date, or ten years from the Regulation's promulgation, whichever is later, to conduct the Assessment and, if required, the Review. The Department believes all of its Regulations (subject to the exceptions listed below) should be Assessed and, if they have a significant economic impact upon a substantial number of small entities, Reviewed. Assessments and Reviews should not be performed only on those Regulations issued after this proposed rule goes into effect. After all, it is likely that some Regulations promulgated decades ago may have become outdated.[91]

Section [XX](c) makes clear that Department Regulations (subject to the exceptions listed below) shall expire if the Assessment and (if required) the Review are not timely performed on them. Both section 3(a) of the RFA and executive orders by multiple presidents over several decades direct the Department to devise plans to periodically review many of its regulations.[92] Although the Department retrospectively reviewed a very limited number of its regulations, it has not reviewed many of its regulations, notwithstanding that observers have over the decades noted that the Department has not always performed retrospective review to a satisfactory extent. Therefore, the Department has concluded that it is appropriate to impose on itself a stronger incentive to ensure it complies with the purposes animating the RFA and the executive orders, as well as to ensure its regulations are not unduly burdening the public. As a CRS report put it, ''[w]ithout some type of enforcement of the review requirement, agencies are unlikely to conduct many more reviews than have occurred pursuant to Section 610.'' [93] This is one reason why analyses

[90] 5 U.S.C. 551(4) (providing that '' 'rule' means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing'').

[91] *See, e.g.,* Office of Mgmt. & Budget, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, at 46–47 (2005) *http://perma.cc/R8LX-BQMJ;* Cynthia Morgan and Nathalie B. & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs,* 5 J. Benefit Cost Anal. no. 2, 2014, at 259–84 *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf.*

[92] The RFA and the Executive Orders direct agencies to review overlapping, but not identical, sets of regulations. The RFA directs agencies to have plans to review regulations that have a ''significant economic impact upon a substantial number of small entities.'' 5 U.S.C. 610. By contrast, Executive Order 12866 directed agencies to submit to OIRA programs to periodically review ''significant regulations.'' Exec. Order 12866, sec. 5(a). ''Significant regulations'' are not necessarily those that have a ''significant economic impact upon a substantial number of small entities.'' *Id.* at sec. 3(f) (defining ''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 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 this Executive order.''). Executive Order 13563 also directed agencies to review ''significant regulations.'' Exec. Order. 13563, sec. 6. The Department has proposed to Review those regulations that satisfy the RFA criteria, since those are the regulations that Congress directed agencies to have plans to review. The Department requests comment on whether additional regulations, such as significant regulations, should also be Reviewed.

[93] Curtis W. Copeland, Cong. Research Serv., RL32801, Reexamining Rules: Section 610 of the

Continued

have found that sunset provisions are an effective way to improve governance and reduce undue regulatory burdens.[94] States have imposed similar expiration dates for many of their regulations unless they are reviewed or readopted.

It complies with the APA to amend Regulations to add dates by which Regulations expire unless the Assessment and/or Review is timely performed. An agency can, through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date.[95] An agency can also provide that its regulations expire upon the occurrence of a condition.[96] That is what the Department is proposing in this proposed rule. To be sure, an agency generally must ''articulate a satisfactory explanation'' for its action, ''including a rational connection between the facts found and the choice made,'' and cannot ''entirely fail[] to consider an important aspect of the problem.'' [97] The Department anticipates that if a Regulation expires because the Department does not timely Review it, a litigant might object to the expiration on the grounds that the Department by definition did not ''articulate a satisfactory explanation'' or ''failed to consider an important factor,'' because in not performing a Review, the Department failed to consider any factors. The Department rejects such arguments. In this rulemaking, the Department is considering the important factors. It issues this notice of proposed rulemaking because, for the reasons described herein, the Department believes the benefits of retrospective review, and the need to strongly incentivize it, are so great that the risk of a Regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review in this manner. Forty years of experience since the RFA's enactment; the decades since relevant Executive Orders were enacted; and other Federal government efforts to spur the Department to conduct more retrospective reviews indicate that, absent such a forcing mechanism, the Department will not conduct as many retrospective reviews as desired.

The Department believes that the benefits of retrospective review also outweigh the burden from any additional work that the Department would be required to perform. The Department intends to timely Assess all its Regulations (and timely Review those it must Review), but has considered that there is some risk that a Regulation could expire because the Department failed to timely Assess or Review it. The Department proposes to mitigate this risk by setting up a website where, if the deadline for publishing an Assessment or Review is nearing and the Department has not yet announced that it has commenced the Assessment or Review, the public can submit a comment requesting that the Department begin the Assessment or Review. This requirement is described in more detail in the discussion of proposed Section [XX](g). Therefore, in this rulemaking process, which amends Department regulations through the notice-and-comment process, the Department is considering the important factors.

The Department proposes to perform the Assessment and (if required) the Review on each Regulation every ten years. Some states provide that, unless readopted or re-reviewed, their regulations expire in seven years,[98] while at least one state uses a ten-year time period.[99] The Department proposes to perform the Assessment and (if required) the Review every ten years, because ten years is the period listed in 5 U.S.C. 610. The Department has many Regulations, some of which are complex, so having to perform the Assessment and Review more than once every ten years could unduly burden the Department and increase the likelihood that a Regulation inadvertently expires because it is not Assessed or Reviewed.

The proposed rule would provide that Regulations promulgated more than ten years ago will expire at the end of two calendar years from the date this proposed rule, if finalized, becomes effective, unless the Assessment and (if required) the Review is performed on those Regulations. The Department believes that two years is a sufficient amount of time to conduct the initial Assessments and (if required) Reviews of those Regulations. The Assessments will be similar to, but not as burdensome as, the determinations made during rulemaking about whether a rule has a significant economic impact upon a substantial number of small entities. Assessments will be less burdensome because those performing the Assessments can in many instances benefit from the work already performed when the Regulation is initially promulgated. Likewise, the Reviews will be similar to the section 610 reviews that agencies currently perform. The Reviews will be less burdensome than regulatory impact analyses or regulatory flexibility analyses, because they are limited to assessing the five factors listed in 5 U.S.C. 610 and certain legal considerations. The regulatory flexibility analyses and regulatory impact analyses for HHS' rulemakings are typically performed in far less than two years. Therefore, even if this proposed rule increases substantially the volume of Assessments and Reviews to perform,[100] two years should be a sufficient amount of time to perform the Reviews that need to be performed during that time frame. This is discussed in more detail in the regulatory impact analysis below. The Department believes Regulations promulgated more than ten years ago should be Assessed and, if needed, Reviewed in fairly short order, since they are presumably generally the ones most likely to have become obsolete. The Department is interested in public

Regulatory Flexibility Act 11 (2008); *see also* Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 895–96 (2013) (setting forth possible reasons why agencies, even when they have adequate resources, may be reluctant to perform retrospective reviews).

[94] Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* (Mercatus Ctr., Working Paper No. 12–18 (2012), at 36); *Occupational Licensing: A Framework for Policymakers,* at 48–50 (July 2015).

[95] *See, e.g.,* Amendment to the Interim Final Regulation for Mental Health Parity, 70 FR 42276 (July 22, 2005) (amending interim final rule, to provide that ''the requirements of the MHPA interim final regulation apply to group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan during the period commencing August 22, 2005 through December 31, 2005. Under the extended sunset date, MHPA requirements do not apply to benefits for services furnished after December 31, 2005.''); *see generally Clean Air Council,* 862 F.3d at 9 (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking).

[96] *See, e.g.,* Control of Communicable Diseases; Foreign Quarantine 85 FR 7874, 7874 (Feb. 12, 2020 (providing that, unless extended, interim final rule ''will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of 2019–nCoV, or (2) when the Secretary determines there is no longer a need for this interim final rule''); Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 54820, 54820 (Sept. 2, 2020) (providing that an interim final rule applies ''for the duration of the [public health emergency] for COVID–19'').

[97] *Little Sisters of the Poor Saints Peter and Paul Home* v. *Pennsylvania,* 140 S. Ct. 2367, 2383–84 (2020) (quoting *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.,* 463 U.S. 29, 43 (1983)).

[98] *See, e.g.,* N.J.A.C 1:30–6.4 (regulations expire every seven years unless readopted, subject to certain exceptions); Ind. Code 4–22–2.5–2 (imposing seven-year expiration date on regulations unless readopted).

[99] N.C. Gen. Stat. 150B–21.3A.

[100] The Department has roughly 12,400 regulations that were promulgated more than ten years ago. *See* Enhancing Regulatory Reform Through Advanced Machine Learning Findings (internal HHS slide). Since many of these regulations were promulgated as part of the same rulemakings, the numbers of Reviews to be performed in two years is roughly a fifth this number.

comment on whether two years is an appropriate time period to Assess and (if required) Review Regulations promulgated more than ten years ago.

The Department has decided that all of its Regulations (subject to the exceptions listed below) should be periodically assessed to determine whether they have a significant economic impact upon a substantial number of small entities. Without performing the Assessment, the Department may not know which regulations have or will have a significant economic impact upon a substantial number of small entities. Due to changed circumstances, a regulation that did not have such an impact at the time it was promulgated may now have such an impact. The Department is also aware of literature suggesting that agencies have not been consistent in deciding which rules have a significant economic impact on a substantial number of small entities, or have avoided such a finding in order to avoid complying with the RFA's requirements.[101] By Assessing all of its Regulations (subject to the exceptions described herein) and publishing the results of the Assessments, the Department can avoid concern that the Department is failing to Assess or Review Regulations that have a significant economic impact on a substantial number of small entities.

The Department should in many cases perform a single Assessment (and, where required, a single Review) that considers all Regulations issued as part of the same rulemaking. That would generally make sense from an economic perspective, for the same reasons as why the Department in many cases does a single regulatory impact analysis on all Regulations that are issued as part of the same rulemaking. Such an approach is not only permissible, but is encouraged, under this proposed rule. It would in some cases be nonsensical to Assess or Review a Regulation in isolation from the other Regulations promulgated as part of the same or a related rulemaking. Indeed, 5 U.S.C. 605(c) provides that ''[i]n order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.'' Moreover, if a series of Regulations were issued as part of the same rulemaking and one of those Regulations was subsequently amended, the Department would in many cases take the view that the series of Regulations could be Assessed or Reviewed together for purposes of this proposed rule.

For Regulations that were issued in coordination with another Agency, that function in concert with another Agency's regulations, or that have a specific, direct impact on regulations issued by another Federal agency, the Department shall consult with that other Agency when undertaking the Assessment or Review, and consider the other Agency's views when considering the factors described in section [XX](d). An example of Regulations that have a specific, direct impact on regulations issued by another Federal agency are the Department's ACA regulations concerning the operation of Exchanges that affect eligibility for the advance premium tax credit. Such regulations have a specific, direct impact on Department of the Treasury regulations.[102]

The Department's understanding is that the decisions based upon Reviews, including the amendment, repeal, or affirmation of Regulations, will constitute final agency action. First, the decisions will mark the consummation of the agency's decisionmaking process with respect to whether a Regulation satisfies the criteria described in section [XX](d). Second, the decisions constitute action by which rights or obligations have been determined, or from which legal consequences will flow. This is because if the Review is not performed, the Regulation would expire.[103] Therefore, because the decisions based upon Reviews constitute final agency action, they must be performed in such a manner that they would withstand judicial review under the arbitrary and capricious standard.[104]

Similarly, if an Assessment concludes that a Regulation does not have a significant economic impact upon a substantial number of small entities, that would mark the consummation of the Department's decisionmaking process with respect to whether a Review must be performed on the Regulation. Such an Assessment's findings would also constitute action by which rights or obligations have been determined, or from which legal consequences will flow, because if the Assessment is not performed, the Regulation would expire. Therefore, Assessments must also be performed in such a manner that they would withstand judicial review under the arbitrary and capricious standard.

Section [XX](d)

Section [XX](d) provides that the Department is required to Review those Regulations that the Department Assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's Review shall consider (1) the continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules; (2) the nature of complaints or comments received concerning the Regulation from the public; (3) the complexity of the Regulation; (4) the extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation since the Regulation was promulgated or the last time the Regulation was Reviewed by the Department; (6) whether the Regulation complies with applicable law; and (7) other considerations as required by relevant executive orders and laws.

This largely mirrors the review described in 5 U.S.C. 610. It is also consistent with ACUS' recommendation that agencies ''consider whether the [existing] regulations are accomplishing their intended purpose or whether they might, to the extent permitted by law, be modified, strengthened or eliminated in order to achieve statutory goals more faithfully, minimize compliance burdens on regulated entities, or more effectively confer regulatory

[101] *See, e.g.,* Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 93–95, 99–101 (2015); Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1222–25 (2006).

[102] *See, e.g.,* 45 CFR 155.340 (regarding administration of advance payments of the premium tax credit and cost-sharing reductions and requiring the Exchange to comply with Treasury regulations).

[103] *See U.S. Army Corps of Engineers* v. *Hawkes Co., Inc.,* 136 S. Ct. 1807, 1813 (2016) (to have final agency action, ''First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow'' (quoting *Bennett* v. *Spear,* 520 U.S. 154, 177–78 (1997)).

[104] *See* 5 U.S.C. 704 (final agency action is reviewable); 5 U.S.C. 706 (a reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law).

benefits.'' [105] Prior to finalization, OIRA may review Reviews, including to coordinate inter-agency participation in the Review process where there are significant inter-agency equities or as otherwise appropriate.[106] For example, when Assessing or Reviewing Regulations that require Executive Order 12250 review and approval by the Attorney General, the Department will consult with the Department of Justice (DOJ) and provide a draft of the findings to DOJ well in advance of the Assessment or Review deadline, so that DOJ can review and approve prior to the publication of the findings. It may be appropriate for OIRA to coordinate this process.

Section [XX](d) provides that the Department shall consider the continued need for the Regulation, ''consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules.'' The quoted phrase is not found in 5 U.S.C. 610, but the Department includes it to clarify that determining the continued need for the Regulation includes determining the extent to which it defines terms or sets standards used in or otherwise applicable to other Federal rules. However, this is not meant to be the only factor the Department should consider when determining the continued need for the Regulation. The Department shall consider any factors that, for the particular Regulation, are relevant to determining whether there is a continued need for the Regulation.

In addition to this phrase, two factors listed in section [XX](d) are not found in 5 U.S.C. 610. The first is that section [XX](d) states that the Review should take into account ''whether the Regulation complies with applicable law.'' Since applicable law may have changed since the Regulation was promulgated, the Department wants to ensure that its Regulations are regularly reviewed to ensure that they comply with applicable law. Second, section [XX](d) states that the Review should take into account ''other considerations as required by relevant executive orders and laws.'' To the extent Executive Orders or laws enacted since section 610 require the Department to consider additional factors when performing retrospective review of particular regulations, the Department wishes to comply with those Executive Orders and laws. A recent Department of Transportation rule similarly required that agency, when periodically reviewing its regulations, to consider ''[o]ther considerations as required by relevant executive orders and laws.'' *See* 49 CFR 5.13(d)(2)(vi).

The Department anticipates that the Reviews would be similar to the section 610 analyses currently performed by agencies. The Reviews would benefit from real-world data and information gathered since the Regulation was promulgated to potentially discern the impact of the Regulation on small entities and on society more generally.

Section [XX](d) requires only that regulations that have a significant economic impact upon a substantial number of small entities be Reviewed, because those are the regulations that 5 U.S.C. 610 requires agencies have a plan to periodically review.

Section [XX](e)

Section [XX](e) provides that if the Review concludes that a Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the Review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

The Department includes this provision, because if the Review concludes that a Regulation should be amended or rescinded, the Regulation should in fact be amended or rescinded. The Department believes that two years will generally be an adequate amount of time to amend or rescind a Regulation, since the Department has already conducted a Review of the Regulation. In circumstances where amendment is not feasible within that time period, the Secretary can so certify in a statement published in the **Federal Register** and extend the completion date by one year at a time for a total of not more than five years.

When the Review determines that a Regulation should be amended or rescinded, the Department would, on a case-by-case basis as appropriate, use enforcement discretion to not enforce the Regulation or a portion of the Regulation until it is amended or rescinded. This is because in many cases the Department would not want to enforce Regulations (or portions of Regulations) that it determines should be amended or rescinded. The Department notes that enforcing a Regulation deemed to require amendment or rescission in some cases raises concerns about whether such enforcement is arbitrary and capricious. Continuing to enforce the Regulation (or portions thereof) would arguably ''run[ ] counter to the evidence before the agency.'' [107]

Section [XX](f)

Next, section [XX](f) provides that the results of all Assessments and Reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which Assessments and Reviews were conducted during that calendar year. The document shall also specify the year by which the next Assessment (and, if required, the next Review) of the Regulation shall be completed.

The Department includes this requirement so that both the Department and the public can readily know which Regulations were Assessed and Reviewed each year. If Assessments and Reviews were published in disparate places throughout the year, it could become extraordinarily difficult for both the Department and the public to know which Regulations were Assessed and Reviewed each year. Section [XX](f) will enable both the Department and the public to look in one place to know which Assessments and Reviews were conducted each calendar year, and know the findings of those Assessments and Reviews.

When publishing the findings of an Assessment or Review, the Department should include the full underlying analyses and data used to support the results, subject to any applicable privilege, protections for confidential business information, or explicit prohibition on disclosure. This will increase transparency and permit the public to see how the Department reached its conclusion. By requiring publication of the Reviews and the underlying analyses and data, the Department also incorporates ACUS' suggestion that ''[a]gencies should

[105] Administrative Conference of the United States, Recommendation 2014–5, 79 Fed. App'x—Recommendations of the Administrative Conference of the United States, 79 FR 75114, 75117 (Dec. 17, 2014).

[106] OIRA may also coordinate inter-agency participation in the Assessment process where there are significant inter-agency equities or as otherwise appropriate.

[107] *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983).

disclose relevant data concerning their retrospective analyses'' so as to ''allow private parties to recreate the agency's work and to run additional analyses concerning existing rules' effectiveness.'' [108]

The Department does not believe that the deliberative process privilege would generally bar disclosing the final underlying analyses and data referred to in section [XX](f).[109]

Section [XX](f) also provides that the document published in the **Federal Register** shall specify the year by which the next Assessment (and, if required, the next Review) of the Regulation shall be completed. This can be particularly helpful if the Department conducts an Assessment or Review of a Regulation prior to the deadline year.

Section [XX](g)

Section [XX](g) provides that paragraph (c) of the proposed rule shall not apply to Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For such Regulations that are adopted after the effective date of this section, the Federal law described shall be cited in the notice of adoption. Section [XX](g) also provides that paragraph (c) of the proposed rule shall not apply to (1) Regulations whose expiration pursuant to this section would violate any other Federal law; (2) this section; (3) Regulations that involve a military or foreign affairs function of the United States; (4) Regulations addressed solely to internal agency management or personnel matters; (5) Regulations related solely to Federal Government procurement; and (6) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

Section [XX](g)(1) excepts Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. This is only the case in rare circumstances. Because the Department lacks discretion over what is contained in these Regulations and cannot rescind them, they are exempted from section [XX](c). For such Regulations that are promulgated after the effective date of this proposed rule, the Department shall describe in the Regulation's notice of adoption the Federal law that results in the Department having no discretion as to whether to promulgate the Regulation and what is prescribed by the Regulation. The proposed rule includes this requirement so the public has notice that such Regulations are exempt from section [XX](c).

Section [XX](g) likewise also exempts from section [XX](c) any Regulation whose expiration pursuant to this section would violate any other Federal law. The exceptions listed in sections [XX](g)(1) and [XX](g)(2) are not satisfied simply because the statutory authority for the Regulation provides that the Secretary ''shall'' prescribe regulations. For example, section 804(b) of the Federal Food Drug & Cosmetic Act, 21 U.S.C. 384(b), provides that the ''Secretary, after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection, *shall* promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States'' (emphasis added). However, although the statute was enacted in 2003, as of January 1, 2020 the Department had not issued any regulations implementing it, indicating the Department's view that section 804(b) did not require the Department to issue regulations. Similarly, Section 1102 of the Social Security Act, 42 U.S.C. 1302, provides that the Secretary ''*shall* make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he] is charged under this Act'' (emphasis added). But the Department does not believe every regulation promulgated pursuant to section 1102 is required to have been issued, or that it would violate Federal law to rescind such regulations.

Section [XX](g) also exempts this proposed rule from section [XX](c). Assuming that no rules expire due to lack of Assessment or Review, this proposed rule cannot, absent other actions, directly impose on the public costs that exceed benefits, since this proposed rule merely requires the Department to periodically Assess and, in some cases, Review its Regulations. Only the failure to perform an Assessment or Review in the future could theoretically impose on the public costs that exceed benefits (assuming expired Regulations were on balance benefiting the public). This proposed rule would improve the Department's Regulations by requiring the Department to evaluate the impact of its Regulations and amend or rescind those Regulations with a significant economic impact upon a substantial number of small entities that the Department determines should be amended or rescinded. Therefore, the rationale for periodic review does not apply to this proposed rule to the extent it applies to other Department regulations. The Department realizes that certain members of the regulated community might rely on particular regulations, but the Department will take that into account when performing Assessments and Reviews. The Department would only determine that a Regulation should be amended or rescinded if the Regulation's burdens outweigh these reliance interests and the other benefits of the Regulation or if other factors, such as a change in law, might compel amendment or rescission. The Department does not intend to avoid Assessing or, if required, Reviewing any Regulation and does not anticipate that an important Regulation would expire due to failure to Assess or Review it. Moreover, the Department anticipates that the public would remind the Department to perform the Assessment or Review if the deadline is nearing and the Department has not yet commenced the Assessment or Review.[110] Accordingly, the Department proposes to exempt this proposed rule from Section [XX](c).

Section [XX](g) also exempts Regulations that involve a military or foreign affairs function of the United States. For purposes of this proposed rule, ''a military or foreign affairs function of the United States'' shall have the same meaning as that phrase has under 5 U.S.C. 553(a). Regulations that involve a military or foreign affairs function of the United States are exempted from this proposed rule for the same reasons that Congress exempted them from the requirements of 5 U.S.C. 553.

Section [XX](g) also exempts Regulations addressed solely to internal agency management or personnel matters and Regulations related solely to

[108] 79 FR 75114, 75117 (Dec. 17, 2014); *see also* Exec. Order 13563, sec. 6(a) (Jan. 18, 2011) (''retrospective analyses, including supporting data, should be released online whenever possible''). Although this proposed rule incorporates several ACUS' recommendations, it does not incorporate all of them. This proposed rule does not set forth a prioritization scheme. That is in part because it is difficult to determine which regulations should be prioritized without having performed Reviews. HHS also invites public comment on how best to integrate retrospective review into new rulemakings, which was another ACUS recommendation.

[109] *See, e.g., Coastal States Gas Corp.* v. *Dep't of Energy,* 617 F.2d 854, 866 (D.C. Cir. 1980) (''[E]ven if the document is predecisional at the time it is prepared, it can lose that status if it is adopted, formally or informally, as the agency position on an issue or is used by the agency in its dealings with the public.'').

[110] *See* the discussion of section [XX](h) *infra.*

Federal Government procurement. Because such Regulations do not directly impact the public, the rationale for retrospective review is weaker with respect to these Regulations.[111]

Section [XX](g) also exempts any Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency. This is because the Department cannot on its own rescind or amend a Regulation issued jointly with another Federal agency. An example of a regulation issued in consultation with other agencies because of a legal requirement to consult with that other agency is section 104 of the Health Insurance Portability and Accountability Act, which directs the Secretaries of HHS, Labor and the Treasury to ensure that regulations issued pursuant to provisions where the Secretaries share interpretive jurisdiction (which includes many of the provisions in Title XXVII of the Public Health Service (PHS) Act) are administered to have the same effect at all times.[112]

The Department considered excepting additional Regulations, but wanted to limit the exceptions to Regulations that legally cannot be rescinded, are otherwise being periodically reviewed by the Department, do not substantially impact the public, or have a very strong countervailing policy. The exceptions listed herein are the only ones the Department tentatively believes satisfy these criteria. The Department seeks comment on whether to retain all these exceptions in a final rule or whether to add additional exceptions.

Section [XX](h)

Section [XX](h) provides that when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the Regulation(s) whose Assessment or Review it is commencing. The public will be able to submit comments regarding these Regulation(s) in the manner specified on this website. Members of the public can also submit comments in the manner specified on the website requesting that the Department begin the Assessment or Review of a Regulation, particularly if they are concerned that the deadline is nearing and the Department has not stated that it has commenced the Assessment or Review.

The Department includes this provision so that, when the Department is Assessing or Reviewing a Regulation, the public can submit comments for the Department's consideration. The Department believes this will maximize transparency, public participation, and the Department's knowledge of the real-world impacts of its Regulations.

The Department also proposes in this provision to allow the public to submit a comment on the website requesting that the Department begin the Assessment or Review of a Regulation. The Department has considered the risk that a Regulation could expire because the Department inadvertently did not Assess or Review it. The Department proposes to mitigate this risk by allowing members of the public to submit comments requesting that the Department commence the Assessment or Review of a Regulation. If a person is concerned that the Department has not announced the Assessment or Review of a Regulation and the deadline is nearing, the person can remind the Department to conduct the Assessment or Review.

The Department intends to timely Assess and, where required, Review all its Regulations. The Department notes, however, that if it has not announced that it is Assessing or Reviewing a Regulation, and the deadline is nearing, those who rely on the Regulation are on notice that it might expire, just as the public is on notice that a regulation might be rescinded when an agency issues a notice of proposed rulemaking to rescind the regulation.

Section [XX](i)

Lastly, this proposed rule includes a severability clause. The Department believes this proposed rule fully complies with applicable law, but does not wish to see the entire proposed rule vacated in the event that a portion of it is vacated. For example, the Department does not wish to see this entire proposed rule vacated because one of the exceptions listed in section [XX](g) is invalidated. However, the Department requests comment on whether the amendments to add expiration dates should be severable from other portions of the proposed rule, including the requirements to perform Assessments and Reviews. It is not clear that this proposed rule could properly function without the expiration dates, so the Department requests comment on this.

V. Request for Comment

HHS requests comment on all aspects of this notice of proposed rulemaking, including its likely costs and benefits. HHS is particularly interested in comments on:

- Whether the exceptions listed in section [XX](g) should be retained in the final rule.
- Whether the exceptions listed in section [XX](g), if worded as they currently are, will lead to uncertainty and litigation and, if so, how they should be revised.
- Whether additional exceptions should be included in section [XX](g).
- Regulations of particular importance that HHS needs to ensure are Assessed or Reviewed so they do not expire.
- Whether the Review should consider, in addition to the factors listed in 5 U.S.C. 610, whether the Regulation remains cost-effective and/or cost-justified. If so, how should the Department determine if a Regulation is cost-effective and/or cost-justified?
- When the Department performs a Review and determines that a Regulation should be amended or rescinded, what course of conduct should the Department take during the interim period before the Regulation is amended or rescinded? For example, should the final rule mandate that such a regulation cannot be enforced prior to amendment or rescission; should the Department determine whether to exercise enforcement discretion on a case-by-case basis; should the Department continue to enforce the Regulation in the same manner as prior to the Review; or should the Department follow a different course of conduct?
- If, when the Review concludes that a Regulation should be amended or

[111] The portion of the proposed rule applying to Title 42 also exempts 42 CFR 1001.952 from expiration. 42 CFR 1001.952 provides a safe harbor for various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. The Department exempts this regulation because it is concerned that certain otherwise permissible behavior could become criminal simply because the Department did not Review this Regulation. The portion of the proposed rule applying to Title 42 also exempts 42 CFR part 73. 42 U.S.C. 262a provides that, with respect to Part 73, the ''Secretary shall review and republish [a list of certain biological agents and toxins] biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.'' Since those regulations are already being reviewed biennially, there is no need for this proposed rule to apply to 42 CFR part 73. Similarly, the portion of the proposed rule applying to Title 42 also exempts the annual Medicare Part A and Part B payment methodology update rules. Since these are amended annually, it does not make sense to Review them every ten years. Lastly, the portion of the proposed applying to Title 42 also exempts 42 CFR 100.3, since the statutory basis for this regulation provides that it cannot be amended unless (1) a proposed regulation is provided to the Advisory Committee on Childhood Vaccines (ACCV) and the ACCV is provided at least 90 days to make recommendations and comments, and (2) there is subsequently a 180-day public comment period. *See* 42 U.S.C. 300aa–14(c).

[112] *See* Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, 110 Stat. 1978.

rescinded, should the Secretary be allowed to extend the completion date for amendment or rescission beyond two years? If extensions are permitted, should the Secretary be allowed to extend the completion date by one year at a time for a total of not more than five years, or should he be permitted to extend for a shorter or longer period of time?

- Whether the Department should Review a different set of regulations than those that have a significant economic impact upon a substantial number of small entities (*i.e.,* whether it should Review all Department regulations; those that were, upon issuance, designated significant under Executive Order 12866; those that have a significant adverse economic impact upon a substantial number of small entities; or some other group). If the Department reviews a different set of regulations, should it review them using the criteria described in 5 U.S.C. 610(b) or different criteria, such as the criteria described in section 5(a) of Executive Order 12866?
- How best to integrate plans for retrospective review into new rulemakings.
- What timeframe to use when Assessing or Reviewing Regulations, and whether the timeframe should vary based on how old the Regulation is.
- What the baseline should be when Assessing or Reviewing Regulations, and what factors to consider when determining the baseline.
- Any other factors that would improve the rigor or methodology of the Assessments or Reviews.
- The regulatory impact of this proposed rule.
- The impact of this proposed rule on small entities, as that term is defined in the RFA.
- How this proposed rule, if finalized, should be designated under Executive Order 13771.

VI. Regulatory Impact Analysis

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 and not prohibited by statute, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation (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. OMB has designated this rule as economically significant for the purposes of Executive Orders 12866 and 13563. This proposed rule's designation under Executive Order 13771 will be informed by comments received.

Section 5 of Executive Order 12866 requires agencies to submit to the Office of Information and Regulatory Affairs (OIRA) a plan to periodically review their existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and principles. Section 6 of Executive Order 13563 similarly requires agencies to submit to OIRA a plan to periodically review their existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.

This proposed rule would require the Department to assess whether its regulations have a significant economic impact upon a substantial number of small entities, and periodically review the impacts of such regulations using the criteria listed in section 3(a) of the RFA (as well as determine whether such regulations comply with applicable law).

The need for a Department-wide regulatory review process is also supported by the Department's regulatory reform project, which piloted an approach to augment expert policy insights with AI-driven data analysis. Machine learning surfaced a number of potential reform opportunities, identifying over 1,200 CFR section citations that merited consideration for reform and 159 CFR sections that could benefit from regulatory streamlining based on their similarities to other sections.[113] The project also uncovered that 85% of Department regulations created before 1990 have not been edited, and the Department has nearly 300 broken citation references in the CFR (*i.e.,* CFR sections that reference other CFR sections that no longer exist). Without a clear process for periodically reviewing these regulations, there is no guarantee that regulations will be reviewed and revised (if needed) to align with technological, economic, and other developments. (*Supra* Section II.)

This proposed rule would result in the Department assessing which of its regulations have a significant economic impact upon a substantial number of small entities, and Reviewing those regulations to determine whether they should be continued without change, amended, or rescinded. Where the Review determines that the Department's Regulations should be continued without change, those Regulations will be maintained in their current form. Where the Review determines that, based upon current data and information, the Regulation should be amended or rescinded, the Department will begin rulemaking to amend or rescind the Regulation. Thus, Regulations that have become outmoded will be amended or rescinded, whereas those Regulations that satisfy the Review criteria will be maintained. The Department believes it can complete Reviews for all Regulations that are more than ten years old in the proposed two-year timeframe. However, the Department recognizes that there is a risk that a Regulation whose benefits outweigh its costs could expire because the Department failed to Assess or Review it. The Department believes that risk may be lowered by members of the public reminding the Department if the Assessment or Review deadline is nearing and the Department has not commenced the Assessment or Review of a Regulation.

The Department recognizes that this proposed rule requires the Department to undertake certain tasks. But the Department believes that retrospective review of regulations should be a priority, and is willing to commit the necessary resources towards performing the Assessments and Reviews. Moreover, in assessing the burdens of this proposed rule on the Department, it is important to note that the Department

[113] Regulatory Streamlining & Analysis, at 11 (Mar. 2019).

is already required to periodically review its regulations that have a significant economic impact upon a substantial number of small entities. *See* 5 U.S.C. 610. Implicit in 5 U.S.C. 610 is the requirement to determine which regulations have a significant economic impact upon a substantial number of small entities. Therefore, the Review requirements in the proposed rule do not impose new burdens not already imposed on the Department, if incomplete compliance is not accounted for in the regulatory baseline. If the Department believes a Regulation is important enough to justify imposing its requirements on the public, the Department should be able to prioritize periodically assessing the Regulation's impact.

To obtain additional insight into the potential benefits, costs, and burdens of this proposed rule, the Department performed several analyses. First, it examined recently-completed actions that occurred as a result of the relatively rare section 610 reviews that the Department has performed:

TABLE—RECENTLY-COMPLETED ACTIONS AS A RESULT OF SECTION 610 REVIEWS

Name of rulemaking	CFR citation and RIN	Year	Regulatory changes made as a result of section 610 reviews
Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care.	42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494. RIN 0938–AT23	2019 (Final Rule)	Reformed Medicare regulations that were identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, and increased the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care. Updated fire safety standards for Medicare and Medicaid participating End-Stage Renal Disease (ESRD) facilities by adopting the 2012 edition of the Life Safety Code and the 2012 edition of the Health Care Facilities Code, and updated the requirements that hospitals and Critical Access Hospitals must meet to participate in the Medicare and Medicaid programs. Requirements were intended to conform to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.
Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies.	42 CFR Parts 409, 410, 418, 440, 484, 485 and 488. RIN 0938–AG81	2017 (Final Rule)	Revised the conditions of participation that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. The new requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements.
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities.	42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489. RIN 0938–AR61	2016 (Final Rule)	Revised the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety.

These results suggest that, if the Department performs additional Reviews, additional benefits will be achieved from revising and streamlining certain regulatory requirements.

The Department also performed the following analysis to estimate the costs and burdens to the Department from (1) assessing which Department regulations have a significant economic impact upon a substantial number of small entities, and (2) Reviewing those regulations.[114] The Department has roughly 18,000 regulations, the vast majority of which it believes would need to be Assessed.[115] Roughly 12,400 of these regulations are over ten years old.[116] The vast majority of these would need to be Assessed within two years if this proposed rule were finalized. But because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480.

To help estimate the impact of this proposed rule, the Department conducted a random sample [117] of its regulations and assessed whether the sampled regulations would be exempt from this proposed rule and whether, at the time of issuance, the regulations were: Economically significant; found to have a significant economic impact upon a substantial number of small entities (SEISNOSE); or subject to the

[114] The Department is generally already required to undertake reviews under 5 U.S.C. 610. The Department includes this analysis because it may be informative for the public to see an estimate of the costs and burdens of assessing which regulations have a significant economic impact upon a substantial number of small entities, and Reviewing the Regulations that have such an impact.

[115] *See* Enhancing Regulatory Reform Through Advanced Machine Learning Findings (internal HHS slide) (the sum of the numbers listed in the table under the column denoted ''#'' is 17,890 Department regulations).

[116] *See id.* (adding the figures listed in the ''#'' columns for the 1950s, 1960s, 1970s, 1980s, 1990s, and 2000s yields 12,383 regulations).

[117] With the aid of a random number generator, the Department selected Department regulations in the Code of Federal Regulations. The Department then reviewed the relevant rulemaking associated with the specific regulation selected and analyzed those rulemakings in view of the categories listed in the table.

Unfunded Mandates Reform Act of 1995. Also included in the table is the estimated impact of the regulations when they were first promulgated. The findings of this sample are below:

Title	Rulemaking	Citation	Exempt from this proposed rule?	Economically significant?	SEISNOSE?	Subject to UMRA?	Impact estimates at issuance
21	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products.	73 FR 63886	No	No	No	No	"[O]ne-time costs will range from approximately $38.0 million to $49.6 million and annual costs will range from $12.4 million to $46.3 million."[118]
21	Unique Device Identification System.	78 FR 58786	No	Yes	Yes	Yes	"Over 10 years, the estimated present value of the total domestic costs is $642.2 million using a 7 percent discount rate and $737.7 million using a 3 percent rate, and the annualized costs are $85.7 million using a 7 percent discount rate and $84.1 million using a 3 percent discount rate."[119]
21	Requirements for Foreign and Domestic Establishment Registration And Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs.	81 FR 60170	No	No	No	No	"We estimate one-time total costs of $59.7 million and recurring costs of $0.5 million. These costs represent total annualized costs of $9 million when calculated at a 7-percent discount rate over 10 years, and $7.5 million when calculated using a 3-percent discount rate. The largest cost elements will be for registrants reading and understanding the final rule and making changes to their standard operating procedures."[120]
21	Human Tissue Intended for Transplantation.	62 FR 40429	No	No	No	No	FDA confirmed "that the only economic impact of the rule would be related to recordkeeping burdens" that already existed.[121]
42	Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care.	70 FR 57368	No	Yes	No	No	"The Congress provided $142,000,000 for the loan program effective July 1, 2004 through September 30, 2008, and not more than $2,000,000 may be used for the administration of the loan program for each of the fiscal years (that is, 2004 through 2008)."[122]

Title	Rulemaking	Citation	Exempt from this proposed rule?	Economically significant?	SEISNOSE?	Subject to UMRA?	Impact estimates at issuance
42	Organ Procurement and Transplantation Network.	63 FR 16296	No	Yes	No	No	Although incremental effects attributable to the rule were not estimated, impact categories would have included life-years saved by non-renal organ transplants, quality of life improvements for kidney recipients, and the admittedly expensive costs of transplantation.[123]
42	Medicare Program; Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement.	53 FR 47199	No	No	No	N/A (rule issued prior to UMRA being enacted).	N/A: "We have determined that a regulatory impact analysis is not required for these rules because they would not have an annual impact of $100 million or more." [124]
45	Cooperation in Identifying and Providing Information To Assist States in Pursuing Third Party Health Coverage.	56 FR 8926	No	No	No	N/A (rule issued prior to UMRA being enacted).	"[T]he cost of implementation is expected to be insignificant." [125]
45	Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.	76 FR 53256	No	No	No	No	Estimated annual cost of $23,236,238.[126]
45	Rate Increase Disclosure and Review.	76 FR 29964	No	No	No	No	"CMS estimates that issuers will incur approximately $10 million to $15 million in one-time administrative costs, and $0.6 million to $5.5 million in annual ongoing administrative costs related to complying with the requirements of this final rule from 2011 through 2013. In addition, States will incur very small additional costs for reporting the results of their reviews to the Federal government, and the Federal government will incur approximately $0.7 million to $5.9 million in annual costs to conduct reviews of justifications filed by issuers in States that do not perform effective reviews." [127]

None of the sampled regulations would be exempt from this proposed rule. At the time the ten sampled regulations were promulgated, the Department believed that one of the ten had a significant economic impact upon a substantial number of small entities. If the Assessments' findings mirror the findings from the time of issuance, one of the ten sampled regulations would need to be Reviewed. Similarly, an academic study that found 11.1% of Department final rules issued in 1993 had a significant economic impact upon a substantial number of small entities.[128] A more recent study found that agencies exempted over 92% of their rules from the RFA.[129] If the Department has roughly 2,480 rulemakings that are more than ten years old, and roughly 11% have a significant economic impact upon a substantial number of small entities, the Department would need to perform roughly 273 Reviews [130] in the two years after this proposed rule is finalized. If the Department has roughly 3,600 total rulemakings and roughly 11% [131] have a significant economic impact upon a substantial number of small entities, the Department would have to perform roughly 396 Reviews in the ten years after this proposed rule is finalized.[132]

Of the 273 rulemakings subject to Reviews in the first two years, the Department estimates roughly 16%,[133] or 44, of those rulemakings were promulgated prior to the requirement for prospective regulatory flexibility analyses. As described further below, those 44 Reviews will require more Department resources than the estimated 229 Reviews of rulemakings promulgated after the prospective analysis requirement went into effect.

A. Costs Related to Section 610 Reviews of Regulations More Than Ten Years Old

The Department estimates that a total of between 20,160 and 44,900 hours will be spent on Reviews outside the Assessment process during the first two years, which will clear the backlog of section 610 reviews for regulations ten years old or older. The Department assumes 40 to 100 hours per Review for the estimated 229 Reviews for which an initial prospective analysis was performed. The Department assumes 250 to 500 hours per Review for the estimated 44 Reviews where no such initial prospective analysis was performed.

HHS estimates that the fully-loaded cost per hour to the Department to employ a person to conduct a Review or Assessment is $244.98 per hour (referred to as ''*LaborCost*'').[134] Accordingly, multiplying the 20,160 to 44,900 estimated hours by *LaborCost* yields an estimated cost of between roughly $4,938,797 to $10,999,602, or approximately 17.4 to 38.7 FTEs working at *LaborCost,* to initiate and conduct Reviews in the first two years if this proposed rule were finalized. Thus, the average cost per year in the first two years would be between roughly $2,469,399 and $5,499,801.

B. Costs Related to Rulemakings That ''Age In'' to Section 610 Review

For years three through ten after this proposed rule were finalized, the Department estimates it will require between 4,920 to 12,300 hours to Review the estimated 123 rulemakings that ''age in'' [135] to the section 610 review during that time period. The Department assumes those 123 Reviews would take between 40 to 100 hours per Review, as each of those rulemakings were promulgated after prospective regulatory analysis was required. Multiplying the estimated 4,920 to 12,300 estimated hours by *LaborCost* yields total costs of between roughly $1,205,302 and $3,013,254, or approximately 4.2 to 10.6 FTEs working at *LaborCost,* to conduct 123 Reviews in the eight years following the first two years if the proposed rule were finalized, *i.e.,* years 3 to 10.

C. Costs Related to Assessments

In addition to performing Reviews of rulemakings already deemed to have a SEISNOSE, the Department will allocate resources to conducting Assessments of its rulemakings to determine whether a Review is required. The Department believes each Assessment will require between three and 10 hours to perform. The Department estimates that it will have to conduct roughly 2,207 [136] Assessments in the first two years if this proposed rule were finalized, and an additional roughly 997 [137] Assessments in the subsequent eight years, for a total of 3,204 Assessments across ten years. As such, the Department believes 6,621 to 22,070 hours will be spent on Assessments in the first two years and 2,991 to 9,970 hours over the next eight years. Multiplying those hour estimates by *LaborCost* yields roughly $1,622,013 to $5,406,709, or approximately 5.7 to 19.0 FTEs working at *LaborCost,* to conduct 2,207 Assessments in the first two years, and roughly $732,735 to $2,442,451, or approximately 2.6 to 8.6 GS–15 FTEs working at *LaborCost,* to conduct 997 Assessments in the

[118] Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products, 73 FR 63886, 63892 (Oct. 28, 2008).

[119] Unique Device Identification System, 78 FR 58786, 58811 (Sept. 24, 2013).

[120] Requirements for Foreign and Domestic Establishment Registration And Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, 81 FR 60170, 60171 (Aug. 31, 2016).

[121] Human Tissue Intended for Transplantation, 62 FR 40429, 40442 (Jul. 29, 1997).

[122] Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care, 70 FR 57368, 57372 (Sept. 30, 2005).

[123] Organ Procurement and Transplantation Network, 63 FR 16296, 16321–29 (Apr. 2, 1998).

[124] Medicare Program; Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement, 53 FR 47199, 47201 (Nov. 22, 1988).

[125] Cooperation in Identifying and Providing Information To Assist States in Pursuing Third Party Health Coverage, 56 FR 8926, 8929 (Mar. 4, 1991).

[126] Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 FR 53256, 53280 (Aug. 25, 2011).

[127] Rate Increase Disclosure and Review, 76 FR 29964, 29978 (May 23, 2011).

[128] Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1218 (2006).

[129] Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 69 (2015).

[130] This figure is a bit high, since some of these regulations will be exempt from this proposed rule.

[131] The Department chooses 11%, rather than 8% or 10%, to err on the side of assuming a larger burden to the Department and because the study that found 11.1% of Department regulations had a significant economic impact upon a substantial number of small entities was focused solely on the Department's regulations.

[132] Roughly 273 of these would be performed in the first two years after this proposed rule were finalized, and the other 123 Reviews would occur in years 3–10. For purposes of this analysis, the Department assumes it will have to Review all Department regulations that the Department previously found had a SEISNOSE. If some of those regulations are determined to no longer have a SEISNOSE, the cost and burden to the Department would be less than estimated in this proposed rule.

[133] 16% is the percentage of Department regulations that are more than ten years old that were promulgated prior to 1980, when Congress passed the RFA.

[134] Here, the Department uses the reported ''FY 2021 average fully supported cost to [FDA of] $284,174 per FTE,'' divided by 1,160 ''Net Supported Direct FDA Work Hours Available for Assignments'' per year to arrive at $244.98 per hour. Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2021, 85 FR 46669, 46670 (Aug. 3, 2020).

[135] ''Age in,'' meaning that the rules become ten years old during years three through ten.

[136] 2,207 is derived from 2,480 Department rulemakings that are at least 10 years old minus the 273 rulemakings reviewed in years 1 and 2.

[137] 3,600 total rulemakings minus the 2,480 rulemakings that are over 10 years old yields 1,120 rulemakings that are left to be assessed during years 3–10. 123 of these rulemakings will be reviewed in years 3–10, leaving 997 rulemakings to be assessed (1,120 less 123 equals 997).

following eight years. Therefore, the Department estimates $2,354,748 to $7,849,160 will be incurred on Assessments in the first ten years if the proposed rule were finalized.

D. Costs Related to Review of Rulemakings Found to Have a SEISNOSE

Depending on the outcome of the Assessments, the Department may have to Review additional rulemakings. The Department estimates roughly 5% of Assessments of Regulations not initially found to have a SEISNOSE will conclude that a Review is required. The Department believes this is a reasonable estimate, because the 5% rate is roughly half of the percentage of all Department regulations the Department currently believes have a SEISNOSE. Accordingly, the Department estimates 110 [138] Reviews will be required in the first two years, and 50 [139] Reviews will be required in the subsequent eight years, for a total of 160 Reviews. During the first two years, the Department estimates the 110 Reviews will require 4,400 to 11,000 hours,[140] and that the 50 Reviews will require 2,000 to 5,000 hours in the subsequent eight years. Multiplying these hour estimates by *LaborCost* yields an estimated roughly $1,077,912 to $2,694,780, or 3.8 to 9.5 FTEs for post-Assessment Reviews in the first two years, and roughly $489,960 to $1,224,900, or 1.7 to 4.3 FTEs for post-Assessment Reviews in the subsequent eight years, for a total cost of $1,567,872 to $3,919,680 over ten years for post-Assessment Reviews.

E. Total Estimated Costs to the Department From Implementing This Rulemaking

In sum, the Department estimates a total cost of between roughly $10,066,719 to $25,781,696, or approximately 35.4 to 90.7 FTEs working at *LaborCost,* over ten years in order to do the following: (a) Clear the backlog of section 610 reviews for Department rulemakings more than ten years old that have never been subject to retrospective review in years 1 to 2, (b) conduct section 610 reviews of rulemakings that ''age in'' to section 610 review in years 3 to 10, (c) conduct Assessments of 3,204 rulemakings in years 1 to 10, and (d) conduct section 610 reviews of an estimated 160 rulemakings deemed to be subject to Review following an Assessment in years 1 to 10.[141] The cost in the first two years is estimated to be roughly $7,638,722 to $19,101,091, and roughly $2,427,997 to $6,680,605 in the following eight years. If the proposed rule were finalized, the Department estimates a total investment of 26.9 to 67.2 FTEs in the first two years, and 8.5 to 23.5 FTEs in the subsequent eight years, each FTE working at *LaborCost.* The Department estimates the annual cost of conducting Assessments and Reviews of between roughly $1,006,672 to $2,578,170 per year over ten years.

As noted above, the Department estimates one Review will take between 40 and 100 hours on average to perform. A full initial Regulatory Flexibility Act (RFA) analysis requires 250 to 500 hours to complete, because federal agencies must analyze the impact of their regulatory actions on small entities (small businesses, small non-profit organizations and small jurisdictions of government) and, where the regulatory impact is likely to be ''significant,'' affecting a ''substantial number'' of these small entities, seek less burdensome alternatives for them. This involves defining the market and determining costs for each small entity. The section 610 review is a more streamlined analysis because the regulatory flexibility analysis is the starting point, and it will focus on, in addition to certain legal considerations, 5 areas of analysis: (1) Whether there is a continued need for the rule, (2) whether there is duplication, (3) the number and nature of complaints, (4) the complexity of the regulation, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule. As such, the Department estimates that a Review will require significantly less time than a full RFA analysis.

The Department recognizes that some regulations were promulgated prior to when the requirement for prospective regulatory analysis went into effect, and that section 610 review of such rulemakings may be more time-intensive. The Department estimates 203 rulemakings will be subject to section 610 review where some prospective analysis has been performed, in which case such reviews will take 40 to 100 hours. HHS estimates it will undertake section 610 reviews of 39 rules for which no prospective regulatory review was performed. HHS assumes that between 250 to 500 hours may be required for these reviews, even though the section 610 review is more circumscribed than a full regulatory flexibility analysis and will therefore generally take less time to perform.

The Department also notes that there could be costs associated with publishing the notices of Assessments and Reviews to the Department's website for public comment, but that such costs will be minimal and would not require the hiring of additional personnel.

Alternatives Considered

The Department considered alternatives, including not issuing this proposed rule. But the RFA and certain Executive Orders direct the Department to periodically review certain Department regulations. Moreover, the literature suggests that in some cases the actual impacts of regulations differ from the projected impacts at the time of promulgation, so regulations should be periodically reviewed. The Department's experience over the last forty years suggests that, absent a strong incentive such as the potential expiration of a regulation, the Department will not review an adequate number of its regulations. The Department considered Reviewing all of its Regulations, but determined that that might be too burdensome. It also considered only Reviewing those regulations that, at the time of promulgation, the Department determined had a significant economic impact upon a substantial number of small entities. But such determinations were not made for regulations that precede the RFA, and some post-RFA regulations that did not have such an impact at the time of promulgation might have such an impact today. In addition, the Department is aware of literature suggesting that agencies have not been consistent in deciding which rules have a significant economic impact on a substantial number of small entities, or have avoided such a finding in order to avoid complying with the RFA's requirements.[142] Therefore, the Department proposes to Assess all of its Regulations (subject to the exceptions listed herein) to determine which have a significant economic impact upon a substantial number of small entities, and Review those Regulations using the criteria listed in 5 U.S.C. 610. The Department also considered reviewing

[138] Which is 5% of the 2,207 assessments done in years 1–2.

[139] Which is 5% of the 997 assessments done in years 3–10.

[140] Each review will take 40–100 hours to assess.

[141] In reality, the total cost will likely be less, since this analysis does not account for certain Regulations being exempt from the Assessment and Review requirements.

[142] *See, e.g.,* Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 93–95, 99–101 (2015); Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1222–25 (2006).

all significant regulations, as that term is defined in Executive Order 12866. The Department is proposing to Review those regulations that have a significant economic impact upon a substantial number of small entities, in order to hew closely to the RFA. But the Department requests comment on whether to also review additional regulations, such as those that are significant under Executive Order 12866.

The Department also considered including in the proposed rule an opportunity for the Department to extend the ten-year deadline to Assess or Review Regulations in certain circumstances. However, the Department decided against including such a provision. First, the RFA does not permit such an extension for rules issued after the RFA's enactment, even though it allows the Department to extend the time to complete the review of rules existing at the time of the RFA's enactment. *See* 5 U.S.C. 610(a). Second, ten years is a long time and the Department believes it affords adequate time to perform the Assessments and (where required) Reviews. The Department is concerned that if it granted itself extensions, that would cause the Department to have more work to do in future years and therefore require it to grant extensions to Assess or Review Regulations whose expiration dates are in subsequent years. This could become a vicious cycle.[143]

Regulatory Flexibility Act

The Department has examined the economic implications of this proposed rule as required by the RFA (5 U.S.C. 601–612). The RFA generally requires that when an agency issues a proposed rule, or a final rule pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. 5 U.S.C. 603, 604. Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. 601(3)–(6). Except for such small government jurisdictions, neither State nor local governments are ''small entities.'' Similarly, for purposes of the RFA, individual persons are not small entities. The requirement to conduct a regulatory impact analysis does not apply if the head of the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). The agency must, however, publish the certification in the **Federal Register** at the time of publication of the rule, ''along with a statement providing the factual basis for such certification.'' *Id.* If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA's waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the **Federal Register** at the time of promulgation or, if the rule is promulgated in response to an emergency that makes timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. 604(a), 608(b).

The Department considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. Department regulations impact at least NAICS industry sectors 11, 31–33, 42, 44–45, 48–49, 52, 54, 62, 81, and 92.

This proposed rule would require the Department to review its existing regulations (subject to certain exceptions) that have a significant economic impact upon a substantial number of small entities using the criteria described in the RFA. To the extent that the review determines that the criteria described in section 3(a) of the RFA favor rescinding or amending a regulation, HHS would do so. Thus, this proposed rule is not expected to impose direct burdens on small entities, as defined in the RFA. In the event that the Department does not announce that it has commenced an Assessment or Review, there may be some burden on small entities associated with requesting that the Department perform an Assessment or Review. The Department assumes that regulated entities would already be familiar with any regulations that they would not want to expire, and thus the burden associated with the request to perform an Assessment or Review would be minimal. The Department seeks comment on this assumption. Any other burdens on small entities would result from future actions independent of this proposed rule (*i.e.* the determination that a regulation should be amended or rescinded based on the RFA review criteria and other legal considerations).

The indirect costs and benefits from this proposed rule cannot be fully determined until the Department performs the Reviews of its Regulations and determines their present-day impacts. However, the Department believes that the benefits to small entities from this proposed rule will outweigh its costs to them. When the Department first promulgates regulations, it often has to speculate about the economic impact of the regulations on small entities. After a regulation has been in place for years, however, the Department will be able to learn from the real-world impacts of its regulations and minimize any significant economic impact of the regulations on a substantial number of small entities and promote simplification. To the extent this proposed rule resulted in amendment or rescission of a Regulation, the Department would be doing so to minimize any significant economic impact upon a substantial number of small entities. Moreover, the Department anticipates that any amendment or rescission undertaken by the Department in response to the reviews would be conducted in a manner that complies with the RFA. For the same reasons, this proposed rule would minimize any significant economic impact on a substantial number of small rural hospitals.

The Department recognizes that there is a risk that small entities could be adversely impacted if a Regulation that has a positive economic impact on small entities expires because the Department failed to Review it. But the Department believes that risk is low, particularly since members of the public will remind the Department if the Review deadline is nearing and the Department has not commenced the Review of a Regulation that the public believes is important or beneficial.[144] Even if a Regulation with

[143] Section [XX](c) proposes to allow the Department to extend the deadline to amend or rescind Regulations that the Department concludes should be amended or rescinded. The Department does so in part because the vicious cycle concern does not apply with equal force to such circumstances. That is because the Department expects that only a subset of its Regulations will need to be amended, whereas the Review Assessment must be performed on nearly all of the Department's Regulations. In addition, the universe of Regulations to be Reviewed will presumably be larger than the universe of Regulations to amend or rescind.

[144] While the Department does not anticipate that every small entity will closely monitor the Department-managed website, the Department believes that for Regulations that have a truly significant impact on small entities, at least one

Continued

a positive economic impact on small entities somehow expired because the Department did not Review it, the Department believes such costs are far outweighed by the benefits achieved by periodically Reviewing Regulations and amending or rescinding those determined to no longer be appropriate based on current data and information. In addition, both the hearings that spurred passage of the RFA and subsequent data suggest that regulations tend to disproportionately burden small entities.[145] To the extent this is the case, any rescission could very well benefit small entities. Moreover, the opportunity for small entities to comment on Regulations during the Review process will enable the Department to better assess the economic impacts of its Regulations on small entities and minimize any significant economic impacts that its Regulations are having upon a substantial number of small entities. The Department realizes that this proposed rule, if finalized, could result in some uncertainty for small entities in that there is a possibility that a regulation could expire. However, small entities will be on notice that a regulation could expire if the Review deadline is nearing and the Department has not announced that it has commenced the Review of the regulation. Moreover, there is always some risk that any particular regulation could be rescinded.

Therefore, the Department believes the benefits from the widespread retrospective reviews to minimize the substantial economic impact upon a significant number of small entities that would result from this proposed rule would far outweigh the costs from any uncertainty resulting from this proposed rule. Small entities may incur additional costs if the regulatory environment turns out to be different than anticipated.

As a result, the Department has determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small entities.

The Department seeks comment on this analysis of the impact of the proposed rule on small entities and small rural hospitals, and the assumptions that underlie this analysis.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a 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 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $154 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The Department has preliminarily determined that this proposed rule is not expected to result in expenditures by State, local, and tribal governments, or by the private sector, of $154 million or more in any one year. The Department seeks comment on this determination. This proposed rule would establish a requirement for the Department to periodically assess and, in some cases, review its regulations. Accordingly, the Department has not prepared a budgetary impact statement. The Department has nonetheless in this proposed rule addressed regulatory alternatives that it considered.

National Environmental Policy Act (NEPA)

HHS has determined that the proposed rule will not have a significant impact on the environment.

Executive Order 12988: Civil Justice Reform

HHS has reviewed this rule under Executive Order 12988 on Civil Justice Reform and has determined that this proposed rule complies with this Executive Order.

Executive Order 13132: Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct costs on State and local governments or has federalism implications. The Department has determined that this proposed rule does not impose substantial direct costs on State and local governments or have federalism implications as defined in Executive Order 13132. The proposed rule requires the Department to periodically review certain of its regulations, and provides that if the regulations are not reviewed by a certain date, they will expire. Any rescission of a regulation would only occur because of acts independent of this proposed rule—either the findings of a Review determining a regulation should be amended, or a failure to perform an Assessment or Review. Thus, this proposed rule would impose no substantial direct costs on State and local governments.

The Department notes, though, that the proposed rule might, if finalized, indirectly have beneficial federalism implications. Among other things, the Reviews called for by this proposed rule require the Department to determine if its regulations overlap, duplicate or conflict with State and local government rules and, if so, to consider that when determining whether to amend or rescind the regulations. If a Review conducted pursuant to this proposed rule were to find that a Department regulation should be amended or rescinded, the Department would comply with Executive Order 13132 in amending or rescinding the regulation.

The Department requests comment on this analysis.

Plain Writing Act of 2010

Under the Plain Writing Act of 2010 (Pub. L. 111–274, October 13, 2010), executive departments and agencies are required to use plain language in documents that explain to the public how to comply with a requirement the federal government administers or enforces. The Department has attempted to use plain language in promulgating this proposed rule, consistent with the Federal Plain Writing Act guidelines.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998) requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being. Section 601 (note) required agencies to assess whether a regulatory action (1) impacted the stability or safety of the family, particularly in

affected small entity, or small entity trade association(s), would.

[145] *See, e.g., Regulatory Reform: Hearings on S. 104, S. 262, S. 755, S. 1291 Before the Subcomm. on Admin. Practice & Procedure of the Comm. on the Judiciary,* 96th Cong. 3–4 (1979) (statement of Peter J. Petkas, Director, The Regulatory Council) (describing the disproportionate impact on small businesses and uncertainty about benefits resulting from burdensome regulations); 142 Cong. Rec. 3881 (1996) (statement of Sen. Bond) (''The SBA chief counsel for advocacy released a report that said that small businesses bear a disproportionate share of the regulatory burden.''); Nicole V. Crain & W. Mark Crain, *The Impact of Regulatory Costs on Small Firms,* (U.S. Small Bus. Admin., Office of Advocacy, Washington, DC), at 55, 57 (2010) (finding that ''regulations cost small firms an estimated $10,585 per employee. Regulations cost medium-sized firms $7,454 per employee, and large firms $7,755 per employee,'' and that in the health care sector, the cost per employee is 45 percent higher in small firms than in medium-sized firms, and 28 percent higher in small firms than in large firms).

terms of marital commitment; (2) impacted the authority of parents in the education, nurturing, and supervision of their children; (3) helped the family perform its functions; (4) affected disposable income or poverty of families and children; (5) was justified if it financially impacted families; (6) was carried out by State or local government or by the family; and (7) established a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society.

This proposed rule would amend Department Regulations to add dates by which they would expire unless the Department periodically reviews the Regulations using certain criteria. Standing alone, absent the failure to perform a Review, this proposed rule would have no direct impact, other than resulting in the Department amending or rescinding Regulations that it determines do not satisfy the Review criteria.

If the family well-being determination requirement were still in force, the Department assumes that the benefits to the public, including families, that flow from periodic Reviews of Regulations far outweigh any potential adverse impact on family well-being that might result from a Regulation expiring because the Department did not Review it. The Department believes that impacted families benefit greatly when a regulatory body considers the real-world impacts of its regulations, and whether changes in technology, the economy, or the legal landscape counsel in favor of amending or rescinding regulations. It is conceivable that a Regulation affecting the disposable income or poverty of families or children could expire. It is also possible that the expiration of a Regulation that the Department does not Review could have beneficial impacts on family well-being.

Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), HHS has reviewed this proposed rule and has determined that there are no new collections of information contained therein.

List of Subjects

21 CFR Part 6

Administrative practice and procedure.

42 CFR Part 1

Administrative practice and procedure.

42 CFR Part 404

Administrative practice and procedure.

45 CFR Part 6

Administrative practice and procedure.

For the reasons set forth in the preamble, the Department amends 21 CFR, chapter I, 42 CFR chapters I and IV and 45 CFR subtitle A as follows:

Title 21—Food and Drugs

■ 1. Add 21 CFR part 6 to read as follows:

PART 6—REVIEW OF REGULATIONS

Sec.

Authority: 5 U.S.C. 301; 15 U.S.C. 402, 409, 1261–1276, 1333, 1451–1461, 4402; 18 U.S.C. 1905; 19 U.S.C. 1490–1491, 2531–2582; 21 U.S.C. 321–394, 679, 802, 811–812, 821–831, 842, 875, 877, 951–958, 965, 971, 1034; 28 U.S.C. 2112; 35 U.S.C. 156; 42 U.S.C. 201–263, 263a, 263b–264, 265, 300aa–28, 300u through 300u–5, 300aa–1, 300aa–28, 4321, 7671 *et seq.;* Pub. L. 113–54; Pub. L. 111–353, 124 Stat. 3885, 3889; Pub. L. 111–31, 123 Stat. 1776; Pub. L. 108–155; Pub. L. 107–188, 116 Stat. 594, 688–690; Pub. L. 107–109; Pub. L. 105–115, 111 Stat. 2322, 5 U.S.C. 610.

§ 6.1 Retrospective review of existing regulations.

(a) This section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in this title.

(b) For purposes of this section:

(1) ''Assess'' shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) ''Review'' shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Regulations upon a substantial number of small entities.

(3) ''Regulation'' shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.

(4) ''Year of the Regulation's promulgation'' shall mean the year the Regulation first became effective, irrespective of whether it was subsequently amended.

(5) ''Significant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

(c)(1) Unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title shall expire at the end of:

(i) Two calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Regulation's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Regulation is required pursuant to paragraph (d)) reviewed the Regulation, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Regulation is required) reviewed the Regulation shall be the year during which the findings of the assessment and (if required) the review of a Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

(d) The Department is required to review those Regulations that the Department Assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's Review shall consider the following factors—

(1) The continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the Regulation from the public;

(3) The complexity of the Regulation;

(4) The extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the Regulation since the Regulation was promulgated or the last time the Regulation was reviewed by the Department;

(6) Whether the Regulation complies with applicable law; and

(7) Other considerations as required by relevant executive orders and laws.

(e) If the review concludes the Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

(f) The results of all assessments and eviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Regulation shall be completed.

(g) Paragraph (c) of this section shall not apply to

(1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For Regulations described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Regulations whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Regulations that involve a military or foreign affairs function of the United States.

(5) Regulations addressed solely to internal agency management or personnel matters.

(6) Regulations related solely to Federal Government procurement.

(7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Regulation(s) whose assessment or review it is commencing. The public will be able to submit comments regarding the Regulation(s) in the manner specified on this website. The public can also submit comments in the manner specified on the website requesting that the Department assess or review a Regulation.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 6.2 through 6.5 [Reserved].

Title 42—Public Health

■ 2. Add 42 CFR part 1 to read as follows:

PART 1—REVIEW OF REGULATIONS

Sec.

Authority: 5 U.S.C. 301, 42 U.S.C. 216, 42 U.S.C. 300a–4, 42 U.S.C. 10801, 42 U.S.C. 1302, 42 U.S.C. 702(a), 42 U.S.C. 702(b)(1)(A), 42 U.S.C. 706(a)(3), 42 U.S.C. 247b, 247c, 31 U.S.C. 1243 note, 42 U.S.C. 254c, 42 U.S.C. 262a, 42 U.S.C. 264–271, 42 U.S.C. 290aa(m), 42 U.S.C. 284g, 42 U.S.C. 285a–6(c)(1)(E), 42 U.S.C. 285a–7(c)(1)(G), 42 U.S.C. 285b–4, 42 U.S.C. 285c–5, 42 U.S.C. 285c–8, 42 U.S.C. 285d–6, 42 U.S.C. 285e–2, 42 U.S.C. 285e–3, 42 U.S.C. 285e–10a, 42 U.S.C. 285f–1, 42 U.S.C. 285g–5, 42 U.S.C. 285g–7, 42 U.S.C. 285g–9, 42 U.S.C. 285m–3, 42 U.S.C. 285o–2, 42 U.S.C. 286a–7(c)(1)(G), 42 U.S.C. 287c–32(c), 42 U.S.C. 288, 42 U.S.C. 300cc–16, 42 U.S.C. 1302, 5 U.S.C. 610.

§ 1.1 Retrospective review of existing regulations.

(a) This section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in this title (other than those Regulations in parts 400–429 and parts 475–499).

(b) For purposes of this section,

(1) ''Assess'' shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) ''Review'' shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Regulations upon a substantial number of small entities.

(3) ''Regulation'' shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.

(4) ''Year of the Regulation's promulgation'' shall mean the year the Regulation first became effective, irrespective of whether it was subsequently amended.

(5) ''Significant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

(c)(1) Unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title (other than those Regulations in parts 400–429 and parts 475–499) shall expire at the end of:

(i) Two calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Regulation's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Regulation is required pursuant to paragraph (d)) reviewed the Regulation, whichever is latest.

(2) The last year in which the Department Assessed and (if review of the Regulation is required) reviewed the Regulation shall be the year during which the findings of the assessment and (if required) the review of a Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

(d) The Department is required to review those Regulations that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors—

(1) The continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the Regulation from the public;

(3) The complexity of the Regulation;

(4) The extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the Regulation since the Regulation was promulgated or the last time the Regulation was reviewed by the Department;

(6) Whether the Regulation complies with applicable law; and

(7) Other considerations as required by relevant executive orders and laws.

(e) If the review concludes the Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next Review) of the Regulation shall be completed.

(g) Paragraph (c) of this section shall not apply to

(1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For Regulations described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Regulations whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Regulations that involve a military or foreign affairs function of the United States.

(5) Regulations addressed solely to internal agency management or personnel matters.

(6) Regulations related solely to Federal Government procurement.

(7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) 42 CFR part 73.

(9) 42 CFR 1001.952.

(10) 42 CFR 100.3.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Regulation(s) whose assessment or review it is commencing. The public will be able to submit comments regarding the Regulation(s) in the manner specified on this website. The public can also submit comments in the manner specified on the website requesting that the Department assess or review a Regulation.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 1.2 through 1.5 [Reserved].

■ 3. Add 42 CFR part 404 to read as follows:

PART 404—REVIEW OF REGULATIONS

Sec.

Authority: 5 U.S.C. 301, 42 U.S.C. 216, 42 U.S.C. 300a–4, 42 U.S.C. 10801, 42 U.S.C. 1302, 42 U.S.C. 702(a), 42 U.S.C. 702(b)(1)(A), 42 U.S.C. 706(a)(3), 42 U.S.C. 247b, 247c, 31 U.S.C. 1243 note, 42 U.S.C. 254c, 42 U.S.C. 262a, 42 U.S.C. 264–271, 42 U.S.C. 290aa(m), 42 U.S.C. 284g, 42 U.S.C. 285a–6(c)(1)(E), 42 U.S.C. 285a–7(c)(1)(G), 42 U.S.C. 285b–4, 42 U.S.C. 285c–5, 42 U.S.C. 285c–8, 42 U.S.C. 285d–6, 42 U.S.C. 285e–2, 42 U.S.C. 285e–3, 42 U.S.C. 285e–10a, 42 U.S.C. 285f–1, 42 U.S.C. 285g–5, 42 U.S.C. 285g–7, 42 U.S.C. 285g–9, 42 U.S.C. 285m–3, 42 U.S.C. 285o–2, 42 U.S.C. 286a–7(c)(1)(G), 42 U.S.C. 287c–32(c), 42 U.S.C. 288, 42 U.S.C. 300cc–16, 42 U.S.C. 1302, 42 U.S.C. 1395hh, 5 U.S.C. 610.

§ 404.1 Retrospective review of existing regulations.

(a) This section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in parts 400–429 and parts 475–499 of this title.

(b) For purposes of this section,

(1) ''Assess'' shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) ''Review'' shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Regulations upon a substantial number of small entities.

(3) ''Regulation'' shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.

(4) ''Year of the Regulation's promulgation'' shall mean the year the Regulation first became effective, irrespective of whether it was subsequently amended.

(5) ''Significant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory

Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

(c)(1) Unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in parts 400–429 and parts 475–499 of this title shall expire at the end of:

(i) Two calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Regulation's promulgation; or

(3) Ten calendar years after the last year in which the Department assessed and (if review of the Regulation is required pursuant to paragraph (d)) reviewed the Regulation, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Regulation is required) reviewed the Regulation shall be the year during which the findings of the assessment and (if required) the review of a Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

(d) The Department is required to review those Regulations that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors—

(1) The continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the Regulation from the public;

(3) The complexity of the Regulation;

(4) The extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the Regulation since the Regulation was promulgated or the last time the Regulation was Reviewed by the Department;

(6) Whether the Regulation complies with applicable law; and

(7) Other considerations as required by relevant executive orders and laws.

(e) If the review concludes the Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Regulation shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For Regulations described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Regulations whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Regulations that involve a military or foreign affairs function of the United States.

(5) Regulations addressed solely to internal agency management or personnel matters.

(6) Regulations related solely to Federal Government procurement.

(7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) The annual Medicare Part A and Part B payment methodology update rules.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Regulation(s) whose assessment or review it is commencing. The public will be able to submit comments regarding the Regulation(s) in the manner specified on this website. The public can also submit comments in the manner specified on the website requesting that the Department assess or review a Regulation.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 404.2 through 404.5 [Reserved].

Title 45—Public Welfare

■ 4. Add 45 CFR part 6 to read as follows:

PART 6—REVIEW OF REGULATIONS

Sec.

6.1 Retrospective Review of Existing Regulations

6.2 through 6.5 [Reserved]

Authority: 5 U.S.C. 301, 504, 552, 552a, 552b, 553, 3401–3408, 5514, 7301; 5 U.S.C. App. 1, App. 8G(a)(2); 6 U.S.C. 279; 8 U.S.C. 1103(a)(3), 1182, 1232, 1255a, 1522 and note; 10 U.S.C. 4594; 16 U.S.C. 2401 *et seq.;* 18 U.S.C. 207, 506, 701, 1017, 1905; 20 U.S.C. 91, 959, 971–977, 1405, 1501 *et seq.,* 1681–1688, 2001–2012, 4501 *et seq.;* 21 U.S.C. 853a, 1174; 21 U.S.C. 853a, 1174; 22 U.S.C. 1621(a)(2), 1622, 2151b(f), 2451 *et seq.,* 7631; 24 U.S.C. 321–329; 25 U.S.C. 1603(12), 1621e; 28 U.S.C. 1746, 2461 and note, 2672; 29 U.S.C. 669(a)(5), 709, 791 *et seq.,* 2996e(d)(5), 3343; 31 U.S.C. 200–212, 1243 note, 1352, 3701–3720A, 3720D, 3721, 3801–3812, 6505–6506, 7501–7507, 9701; 35 U.S.C. 200–212; 36 U.S.C. 124; 39 U.S.C. 3220; 40 U.S.C. 72, 104, 106, 121, 318–318d, 484, 486, 1001; 41 U.S.C. 701 *et seq.;* 42 U.S.C. 216, 217b, 238n, 263a(f)(1)(E), 280g–1(d), 289(a), 289b–1, 290bb–36(f), 290dd–2, 299c–4, 300a–7, 300v–1(b), 300w *et seq.,* 300x *et seq.,* 300y *et seq.,* 300aa–11, 300gg through 300gg–63, 300gg–91, 300gg–92, 300gg–94, 300jj–11, 300jj–14, 300jj–52, 303, 601 and note, 602 and note, 603, 604, 605, 606, 607, 608, 608, 609, 610, 611, 612, 613(i), 616, 618, 619, 620 *et seq.,* 651 through 658, 658a, 659a, 660, 663, 664, 666 through 669A, 670 *et seq.,* 701 *et seq.,* 862a, 1202, 1203, 1301, 1301, 1302, 1302, 1306, 1308, 1308, 1310, 1313, 1315, 1315a, 1316, 1320a–1, 1320a–7e, 1320c–11, 1320d through 1320d–9, 1337, 1352, 1353, 1382 note, 1383 note, 1395b–4, 1395cc(f), 1395i–3, 1395i–5, 1395w–22(j)(3)(B), 1395w–26, 1395w–27, 1395x, 1396a, 1396b, 1396f,

1396k, 1396r, 1396r–2, 1396s(c)(2)(B)(ii), 1396u–2(b)(3)(B), 1397 *et seq.,* 1397j–1(b), 1870, 1871, 1973gg–5, 1975, 1975a, 1975b, 2000d to 2000d–7, 2991 *et seq.,* 2996(5), 2996(b)(2), 2996c(g), 2996d(b)(2), 2996e, 2996f, 2996g, 3001 *et seq.,* 3121, 3334, 3505, 3515e, 3535(d), 4950 *et seq.,* 4321, 4371 *et seq.,* 4601 note, 4633, 4950 *et seq.,* 4951 *et seq.,* 5024, 5043, 5044(a), 5052, 5057, 5059, 5060, 5065, 5106i(a), 5701, 6101–6107, 7609, 8621 *et seq.,* 9801 *et seq.,* 9858, 9901 *et seq.,* 10401 *et seq.,* 11101–11152, 11302, 11411, 11461–11464, 11472, 12501 *et seq.,* 12521–12529, 12541–12547, 12561, 12571–12595, 12601–12606, 12631–12638, 12645g, 12651b through 12651d, 12653, 12653o, 12657, 14406, 15001 *et seq.,* 15607(d), 18021–18024, 18031–18032, 18041–18042, 18044, 18051, 18054, 18061, 18063, 18071, 18081–18083, 18113, 18116; 44 U.S.C. 2104(a); 48 U.S.C. 1469a; 49 U.S.C. 794; 50 U.S.C. App. 2001, App. 2061–2171; Pub. L. 115–245, div. B, secs. 209, 507(d), 132 Stat. 2981; Pub. L. 114–328, sec. 1705(a)(2), 130 Stat. 2644; Pub. L. 114–74, sec. 701, 129 Stat. 584; Pub. L. 112–96, sec. 4004, 126 Stat. 197; Pub. L. 111–5, secs. 13400–13424, 123 Stat. at 258–279; Pub. L. 111–148, secs. 1019, 1104, 1311, 1312, 1334, 1411, 1412, 124 Stat. 119; Pub. L. 111–13, sec. 1612, 123 Stat. 1459; Pub. L. 109–171, sec. 7102, 120 Stat. 135; Pub. L. 105–277, 112 Stat. 2681; Pub. L. 105–119, tit. V, secs. 501(b) and (c), 502, 503, 504, and 505, 111 Stat. 2440, 2510–12; Pub. L. 104–208, 110 Stat. 3009; Pub. L. 104–134, tit. V, secs. 503(f), 504, 509(c), 110 Stat. 1321, 1321–53, 1321–59; Pub. L. 102–325, sec. 471(a), 106 Stat. 606; Pub. L. 101–426, sec. 6(h)(2), 104 Stat. 925; Pub. L. 101–410, 104 Stat. 890; Pub. L. 101–392, sec. 501(c), 104 Stat. 831; Pub. L. 101–239, sec. 10405, 103 Stat. 2489; Pub. L. 101–201, sec. 1(a), 103 Stat. 1795; Pub. L. 101–121, 103 Stat. 701; Pub. L. 100–707, sec. 105(i), 102 Stat. 4693; Pub. L. 100–383, secs. 105(f) and 206(d), 102 Stat. at 908, 914; Pub. L. 100–259, 102 Stat. 28; Pub. L. 100–241, sec. 15, 101 Stat. 1812; Pub. L. 100–77, sec. 501, 101 Stat. 509–10; Pub. L. 99–603, 100 Stat. 3359; Pub. L. 99–514, sec. 1883, 100 Stat. 2916; Pub. L. 98–64, sec. 2, 97 Stat. 365; Pub. L. 97–458, sec. 4, 96 Stat. 2513; Pub. L. 97–248, 96 Stat. 324; Pub. L. 95–437, 92 Stat. 1055; Pub. L. 94–114, sec. 6, 89 Stat. 579; Pub. L. 93–579, 88 Stat. 1896; Pub. L. 93–113, secs. 402(14), 417, 420, 87 Stat. 398, 407, and 414; Pub. L. 93–113, 87 Stat. 394; Pub. L. 89–506, sec. 1(a), 80 Stat. 306; Pub. L. 87–293, sec. 5(a), 75 Stat. 613; Pub. L. 86–571, secs. 1–11, 74 Stat. 308–310; Pub. L. 81–808, 64 Stat. 903; Pub. L. 81–152, sec. 203, 63 Stat. 377, 385; Reorganization Plan No. 1 of 1953, secs. 1, 5, 6, and 7, 67 Stat. 631; 5 U.S.C. 610.

§ 6.1 Retrospective Review of Existing Regulations.

(a) This section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in this title.

(b) For purposes of this section,

(1) ''Assess'' shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) ''Review'' shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Regulations upon a substantial number of small entities.

(3) ''Regulation'' shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.

(4) ''Year of the Regulation's promulgation'' shall mean the year the Regulation first became effective, irrespective of whether it was subsequently amended.

(5) ''Significant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

(c)(1) Unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title shall expire at the end of:

(i) Two calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Regulation's promulgation, or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Regulation is required pursuant to paragraph (d)) reviewed the Regulation, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Regulation is required) reviewed the Regulation shall be the year during which the findings of the assessment and (if required) the review of a Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

(d) The Department is required to review those Regulations that the Department assesses have a significant economic impact upon a substantial number of small entities. In Reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors—

(1) The continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the Regulation from the public;

(3) The complexity of the Regulation;

(4) The extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the Regulation since the Regulation was promulgated or the last time the Regulation was reviewed by the Department;

(6) Whether the Regulation complies with applicable law; and

(7) Other considerations as required by relevant executive orders and laws.

(e) If the review concludes the Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Regulation shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For Regulations described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Regulations whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Regulations that involve a military or foreign affairs function of the United States.

(5) Regulations addressed solely to internal agency management or personnel matters.

(6) Regulations related solely to Federal Government procurement.

(7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Regulation(s) whose assessment or review it is commencing. The public will be able to submit comments regarding the Regulation(s) in the manner specified on this website. The public can also submit comments in the manner specified on the website requesting that the Department assess or review a Regulation.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 6.2 through 6.5 [Reserved].

Dated: October 21, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–23888 Filed 11–3–20; 4:15 pm]

BILLING CODE 4150–26–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 192 and 195

[Docket No. PHMSA–2019–0199]

Pipeline Safety: Midstream Facilities Frequently Asked Questions

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notification and request for comments.

SUMMARY: PHMSA is making available for comment a set of draft frequently asked questions (FAQs) regarding federal oversight of midstream processing facilities. Specifically, this guidance will delineate where PHMSA and the Occupational Safety and Health Administration (OSHA) will each perform inspection and enforcement activities for midstream processing facilities where there is overlapping authority. The proposed guidance consists of a set of seven FAQs that were developed by the Midstream Processing Working Group (Working Group) established by the Technical Pipeline Safety Standards Committee, also known as the Gas Pipeline Advisory Committee (GPAC), and the Technical Hazardous Liquid Pipeline Safety Standards Committee, also known as the Liquid Pipeline Advisory Committee (LPAC).

DATES: Persons interested in submitting comments on the draft FAQs must do so by January 4, 2021.

ADDRESSES: You may submit comments, which should be identified by docket number PHMSA–2019–0199, by any of the following methods:

- *Federal eRulemaking Portal:* Comments may be submitted to *http://www.regulations.gov.* Please follow the online instructions to submit comments.
- *Mail:* Comments may be submitted by mailing them to the Dockets Management System, U.S. Department of Transportation, Dockets Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Comments may be submitted by hand-delivering them to 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001. Comments may be delivered between 9 a.m. and 5 p.m. ET, Monday through Friday, except for Federal holidays.
- *Fax:* Comments may be faxed to 202–493–2251.
- *Instructions:* Identify docket number PHMSA–2019–0199 at the beginning of your comments. If you submit your comments by mail, you must submit two copies. If you wish to receive confirmation that PHMSA received your comments, you must include a self-addressed stamped postcard. Internet users should submit comments at *http://www.regulations.gov.*
- *Privacy Act:* DOT may solicit comments from the public regarding certain general notices. 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.*
- *Confidential Business Information:* 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 document 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 document, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 CFR 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under FOIA, and they will not be placed in the public docket of this notification. Submissions containing CBI should be sent to Sayler Palabrica at *sayler.palabrica@dot.gov.* Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.
- *Docket:* The docket containing background documents and received comments is available at *http://www.regulations.gov.* Once on this site, please follow the online instructions for accessing the dockets. Alternatively, you may review these documents in person at the street address listed above.

FOR FURTHER INFORMATION CONTACT: Sayler Palabrica, Transportation Specialist, at 202–366–0559.

SUPPLEMENTARY INFORMATION: PHMSA provides written clarification regarding the pipeline safety regulations found at 49 CFR parts 190–199 in the form of FAQs and other guidance materials. PHMSA is requesting public comment on a set of draft FAQs that were developed by the Working Group that was established by the GPAC and LPAC. These draft FAQs are intended to clarify when each of PHMSA or OSHA intends to exercise its respective regulatory inspection and enforcement authority over midstream processing facilities involved in pipeline transportation of energy products. The intent of this guidance is to ensure that there is no confusion or unnecessary gaps or overlaps in Federal oversight of midstream processing facilities. All guidance, including these draft FAQs, is intended to be explanatory in nature. FAQs are provided to help the regulated community understand how to comply with the regulations, but they are not substantive rules themselves and do not create legally enforceable rights, assign duties, or impose new obligations not otherwise contained in the existing regulations and standards. However, an operator who is able to demonstrate compliance with the FAQs is likely to be able to demonstrate compliance with the relevant regulations. If a different course of action is taken by an operator, the operator must be able to demonstrate that its conduct is in accordance with the regulations.

The draft FAQs are included in this document. Comments submitted in response to this document and other supporting documents may be found in Docket No. PHMSA–2019–0199 at *https://www.regulations.gov.* Before finalizing the FAQs, PHMSA will consider all substantive comments received on or before the comment closing date. Comments received after the closing date will be considered to the extent practicable. Once finalized, the FAQs will be posted on PHMSA's public website at *https://www.phmsa.dot.gov/about-phmsa/phmsa-faqs.*

Background

Natural gas, crude oil, and associated fluids typically go through a number of processing steps before they can be delivered to end users as refined petroleum products, natural gas liquids, natural gas, and other products. Some of the facilities where these processes take place are midstream processing facilities downstream of initial production but upstream of end users.

For the purposes of this guidance document, a ''midstream processing facility'' is a processing facility that receives products being transported by PHMSA-jurisdictional pipelines and re-injects those products for continued transportation by pipeline. In other words, a midstream processing facility is a processing facility with piping or storage that is engaged in the transportation of gas or hazardous liquids by pipeline, and is therefore a pipeline facility subject to PHMSA jurisdiction. The pipeline systems within or associated with midstream processing facilities may be subject to regulation by one or more Federal agencies, depending on the facility's purpose and configuration. PHMSA regulates the safety of transportation-related pipeline systems associated with midstream processing facilities in 49 CFR parts 190–199, while OSHA regulates safety within midstream processing facilities using the Process Safety Management (PSM) regulations (29 CFR 1910.119). Uncertainty regarding where each of these respective regulatory authorities begins and ends in connection with midstream processing facilities has led to confusion among regulated entities and unnecessary duplication of regulatory efforts by the Federal Government.

To address these issues, the GPAC and LPAC established the Working Group in 2014. The Working Group consisted of members representing PHMSA, OSHA, and the midstream processing industry. The goal of the Working Group was to better understand and improve the safety of midstream processing facilities by increasing clarity and eliminating unnecessary gaps and overlaps in Federal safety oversight. In particular, the Working Group was tasked with evaluating the equivalency of PHMSA and OSHA midstream processing facility safety requirements; identifying means to delineate exercise of inspection and enforcement responsibilities (''regulatory oversight activities'') between the two agencies by clarifying the inlet and outlet boundaries of midstream processing facilities; and addressing the oversight of midstream processing facilities with pass-through, bypass, and storage configurations, including storage-related piping.

The Working Group met on several occasions in 2014 and 2015. During that time, the Working Group found that PHMSA's pipeline safety regulations in 49 CFR parts 190–199 and OSHA's PSM requirements at 29 CFR 1910.119 provide equivalent safety for midstream processing facilities. However, the enforcement of both their regulatory regimes to the same facilities created unnecessary contradictions and confusion, potentially decreasing safety. Therefore, in the interest of improving safety, ensuring effective government oversight, and reducing regulatory redundancy, PHMSA and OSHA agreed to delineate where they each would perform regulatory oversight activities for midstream processing facilities based on the predominate use of the facilities in question. As discussed during the Working Group's presentation to the GPAC and the LPAC on August 26, 2015, in order to apply the FAQs, an operator will be expected to make records and documentation that prove the predominate use of a facility available to PHMSA and OSHA for review and verification. See pages 71–75 of the transcript for the second day of the meeting, available in the docket for this document and at *https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=105&nocache=8221.*

These FAQs reflect agreement by PHMSA and OSHA to prioritize safety and regulatory clarity in regulatory oversight activities; however, nothing in these FAQs changes the agencies' statutory authority with respect to midstream processing facilities. For example, PHMSA may still issue a corrective action order under 49 U.S.C. 60112 or a safety order under 49 U.S.C. 60117(l) if a safety issue is identified.

The Working Group proposed seven draft FAQs to help clarify the delineation of regulatory oversight activities between PHMSA and OSHA for the regulated industry and Federal and State pipeline safety inspection and enforcement staff. PHMSA is soliciting public comments on these draft FAQs, which address the following issues:

- Defining the terms ''processing'' and ''processing facility.''
- Addressing oversight issues associated with bypass configurations, complex facilities with multiple processing units, and gas storage systems.
- Identifying the upstream and downstream demarcation points between pipeline transportation facilities that will be subject to regulatory oversight activities under PHMSA's pipeline safety regulations in 49 CFR parts 190 through 199, and processing facilities that will be subject to regulatory oversight activities by OSHA under its PSM requirements in 29 CFR 1910.119.

Historically, PHMSA and OSHA have coordinated efforts to ensure that there are no gaps in oversight over any

individual facility and this cooperation will continue after this guidance is finalized.

The proposed definitions contained within these FAQs are limited in use for applying these FAQs for the purpose of delineation between PHMSA and OSHA exercise of their respective regulatory oversight authorities. The proposed FAQ definitions will not be codified in Parts 190 through 199, and are not intended to be used for purposes other than to help the public interpret the application of PHMSA and OSHA's regulations to a pipeline facility.

Executive Order 13891 and DOT Guidance Procedures

This draft guidance document has been reviewed and cleared by the PHMSA Office of Chief Counsel in accordance with the Department's guidance procedures in 49 CFR 5.25–5.51. It has been determined to be non-significant and, as defined in 49 CFR 5.37, not otherwise of importance to the Department's interest. This draft guidance document will be posted on PHMSA's website in accordance with 49 CFR 5.31 and Executive Order 13891.

Draft Midstream Processing Facilities FAQs

This draft guidance document is intended to provide clarity to the public regarding existing pipeline safety standards. 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, but pipeline operators must comply with the underlying safety standards.

Q 1: Definitions

Q 1–A: What is Processing?

For the purposes of this guidance document, ''processing'' is defined as the treatment of products including, but not limited to dehydration, removal of contaminants by separation or filtration, blending with other products, and heating or cooling units that separate or purify products and remove condensates by distillation.

These FAQs do not cover facilities used for the chemical conversion of crude oil into refined petroleum products (*i.e.* refining facilities).

Q 1–B: What is a Processing Facility?

A ''processing facility'' comprises one or more individual units that perform a processing operation (see Q 1–A) and meets the criteria for applicability of the Occupational Safety and Health Administration(OSHA) process safety management regulations (29 CFR 1910.119).

Q 2: How does one delineate the boundary between pipeline transportation and a processing facility?

PHMSA policy indicates that, in deference to OSHA's exercise of its authority, it will not conduct inspection and enforcement activities (''regulatory oversight activities'') under 49 CFR part 192 and 195 for pipelines downstream of the first pressure control device entering a processing facility, and upstream of the last pressure control device leaving that processing facility, except as described in provisions of FAQ 4.

Q 3: How does PHMSA's policy apply to regulatory oversight of a pipeline entering a processing facility that bypasses a pressure control device?

A pipeline that predominantly (more than 50% of the time during the preceding calendar year) bypasses a pressure control device will be subject to PHMSA regulatory oversight activities under 49 CFR part 192 or 195. Further, if a pipeline bypasses a pressure control device that is permanently no longer in service, the pipeline will be subject to PHMSA regulatory oversight activities under 49 CFR part 192 or 195.

Q 4: How does PHMSA's policy apply to regulatory oversight of piping that bypasses processing downstream of the first pressure control device?

Piping that is downstream of the first pressure control device that is not predominately (more than 50% of the time during the previous calendar year) used to bypass processing will be subject to regulatory oversight activities by OSHA under its's process safety management regulations. Piping that is downstream of the first pressure control device that is predominantly (more than 50% of the time during the previous calendar year) used to bypass processing will be subject to PHMSA regulatory oversight activities under 49 CFR part 192 or 195.

Q 5: What if a given section of piping located on the grounds of a processing facility served by PHMSA-regulated pipelines connects two processing units or is otherwise used for a processing function?

If the piping is located downstream of the first pressure control device entering the facility and upstream of the last pressure control device leaving the facility, it would be subject to regulatory oversight activities by OSHA under its process safety management regulations. PHMSA policy indicates that in deference to OSHA's exercise of its authority, this section of piping would not be subject to PHMSA regulatory oversight activities under 49 CFR part 192 or 195.

Q 6. How is underground storage and associated piping located on the grounds of a processing facility regulated?

Piping associated with underground storage used for the ''purpose of managing processing facility inventory'' will be subject to regulatory oversight activities by OSHA under its process safety management regulations. Piping associated with storage caverns used for transportation will be subject to PHMSA regulatory oversight activities under 49 CFR part 192 or 195. Additionally, underground natural gas storage facilities, as defined in § 192.3, must comply with the applicable reporting requirements in 49 CFR part 191 and underground natural gas storage safety requirements in § 192.12.

Q 7. How are pipelines connecting storage or processing facilities regulated when traversing public or private lands (outside the grounds of storage or processing facilities)?

Pipelines exiting a pressure control device of storage or processing facilities and traversing public or private lands outside the grounds of storage or processing facilities will be subject to PHMSA regulatory oversight activities under 49 CFR part 192 or 195.

Issued in Washington, DC, on September 1, 2020, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2020–24011 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–60–P

Notices

Federal Register
Vol. 85, No. 214
Wednesday, November 4, 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

Foreign Agricultural Service

Information on Dairy Import Licenses for the 2021 Tariff-Rate Quota (TRQ) Year—United Kingdom Designation of Importers for Dairy Import Licenses

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture (USDA) has determined that, for the 2021 quota year, the United Kingdom (UK) may designate importers to receive import licenses for specified quantities under certain dairy tariff-rate quotas (TRQs) allocated to the EU–27. In accordance with the definitions in Chapter 4 of the U.S. Harmonized Tariff Schedule (HTS), the UK continues to be eligible to export under dairy TRQ allocations to the EU–27. In previous years, the European Commission (EC) designated importers on behalf of the UK and all other eligible European Union (EU) Member States for dairy TRQ amounts reserved for designated licenses. However, the EC has informed the United States that it no longer has the authority to designate importers on behalf of UK exporters for trade transactions that will occur after December 31, 2020. Accordingly, the EU and the UK have each requested that the UK be permitted to designate importers for portions of certain dairy TRQs for the 2021 quota year. The USDA has agreed to the EU's and UK's requests.

DATES: November 4, 2020.

FOR FURTHER INFORMATION CONTACT: Abdelsalam El-Farra, Multilateral Affairs Division, Foreign Agricultural Service, U.S. Department of Agriculture, at (202) 720–9439; or by email at: *abdelsalam.el-farra@fas.usda.gov.*

SUPPLEMENTARY INFORMATION: The Dairy Tariff-Rate Quota Import Licensing Regulation promulgated by USDA and codified at 7 CFR 6.20–6.36 provides for the issuance of licenses, including designated licenses, to import certain dairy articles that are subject to TRQs set forth in the HTS. Those dairy articles may only be entered into the United States at the in-quota TRQ tariff-rates by or for the account of a person or firm to whom such licenses have been issued. USDA annually publishes by notice in the **Federal Register** the amounts of each dairy TRQ for which the government of the applicable country may, not later than October 31 prior to the beginning of a quota year, designate the importers that are to be issued licenses by the Licensing Authority. *See* Adjustment of Appendices under the Dairy Tariff-Rate Quota Import Licensing Regulation for the 2021 Tariff-Rate Quota Year, 85 FR 67706 (October 26, 2020) (Appendices 3 & 4).

In accordance with the definitions in Chapter 4 of the HTS, the UK continues to be eligible to export under U.S. dairy TRQs allocated to the EU–27.[1] In previous years, the EC designated importers on behalf of the UK and all other eligible EU Member States. However, because the UK has withdrawn from the EU, the EC has informed the United States that it no longer has the authority to designate importers on behalf of UK exporters for trade transactions that will occur after December 31, 2020. The EU and the UK have each requested that the UK be permitted to designate importers for portions of certain dairy TRQs for the 2021 quota year. To maintain the status quo, the Licensing Authority has agreed to the EU's and the UK's requests and has determined that, for the 2021 quota year, the UK Government may designate importers for licenses for the quantities of cheese that have historically been supplied by UK exporters under designated licenses. Accordingly, the UK and EU may designate importers for licenses for dairy TRQs as follows:

—The UK will designate importers for the following three commodities for no more than the specified quantities: Cheese and Curd (Note 16) in the amount of 73,165 kg for the Tokyo Round and 277,403 kg for the Uruguay Round; Blue Mold (Note 17) in the amount of 2,905 kg for the Uruguay Round; and Cheddar (Note 18) in the amount of 716,520 kg for the Uruguay Round;

—The EU will designate importers for these three commodities for no more than the specified quantities: Cheese and Curd (Note 16) in the amount of 835,712 kg for the Tokyo Round and 3,168,597 kg for the Uruguay Round; Blue Mold (Note 17) in the amount of 347,095 kg for the Uruguay Round; and Cheddar (Note 18) in the amount of 333,480 kg for the Uruguay Round; and

—For all other cheese TRQs, the EU will designate importers for the entire quantity available for designated licenses allocated to the EU–27 on behalf of EU exporters.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs has designated this notice as not a major rule, as defined by 5 U.S.C. 804(2).

Lori Tortora,

Licensing Authority.

[FR Doc. 2020–24393 Filed 11–3–20; 8:45 am]

BILLING CODE 3410–10–P

[1] For purposes of Chapter 4 of the HTS, ''the expression 'EU27' refers to articles the product of one of the following: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, the Federal Republic of Germany, Hungary, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Spain, Slovenia, the Slovak Republic, Sweden or the United Kingdom.''

AMERICAN BATTLE MONUMENTS COMMISSION

Performance Review Board Appointments

AGENCY: American Battle Monuments Commission.

ACTION: Notice of performance review board appointments.

SUMMARY: This notice provides the names of individuals who have been appointed to serve as members of the American Battle Monuments Commission Performance Review Board. The publication of these appointments is required by the Civil Service Reform Act of 1978.

DATES: These appointments are effective as of 25 October 2020.

FOR FURTHER INFORMATION CONTACT: Jamilyn Smyser, Chief of Human Resources and Administration, American Battle Monuments Commission, Courthouse Plaza II Suite 500, 2300 Clarendon Boulevard, Arlington, Virginia 22201. Telephone number: (703) 696–7969.

American Battle Monument Commission SES Performance Review Board—2019/2020

Mark Averill, Deputy Administrative Assistant to the Secretary of the Army
Dr. Erin Mahan, Chief Historian, Office of the Secretary of Defense
Michael Conley, Chief of Staff, American Battle Monuments Commission

Jamilyn Smyser,

Chief, Human Resources and Administration.

[FR Doc. 2020–24373 Filed 11–3–20; 8:45 am]

BILLING CODE 6120–01–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission Public Briefing, *Racial Disparities in Maternal Health,* notice of commission business meeting, and call for public comments.

DATES: Friday, November 13, 2020, 10:00 a.m. ET.

ADDRESSES: Virtual Briefing and Business Meeting.

FOR FURTHER INFORMATION CONTACT: Angelia Rorison (202) 376–8359; TTY: (202) 376–8116; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: On Friday, November 13, 2020, at 10:00 a.m. Eastern Time, the U.S. Commission on Civil Rights will hold a virtual briefing to examine the federal role in addressing racial disparities in maternal health outcomes, including negative pregnancy-related health outcomes and pregnancy-related deaths of women in the United States. The Commission will analyze current data regarding pregnancy-related and pregnancy-associated deaths, including data collected by the Centers for Disease Control and Prevention, the National Institute of Minority Health and Health Disparities, and the Department of Health and Human Services' State Partnership Initiative to Address Health Disparities. This briefing is open to the public via Weblink. The event will live-stream at *https://www.youtube.com/user/USCCR/videos.* (Streaming information subject to change.) Public participation is available for the event with view access, along with an audio option for listening.

Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, November 13, 2020, is *https://www.streamtext.net/player?event=USCCR.* Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript. To request additional accommodations, persons with disabilities should email *access@usccr.gov* by Monday, November 6, 2020 indicating ''accommodations'' in the subject line.

Briefing Agenda for Racial Disparities in Maternal Health: 10:00 a.m.–1:30 p.m.

All Times Eastern Time

I. Introductory Remarks: Chair Catherine E. Lhamon: 10:00–10:05 a.m.
II. Panel 1: Policy and Legislation: 10:05–11:05 a.m.
III. Break: 11:05–11:15 a.m.
IV. Panel 2: Service Providers/Private Organizations: 11:15 a.m.–12:15 p.m.
V. Break: 12:15–12:25 p.m.
VI. Panel 3: Lived Experience: 12:25–1:25 p.m.
VII. Closing Remarks: Chair Catherine E. Lhamon: 1:25–1:30 p.m.
VIII. Adjourn Meeting

Schedule is subject to change.

Call for Public Comments:

In addition to the testimony collected on Friday, November 13, 2020, via virtual briefing, the Commission welcomes the submission of material for consideration as we prepare our report. Please submit such information to *maternalhealth@usccr.gov* no later than December 14, 2020, or by mail to OCRE/Public Comments, ATTN: Maternal Health, U.S. Commission on Civil Rights, 1331 Pennsylvania Ave. NW, Suite 1150, Washington, DC 20425. The Commission encourages the use of email to provide public comments due to the current COVID–19 pandemic.

Dated: November 2, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–24582 Filed 11–2–20; 4:15 pm]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–131–2020]

Approval of Subzone Status; Childers Guns, LLC, Fairmont, West Virginia

On July 29, 2020, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the West Virginia Economic Development Authority, grantee of FTZ 229, requesting subzone status subject to the existing activation limit of FTZ 229, on behalf of Childers Guns, LLC, in Fairmont, West Virginia.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (85 FR 47165, August 4, 2020). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 229D was approved on October 29, 2020, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 229's 2,000-acre activation limit.

Dated: October 29, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–24420 Filed 11–3–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–016]

Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on certain passenger vehicles and light truck tires (passenger tires) from the People's Republic of China (China) would be likely to lead to the continuation or recurrence of dumping at the levels indicated in the ''Final Results of Review'' section of this notice.

DATES: Applicable November 4, 2020.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2015, the Department of Commerce (Commerce) issued the AD

Order on passenger tires.[1] On July 1, 2020, Commerce published the *Notice of Initiation* of the first sunset review of the *Order* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On July 16, 2020, Commerce received a notice of intent to participate from the petitioner [3] submitted within the 15-day deadline specified in 19 CFR 351.218(d)(1)(i). The petitioner claimed interested party status under section 771(9)(D) of the Act as a certified union or recognized union or group of workers which is representative of an industry engaged in the manufacture, production, or wholesale of a domestic like product.

On July 31, 2020, Commerce received an adequate substantive response to the *Notice of Initiation* from the petitioner within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive responses from respondent interested parties.

On August 20, 2020, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[5] On September 9, 2020, we received comments on adequacy from the petitioner.[6] As a result, pursuant to 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce has conducted an expedited sunset review of the *Order.*

Scope of the Order

The merchandise covered by the *Order* is passenger vehicle and light truck tires. Passenger vehicle and light truck tires are new pneumatic tires, of rubber, with a passenger vehicle or light truck size designation. Tires covered by this *Order* may be tube-type, tubeless, radial, or non-radial, and they may be intended for sale to original equipment manufacturers or the replacement market.

The products covered by the *Order* are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.10.10.10, 4011.10.10.20, 4011.10.10.30, 4011.10.10.40, 4011.10.10.50, 4011.10.10.60, 4011.10.10.70, 4011.10.50.00, 4011.20.10.05, and 4011.20.50.10. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.99.45.10, 4011.99.45.50, 4011.99.85.10, 4011.99.85.50, 8708.70.45.45, 8708.70.45.60, 8708.70.60.30, 8708.70.60.45, and 8708.70.60.60.

While HTSUS subheadings are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive. A full description of the scope of the *Order* is contained in the accompanying Issues and Decision Memorandum (Issues and Decision Memorandum).[7]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. The issues discussed in the Issues and Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the *Order* is revoked. The Issues and 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.* A list of topics discussed in the Issues and Decision Memorandum is included as an Appendix to this notice. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Reviews

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the AD *Order* on passenger tires from China would be likely to lead to the continuation or recurrence of dumping at weighted-average dumping margins up to 87.99 percent.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing the final results and this notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218 and 351.221(c)(5)(ii).

Dated: October 29, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2020–24441 Filed 11–3–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–891]

Hand Trucks and Certain Parts Thereof From the People's Republic of China: Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this sunset review, the Department of Commerce (Commerce) finds that revocation of the

[1] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Amended Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 47902 (August 10, 2015) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 67 (January 2, 2020) (*Notice of Initiation*).

[3] The petitioner is the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial Workers Union, AFL–CIO, a certified union representative of an industry engaged in the manufacture, production or wholesale in the United States of PVLT. *See* Petitioner's Letter, ''Certain Passenger Vehicle and Light Truck from the People's Republic of China: Notice of Intent to Participate,'' dated July 16, 2020.

[4] *See* Petitioner's Letter, ''Passenger Vehicle and Light Truck Tires from China, AD Order, First Sunset Review: Substantive Response of the USW,'' dated July 31, 2020 (Substantive Response).

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on July 1, 2020,'' dated August 20, 2020.

[6] *See* Petitioner's Letter, ''Passenger Vehicle and Light Truck Tires from China; AD/CVD orders, First Sunset Review: Adequacy Comments of the USW,'' dated September 9, 2020.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Antidumping Duty Order on Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

antidumping duty (AD) order on hand trucks and certain parts thereof (hand trucks) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping. The magnitude of the dumping margins likely to prevail is indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 4, 2020.

FOR FURTHER INFORMATION CONTACT: Margaret Collins, AD/CVD Operations, Office VI, Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–6250.

SUPPLEMENTARY INFORMATION:

Background

The antidumping duty order on hand trucks from China was published on December 2, 2004.[1] On July 1, 2020, Commerce published the notice of initiation of the third sunset review of the antidumping duty order on hand trucks from China pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2]

In accordance with 19 CFR 351.218(d)(1)(i) and (ii), Commerce received a notice of intent to participate in this sunset review from Gleason Industrial Products, Inc. and Precision Products, Inc. (collectively, the petitioners), within 15 days after the date of publication of the *Sunset Initiation.* The petitioners claimed interested party status under section 771(9)(C) of the Act, as domestic producers of the domestic like product.

On July 23, 2020, Commerce received a complete substantive response to the notice of initiation from the petitioners within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). Commerce received no substantive response from any respondent interested parties. As a result, Commerce conducted an expedited, *i.e.,* 120-day, sunset review of this order pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2).

Scope of the Order

The merchandise subject to the order consists of hand trucks manufactured from any material, whether assembled or unassembled, complete or incomplete, suitable for any use, and certain parts thereof, namely the vertical frame, the handling area and the projecting edges or toe plate, and any combination thereof. They are typically imported under heading 8716.80.50.10 of the Harmonized Tariff Schedule of the United States (HTSUS), although they may also be imported under heading 8716.80.50.90 and 8716.90.50.60. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description is dispositive. A full description of the scope of the order is contained in the accompanying Issues and Decision Memorandum.[3]

Analysis of Comments Received

All issues raised in this review are addressed in the Issues and Decision Memorandum, including the likelihood of continuation or recurrence of dumping in the event of revocation, and the magnitude of dumping margins likely to prevail if the order were revoked. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in the Issues and Decision Memorandum, which 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 Issues and Decision Memorandum can be accessed directly at *http://trade.gov/enforcement/.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 752(c)(1) and (3) of the Act, we determine that revocation of the antidumping duty order on hand trucks from the China would be likely to lead to continuation or recurrence of dumping at weighted-average margins up to 383.60 percent.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested.

Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Commerce is issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: October 29, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2020–24476 Filed 11–3–20; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Notice of Antidumping Duty Order: Hand Trucks and Certain Parts Thereof from the People's Republic of China,* 69 FR 70122 (December 2, 2004).

[2] *See Initiation of Five-Year (''Sunset'') Reviews,* 85 FR 39526 (July 1, 2020) (*Sunset Initiation*).

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order on Hand Trucks and Certain Parts Thereof from the People's Republic of China,'' dated concurrently with and hereby adopted by this notice (Issues and Decision Memorandum).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA614]

Marine Mammals; File No. 24356

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Plimsoll Productions, Whiteladies House, 51–55 Whiteladies Road, Bristol BS8 2LY, United Kingdom (Responsible Party: James Manisty), has applied in due form for a permit to conduct commercial or educational photography on northern elephant seals (*Mirounga angustirostris*).

DATES: Written, telefaxed, or email comments must be received on or before December 4, 2020.

ADDRESSES: These documents are available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 24356 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to

NMFS.Pr1Comments@noaa.gov. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Sara Young or Shasta McClenahan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to film northern elephant seals at Año Nuevo State Park in California. Footage would be used to create a documentary series for National Geographic that will be broadcast on multiple platforms in 2022. Up to 1,400 northern elephant seals would be filmed over the duration of the project from land or from unmanned aircraft systems. One hundred California sea lions (*Zalophus californianus*), 100 harbor seals (*Phoca vitulina*), and 100 Steller sea lions from the eastern distinct population segment (*Eumetopias jubatus*) may be opportunistically filmed or harassed if encountered over the duration of the project. Filming is expected to occur over 4 weeks between January 2021 and March 2022, concentrated in the months of January and February. The permit would expire on March 1, 2022.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement. Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: October 30, 2020.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–24432 Filed 11–3–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA617]

Western Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold meetings of its American Samoa Archipelago Fishery Ecosystem Plan (FEP) Advisory Panel (AP), Mariana Archipelago FEP-Guam AP, Hawaii Archipelago FEP AP, and Mariana Archipelago FEP-Commonwealth of the Northern Mariana Islands (CNMI) AP to discuss and make recommendations on fishery management issues in the Western Pacific Region.

DATES: The American Samoa Archipelago FEP AP will meet on Wednesday, November 18, 2020, from 5 p.m. to 7:30 p.m.; the Mariana Archipelago FEP-Guam AP will meet on Thursday, November 19, 2020, from 6:30 p.m. to 8:30 p.m.; the Hawaii Archipelago FEP AP will meet on Friday, November 20, 2020, from 9 a.m. to 11 a.m.; and the Mariana Archipelago FEP–CNMI AP will meet on Saturday, November 21, 2020, from 9 a.m. to 11 a.m. All times listed are local island times. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Each of the meetings will be held by web conference. Audio and visual portions for all of the web conferences can be accessed at: *https://wprfmc.webex.com/join/info.wpcouncilnoaa.gov.* Web conference access information will also be posted on the Council's website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: Public comment periods will be provided in the agenda. Information on how to provide public comment will be posted on the Council's website at *www.wpcouncil.org.* The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the American Samoa FEP AP Meeting

Wednesday, November 18, 2020, from 5 p.m.–7:30 p.m.

1. Welcome and Introductions
2. Review of the Last AP Meeting and Recommendations
3. Council Issues
   - A. American Samoa Bottomfish
     - i. Development of Annual Catch Limits for 2020–21
     - ii. Development of a Stock Rebuilding Plan
   - B. Considerations for Developing Reasonable and Prudent Measures (RPMs) and/or Reasonable and Prudent Alternatives (RPAs) for the American Samoa Longline Fishery
4. American Samoa Reports
5. Report on American Samoa Archipelago FEP AP Plan Activities
6. Fishery Issues and Activities
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Schedule and Agenda for the Mariana Archipelago FEP-Guam AP Meeting

Thursday, November 19, 2020, 6:30 p.m.–8:30 p.m.

1. Welcome and Introductions
2. Review of the Last AP Meeting and Recommendations
3. Council Issues
   - A. Development of a Bottomfish Stock Rebuilding Plan
4. Guam Reports
5. Report on Mariana Archipelago FEP Advisory Panel Plan Activities
6. Fishery Issues and Activities
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Schedule and Agenda for the Hawaii Archipelago FEP AP Meeting

Friday, November 20, 2020, 9 a.m.–11 a.m.

1. Welcome and Introductions
2. Review of the Last AP Meeting and Recommendations
3. Council Issues
   - A. Options for Including Tori Lines in the Hawaii Longline Fishery Seabird Mitigation Measures
   - B. Considerations for Developing Reasonable and Prudent Measures and/or Reasonable and Prudent Alternatives for the Hawaii Longline Fishery
   - C. Comments on False Killer Whale Take and Recovery Plans
   - D. Hawaii Fishery Management Plans
4. Hawaii Reports
5. Report on Hawaii Archipelago FEP AP Plan Activities
6. Fishery Issues and Activities

7. Public Comment
8. Discussion and Recommendations
9. Other Business

Schedule and Agenda for the Mariana Archipelago FEP–CNMI AP Meeting

Saturday, November 21, 2020, 9 a.m.–11 a.m.

1. Welcome and Introductions
2. Review of the Last AP Meeting and Recommendations
3. Council Issues
   A. Development of a Bottomfish Stock Rebuilding Plan for Guam
4. CNMI Reports
5. Report on Mariana Archipelago FEP AP Plan Activities
6. Fishery Issues and Activities
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 30, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–24433 Filed 11–3–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA543]

Determination of Overfishing or an Overfished Condition

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: This action serves as a notice that NMFS, on behalf of the Secretary of Commerce (Secretary), has found that Atlantic herring is now overfished, and Gulf of Maine thorny skate and Pacific sardine are both still overfished. NMFS, on behalf of the Secretary, notifies the appropriate regional fishery management council (Council) whenever it determines that overfishing is occurring, a stock is in an overfished condition, or a stock is approaching an overfished condition.

FOR FURTHER INFORMATION CONTACT: Regina Spallone, (301) 427–8568.

SUPPLEMENTARY INFORMATION: Pursuant to section 304(e)(2) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1854(e)(2), NMFS, on behalf of the Secretary, must notify Councils, and publish in the **Federal Register**, whenever it determines that a stock or stock complex is subject to overfishing, overfished, or approaching an overfished condition.

NMFS has determined that Atlantic herring is now overfished and Gulf of Maine thorny skate is still overfished. The Atlantic herring determination is based on the most recent assessment, completed in 2020, using data through 2019, which indicates that this stock is overfished because the spawning stock biomass is below the threshold. The thorny skate determination is based on the most recent stock status update, completed in 2020, using data through 2019, which indicates that this stock is still overfished because the 3-year average biomass index remains below the threshold. NMFS has notified the New England Fishery Management Council of the requirement to rebuild these stocks.

NMFS has determined that Pacific sardine is still overfished. This determination is based on the most recent assessment, completed in 2020, using data through 2019, which indicates that this stock is still overfished because the biomass remains below the threshold. NMFS has notified the Pacific Fishery Management Council of the requirement to rebuild this stock.

Dated: October 29, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–24385 Filed 11–3–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA618]

Western Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold a meeting of the Pacific Pelagics Fishery Ecosystem Plan (FEP) Plan Team (PT) to discuss fishery management issues and develop recommendations to the Council for future management of pelagic fisheries in the Western Pacific region.

DATES: For the dates, times and agenda, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held by web conference. Audio and visual portions of the web conference can be accessed at: *https://wprfmc.webex.com/wprfmc/onstage/g.php?MTID=e6f56f181a8490aa50b88d7d27030ca3d.* Event number (if prompted): 133 176 7822. Event password (if prompted): PelagicPT112. Web conference access information will also be posted on the Council's website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: The Pelagic PT meeting will be held on November 19, 2020, and run each day from 1 p.m. to 5 p.m. Hawaii Standard Time (HST) (12 p.m. to 4 p.m. Samoa Standard Time (SST); 9 a.m. to 1 p.m. on November 20, 2020, Chamorro Standard Time (ChST)). Public comment periods will be provided in the agenda. The order in which agenda items are addressed may change. The meeting will run as late as necessary to complete scheduled business.

Agenda for the Pelagic Plan Team Meeting

Thursday, November 19, 2020, 1 p.m. to 5 p.m. HST

1. Welcome and Introductions
2. Approval of Agenda
3. Oceanic Whitetip Working Group Report
   A. Monte Carlo Analyses of Mitigation Measures
   B. Post Release Mortality, Handling, and Trailing Gear
   C. Vessel Specific Impact Analyses
   D. EBFM Project Updates
   E. Working Group Report Summary
4. Possible North Pacific Striped Marlin Rebuilding Measure(s)
5. Stock Status Determination of Western and Central Pacific Silky Shark
6. Tori Line Options for Hawaii Longline Fisheries
7. Hawaii Deep-set Longline and American Samoa Longline Reasonable and Prudent Measure Development
8. Hawaii Non-longline Fishery Management

9. Public Comment
10. Pelagic Plan Team Recommendations
11. Other Business

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 30, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–24434 Filed 11–3–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0168]

Agency Information Collection Activities; Comment Request; Comprehensive Transition Program (CTP) for Disbursing Title IV Aid to Students With Intellectual Disabilities Expenditure Report

AGENCY: Federal Student Aid, Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before January 4, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0168. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

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 Transition Program (CTP) for Disbursing Title IV Aid to Students with Intellectual Disabilities Expenditure Report.

OMB Control Number: 1845–0113.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private.

Total Estimated Number of Annual Responses: 104.

Total Estimated Number of Annual Burden Hours: 208.

Abstract: The Higher Education Opportunity Act, Public Law 110–315, added provisions to the Higher Education Act of 1965, as amended, in section 750 and 766 that enable eligible students with intellectual disabilities to receive Federal Pell Grant, Federal Supplemental Educational Opportunity Grant, and Federal Work Study funds if they are enrolled in an approved program. The Comprehensive Transition Program (CTP) for Disbursing Title IV Aid to Students with Intellectual Disabilities expenditure report is the tool for reporting the use of these specific funds. The data is used by the Department to monitor program effectiveness and accountability of fund expenditures. The data is used in conjunction with institutional program reviews to assess the administrative capability and compliance of the applicants.

Dated: October 30, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–24401 Filed 11–3–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP20–68–000; CP20–70–000]

Enable Gas Transmission, LLC; Enable Gulf Run Transmission, LLC; Notice of Availability of the Environmental Assessment for the Proposed Gulf Run Pipeline and Line CP Modifications Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Gulf Run Pipeline and Line CP Modifications Project (Project), proposed by Enable Gas Transmission, LLC and Enable Gulf Run Transmission, LLC (collectively, Enable) in the above-referenced docket. Enable requests authorization to construct, operate, and maintain natural gas pipeline facilities in Texas and Louisiana. The project would include modifications to existing facilities to allow bi-directional flow, a new natural gas pipeline, and ancillary facilities which would allow transport up to 1,650,000 dekatherms of natural gas per day.

The EA assesses the potential environmental effects of the construction and operation of the Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of

the proposed Project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The U.S. Army Corps of Engineers (USACE)—New Orleans, Fort Worth, Galveston, and Vicksburg Districts participated as a cooperating agency in the preparation of the EA. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the NEPA analysis. Because the USACE must comply with the requirements of NEPA before issuing permits under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act, it has elected to cooperate in this NEPA process and adopt the EA per Title 40 of the Code of Federal Regulations, Part 1506.3.

The proposed Project would include the following facilities:

Gulf Run Pipeline

- approximately 134 miles of 42-inch-diameter natural gas transmission pipeline in Red River, DeSoto, Sabine, Vernon, Beauregard, and Calcasieu Parishes, Louisiana;
- a new delivery meter station (Golden Pass Pipeline Meter Station) near the terminus of the Gulf Run Pipeline at milepost 134.0 in Calcasieu Parish, Louisiana; and
- ancillary facilities including mainline valves and pig launcher/receiver facilities at various locations.

Line CP Modifications

- modifications at the existing Westdale Compressor Station in Red River Parish, Louisiana;
- modifications at the existing Vernon Compressor Station in Jackson Parish, Louisiana;
- modifications at the ANR Meter Station, Columbia Gulf Meter Station, and Midcontinent Express Pipeline Meter Station in Richland Parish, Louisiana;
- a new meter station (EGT Meter Station) in Richland Parish, Louisiana; and
- a new meter station (CP–3 Meter Station) in Panola County, Texas.

The Commission mailed a copy of this *Notice of Availability* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the Project area. The EA is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the natural gas environmental documents page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). In addition, the EA may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://elibrary.ferc.gov/eLibrary/search*), select ''General Search'' and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.,* CP20–68 or CP20–70). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

The EA is not a decision document. It presents Commission staff's independent analysis of the environmental issues for the Commission to consider when addressing the merits of issues raised in this proceeding. Any person wishing to comment on the EA may do so. Your comments should focus on the EA's disclosure and discussion of potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this Project, it is important that we receive your comments in Washington, DC on or before 5:00 p.m. Eastern Time on November 30, 2020.

For your convenience, there are three methods you can use to file your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. This is an easy method for submitting brief, text-only comments on a Project;

(2) You can also file your comments electronically using the eFiling feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular Project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the Project docket numbers (CP20–68–000 and CP20–70–000) on your letter. 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, MD 20852.

Filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered. Only intervenors have the right to seek rehearing or judicial review of the Commission's decision. At this point in this proceeding, the timeframe for filing timely intervention requests has expired. Any person seeking to become a party to the proceeding must file a motion to intervene out-of-time pursuant to Rule 214(b)(3) and (d) of the Commission's Rules of Practice and Procedures (18 CFR 385.214(b)(3) and (d)) and show good cause why the time limitation should be waived. Motions to intervene are more fully described at *https://www.ferc.gov/ferc-online/ferc-online/how-guides.*

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Dated: October 29, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24457 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14861–002]

FFP Project 101, LLC; Notice Soliciting Scoping Comments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. *Project No.:* 14861–002.

c. *Date Filed:* June 23, 2020.

d. *Submitted By:* Rye Development on behalf of FFP Project 101, LLC (FFP).

e. *Name of Project:* Goldendale Pumped Storage Project.

f. *Location:* Off-stream on the north side of the Columbia River at River Mile 215.6 in Klickitat County, Washington, with transmission facilities extending into Sherman County, Oregon. The project would be located approximately 8 miles southeast of the City of Goldendale, Washington. The project would occupy 18.1 acres of lands owned by the U.S. Army Corps of Engineers and administered by the Bonneville Power Administration.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Erik Steimle, Rye Development, 220 Northwest 8th Avenue Portland, Oregon 97209; (503) 998–0230; email—*erik@ryedevelopment.com.*

i. *FERC Contact:* Michael Tust at (202) 502–6522; or email at *michael.tust@ferc.gov.*

j. *Deadline for filing scoping comments:* December 28, 2020.

The Commission strongly encourages electronic filing. Please file scoping comments using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, 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. All filings must clearly identify the project name and docket number on the first page: Goldendale Pumped Storage Project (P–14861–002).

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. The application is not ready for environmental analysis at this time.

l. The project would include the following new facilities: (1) A 61-acre upper reservoir formed by a 175-foot-high, 8,000-foot-long rockfill embankment dam at an elevation of 2,950 feet mean sea level (MSL) with a vertical concrete intake-outlet structure; (2) a 63-acre lower reservoir formed by a 205-foot-high, 6,100-foot-long embankment at an elevation of 590 feet MSL with a horizontal concrete intake-outlet structure and vertical steel slide gates; (3) an underground conveyance tunnel system connecting the two reservoirs consisting of a 2,200-foot-long, 29-foot-diameter concrete-lined vertical shaft, a 3,300-foot-long, 29-foot-diameter concrete-lined high pressure tunnel, a 200-foot-long, 22-foot-diameter high pressure manifold tunnel, three 600-foot-long, 15-foot-diameter steel/concrete penstocks, three 200-foot-long, 20-foot-diameter steel-lined draft tube tunnels with bonneted slide gates, a 200-foot-long, 26-foot-diameter concrete-lined low-pressure tunnel, and a 3,200-foot-long, 30-foot-diameter concrete-lined tailrace tunnel; (4) an underground powerhouse located between the upper and lower reservoir in a 0.83-acre powerhouse cavern containing three, 400-megawatt (MW) Francis-type pump-turbine units for a total installed capacity of 1,200 MW; (5) a 0.48-acre underground transformer cavern adjacent to the powerhouse containing intermediate step-up transformers that will step up the voltage from 18 kilovolts (kV) to 115 kV; (6) two 30-foot-diameter tunnels for accessing the powerhouse and transformer caverns; (7) a 0.84-mile-long, 115-kV underground transmission line extending from the transformer gallery through the combined access/transmission tunnel to where it emerges aboveground near the west side of the lower reservoir and extending an additional 0.27 miles to an outdoor 7.3-acre substation/switchyard where the voltage would be stepped up to 500 kV; (8) a 3.13-mile-long, 500-kV transmission line routed from the substation/switchyard south across the Columbia River and connecting to Bonneville Power Administration's existing John Day Substation; (9) a buried 30-inch-diameter water fill line leading from a shut-off and throttling valve within a non-project water supply vault owned by Klickitat Public Utility District (KPUD) to an outlet structure within the lower reservoir to convey water to fill the reservoirs; and (10) appurtenant facilities. The project would also include an existing 0.7-mile road for accessing the lower reservoir site and an existing 8.6-mile-long road for accessing the upper reservoir site both of which may be modified to provide access for construction vehicles.

The water supply used to initially fill the lower reservoir as well as to provide make-up water would be purchased from KPUD and would be obtained from KPUD's existing intake pond on the Columbia River. The project water fill line would connect to a new KPUD-owned flanged water supply service connection in a water supply vault located near the lower reservoir. Within the vault, and just downstream of the service connection, there would be a project shut-off and throttling valve to allow control of the initial fill and make-up water flow rate into the lower reservoir. The initial fill would require 7,640 acre-feet of water and would be completed in about six months at an average flow rate of approximately 21 cubic feet per second (maximum flow rate available is 35 cubic feet per second). It is estimated that the project would need 360 acre-feet of water each year to replenish water lost through evaporation.

m. 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 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. 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 TYY, (202) 502–8659.

n. You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Scoping Process

Commission staff will prepare either an environmental assessment (EA) or an Environmental Impact Statement (EIS) that describes and evaluates the probable effects, if any, of the licensee's proposed action and alternatives. The EA or EIS will consider environmental impacts and reasonable alternatives to the proposed action. The Commission's scoping process will help determine the required level of analysis and satisfy the NEPA scoping requirements, irrespective of whether the Commission prepares an EA or an EIS. Due to restrictions on mass gatherings related to COVID–19, we do not intend to conduct a public scoping meeting and site visit in this case. Instead, we are soliciting written comments and suggestions on the preliminary list of issues and alternatives to be addressed in the NEPA document, as described in scoping document 1 (SD1), issued October 29, 2020.

Copies of the SD1 outlining the subject areas to be addressed in the NEPA document were distributed to the parties on the Commission's mailing list and the applicant's distribution list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call 1–866–208–3676 or for TTY, (202) 502–8659.

Dated: October 29, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24460 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD21–2–2000]

Heart Mountain Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On October 23, 2020, Heart Mountain Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed Ralston Lateral Hydrokinetic Project would have an installed capacity of 10 kilowatts (kW), and would be located in an existing irrigation lateral in Powell, Park County, Wyoming.

Applicant Contact: Tyler Weckler, District Manager, 1206 Rd 18, Powell, Wyoming 82435, Phone No. (307) 754–4685, Email: *hmid00@tritel.net.*

FERC Contact: Christopher Chaney, Phone No. (202) 502–6778, Email: *christopher.chaney@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) One 10-kW hydrokinetic module; and (2) appurtenant facilities. The proposed project would have an estimated annual generation of approximately 44 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar man-made water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity..	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 40 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed Ralston Lateral Hydrokinetic Project will not alter the primary purpose of the conduit, which is used to distribute water for agricultural irrigation. Therefore, based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions To Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 30 days from the issuance date of this notice. Deadline for filing motions to intervene is 30 days from the issuance date of this notice. Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may send a paper copy. Submissions sent via the U.S. Postal Service must be

[1] 18 CFR 385.2001–2005 (2020).

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, MD 20852. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Locations of Notice of Intent: 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 website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (*i.e.,* CD21–2) in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. Copies of the notice of intent can be obtained directly from the applicant. 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, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: October 29, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24456 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AC19–122–000]

Pacific Gas and Electric Company; Notice of Filing

Take notice that on October 15, 2020, Pacific Gas and Electric Company (PG&E) filed an Offer of Settlement and Stipulation in its Formula Rate Proceedings (Docket Nos. ER19–13–000, ER19–1816–000, and ER20–2265–000) which included adjustments to PG&E's regulatory capital structure used in its Formula Rate. As such, PG&E states that the parties filing interventions and/or comments/protests in Docket Nos. AC19–122–000 and AC20–150–000 are also parties to the Settlement in the Formula Rate Proceedings.

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 or 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. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of 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://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. 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 p.m. Eastern Time on November 12, 2020.

Dated: October 28, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24450 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–7–000]

Gulf South Pipeline Company, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on October 21, 2020, Gulf South Pipeline Company, LLC (Gulf South), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, filed a prior notice application pursuant to sections 157.205(b), 157.208(c) and 157.210 of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act, and Gulf South's blanket certificate issued in Docket No. CP82–430–000. Gulf South proposes to replace four reciprocating compressor units totaling 13,200 horsepower with one, 13,058 horsepower Solar Mars 100 compressor unit located at Gulf South's Marksville Compressor Station in Avoyelles Parish, Louisiana, all as more fully set forth in the application, which is open to the public for inspection.

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.

Any questions regarding this application should be directed to Juan Eligio, Jr., Supervisor of Regulatory Affairs, Gulf South Pipeline Company, LLC, 9 Greenway Plaza, Houston, Texas 77046, at (713) 479–3480 or by email to *juan.eligio@bwpipelines.com.* Questions may also be directed to Payton Barrientos, Sr., Regulatory Analyst, Gulf South Pipeline Company, LLC, 9 Greenway Plaza, Houston, Texas 77046, at (713) 479–8157 or by email to *payton.barrientos@bwpipelines.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on December 28, 2020. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[1] any person [2] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[3] and must be submitted by the protest deadline, which is December 28, 2020. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is December 28, 2020. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before December 28, 2020. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP21–7–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [6]

(2) You can file a paper copy of your submission by mailing it to the address below.[7] Your submission must reference the Project docket number CP21–7–000.

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: 9 Greenway Plaza, Houston, Texas 77046 or at *juan.eligio@bwpipelines.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: October 29, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24459 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 157.205.

[2] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[3] 18 CFR 157.205(e).

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

[6] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

[7] Hand-delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1818–023.
Applicants: Public Service Company of Colorado.
Description: Notice of Change in Status of Public Service Company of Colorado.
Filed Date: 10/28/20.
Accession Number: 20201028–5168.
Comments Due: 5 p.m. ET 11/18/20.

Docket Numbers: ER19–465–004.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2020–10–29_Compliance Order 841 Electric Storage Resources to be effective 6/6/2022.
Filed Date: 10/29/20.
Accession Number: 20201029–5016.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER19–1864–005.
Applicants: Public Service Company of Colorado.
Description: Compliance filing: 2020–10–29_OATT–Att N–LGIP–Order 845 Comp–0.6.4 to be effective 12/5/2019.
Filed Date: 10/29/20.
Accession Number: 20201029–5172.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER20–1062–002.
Applicants: Garden Wind, LLC.
Description: Compliance filing: Garden Wind, LLC, Docket No. ER20–1062–002 to be effective 5/1/2020.
Filed Date: 10/29/20.
Accession Number: 20201029–5026.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER20–2280–001.
Applicants: Evergy Metro, Inc.
Description: Compliance filing: Compliance Filing, Electric Interconnection & Delivery Service Agreements to be effective 9/1/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5147.
Comments Due: 5 p.m. ET 11/18/20.

Docket Numbers: ER20–2331–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2020–10–28_SA 3511 Deficiency Response ITC Midwest-MEC FSA (J344) to be effective 9/6/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5091.
Comments Due: 5 p.m. ET 11/18/20.

Docket Numbers: ER20–2333–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2020–10–28 SA 3523 Deficiency Response ITC–IPL FSA (J438) to be effective 6/30/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5079.
Comments Due: 5 p.m. ET 11/18/20.

Docket Numbers: ER20–2353–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2020–10–28_SA 3510 Deficiency Response OTP–GRE FSA (G788) to be effective 8/1/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5151.
Comments Due: 5 p.m. ET 11/18/20.

Docket Numbers: ER20–2421–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2020–10–29_SA 3522 Deficiency Response OTP–NSP FSA (J290) to be effective 8/1/2020.
Filed Date: 10/29/20.
Accession Number: 20201029–5005.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–237–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) Rate Filing: 2020–10–28_PSCo–IREA–NERC Plnner & Plnng Coord–467–0.0.0 to be effective 1/1/2021.
Filed Date: 10/28/20.
Accession Number: 20201028–5133.
Comments Due: 5 p.m. ET 11/18/20.

Docket Numbers: ER21–238–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA, Service Agreement No. 5819; Queue No. AF2–043 to be effective 9/29/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5134.
Comments Due: 5 p.m. ET 11/18/20.

Docket Numbers: ER21–239–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2020–10–29_Manual Redispatch Compensation Filing to be effective 1/20/2021.
Filed Date: 10/29/20.
Accession Number: 20201029–5024.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–240–000.
Applicants: Gulf Power Company.
Description: § 205(d) Rate Filing: Amendments to Service Agreement for Network Integration Transmission Service to be effective 12/31/9998.
Filed Date: 10/29/20.
Accession Number: 20201029–5031.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–241–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Revisions to Attachment W to Update Index of Grandfathered Agreements to be effective 1/1/2021.
Filed Date: 10/29/20.
Accession Number: 20201029–5058.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–242–000.
Applicants: Entergy Texas, Inc.
Description: § 205(d) Rate Filing: ETI–ETEC Wholesale Distribution Service Agreement to be effective 10/1/2020.
Filed Date: 10/29/20.
Accession Number: 20201029–5065.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–243–000.
Applicants: San Diego Gas & Electric Company.
Description: § 205(d) Rate Filing: Appendix X Cycle 9 to be effective 1/1/2021.
Filed Date: 10/29/20.
Accession Number: 20201029–5104.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–244–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: NCMPA1 RS No. 318 Amendment (2021) to be effective 1/1/2021.
Filed Date: 10/29/20.
Accession Number: 20201029–5127.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–245–000.
Applicants: Michigan Electric Transmission Company, LLC.
Description: § 205(d) Rate Filing: Filing of an Amended Interconnection Facilities Agreement to be effective 12/29/2020.
Filed Date: 10/29/20.
Accession Number: 20201029–5133.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–246–000.
Applicants: Duke Energy Carolinas, LLC.
Description: Tariff Cancellation: DEC–PMPA RS. No. 340 Cancellation to be effective 1/1/2021.
Filed Date: 10/29/20.
Accession Number: 20201029–5137.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–247–000.
Applicants: Wisconsin Public Service Corporation.
Description: Tariff Cancellation: Notice of Cancellation of Metering Agent Agreement to be effective 12/31/2020.
Filed Date: 10/29/20.
Accession Number: 20201029–5138.
Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–248–000.
Applicants: Southwestern Public Service Company.

Description: § 205(d) Rate Filing: 2020–10–29_SPS–Tx Transp Comn–Utility Agrmt–0.0.0 to be effective 10/30/2020.

Filed Date: 10/29/20.

Accession Number: 20201029–5151.

Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–249–000.

Applicants: Southern California Edison Company.

Description: Petition for Waiver of Appendix XI, Transmission Maintenance and Compliance Review, et al. of Southern California Edison Company.

Filed Date: 10/29/20.

Accession Number: 20201029–5167.

Comments Due: 5 p.m. ET 11/19/20.

Docket Numbers: ER21–250–000.

Applicants: Duke Energy Progress, LLC.

Description: Tariff Cancellation: DEP-City of Camden RS No. 197 Cancellation to be effective 1/1/2021.

Filed Date: 10/29/20.

Accession Number: 20201029–5166.

Comments Due: 5 p.m. ET 11/19/20.

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: October 29, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24423 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–9033–000]

Obenshain, Suzanne S.; Notice of Filing

October 29, 2020.

Take notice that on October 29, 2020, Suzanne S. Obenshain submitted for filing, application for authority to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d(b) (2020) and part 45 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR part 45.8 (2020).

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. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

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.

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.

Comment Date: 5:00 p.m. Eastern Time on November 19, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24426 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–455–000]

Freeport LNG Development, L.P., FLNG Liquefaction, LLC, FLNG Liquefaction 2, LLC and FLNG Liquefaction 3, LLC; Notice of Schedule for Environmental Review of the Noble Gas Project

On May 13, 2020, Freeport LNG Development, L.P., FLNG Liquefaction, LLC, FLNG Liquefaction 2, LLC, and FLNG Liquefaction 3, LLC (together referred to as Freeport LNG) filed an application in Docket No. CP20–455–000 requesting authorization pursuant to Section 3 of the Natural Gas Act to construct and operate certain modifications to its Pretreatment Facility in Brazoria County, Texas. The proposed project is known as the Noble Gas Project (Project).

On May 28, 2020, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the project. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the project.

Schedule for Environmental Review

Issuance of EA—December 18, 2020
90-day Federal Authorization Decision Deadline—March 18, 2021

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the project's progress.

Project Description

Freeport LNG requests authorization to construct and operate modifications to Freeport LNG's existing Pretreatment Facility in Brazoria County, Texas, to allow for the extraction of helium from the existing compressed boil-off gas (BOG) pipeline. The Pretreatment Facility is part of the Freeport LNG

Terminal, and is located about 1.5 miles from the liquefaction facilities on Quintana Island. The modifications to the Pretreatment Facility include tie-ins to the BOG pipeline, a firewater system, and a nitrogen utility unit at the Pretreatment Facility. The project also requires a non-jurisdictional helium extraction and purification plant and associated electric supply tie-in.

Background

On July 16, 2020, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Noble Gas Project and Request for Comments on Environmental Issues* (NOI). The NOI was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. The Commission received no comments in response to the NOI. The U.S. Department of Transportation—Pipeline and Hazardous Materials Safety Administration is a cooperating agency in the preparation of the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP20–455), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: October 29, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24458 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AC20–150–000]

Pacific Gas and Electric Company; Notice of Filing

Take notice that on October 15, 2020, PG&E filed an Offer of Settlement and Stipulation in its Formula Rate Proceedings (Docket Nos. ER19–13–000, ER19–1816–000, and ER20–2265–000) which included adjustments to PG&E's regulatory capital structure used in its Formula Rate. As such, PG&E states that the parties filing interventions and/or comments/protests in Docket Nos. AC19–122–000 and AC20–150–000 are also parties to the Settlement in the Formula Rate Proceedings.

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 or 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. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of 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://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. 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 p.m. Eastern Time on November 12, 2020.

Dated: October 28, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24452 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC20–24–000]

Commission Information Collection Activities (FERC–725A(1C)); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of extension information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (''Commission'' or ''FERC'') is soliciting public comment on the renewal of currently approved information collection, FERC–725A(1C) (Mandatory Reliability Standards for Bulk-Power System: Reliability Standard TOP–001–4) which will be submitted to the Office of Management and Budget (OMB) for a review of the information collection requirements.

DATES: Comments on the collection of information are due December 4, 2020.

ADDRESSES: Send written comments on the information collections to OMB through *www.reginfo.gov/public/do/PRAMain.* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number(s) in the subject line of your comments. Comments should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

A copy of the comments should also be sent to the Commission, in Docket

No. IC20–20–000, by any of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *U.S. Postal Service Mail:* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.
- Effective 7/1/2020, delivery of filings other than by eFiling or the U.S. Postal Service should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Instructions:

OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review'' field, select Federal Energy Regulatory Commission; click ''submit,'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725A(1C) (Mandatory Reliability Standards for Bulk-Power System: Reliability Standard TOP–001–4).

OMB Control No.: 1902–0298.

Type of Request: Three-year approval of FERC–725A(1C) to the information collection, with no changes to the reporting and recordkeeping requirements.

Abstract: In a petition dated March 6, 2017, the North American Electric Reliability Corporation (''NERC'') requested Commission approval for proposed Reliability Standard TOP–001–4 (Transmission Operations). NERC stated that the ''proposed Reliability Standards address the Commission directives in Order No. 817 related to: (i) Transmission operator monitoring of non-bulk electric system (''BES'') facilities; (ii) redundancy and diverse routing of transmission operator, balancing authority, and reliability coordinator data exchange capabilities; and (iii) testing of alternative or less frequently used data exchange capabilities''. In an order on April 17, 2017,[1] the implementation of Reliability Standard TOP–001–4 and the retirement of Reliability Standard TOP–001–3 was approved.[2]

The 60-day **Federal Register** notice published on August 28, 2020 (85 FR 53355) and no comments were received.

Type of Respondents: Transmission Operators (TOP) and Balancing Authorities (BA).

Estimate of Annual Burden:[3] The Commission estimates the annual public reporting burden and cost as follows.

Information collection requirements	Number of respondents & type of entity[4]	Annual number of responses per respondent	Total number of responses	Average burden hours & cost per response ($)	Total annual burden hours & total annual cost ($)
	(1)	(2)	(1) * (2) = (3)	(4)[5]	(3) * (4) = (5)
FERC–725A(1C)					
TOP–001–4[6]					
Reporting (R10, R20, & R21), ongoing	321 (TOP)	1	321	3 hrs.; $210.57	963 hrs.; $67,592.97.
Recordkeeping, ongoing	321 (TOP)	1	321	2 hrs.; $82.06	642 hrs.; $26,341.26.
TOP Sub-Totals				5 hrs.; $292.63	1,605 hrs.; $93,934.23.
Reporting (R23 & R24), ongoing	97 (BA)	1	97	2 hrs.; $140.38	194 hrs.; $13,616.86.
Recordkeeping, ongoing	97 (BA)	1	97	4 hrs.; $164.12	388 hrs.; $15,919.64.
BA Sub-Totals				6 hrs.; $304.50	582 hrs.; $29,536.50.
FERC–725A(1C) ongoing total					2,187 hrs.; $123,470.73.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: October 28, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24454 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

[1] The Delegated Letter Order is available in the Commission's eLibrary at *https://elibrary.ferc.gov/idmws/common/OpenNat.asp?fileID=14560616.*

[2] TOP–001–5 soon formerly TOP–001–4 has been approved by the commission and is being submitted for approval through Final Rule issued on September 17, 2020. Although 725A(1C) is included in the Final Rule (9/17/2020) it will be submitted to OMB in 725A because only one OMB No. can be submitted at a time to OMB.

[3] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 Code of Federal Regulations 1320.3.

[4] Our estimates are based on the NERC Compliance Registry of 7/17/2020, which indicates there are 321 entities registered as TOPs and 97 entities registered as BAs within the United States. One entity may be registered as having several roles.

[5] The hourly cost figures, for salary plus benefits, for the reliability standards are based on Bureau of Labor Statistics (BLS) information (at *http://www.bls.gov/oes/current/naics2_22.htm*), as of May 2019. For reporting requirements, an electrical engineer (code 17–2071) is $70.19/hour; for the recordkeeping requirements, an information and record clerk (code 43–4199) is $41.03/hour.

[6] Requirement R21 (applicable to TOPs in ongoing yrs.) covers quarterly testing and associated reporting and recordkeeping requirements. Requirement R24 (applicable to BAs in ongoing yrs.) covers quarterly testing and associated engineering and recordkeeping requirements.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM18–9–000]

Participation of Distributed Energy Resource Aggregations in Markets Operated by Regional Transmission Organizations and Independent System Operators; Notice of Correction in Federal Register of Compliance Deadline

On September 17, 2020, the Commission issued Order No. 2222.[1] Order No. 2222 provides that ''each [Regional Transmission Organization or Independent System Operator (RTO/ISO)] must file the tariff changes needed to implement the requirements of this final rule within 270 days of the publication date of this final rule in the **Federal Register**.'' [2]

On October 21, 2020, notice of Order No. 2222 was published in the **Federal Register**, 85 FR 67094, providing that: ''Each RTO/ISO must file the tariff changes needed to implement the requirements of this final rule by September 17, 2021.''

On October 29, 2020, a correction regarding the October 21 notice concerning Order No. 2222 was published in the **Federal Register**, 85 FR 68450, stating that: '' 'September 17, 2021' should read 'July 19, 2021'.''

Notice is hereby given that the deadline to submit filings to comply with Order No. 2222 has been corrected and is July 19, 2021.

Dated: October 29, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24461 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4451–024]

Green Mountain Power Corporation; City of Somersworth, New Hampshire; Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 4451–024.

c. *Date filed:* April 30, 2020.

d. *Applicants:* Green Mountain Power, City of Somersworth, New Hampshire.

e. *Name of Project:* Lower Great Falls Hydroelectric Project.

f. *Location:* On the Salmon Falls River in Strafford County, New Hampshire, and York County, Maine. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. John Greenan, Green Mountain Power Corporation, 1252 Post Road, Rutland, VT 05701; Phone at (802) 770–2195, or email at *john.greenan@greenmountainpower.com.*

i. *FERC Contact:* Amanda Gill, (202) 502–6773 or *amanda.gill@ferc.gov.*

j. *Deadline for filing motions to intervene and protests:* 60 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests 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–4451–024.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing, but is not ready for environmental analysis at this time.

l. *Project Description:* The existing Lower Great Falls Project consists of: (1) A 297-foot-long, 32-foot-high stone masonry and concrete dam that includes the following sections: (a) A 176-foot-long spillway section with a crest elevation of 102.37 feet National Geodetic Vertical Datum of 1929 (NGVD) and 4-foot-high flashboards at an elevation of 106.37 feet NGVD at the top of the flashboards; (b) a 50-foot-long left abutment section; and (c) a 71-foot-long right abutment section; (2) an impoundment with a surface area of 32 acres and a storage capacity of 467 acre-feet at an elevation of 106.37 feet NGVD; (3) a 40.5-foot-wide, 20-foot-high intake structure with four 5-foot-wide, 10.5-foot-high steel frame gates and a trashrack with 2-inch bar spacing; (4) two steel penstocks that include: (a) An 8.5-foot-diameter, 120-foot-long left penstock that bifurcates into a 5.3-foot-diameter, 85-foot-long section and a 7.6-foot-diameter, 85-foot-long section; and (b) an 8.5-foot-diameter, 140-foot-long right penstock that bifurcates into a 7-foot-diameter, 85-foot-long section and a 7.6-foot-diameter, 85-foot-long section; (5) a 46-foot-long, 30-foot-wide concrete and brick powerhouse with four Francis turbine-generator units with a total capacity of 1.28 megawatt; (6) a 55-foot-long, 30-foot-wide tailrace; (7) a 260-foot-long underground transmission line that delivers power to a 4.16-kilovolt distribution line; and (8) appurtenant facilities. The project creates a 250-foot-long bypassed reach of the Salmon Falls River between the dam and the downstream end of the tailrace.

The project operates as a run-of-river (ROR) facility with no storage or flood control capacity. The project impoundment is maintained at a flashboard crest elevation of 106.37 feet NGVD. The current license requires the project to maintain a continuous minimum flow of 6.05 cubic feet per second (cfs) or inflow, whichever is less, to the bypassed reach for the purpose of protecting and enhancing aquatic resources in the Salmon Falls River. The average annual generation production of the project was 3,916,825 kilowatt-hours from 2005 through 2018.

The applicant proposes to: (1) Continue operating the project in a ROR mode; (2) provide a minimum flow of 30 cfs or inflow, whichever is less, to the bypassed reach; (3) install an eel ramp for upstream eel passage at the project; (4) implement targeted nighttime turbine shutdowns to protect eels during downstream passage; and (5) install a downstream fish passage structure for eels and other resident fish species.

m. A copy of the application is available for review via the internet through the Commission's Home Page

[1] *Participation of Distributed Energy Resource Aggregations in Markets Operated by Regional Transmission Organizations and Independent System Operators,* Order No. 2222, 172 FERC ¶ 61,247 (2020).

[2] *Id.* PP 9, 360.

(*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–4451). 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 Online Support.

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'', or ''MOTION TO INTERVENE;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

o. *Procedural schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Issue Scoping Document 1 for comments—November 2020
Request Additional Information (if necessary)—January 2021
Issue Scoping Document 2—February 2021
Issue Notice of Ready for Environmental Analysis—February 2021
Commission issues Environmental Assessment—August 2021

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: October 28, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24455 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP21–101–000.
Applicants: Kern River Gas Transmission Company.
Description: (doc-less) Motion to Intervene of Calpine Energy Services, L.P. under RP21–101.
Filed Date: 10/28/20.
Accession Number: 20201028–5080.
Comments Due: 5 p.m. ET 11/9/20.

Docket Numbers: RP21–102–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Non-Conforming Agreement—National Grid 511110 to be effective 11/1/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5060.
Comments Due: 5 p.m. ET 11/9/20.

Docket Numbers: RP21–103–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—National Grid 511110 to be effective 11/1/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5061.
Comments Due: 5 p.m. ET 11/9/20.

Docket Numbers: RP21–104–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Conoco 910662 Releases eff 11–01–2020 to be effective 11/1/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5099.
Comments Due: 5 p.m. ET 11/9/20.

Docket Numbers: RP21–105–000.
Applicants: Enable Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—November 1 2020 GEP to be effective 11/1/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5154.
Comments Due: 5 p.m. ET 11/9/20.

Docket Numbers: RP21–106–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Filing to Correct Currently Effective Rate Section to be effective 10/28/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5158.
Comments Due: 5 p.m. ET 11/9/20.

Docket Numbers: RP21–107–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Eversource 510066 Releases to be effective 11/1/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5161.
Comments Due: 5 p.m. ET 11/9/20.

Docket Numbers: RP21–108–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: 261 Upgrade Project—Recourse Rate to be effective 11/1/2020.
Filed Date: 10/28/20.
Accession Number: 20201028–5162.
Comments Due: 5 p.m. ET 11/9/20.

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: October 29, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24424 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–9032–000]

Hewa, John D., Jr.; Notice of Filing

Take notice that on October 28, 2020, John D. Hewa Jr., submitted for filing, application for authority to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d(b) (2020) and Part 45 of

the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR part 45.8 (2020).

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. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

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.

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.

Comment Date: 5:00 p.m. Eastern Time on November 18, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24425 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC20–20–000]

Commission Information Collection Activities (Ferc–523); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on a renewal of currently approved information collection, FERC–523 (Application for Authorization for the Issuance of Securities or the Assumption of Liabilities).

DATES: Comments on the collection of information are due December 4, 2020.

ADDRESSES: Send written comments on the information collections to OMB through *www.reginfo.gov/public/do/PRAMain.* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number(s) in the subject line of your comments. Comments should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

A copy of the comments should also be sent to the Commission, in Docket No. IC20–20–000, by any of the following methods:

- *eFiling at Commission's website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *U.S. Postal Service Mail:* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.
- Effective 7/1/2020, delivery of filings other than by eFiling or the U.S. Postal Service should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Instructions:

OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review'' field, select Federal Energy Regulatory Commission; click ''submit,'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–523, Application for Authorization for the Issuance of Securities or the Assumption of Liabilities.

OMB Control No.: 1902–0043.

Type of Request: Three-year approval of the FERC–523 information collection requirements with no changes to the current reporting requirements.

Abstract: The information collected by FERC–523 is required to implement the statutory provisions of section 204 of the Federal Power Act (FPA) (16 U.S.C. 824c). Under section 204 of the FPA, no public utility or licensee shall issue any security, or assume any obligation or liability as guarantor, endorser, surety, or otherwise in respect of any security of another person, until the public utility applies for and receives Commission approval by order authorizing the issuance or assumption of the liability. The Commission issues an order if it finds that such issuance or assumption (a) is for lawful object, within the corporate purposes of the applicant and compatible with the public interest, which is necessary or appropriate for or consistent with the proper performance by the applicant as a public utility, and which will not impair its ability to perform that service, and (b) is reasonably necessary or appropriate for such purposes.

The Commission uses the information contained in filings to determine its acceptance and/or rejection of applications for authorization to either issue securities or to assume an obligation or liability by the public utilities and licensees who submit these applications.

The specific application requirements and filing format are found at 18 CFR part 34, and 18 CFR 131.43 and 131.50. This information is filed electronically. The 60-day **Federal Register** notice published on August 18, 2020 (85 FR 50823) with no comments were received.

Type of Respondents: Public utilities subject to the Federal Power Act.

Estimate of Annual Burden[1] *and cost*[2]*:* The Commission estimates the reduction in the annual public reporting burden for the FERC–523, as follows:

FERC–523, APPLICATION FOR AUTHORIZATION FOR ISSUANCE OF SECURITIES OR THE ASSUMPTION OF LIABILITIES

Number of respondents	Annual number of responses per respondent	Total number of responses[3]	Average burden hrs. & cost ($) per response	Total annual burden hrs. & total annual cost ($)	Cost per respondent ($)
(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1))
57	1	57	70 hrs.; $5,810	3,990 hrs.; $331,170	$5,810

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: October 28, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24453 Filed 11–3–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0260; FRL–10010–13]

Pesticides; Draft Guidance for Pesticide Registrants on the List of Pests of Significant Public Health Importance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and seeking public comment on a draft Pesticide Registration Notice (PR Notice) entitled, ''Draft List of Pests of Significant Public Health Importance—Revised 2020.'' PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This particular draft PR Notice provides guidance to the registrant concerning the proposal to update and replace the Pesticide Registration Notice (PRN) 2002–1, which identifies pests of significant public health importance. The United States Department of Health and Human Services (HHS), United States Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) determined that updating the list to reflect the current public health situation was warranted because vector-borne diseases and related research has changed significantly since the original PR Notice was published almost 20 years ago. This update includes the addition or removal of pests, new impacts, renaming pests, or grouping pests of similar species.

DATES: Comments must be received on or before January 4, 2021.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2020–0260, through *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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 information on EPA/DC services, submitting comments and docket access, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Jennings, Immediate Office (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (706) 355–8574; email address: *jennings.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in

[1] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 Code of Federal Regulations 1320.3.

[2] Commission staff estimates that the industry's skill set and cost (for wages and benefits) for FERC–523 are approximately the same as the Commission's average cost. The FERC 2020 average salary plus benefits for one FERC full-time equivalent (FTE) is $172,329/year (or $83.00/hour).

[3] The number of responses has decreased from the collection renewal in 2017 due to normal fluctuations in industry.

accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

C. How can I get copies of this document and other related information?

A copy of the draft PR Notice is available in the docket, identified by docket ID number EPA–HQ–OPP–2020–0260, at *http://www.regulations.gov.*

II. What guidance does this PR Notice provide?

This draft PR Notice provides guidance to the registrant concerning the proposal to update and replace the Pesticide Registration Notice (PRN) 2002–1, which identifies pests of significant public health importance. The list was first published in 2002, fulfilling the requirement of FIFRA section 28(d) to identify pests of significant public health importance (see the original list: *https://www.epa.gov/sites/production/files/2014-04/documents/pr2002-1.pdf*). EPA, HHS and USDA believe that pests, diseases and control techniques have evolved since 2002. The list provides an interagency baseline for the federal government and the public to begin any discussions on government regulation and control of disease or disease vectors. EPA uses the list of pests of significant public health importance to develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological and other methods to control pests of public health importance. When a pest is added to this list, it reflects a determination that the pest is a pest of significant public health importance and the list serves as a public reference to that effect. The publication of the updated list does not affect the regulatory status of any registration or application for registration of any pesticide product, therefore, registrants do not need to take any action.

EPA requests comment on whether there are any pests, such as the Asian giant hornet (*Vespa mandarinia*) or the Turkestan cockroach (*Blatta lateralis*), that should be added to this list to address emergent pest issues.

III. Do PR Notices contain binding requirements?

The PR Notice discussed in this document is intended to provide guidance to EPA personnel and decisionmakers and to pesticide registrants. While the requirements in the statutes and Agency regulations are binding on EPA and the applicants, this PR Notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or situation.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 30, 2020.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2020–24483 Filed 11–3–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10015–38–Region 3]

Notice of Tentative Approval and Opportunity for Public Comment and Public Hearing for Public Water System Supervision Program Revision for Pennsylvania

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of approval and solicitation of requests for public hearing.

SUMMARY: Notice is hereby given that the Commonwealth of Pennsylvania is revising its approved Public Water System Supervision Program. Pennsylvania has adopted drinking water regulations for the Ground Water Rule and the Long Term 2 Enhanced Surface Water Treatment Rule. The U.S. Environmental Protection Agency (EPA) has determined that Pennsylvania's Ground Water Rule and Long Term 2 Enhanced Surface Water Treatment Rule meet all minimum federal requirements, and that these are no less stringent than the corresponding federal regulations. Therefore, EPA has tentatively decided to approve the State program revisions.

DATES: Comments or a request for a public hearing must be submitted by December 4, 2020. This determination shall become final and effective on December 4, 2020 if no timely and appropriate request for a hearing is received, and the Regional Administrator does not elect to hold a hearing on his own motion, and if no comments are received which cause EPA to modify its tentative approval.

ADDRESSES: As a result of impacts related to the COVID–19 pandemic, all requests for documents relating to this determination must be submitted by electronic mail to the address below. Comments or a request for a public hearing must also be submitted via electronic mail.

FOR FURTHER INFORMATION CONTACT: Kelly Moran, EPA Region III, Drinking Water Section by email at *moran.kelly@epa.gov,* or telephone (215) 814–2331.

SUPPLEMENTARY INFORMATION: All interested parties are invited to submit written comments on this determination and may request a hearing. All comments will be considered, and if necessary, EPA will issue a response. Frivolous or insubstantial requests for a hearing will be denied by the Regional Administrator. If a substantial request for a public hearing is made by December 4, 2020, a public hearing will be held. A request for public hearing shall include the following: (1) The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; (2) a brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intends to submit at such hearing; and (3) the signature of the individual making the request; or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

Dated: October 23, 2020.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2020–24375 Filed 11–3–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2019–0499; FRL–10015–51]

Carbon Tetrachloride (CCl_4); 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 Carbon Tetrachloride (CCl_4). 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 CCl_4 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 take regulatory action 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–2019–0499, 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 Public Reading Room are closed to visitors with limited exceptions. The EPA/DC staff continue 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: Dr. Karen Eisenreich, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–7843; email address: *eisenreich.karen@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 EPA'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 CCl_4 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 CCl_4 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–2016–0733);
- Draft risk evaluation, and final risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0499);
- All notices, determinations, findings, consent agreements, and orders (in Docket ID No. EPA–HQ–OPPT–2019–0499);
- Any information required to be provided to the Agency under 15 U.S.C. 2603 (in Docket ID No. EPA–HQ–OPPT–2016–0733 and Docket ID No. EPA–HQ–OPPT–2019–0499);
- A nontechnical summary of the risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0499);
- A list of the studies, with the results of the studies, considered in carrying out each risk evaluation (Risk Evaluation for Carbon Tetrachloride (CCl_4)) in Docket ID No. EPA–HQ–OPPT–2019–0499);
- 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–2019–0499); and
- Response to public comments received on the draft scope and the draft risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0499).

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 review 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 is being 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 report from the peer review committee and public comments and has amended the risk evaluation in response to these comments as appropriate. The public comments, peer review report, and EPA's response to comments is in Docket ID No. EPA–HQ–OPPT–2019–0499. 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 ID No. EPA–HQ–OPPT–2016–0733. Additionally, information about the scope, problem formulation, and draft risk evaluation phases of the TSCA risk evaluation for this chemical is available at EPA's website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-carbon-tetrachloride.*

B. What is carbon tetrachloride (CCl_4)?

Carbon tetrachloride (CCl_4) is used as a feedstock in the production of hydrochloro fluorocarbons (HCFCs), hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs), and is a high-production volume solvent. It is also used as a process agent in the manufacturing of petrochemicals-derived and agricultural products and other chlorinated compounds such as chlorinated paraffins, chlorinated rubber and others that may be used downstream in the formulation of solvents for degreasing and cleaning, adhesives, sealants, paints, coatings, rubber, cement and asphalt formulations.

Authority: 15 U.S.C. 2601 *et seq.*

Andrew Wheeler,

Administrator.

[FR Doc. 2020–24478 Filed 11–3–20; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMMISSION

Sunshine Act Meeting

DATE AND TIME: Monday, November 9, 2020, 1:00 p.m. Eastern Time.

PLACE: Because of the COVID–19 pandemic, the meeting will be held as an audio-only conference.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED: The following item will be considered at the meeting:

Update to the Compliance Manual Section on Religious Discrimination.

Note: (In addition to publishing notices on EEOC Commission meetings in the **Federal Register,** the Commission also provides information about Commission meetings on its website, *www.eeoc.gov.,* and provides a recorded announcement a week in advance on future Commission sessions.)

Please telephone (202) 663–7100 (voice) or email *commissionmeetingcomments@eeoc.gov* at any time for information on this meeting.

CONTACT PERSON FOR MORE INFORMATION: Bernadette B. Wilson, Executive Officer on (202) 663–4077.

Raymond L. Peeler,

Assistant Legal Counsel, Office of Legal Counsel.

[FR Doc. 2020–24560 Filed 11–2–20; 11:15 am]

BILLING CODE 6570–01–P

EXPORT-IMPORT BANK

Sunshine Act Meetings; Notice of Open Meeting of the Sub-Saharan Africa Advisory Committee of the Export-Import Bank of the United States (EXIM)

TIME AND DATE: Tuesday, November 17, 2020 from 2:00–4:00 p.m. EST.

PLACE: The meeting will be held virtually.

STATUS: *Public Participation:* The meeting will be open to public participation and time will be allotted for questions or comments submitted online. Members of the public may also file written statements before or after the meeting to *external@exim.gov.* Interested parties may register for the

meeting at *https://www.exim.gov/register-attend.*

MATTERS TO BE CONSIDERED: Discussion of EXIM policies and programs designed to support the expansion of financing support for U.S. manufactured goods and services in Sub-Saharan Africa.

CONTACT PERSON FOR MORE INFORMATION: For further information, contact Brittany J. Walker, Deputy to the Senior Vice President for External Engagement, at 202–565–3216.

Kita L. Hall,

Program Specialist.

[FR Doc. 2020–24519 Filed 11–2–20; 11:15 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1271; FRS 17195]

Information Collection Approved by the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Federal Communications Commission (Commission) has received Office of Management and Budget (OMB) approval for a revision of a currently approved information collection pursuant to the Paperwork Reduction Act (PRA) of 1995. An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number, and no person is required to respond to a collection of information unless it displays a currently valid OMB control number. Comments concerning the accuracy of the burden estimates and any suggestions for reducing the burden should be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nicole Ongele at (202) 418–2991 or via email: *Nicole.Ongele@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1271.

OMB Approval Date: October 7, 2020.

OMB Expiration Date: October 31, 2023.

Title: Promoting Telehealth for Low-Income Consumers; COVID–19 Telehealth Program.

Form No.: FCC Forms 460, 461, 462, and 463.

Respondents: Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local, or Tribal governments.

Number of Respondents and Responses: 7,300 respondents; 34,623 responses.

Estimated Time per Response: 0.30–25 hours.

Frequency of Response: One-time and annual reporting requirements.

Total Annual Burden: 198,347 hours.

Total Annual Cost: No Cost.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in sections 1–4, 201–205, 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 201–205, 214, 254, 303(r), and 403, and Division B of the Coronavirus Aid Relief, and Economic Security (CARES) Act, Public Law 116–136, 134 Stat. 281 (2020).

Privacy Act Impact Assessment: No Impact(s).

Nature and Extent of Confidentiality: There is no assurance of confidentiality provided to respondents concerning this information collection. Information submitted on Rural Health Care Program FCC Forms for the Connected Care Pilot Program is subject to public inspection and is used by the Universal Service Administrative Company (USAC) to update and expand the Connected Care Pilot Program dataset as part of its Open Data Platform. However, respondents may request materials or information submitted to the Commission or to USAC be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The revision to this collection will assist eligible health care providers to provide connected care services to consumers through the Programs. The Commission and USAC will use the information collected to facilitate the administration of the Programs and to determine whether applicants and participating entities are complying with the Commission's rules and to prevent waste, fraud, and abuse. This information also allows the Commission to evaluate the extent to which the Programs are adhering to the applicable rules and procedures and the Telecommunications Act or CARES Act as applicable. The Wireline Competition Bureau will issue a Public Notice announcing the opening date for the application window for the Connected Care Pilot Program.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–24440 Filed 11–3–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201351.

Agreement Name: Foundation Carrier Agreement.

Parties: CMA CGM S.A.; Maersk A/S; and MSC Mediterranean Shipping Company S.A.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The Agreement authorizes the parties (in cooperation with the providers of the TradeLens platform) to form a Foundation Council, provides for the composition of that Council, and sets forth the matters that require approval of, or consultation with, the Foundation Council. In addition, the Agreement sets forth the information that is to be provided to the TradeLens platform by the carrier parties, and details understandings relating to the use of, access to, and confidentiality of such data. It also sets forth understandings relating to the marketing of the platform.

Proposed Effective Date: 12/13/2020.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/36502.

Dated: October 30, 2020.

Rachel Dickon,

Secretary.

[FR Doc. 2020–24418 Filed 11–3–20; 8:45 am]

BILLING CODE 6730–02–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 December 4, 2020.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Security Bancshares Company, Glencoe, Minnesota;* to acquire voting shares of Flagship Financial Group, Inc., Eden Prairie, Minnesota, and thereby indirectly acquire Flagship Bank Minnesota, Wayzata, Minnesota.

Board of Governors of the Federal Reserve System, October 30, 2020.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2020–24439 Filed 11–3–20; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0001; Docket No. 2020–0053; Sequence No. 14]

Information Collection; Standard Form 28, Affidavit of Individual Surety

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on a revision and renewal concerning the Standard Form 28, Affidavit of Individual Surety. DoD, GSA, and NASA invite comments on: Whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through February 28, 2021. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD, GSA, and NASA will consider all comments received by January 4, 2021.

ADDRESSES: DoD, GSA, and NASA invite interested persons to submit comments on this collection through *http://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

Instructions: All items submitted must cite OMB Control No. 9000–0001, Standard Form 28, Affidavit of Individual Surety. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0001, Standard Form 28, Affidavit of Individual Surety.

B. Need and Uses

This clearance covers the information that offerors or contractors must submit to comply with the following Federal Acquisition Regulation (FAR) requirement:

- *Standard Form (SF) 28, Affidavit of Individual Surety.*

This form is used by all executive agencies, including the Department of Defense (DoD), to obtain information from individuals wishing to serve as sureties to Government bonds. Offerors and contractors may use an individual surety as security for bonds required under a solicitation or contract for supplies or services (including construction). It is an elective decision on the part of the offeror or contractor to use individual sureties instead of other available sources of surety or sureties for Government bonds.

The contracting officer uses the information on the SF 28 to determine the acceptability of individuals proposed as sureties.

C. Annual Burden

Respondents: 10.

Total Annual Responses: 20.

Total Burden Hours: 6.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0001, Standard Form 28, Affidavit of Individual Surety.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2020–24417 Filed 11–3–20; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–1215]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Awardee Lead Profile Assessment (ALPA) to the Office

of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 20, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Awardee Lead Profile Assessment (ALPA) (OMB Control No. 0920–1215, Exp. 02/28/2021)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is requesting Paperwork Reduction Act (PRA) clearance for a three-year revised information collection request (ICR) titled ''Awardee Lead Profile Assessment (ALPA)'' (OMB Control No. 0920–1215; expiration date 02/28/2021). The goal of this ICR is to build on the CDC's existing childhood lead poisoning prevention program. Based on program successes over the past three years, CDC has made ALPA an annual reporting requirement for ongoing and new CDC Childhood Lead Poisoning Prevention Programs (CLPPPs), including the FY17 ''Lead Poisoning Prevention—Childhood Lead Poisoning Prevention—financed partially by Prevention and Public Health Funds'' (CDC–RFA–EH17–1701PPHF17); the FY18 ''Childhood Lead Poisoning Prevention Projects, State and Local Childhood Lead Poisoning Prevention and Surveillance of Blood Lead Levels in Children'' (CDC–RFA–EH18–1806); and the FY20 ''Childhood Lead Poisoning Prevention and Surveillance of Blood Lead Levels in Children'' (CDC–RFA–EH20–2001). This annual information collection will be used to; (1) identify common characteristics of funded childhood lead poisoning prevention programs, and (2) inform guidance and resource development in support of the ultimate program goal, which is blood lead elimination in children.

The dissemination of these ALPA results will ensure that both funded and non-funded jurisdictions are able to; (1) identify policies and other factors that support or hinder childhood lead poisoning prevention efforts; (2) understand what strategies are being used by funded public health agencies to implement childhood lead poisoning prevention activities; and (3) use this knowledge to develop and apply similar strategies to support the national agenda to eliminate childhood lead poisoning.

This program management information collection has been revised in several ways. Due to an increase in funding and program growth, CDC is requesting an increase in the number of respondents, defined as state and local governments, or their bona fide agents.

CDC will continue to use two data collection modes, a web survey and an email survey. We anticipate that most of the respondents (n=60; 98 percent) will use the web survey. The estimates of the number and percentage of respondents by mode of data collection are based on previous data collections. In the past, respondents only used the email survey if they had technical difficulties with the web survey, which was rare. For this purpose, we estimate that only 2% (n=1) of the respondents may need to submit an email survey. This represents a change in distribution from the 2018 estimates, which were initially assumed as 83.3% for the web survey and 16.7% for the email survey.

A redistribution by mode of collection will not affect the total time burden requested as the time per response is the same for either mode; however, the time to take the survey has increased from seven minutes in 2018 to 47 minutes per response due to a revision of the survey. This revised time estimate per response is based on pilot tests of the revised survey among nine respondents, and includes the time needed to review the ALPA Training Manual, which is a new addition in this revision ICR.

Thus, CDC is requesting an increase in the annual number of respondents from 48 to a maximum of 61 recipients (n=13 more respondents), and an increase in the total annual time burden from six hours in 2018 to 48 hours (n=42 more hours).

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State or Local Governments (or their bona fide fiscal agents).	ALPA Web Survey	60	1	47/60
	ALPA Email Survey	1	1	47/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–24474 Filed 11–3–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Framework for Conditional Sailing and Initial Phase COVID–19 Testing Requirements for Protection of Crew

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services (HHS), announces a framework for a phased resumption of cruise ship passenger operations. CDC also announces requirements for the initial phases of this framework regarding testing of crew members for COVID–19, an integral part of the initial phases prior to resuming passenger operations. This Order applies to cruise ship operators with cruise ships operating in U.S. waters and cruise ship operators who are operating cruise ships outside of U.S. waters, but intend for their cruise ships to return to operating in U.S. waters while this Order remains in effect.

DATES: This action is effective October 30, 2020.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Phone: 404–498–1600. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: This Order establishes a framework for a phased approach to resuming cruise ship passenger operations in U.S. waters. This phased approach will include: (1) Establishment of laboratory testing of crew onboard cruise ships in U.S. waters; (2) simulated voyages designed to test a cruise ship operators' ability to mitigate COVID–19 onboard cruise ships; (3) a certification process; and (4) a return to passenger voyages in a manner that mitigates the risk of COVID–19 introduction, transmission, or spread among passengers and crew onboard ships and ashore to communities.

As part of the initial crew testing phases, this Order additionally contains requirements for: (1) Shoreside COVID–19 laboratory screening testing of all crew currently onboard cruise ships; (2) onboard diagnostic testing capabilities for symptomatic travelers (crew and future passengers); (3) shoreside COVID–19 laboratory screening testing of all newly embarking crew; and (4) continued compliance with complete, accurate, and acknowledged, No Sail Order Response Plans.

A copy of the Order is provided below and a copy of the signed order can be found at *https://www.cdc.gov/quarantine/cruise/index.html.*

U.S. Department of Health and Human Services (HHS)—Centers for Disease Control and Prevention (CDC)

Order Under Sections 361 & 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 Code of Federal Regulations Part 70 (Interstate) and Part 71 (Foreign): Framework for Conditional Sailing and Initial Phase COVID–19 Testing Requirements for Protection of Crew

Executive Summary

The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), announces this framework for a phased resumption of cruise ship passenger operations. Considering the continued spread of COVID–19 worldwide and increased risk of COVID–19 on cruise ships, a careful approach is needed to safely resume cruise ship passenger operations. CDC is establishing requirements to mitigate the COVID–19 risk to passengers and crew, prevent the further spread of COVID–19 from cruise ships into U.S. communities, and protect public health and safety. After expiration of CDC's No Sail Order (NSO) on October 31, 2020, CDC will take a phased approach to resuming cruise ship passenger operations in U.S. waters.

The initial phases will consist of testing and additional safeguards for crew members. CDC will ensure cruise ship operators have adequate health and safety protections for crew members while these cruise ship operators build the laboratory capacity needed to test future passengers. Subsequent phases will include simulated voyages to test cruise ship operators' ability to mitigate COVID–19 risk, certification for ships that meet specific requirements, and a phased return to cruise ship passenger voyages in a manner that mitigates COVID–19 risk among passengers, crew members, and U.S. communities. These phases are subject to change based on public health considerations and cruise ship operators' demonstrated ability to mitigate COVID–19 risk. CDC will issue additional orders as needed that will be published in the **Federal Register** and technical instructions that will be subsequently posted on CDC's website.

This Order additionally announces requirements for the initial phases relating to crew testing. CDC considers adequate crew safeguards as demonstrated through laboratory testing for SARS coronavirus 2 (SARS–CoV–2), the virus that causes COVID–19, an integral part of the initial phases prior to resuming passenger operations.

Previous Orders and Incorporation by Reference

The findings and other evidence relied upon in issuing the No Sail Order and Other Measures Related to Operations signed by the CDC Director on March 14, 2020,[1] as further modified and extended effective April 15, 2020,[2] July 16, 2020,[3] and September 30, 2020 [4]—are incorporated herein by reference.

Statement of Intent

This Order shall be interpreted and implemented in a manner as to achieve the following paramount objectives:

- Preserving human life;
- Preserving the health and safety of cruise ship crew members, port personnel, and communities;
- Preventing the further introduction, transmission, and spread of COVID–19 into and throughout the United States;
- Preserving the public health and other critical resources of Federal, State, and local governments;

[1] No Sail Order and Suspension of Further Embarkation. *https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation.* Last accessed October 19, 2020.

[2] No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations. *https://www.federalregister.gov/documents/2020/04/15/2020-07930/no-sail-order-and-suspension-of-further-embarkation-notice-of-modification-and-extension-and-other.* Last accessed October 19, 2020.

[3] No Sail Order and Suspension of Further Embarkation, Second Modification and Extension of No Sail Order and Other Measures Related to Operations. *https://www.federalregister.gov/documents/2020/07/21/2020-15810/no-sail-order-and-suspension-of-further-embarkation-second-modification-and-extension-of-no-sail.* Last accessed October 19, 2020.

[4] No Sail Order and Suspension of Further Embarkation; Third Modification and Extension of No Sail Order and Other Measures Related to Operations. *https://www.federalregister.gov/documents/2020/10/05/2020-22030/no-sail-order-and-suspension-of-further-embarkation-third-modification-and-extension-of-no-sail.* Last accessed October 19, 2020.

• Preserving hospital, healthcare, and emergency response resources within the United States; and

• Maintaining the safety of shipping and harbor conditions.

Acronyms, Initialisms, and Definitions

(a): The acronyms and initialisms below will have the following meaning:

aCLI means additional COVID-like illness signs and symptoms as defined by the Council of State and Territorial Epidemiologists (CSTE) and that are not included in the definitions of ARI, ILI, or pneumonia, or as defined by CDC in technical instructions. CDC will use the most current CSTE definition in effect, which may be found at: *https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/.*

ARI means Acute Respiratory Illness defined as the presence of cough, sore throat, or runny nose (rhinorrhea) in the absence of fever and in the absence of a non-infectious diagnosis (*e.g.,* allergies) as determined by the ship's medical provider, or as defined by CDC in technical instructions.

CLI means COVID-like Illness.

CDC means U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, or an authorized representative acting on its behalf.

EDC means Enhanced Data Collection.

ILI means influenza-like illness defined as fever (≥100.4 °F [38 °C]) plus either cough or sore throat or as defined by CDC in technical instructions.

USCG means United States Coast Guard, Department of Homeland Security.

(b): The terms below will have the following meaning:

Controlled Free Pratique has the same meaning as under 42 CFR 71.1.

COVID–19 means the disease caused by the coronavirus SARS–CoV–2.

COVID-like Illness means ARI, ILI, pneumonia, aCLI, or other signs or symptoms of COVID-like illness as defined by CDC in technical instructions.

Crew or Crew member means any individual serving on board a cruise ship who is assigned to perform regular duties or tasks on behalf of a cruise ship operator in exchange for compensation.

Cruise ship means any commercial, non-cargo, passenger-carrying vessel operating in U.S. waters with the capacity to carry 250 or more individuals (passengers and crew) with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.[5]

Cruise ship operator means the master of the vessel (cruise ship) and any other crew member responsible for cruise ship operations and navigation, as well as any person or entity (including a corporate entity) that authorizes or directs the use of a cruise ship (*e.g.,* as owner, lessee, or otherwise). A cruise ship operator may also include the cruise ship captain or the cruise line to which the cruise ship belongs, and the officers and directors of the cruise line.

Director means the Director of the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, or an authorized representative.

Isolation means measures taken by a cruise ship operator to ensure the onboard or onshore separation of passengers or crew displaying signs or symptoms of COVID–19, or who have tested positive SARS–CoV–2, from other passengers or crew who do not display such signs or symptoms or have not tested positive for SARS–CoV–2.

Laboratory Testing or Laboratory Test Results means testing performed in a laboratory certified as meeting the standards of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or CLIA-waived point-of-care testing or the results of such testing. Testing must be performed using tests that are approved, cleared, or authorized for emergency use by the U.S. Food and Drug Administration (FDA) as specified by CDC in technical instructions or orders.

Operate or Operating in U.S. waters means any action by a cruise ship operator to bring or cause a cruise ship to be brought into or transit in or between any waterways (*e.g.,* shifting berths, moving to anchor, discharging waste, making port, or embarking or disembarking passengers or crew) subject to the jurisdiction of the United States.

Passenger means any individual being transported or offered transport on board a cruise ship who is not a crew member, excluding U.S. government personnel.

Passenger operations means any action by a cruise ship operator to cause passengers to embark or disembark a cruise ship.

Person means any individual or partnership, firm, company, corporation, association, organization, or other legal entity.

Quarantine means measures taken by a cruise ship operator to ensure the onboard or onshore separation and restriction of movement of passengers or crew who were potentially exposed to a person with COVID–19 while that person was considered infectious.

Responsible officials means the Chief Executive Officer (or equivalent) of the operating cruise company and all parent companies, the Chief Compliance Officer (or equivalent) of the operating cruise company and all parent companies, and the highest-ranking Medical Officer of the operating cruise company and all parent companies.

Simulated voyage means a mock voyage or series of mock voyages designed and implemented in so far as possible to replicate real world onboard conditions of cruising with measures in place to mitigate the risk of COVID–19.

Social distancing means maintaining a distance of at least 6 feet between one individual and another individual, not gathering in groups, and avoiding crowded places and mass gatherings.

U.S. waters means any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States.

Background and Need To Establish a Framework for Mitigating the Risk of COVID–19 Onboard Cruise Ships Prior to Resuming Passenger Operations

The coronavirus disease 2019 (COVID–19) pandemic continues to spread rapidly around the world with no U.S. Food and Drug Administration (FDA) authorized vaccine. As of October 30, 2020, a cumulative total of over 44 million cases and nearly 1.2 million confirmed deaths have now been reported worldwide. Even in countries that have managed to slow the rate of transmission, the risks for COVID–19 resurgence remains. In the United States, as of October 29, 2020, there have been over 8.8 million cases and over 227,000 confirmed deaths. Based on the evidence gathered and explained in the No Sail Order issued on March 14, as modified and extended on April 15, July 16, and September 30, 2020, there is ample reason to believe that absent mitigation measures of the type needed to prevent further transmission, cruise ship travel has the potential to exacerbate and amplify the spread of SARS coronavirus 2 (SARS–CoV–2) the virus that causes COVID–19.

[5] Cruise ships are defined in the same manner as in CDC's No Sail Orders, as extended and modified, that were issued between March 14 and September 30, 2020. CDC continues to define cruise ships in this manner based on substantial epidemiologic evidence related to congregate settings and mass gatherings. While evidence shows that outbreaks can occur in small settings such as nursing homes, as the numbers of passengers and crew on board a ship increase, certain recommended mitigation efforts such as social distancing become more difficult to implement. Considering the demonstrated rapid spread of COVID–19, the application of this framework to cruise ships carrying 250 or more passengers and crew remains prudent and warranted.

Unrestricted cruise ship travel would likely exacerbate and amplify the spread of SARS coronavirus 2 (SARS–CoV–2) the virus that causes COVID–19. On January 20, 2020, the *Diamond Princess* cruise ship departed Yokohama, Japan. On January 25, 2020, a symptomatic passenger departed the ship in Hong Kong, where he was later confirmed to have COVID–19. Upon the ship's return to Yokohama, Japanese authorities quarantined all passengers and crew on board the ship. Among the 3,711 *Diamond Princess* passengers and crew, 712 (19.2%) were subsequently confirmed to have COVID–19, 37 required intensive care, and nine died. Following this outbreak, two voyages of the *Grand Princess* cruise ship were ultimately associated with 159 confirmed COVID–19 cases, including eight deaths.[6]

Because of these events, and the increased risk of transmission on cruise ships, on March 14, 2020, the CDC Director issued a *No Sail Order and Other Measures Related to Operations* directing cruise ships not voluntarily suspending operations to comply with certain measures (85 FR 16628). This followed a March 13, 2020, announcement by Cruise Line International Association (CLIA), the leading industry trade group, that its members would voluntarily suspend cruise ship operations. On March 17, 2020, CDC issued a Level 3 Travel Health Notice warning all travelers to defer cruise travel worldwide based on widespread ongoing transmission of COVID–19.[7] Despite the announcement by CLIA, the application of the March 14, 2020 Order, and the Level 3 Travel Health Notice, cruise ships continued to be associated with new COVID–19 outbreaks. Between March 14 and April 15, 2020, COVID–19 outbreaks were reported on several additional cruise ships with passengers (85 FR 21004).

Accordingly, to protect public health and safety and prevent the further introduction, transmission, and spread of COVID–19 into and throughout the United States, the CDC Director issued *No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations,* modifying and extending the previous March 14, 2020 Order, which became effective on April 15, 2020 (85 FR 21004). Under the April 15, 2020 Extension, as a condition of obtaining controlled free pratique[8] to continue to engage in cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operations were limited, and cruise lines were required to submit plans to prevent, mitigate, and respond to the spread of COVID–19 on board to ensure a safe work environment and disembarkation for crew members. A cruise ship operator's No Sail Order response plan had to minimize to the greatest extent possible any impact on U.S. Government operations or the operations of any State or local government, or the U.S. healthcare system. While working with cruise ship operators to ensure the completeness and accuracy of these response plans, CDC allowed crew members to disembark from cruise ships in U.S. waters and return home if cruise ship operators formally attested, in writing, to complying with requirements to disembark crew members in such a manner as to minimize the risk to other travelers and communities.

Following the April 15, 2020 Extension, CDC published its *Interim Guidance for Mitigation of COVID–19 Among Cruise Ship Crew* to assist cruise ship operators in preventing, detecting, and medically managing confirmed and suspected SARS–CoV–2 infections and exposures among crew members.[9] During this period, CDC also further assisted cruise ship operators with humanitarian medical evacuations for people in need of lifesaving support. Under the April 15, 2020 Extension, CDC established an enhanced surveillance process to provide a more complete picture of COVID–19 activity on cruise ships through a requirement for weekly submission of the ''Enhanced Data Collection (EDC) During COVID–19 Pandemic Form (OMB Control Number 0920–0134, exp. 03/31/2022)''. Since then, the EDC form has been used to conduct surveillance for COVID–19 among crew who remained on board cruise ships based on cumulative reports of acute respiratory illness (ARI),[10] influenza-like illness (ILI),[11] pneumonia, and other clinical indicators of COVID–19 (85 FR 62732).

As of October 30, 2020, EDC reports have shown a total of 6,725 polymerase chain reaction (PCR) tests performed, 296 (4%) of which were positive; 24 hospitalizations; 2 instances of mechanical ventilation; and 15 medical evacuations for crew on ships within U.S. jurisdiction since April 15, 2020. CDC also recommended that ships' surveillance include routine testing for SARS–CoV–2 infection, including intermittent testing of a random sample of symptomatic and asymptomatic crew members.

In addition to reviewing the No Sail Order response plans, CDC continued to update its *Interim Guidance* as new information became available; provided technical expertise to ships with ongoing outbreaks; created cruise ship-specific websites to inform crew members, the public, and partners; and reviewed hundreds of written attestations submitted by cruise operators for safe disembarkation and transfer of crew members.

CDC established a ''COVID–19 Color Coding System'' for ships applicable to cruise ship operators with an appropriate No Sail Order response plan for crew management. Classification of ships under this system requires cruise company officials to sign an acknowledgment of the completeness and accuracy of their No Sail Order response plans upon completion of CDC review of the plan. CDC assesses the status of a ship by reviewing surveillance data from the weekly EDC form as well as recent embarkations or crew transfers. Additional details regarding the color-coding system and color coding status for individual ships (which is updated weekly) may be found at *https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html.*

To continue to protect public health and safety, and prevent the further introduction, transmission, and spread of COVID–19 into and throughout the United States, the CDC Director signed a *Second Modification and Extension of No Sail Order and Other Measures Related to Operations* on July 16, 2020, (85 FR 44085), and *Third Modification and Extension of No Sail Order and Other Measures Related to Operations* on September 30, 2020, (85 FR 62732).

[6] Moriarty LF, Plucinski MM, Marston BJ, et al. Public Health Responses to COVID–19 Outbreaks on Cruise Ships—Worldwide, February–March 2020. MMWR Morb Mortal Wkly Rep 2020;69:347–352. *https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm.* Last accessed June 25, 2020.

[7] CDC Travel Health Notice, *COVID–19 and Cruise Ship Travel,* at: *https://wwwnc.cdc.gov/travel/notices/warning/coronavirus-cruise-ship* (originally posted, March 17, 2020). Last accessed June 25, 2020.

[8] Under 42 CFR 71.1, controlled free pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

[9] CDC, *Interim Guidance for Mitigation of COVID–19 Among Cruise Ship Crew* at: *https://www.cdc.gov/quarantine/cruise/management/interim-guidance-no-sail-order.html*

[10] Acute Respiratory Illness (ARI) is defined as the presence of cough, sore throat, or rhinorrhea in the absence of fever.

[11] Influenza-like Illness (ILI) is defined as fever (100.4 °F [38 °C]) plus either cough or sore throat.

This last order, among other things, continued to suspend passenger operations on board cruise ships through October 31, 2020.

Current scientific evidence suggests that, absent mitigation measures of the type needed to prevent further transmission, cruise ships would continue to pose a greater risk of COVID–19 transmission than other settings. A recent article published in the Journal of Travel Medicine by Rocklöv et al. demonstrated that the *Diamond Princess* cruise ship experienced an onboard R_0 (basic reproduction rate) for COVID–19 of 14.8 before ship-wide quarantine was enacted.[12] This means that each case onboard the *Diamond Princess* transmitted COVID–19 to approximately 15 other people. This reproduction rate is approximately four times higher than the R_0 of the original epicenter of the outbreak in Wuhan, China, which was 3.7, meaning that each person with COVID–19 in the early days of the outbreak in Wuhan transmitted the disease to approximately four other people. In late February/early March, 149 cases of PCR-confirmed COVID–19 (of 589 tour participants) were found among U.S. residents linked to Egyptian Nile Cruises. This heightened rate of transmission onboard cruise ships has also been documented in other academic publications.[1 13] Absent appropriate interventions to mitigate the spread of COVID–19, cruise ship conditions would likely amplify the spread of an already highly transmissible disease.

Rocklöv et al. surmised that this heightened rate of transmission is due to the high population density on board ships, which are typically more densely populated than cities or most other living situations. While this is one contributing factor, CDC's surveillance data collected through the EDC form and acquired during the period of the No Sail Order show that drastically decreasing population on board, absent other interventions, is not enough to extinguish transmission. Other factors likely contributing to onboard transmission are crews' living and working in close quarters, in a partially enclosed environment, and where social distancing may prove challenging even with a limited number of people onboard.

In addition, the recent investigation by Payne et al. of transmission onboard a U.S. Navy ship demonstrated high transmission rates and high rates of mild disease and asymptomatic infection among crew.[8] These mild presentations and asymptomatic cases make case detection and isolation and quarantine practices based on clinical presentation alone challenging. Thus, covert spread of infection among crew may keep the virus circulating from one voyage to the next. This again stresses the need for appropriate interventions, including routine laboratory testing of crew, prior to restarting passenger operations.

Several cruise ship operators have taken steps to improve their public health response to COVID–19. For example, under the co-chairmanship of former Health and Human Services Secretary, Michael O. Leavitt, and former FDA Commissioner, Dr. Scott Gottlieb, two cruise lines, Royal Caribbean Group and Norwegian Cruise Line Holdings, assembled a ''Healthy Sail Panel'' of subject-matter experts from a variety of disciplines. The World Travel & Tourism Council (WTTC) and Carnival Corporation also recently hosted a global science summit on COVID–19 designed, ''to inform practical, adaptable and science-based solutions for mitigating and living with COVID–19.'' MSC Cruises further established its own industry-led panel with ''competency to review policy initiatives, technical innovations, or operational measures related to COVID–19.''

To gather more information regarding industry-led efforts to respond to COVID–19 and solicit public input, on July 20, 2020, CDC published a Request for Information (RFI) in the **Federal Register** related to cruise ship planning and infrastructure, resumption of passenger operations, and additional summary questions (85 FR 44083). The document had a 60-day comment period that ended on September 21, 2020 and nearly 13,000 comments were received.

Respondents to the RFI included members of the public, the cruise industry, seaport authorities, and the travel and hospitality industries. A majority of respondents (approximately 75%) expressed support for the resumption of passenger cruising in the U.S. Most of these commenters, however, expressed the need for increased public health measures, including health screening, testing, mask use, social distancing, travel insurance, refunds, and shipboard public health capacity as important steps to take before cruising resumes. Approximately 25% of respondents, including many previous cruise passengers, were in favor of delaying the resumption of passenger cruising because of the current state of the pandemic, and supported waiting until a vaccine is widely available.

Comments received related to the reduction of number of passengers, the need for routine testing of passengers and crew, social distancing, coordination between CDC and the cruise industry, limiting ports of call to private islands, agreements with local public health and medical facilities, and the economic benefits of cruising. Approximately 98% of respondents supported cruise ship operators denying boarding to passengers with COVID-like illness or confirmed COVID–19 infection, while approximately 65% of respondents supported denying boarding to passengers with known COVID–19 exposure in the previous 14 days before embarkation. A majority of respondents (74%) also supported requiring that cruise ship operators test passengers and crew prior to embarkation. Furthermore, approximately 90% of respondents supported cruise ship operators reducing passenger and crew loads to reduce the risk of COVID–19 transmission, while approximately 85% supported the wearing of face masks by passengers. While CDC bases its public health determinations on the best available science and not on public opinion, the willingness of the public to accept measures to mitigate the risk of transmitting COVID–19 onboard cruise ships is noteworthy. Accordingly, CDC carefully considered these comments in drafting this framework.

CDC also considered alternatives to this framework. One alternative considered was allowing cruise ship operators to return to unrestricted passenger operations without any public health oversight. This alternative was deemed unacceptable because cruise ship travel is known to contribute to COVID–19 transmission. Furthermore, mild presentations and asymptomatic cases make case detection and isolation and quarantine practices challenging absent robust testing. Thus, covert spread of infection among crew may keep the virus circulating from one voyage to the next and passengers infected on cruise ships could further spread COVID–19 into U.S. communities by traveling interstate after cruising. This would have the effect of increasing morbidity and mortality, and burdening federal, state, and local medical and public health infrastructure. This again stresses the

[12] Rocklöv J, Sjödin H, Wilder-Smith A. COVID–19 Outbreak on the Diamond Princess Cruise Ship: Estimating the Epidemic Potential and Effectiveness of Public Health Countermeasures. J. Travel Med. 2020; 18;27(3):taaa030. doi: 10.1093/jtm/taaa030.

[13] Payne DC, Smith-Jeffcoat SE, Nowak G, et al. SARS–CoV–2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members—USS Theodore Roosevelt, April 2020. MMWR Morb Mortal Wkly Rep 2020;69:714–721. DOI: *http://dx.doi.org/10.15585/mmwr.mm6923e4.*

need for appropriate public health oversight.

Public health oversight is further needed to correct a market failure stemming from information asymmetry, *i.e.,* the public is often not fully informed in such a way to adequately determine the extent to which any given measure mitigates their personal risk, particularly in light of asymptomatic cases. CDC is therefore overcoming this market failure by ensuring that the measures taken by cruise ship operators are those that are most likely to adequately mitigate such risks.

Another alternative considered was continuing to issue No Sail Orders as occurred between March 14 and September 30, 2020. However, this alternative was not found to be as optimal as the current framework. The benefits of this framework outweigh the costs of not allowing cruise ships to sail because it allows for flexibility where cruise ships have taken the necessary precautions to mitigate risk, while continuing to prohibit passenger operations onboard ships that have failed to implement such precautions. As such, the current framework represents a tailored approach that was determined to be preferable to the status quo No Sail Order. This framework allows for individual cruise lines to progress through phases at variable paces. This enables cruise lines successfully implementing public health measures to return to passenger operations more quickly while others by necessity may move more slowly. The framework not only encourages cruise lines that are more successful at mitigating the spread of COVID–19 but provides a realistic timeline that anticipates COVID–19 continuing to be present and affecting cruise ship travel.

While the actions taken by some cruise ship operators to improve their public health response to COVID–19 are encouraging, ongoing public health oversight is needed to ensure uniform standards for mitigating the communicable disease risk to crew and prospective passengers. The public health measures in this framework reflect CDC's considered views as to the minimum standards that must be in place prior to resuming passenger operations in a way that will mitigate the risk of COVID–19.

CDC intends to take a phased approach to resuming passenger operations. These phases include: (1) Establishment of laboratory testing of crew onboard cruise ships in U.S. waters; (2) simulated voyages designed to test a cruise ship operators' ability to mitigate COVID–19 on cruise ships; (3) a certification process; and (4) a return to passenger voyages in a manner that mitigates the risk of COVID–19 introduction, transmission, or spread among passengers and crew onboard ships and ashore to communities. These phases will be further determined based on public health considerations including the trajectory of COVID–19 transmission and the demonstrated ability of cruise ship operators to successfully employ measures that mitigate the risk of COVID–19.

As part of the initial crew testing phases, this Order additionally contains requirements for: (1) Shoreside COVID–19 laboratory screening testing of all crew currently onboard; (2) onboard diagnostic testing capabilities for symptomatic travelers (crew and future passengers); (3) shoreside COVID–19 laboratory screening testing of all newly embarking crew; and (4) continued compliance by cruise ship operators with their complete, accurate, and acknowledged, No Sail Order Response Plans.

Findings and Immediate Action

The continued spread of the COVID–19 pandemic worldwide, risk of resurgence in countries that have suppressed transmission, and ongoing concerns related to the restart of cruising, supports the establishment of a framework designed to mitigate the risk of COVID–19 onboard cruise ships.

Accordingly, and consistent with 42 CFR 70.2, 71.31(b), and 71.32(b), the Director of CDC (''Director'') continues to find that absent measures of the type needed to mitigate further transmission, cruise ship travel exacerbates the global spread of COVID–19, that the scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature, and such transmission has not been controlled sufficiently by the cruise ship industry or individual State or local health authorities. As described in the March 14, 2020, Order, as further modified and extended on April 15, 2020, July 16, 2020, and September 30, 2020, cruise ship travel markedly increases the risk and impact of the COVID–19 disease epidemic within the United States. If unrestricted cruise ship passenger operations were permitted to resume, infected and exposed persons disembarking cruise ships would place federal partners (*e.g.,* Customs and Border Protection and the U.S. Coast Guard), healthcare workers, port personnel, and communities at substantial unnecessary risk. Unrestricted cruise ship travel would also divert and overburden scarce federal, state, and local, public health and healthcare resources during a pandemic.

The Director also continues to find evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease.[14] This reasonable belief is based on information from epidemiologic and other data included in this document and the information described in the March 14, 2020, Order and the April 15, July 16, and September 30, 2020, modifications and extensions. As a result, absent measures of the type needed to mitigate further transmission, persons on board or seeking to board cruise ships may likely be or would likely become infected with or exposed to COVID–19 by virtue of being on board at a time when cases of COVID–19 continue to be reported in increasingly significant numbers globally.[15] Additionally, persons infected on cruise ships would be likely to transmit COVID–19 to U.S. communities by traveling interstate after cruising.

Accordingly, under 42 CFR 70.2, the Director determines that measures taken by State and local health authorities regarding COVID–19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease. Cruise ships by their very nature travel interstate and internationally and can move beyond the jurisdictional boundaries of any single state or local health authority. Furthermore, local transmission of COVID–19 onboard a cruise ship can escalate quickly into additional interstate and international transmission when infected persons travel. Therefore, federal intervention is needed to require public health measures to prevent the further introduction, transmission, or spread of COVID–19 via cruise ships globally and into U.S. communities.

This Order is not a rule within the meaning of the Administrative Procedure Act (''APA''), but rather an emergency action taken under the existing authority of 42 CFR 70.2, 71.31(b), and 71.32(b). CDC published a Request for Information (RFI) in the **Federal Register** that solicited and

[14] COVID–19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

[15] Since the March 14, 2020, Order, the number of global cases of COVID–19 reported by the World Health Organization (WHO) has risen from 142,534 to more than 44 million as of October 30, 2020, with nearly 1.2 million deaths. *See* Situation Reports, WHO, *https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports.*

obtained public comment related to cruise ship planning and infrastructure, resumption of passenger operations, and additional summary questions (85 FR 44083). In the event that this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because CDC has already obtained public comment and good cause exists to dispense with prior public notice and the opportunity to further comment on this Order.[16] Considering the public health emergency caused by COVID–19 based on, among other things, its potential for spread on board cruise ships, it would be impracticable and contrary to the public's health, and by extension the public's interest, to delay the issuance and effective date of this Order. Similarly, if this Order qualifies as a rule per the definition in the APA, the Office of Information and Regulatory Affairs has determined that it would be a major rule, but there would not be a delay in its effective date as the agency has invoked the good cause provision of the APA.

If any provision in this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

In accordance with 42 U.S.C. 264(e), this Order shall supersede any provision under State law (including regulations and provisions established by political subdivisions of States), that conflict with an exercise of Federal authority, including instructions by U.S. Coast Guard or HHS/CDC personnel permitting ships to make port or disembark persons under stipulated conditions, under this Order.

This Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 70.18, 71.2.

Therefore, in accordance with Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 CFR 70.2, 71.31(b), 71.32(b), for all cruise ships described above for the period described below, it is *ordered*:

Framework for Conditional Sailing

Purpose and Scope

(a) *Purpose.* The purpose of this framework is to prevent the further introduction, transmission, and spread of COVID–19 into and throughout the United States via cruise ships. These requirements are in addition to other requirements in regulations or actions taken by HHS/CDC to prevent the introduction, transmission, and spread of communicable diseases under 42 U.S.C. 264 and 42 CFR part 70 and 42 CFR part 71.

(b) *Scope.* This framework applies to any person operating or intending to operate a cruise ship in U.S. waters and to any person operating a cruise ship outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters while this Order remains in effect.

(1) Upon request, cruise ship operators must make their properties and records available for inspection to allow CDC to ascertain compliance with this framework. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records.

(2) CDC may enforce any of the provisions of this framework through additional orders published in the **Federal Register** and issue additional technical instructions as needed.

(3) Nothing in this framework supersedes or preempts enforcement of emergency response requirements imposed by statutes or other regulations.

(4) Cruise ship operators may use the services of professionally licensed and accredited third-party auditors to assist them in meeting the requirements of this framework. Notwithstanding, the cruise ship operator's responsible officials maintain an overall duty and responsibility for meeting the requirements of this framework, including the requirements of any technical instructions or orders. Third-party auditors are prohibited from interfering with CDC's ability to inspect and conduct oversight under this framework, including but not limited to interfering with CDC's ability to interview cruise ship crew and personnel or visually inspect and oversee collection of laboratory specimens and laboratory testing.

Requirements for Protection of Crew for Cruise Ship Operators Operating or Intending To Operate Cruise Ships in U.S. Waters

(a) A cruise ship operator subject to this Order must meet the requirements of this framework as a condition of obtaining or retaining controlled free pratique for operating a cruise ship in U.S. waters or if the cruise ship operator is operating a cruise ship outside of U.S. waters and intends for the ship to return to operating in U.S. waters while this Order remains in effect. These requirements must additionally be met as a condition of obtaining or retaining controlled free pratique for conducting a simulated voyage or applying for a COVID–19 Conditional Sailing Certificate.

(1) The cruise ship operator must have received a determination by CDC that a plan submitted in response to the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (*i.e.,* ''No Sail Order response plan''), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)) is complete and accurate, including having submitted to CDC a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy.

(2) Cruise ships operating in U.S. waters must continue to submit the EDC form as specified in CDC technical instructions or orders. Cruise ship operators with ships that have not been in U.S. waters during the period of March 14 through October 31, 2020, or who voluntarily withdrew their ships during this time period, and who wish to operate those ships in U.S. waters during the period that this framework remains in effect, must additionally submit the EDC form during (at a minimum) the 28 days preceding those ships' expected arrival in U.S. waters and continue to submit the EDC form after the ships' entering U.S. waters.

(3) The cruise ship operator has observed and will continue to observe all elements of its No Sail Order response plan including by following the most current CDC recommendations and guidance for any public health actions related to COVID–19, or if any deviations from the plan have occurred such deviations have been reported and corrective actions taken to the satisfaction of CDC.

(4) The cruise ship operator has arranged for and submitted and will continue to arrange for and submit such laboratory test results as may be required by CDC for every crew member on board ships operating in U.S. waters and/or operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters at any time while this Order remains in effect. Laboratory testing for every crew member must be conducted on a weekly basis or at such other intervals as required by CDC in technical instructions or orders. CDC may conduct oversight of specimen

[16] *See* 5 U.S.C. 553(b)(B), (d)(3).

collection, testing, and laboratory procedures, as necessary.

(5) If the cruise ship received any ship-to-ship transfers in the last 28 days, crew were only transferred from a cruise ship with no confirmed COVID–19 or COVID-like illness during the 28 days before the transfer occurred.

(6) If the cruise ship received any land-based embarking crew, such crew were laboratory tested for COVID–19 upon embarkation and quarantined per CDC technical instructions or orders immediately upon embarking the ship.

(7) Following submission of an application for a COVID–19 Conditional Sailing Certificate, the cruise ship operator shall continue to follow these requirements for protection of crew pending approval of the operator's application.

(b) CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's processes and procedures for protection of crew.

General Prohibition on a Cruise Ship Operator Commencing or Continuing Passenger Operations Without a COVID–19 Conditional Sailing Certificate

(a) A cruise ship operator shall not commence or continue any passenger operations in U.S. waters without a COVID–19 Conditional Sailing Certificate issued by CDC that meets the requirements in this framework for each cruise ship that the cruise ship operator intends to operate with passengers in U.S. waters.

(b) A cruise ship operator shall not violate the terms or conditions of a COVID–19 Conditional Sailing Certificate issued pursuant to this framework.

(c) As a condition of obtaining or retaining a COVID–19 Conditional Sailing Certificate, the cruise ship operator must be in compliance with CDC's standards for mitigating the risk of COVID–19 onboard the cruise ship as set forth in this framework and in CDC technical instructions or orders.

Agreement With Port and Local Health Authorities

(a) As a condition of obtaining or retaining controlled free pratique for conducting a simulated voyage or obtaining and retaining a COVID–19 Conditional Sailing Certificate, a cruise ship operator must document the approval of all U.S. port and local health authorities where the ship intends to dock or make port during a simulated voyage or a restricted passenger voyage. Such written approval must include the following:

(1) A medical care agreement between the cruise ship operator and health care entities, addressing evacuation to onshore hospitals for passengers and crew in need of care, in accordance with CDC technical instructions and orders.

(2) A housing agreement between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of COVID–19 cases and close contacts, respectively, identified from the day of embarkation through disembarkation for each voyage, in accordance with CDC technical instructions and orders.

(3) A port agreement between the cruise ship operator and port authority to determine the number of cruise ships at any single port in order to not overburden the public health response resources of any single jurisdiction in the event of a COVID–19 outbreak.

Minimum Standards for Simulated Voyages Prior to Issuance of COVID–19 Conditional Sailing Certificate

(a) As a condition of applying for a COVID–19 Conditional Sailing Certificate, a cruise ship operator must have successfully conducted a simulated voyage or series of simulated voyages demonstrating the cruise ship operator's ability to mitigate the risks of COVID–19 onboard its cruise ship. A simulated voyage must meet the following requirements:

(1) The cruise ship operators shall inform volunteer passengers in writing that they are participating in a simulation of unproven and untested health and safety protocols for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity.

(2) All volunteer passengers must be at least eighteen years old or older. The cruise ship operator must also obtain from all volunteer passengers a written certification from a healthcare provider that the volunteer passenger has no pre-existing medical conditions that would place that individual at high risk for COVID–19 as determined through CDC guidance. CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's obligation to screen for volunteer passengers who may be at high risk for COVID–19.

(3) The cruise ship operator must conduct any simulation on a consensual basis and not as a condition of employment or in exchange for consideration or future reward. The cruise ship operator must document the informed consent of all participants in writing.

(4) The cruise ship operator must embark additional crew members beyond safe minimum manning levels only as determined through CDC technical instructions or orders.

(5) The cruise ship operator must design and conduct a simulated voyage insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risks of COVID–19 onboard its cruise ship.

(6) The cruise ship operator must conduct a monitored observation period and laboratory testing of volunteer passengers, as directed in CDC technical instructions or orders, prior to embarking volunteer passengers on a simulated voyage.

(7) A simulated voyage must include the following simulated activities:

(i) Embarkation and disembarkation procedures, including terminal check-in,

(ii) on board activities, including at dining and entertainment venues,

(iii) private island shore excursions, if any are planned during restricted passenger voyages,

(iv) evacuation procedures,

(v) transfer of symptomatic passengers or crew, or those who test positive for SARS–CoV–2, from cabins to isolation rooms,

(vi) quarantine of all remaining passengers and non-essential crew, and

(vii) other activities as may be listed in CDC technical instructions and orders.

(8) The cruise ship operator must meet standards for hand hygiene, face coverings, and social distancing for passengers and crew, as well as ship sanitation, as may be required by CDC technical instructions or orders.

(9) The cruise ship operator must modify meal service and entertainment venues to facilitate social distancing during the simulated voyage.

(10) The cruise ship operator must conduct laboratory testing of all passengers and crew on the day of embarkation and the day of disembarkation as required by CDC technical instructions or orders. Laboratory test results must be available prior to passengers embarking and prior to passengers and crew departing for their final destinations after disembarking the ship. Crew and passengers must also be laboratory tested again post-disembarkation as required by CDC technical instructions or orders. Based on public health considerations, CDC may also require additional laboratory testing of passengers and crew and reporting of results, including during a voyage, as required by CDC technical instructions or orders.

(11) The cruise ship operator must immediately conduct laboratory testing

of any passengers and crew who report illness consistent with COVID–19 during the simulated voyage with rapid point-of-care results as required by CDC technical instructions or orders. Identified close contacts of cases must also be laboratory tested with rapid point of care results.

(12) CDC may require the cruise ship operator to immediately end the simulated voyage and take other action to protect the health and safety of volunteer passengers and crew if COVID–19 is detected during the simulation.

(13) The cruise ship operator must document any deficiencies in its health and safety protocols through an ''after-action'' report and address how the cruise ship operator intends to address those deficiencies prior to applying for a COVID–19 Conditional Sailing Certificate. This after-action report must also include test results for any volunteer passengers or crew on the simulated voyage. The after-action report must be submitted to the CDC as soon as practicable at the end of the simulation and as part of the cruise ship operator's application for a COVID–19 Conditional Sailing Certificate.

(14) Based on CDC's review of the after-action report and/or cruise ship operator's application for a COVID–19 Conditional Sailing Certificate, CDC may request that the cruise ship operator modify its practices or procedures and/or engage in additional simulated voyages prior to the issuance of the COVID–19 Conditional Sailing Certificate.

(b) Prior to conducting a simulated voyage in accordance with this section, the cruise ship operator shall provide written notice and request CDC's approval to conduct the simulation. Such written notice must be provided prior to the simulation and specify the time, location, contact information for all individuals or parties involved, and protocols or practices to be simulated.[17]

(c) A cruise ship operator shall not apply for approval to conduct a simulated voyage until all of CDC's requirements relating to the protection of crew onboard ships in U.S. waters have been satisfied. The cruise ship operator's responsible officials must sign the application for permission to conduct a simulation and certify under 18 U.S.C. 1001 that all of CDC's requirements relating to the protection of crew onboard cruise ships in U.S. waters have been satisfied.

(d) CDC will respond to the written notice and request for approval to conduct a simulation in writing in a timely manner. CDC may deny the request to conduct a simulation if the cruise ship operator is not in compliance with any provision of this framework, technical instructions, or orders, or if in CDC's determination the simulation does not provide adequate safeguards to minimize the risk of COVID–19 for all participants.

(e) CDC may conduct such oversight and inspection of simulated voyages as it deems necessary in its discretion, including through in-person or remote means allowing for visual observation.

(f) CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's processes and procedures for conducting and evaluating a simulated voyage prior to applying for a COVID–19 Conditional Sailing Certificate.

Applying for a COVID–19 Conditional Sailing Certificate

(a) A cruise ship operator must submit the following to CDC prior to commencing restricted passenger operations:[18]

(1) A completed CDC registration/application form that must include the signatures of the cruise ship operator's responsible officials;

(2) The name, titles, and contact information for the cruise ship operator's responsible officials and of any third-party auditors.

(3) A completed statement of intent stating the name, carrying capacity for passengers and crew, itinerary, ports of call, length of voyage, and expected onboard or shoreside activities, for the cruise ship that the cruise ship operator intends to have certified for restricted passenger operations.

(4) A copy of the USCG Certificate of Inspection issued in accordance with 46 CFR 2.01–5 that was in effect for the six months preceding the application.

(5) A certification statement signed under 18 U.S.C. 1001 by the responsible officials attesting that the cruise ship operator has complied and remains in compliance with CDC's crew protection requirements of prior to applying for a COVID–19 Conditional Sailing Certificate.

(6) A certification statement signed under 18 U.S.C. 1001 by the responsible officials attesting that the cruise ship operator has adopted health and safety protocols that meet CDC's standards for mitigating the risk of COVID–19 among passengers and crew onboard the cruise ship that will be commencing restricted passenger operations, and will modify these protocols as needed to protect the public's health as required by CDC technical instructions or orders.

(7) A certification statement signed under 18 U.S.C. 1001 by the responsible officials attesting that the cruise ship operator has sufficient medical and point of care laboratory capabilities and staff on board the cruise ship that will be commencing restricted passenger operations to manage severe COVID–19 cases and outbreaks in exigent circumstances as required by CDC technical instructions or orders.

(8) A certification statement signed under 18 U.S.C. 1001 by the responsible officials attesting that the cruise ship operator is in compliance with the other requirements contained in this framework for mitigating the risk of COVID–19 on board cruise ships and agrees to continue to comply with these requirements.

Review of an Application for a COVID–19 Conditional Sailing Certificate

(a) Upon receiving the documentation required by this framework, CDC will review the application for completeness. Based on CDC's determination as to whether the cruise ship operator has met CDC's standards for mitigating the risk of COVID–19 onboard the cruise ship for which the operator intends to commence restricted passenger operations, it shall grant or deny the application. If CDC requires additional information to ascertain whether the cruise ship operator has met CDC's standards for mitigating the risk of COVID–19 on board cruise ships, or if it determines the application to be incomplete, it may hold the application in abeyance pending the submission of such additional information as required by CDC to make such a determination. Applications that are denied may be administratively appealed as described in this framework.

(b) CDC may limit the terms or conditions of a cruise ship operator's COVID–19 Conditional Sailing Certificate in regard to passenger or crew capacity, itinerary, ports of call, length of voyage, onboard or shoreside activities, or in regard to any other passenger, crew, or cruise ship operations, as needed to the health and safety of passengers and crew or the public's health.

(c) As a condition of obtaining or retaining a COVID–19 Conditional Sailing Certificate, the cruise ship operator must upon request make its

[17] This written notice should be submitted at least 30 calendar days prior to the date on which the cruise ship operator proposes to conduct the simulation.

[18] These materials should be submitted at least 60 calendar days prior to the date on which the cruise ship operator proposes to commence restricted passenger operations.

properties and records available for inspection to allow CDC to ascertain compliance with this framework. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records. The cruise ship operator must also make any crew member or other personnel involved in the operation of a cruise ship available for interview by CDC.

(d) As a condition of obtaining or retaining a COVID–19 Conditional Sailing Certificate, CDC may require a cruise ship operator to submit proof of having been inspected by any other agency or entity with authority, jurisdiction, or oversight over any aspect of a cruise ship operator's operations.

(e) As a condition of obtaining or retaining a COVID–19 Conditional Sailing Certificate, cruise ship operators must establish mechanisms to ensure compliance, including reporting mechanisms to notify CDC and USCG in writing within 24 hours of the occurrence of any deviations, whether intentional, or as a result of error or omission, and take corrective steps to rectify those deviations.

(f) As a condition of obtaining or retaining a COVID–19 Conditional Sailing Certificate, cruise ship operators must comply with the requirements of this framework. These requirements apply to any cruise ship operating in U.S. waters and to cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters at any time while Order remains in effect.

Amendment or Modification of COVID–19 Conditional Sailing Certificate

(a) A cruise ship operator may seek to amend or modify a COVID–19 Conditional Sailing Certificate issued under this framework by submitting such amendment or modification to CDC for review and a determination in accordance with this section.

(b) CDC will review the cruise ship operator's request to amend or modify a COVID–19 Conditional Sailing Certificate and either grant or deny the request in writing. If CDC requires additional information to ascertain whether the cruise ship operator's proposed amendment or modification meets CDC's standards for mitigating the risk of COVID–19 on board cruise ships, or if it determines the request to be incomplete, it may hold the request in abeyance pending the submission of such additional information as required by CDC to make such a determination.

(c) CDC may require any cruise ship operator to amend or modify a COVID–19 Conditional Sailing Certificate based on public health considerations specific to the cruise ship, cruise ship operator, or affecting the health or safety of cruise travel as a whole.

(d) Denials of requests to amend or modify a COVID–19 Conditional Sailing Certificate are subject to administrative review as described in this framework.

Minimum Standards for Restricted Passenger Voyages as a Condition of Obtaining and Retaining a COVID–19 Conditional Sailing Certificate

(a) As a condition of obtaining and retaining a COVID–19 Conditional Sailing Certificate, a cruise ship operator must meet the following minimum standards:

(1) The cruise ship operator must in marketing materials, on its website, and in offerings for voyages, notify prospective passengers prior to accepting a reservation of any CDC travel advisory, warning, or recommendation relating to cruise travel. Such notification must further advise prospective passengers that, if a threshold of COVID–19 is detected on board the cruise ship during a voyage, the voyage will be ended immediately and the ship returned to the U.S. port of embarkation, and their subsequent travel, including their return home, may be restricted or delayed.

(2) The cruise ship operator must not sail or offer to sail on an itinerary longer than 7 days. CDC may shorten or lengthen the number of days permitted to sail based on public health considerations and as set forth in technical instructions or orders.

(3) The cruise ship operator must screen passengers and crew before they embark for signs and symptoms or known exposure to COVID–19 and deny boarding to anyone who is suspected of having COVID–19 or is an identified contact of a confirmed or suspected case, in accordance with CDC technical instructions or orders.

(4) The cruise ship operator must conduct laboratory testing of all passengers and crew on the day of embarkation and the day of disembarkation in accordance with CDC technical instructions or orders. Laboratory test results must be available prior to passengers embarking and prior to passengers and crew departing for their final destinations after disembarking the ship.

(5) The cruise ship operator must immediately conduct laboratory testing of any passengers and crew who report illness consistent with COVID–19 during the voyage with rapid point of care results as required by CDC technical instructions or orders. Identified close contacts of cases must also be laboratory tested with rapid point of care results.

(6) The cruise ship operator shall report syndromic surveillance and all laboratory test results using CDC's EDC form as required by CDC technical instructions or orders.

(7) The cruise ship operator must meet standards for hand hygiene, face coverings, and social distancing for passengers and crew, as well as ship sanitation, as required by CDC technical instructions or orders.

(8) The cruise ship operator must modify meal service and entertainment venues to facilitate social distancing.

(b) In light of public health considerations and based on evidence gained through review and evaluation of cruise operators' practices and procedures, including through simulated voyages, CDC may require the following:

(1) A monitored observation period of passengers prior to embarking.

(2) Post day of disembarkation laboratory testing of passengers and crew.

(3) Additional laboratory testing of passengers and crew and reporting of results during a voyage.

(c) CDC may issue additional technical instructions or orders regarding health and safety standards for restricted passenger voyages.

Minimum Standards for Management of Passengers and Crew From COVID–19-Affected Cruise Ships for Restricted Passenger Voyages

(a) Based on a threshold of COVID–19 being detected in passengers or crew, as determined through CDC technical instructions or orders, a cruise ship operator must immediately take the following actions:

(1) Conduct such notifications of passengers, crew members, and other government entities as CDC may require.

(2) Immediately end the restricted passenger voyage, cancel future restricted passenger voyages until directed by CDC that such voyages may resume, and return the ship to the U.S. port of embarkation.

(3) Immediately isolate any sick or infected passengers and crew in single occupancy cabins with private bathrooms and quarantine all remaining passengers and non-essential crew.

(4) Disembark and evacuate passengers and crew only in such a manner as prescribed in the cruise ship operator's preexisting port and local health authority agreements.

(5) Arrange to disembark and transport passengers and crew using noncommercial transportation or other transportation in accordance with CDC's technical instructions and orders.

(6) Instruct disembarking passengers and crew to stay home and continue to practice social distancing after reaching their final destination as per CDC technical instructions or orders.

(7) Inform ship pilots, ground transportation, air charter operators, and other agencies with relevant jurisdiction that COVID–19 has been detected in passengers or crew and confirm that the operators have plans in place to notify and protect the health and safety of their staff (*e.g.,* drivers, air crews).

(b) CDC may issue additional technical instructions or orders regarding what measures cruise ship operators must take in the event that COVID–19 is detected in passengers or crew.

Denials, Suspension, Revocation, and Reinstatement of a Cruise Ship Operator's COVID–19 Conditional Sailing Certificate

(a) CDC may deny an application for a COVID–19 Conditional Sailing Certificate, or revoke, or suspend a COVID–19 Conditional Sailing Certificate if:

(1) The cruise ship operator is not in compliance with CDC's standards for mitigating the risk of COVID–19 on board cruise ships; or

(2) the cruise ship operator is not in compliance with the terms of its COVID–19 Conditional Sailing Certificate; or

(3) necessary to protect human health or safety based on public health considerations specific to the particular cruise ship operator, cruise ship, or affecting cruise travel as a whole.

(b) CDC may reinstate a suspended or revoked COVID–19 Conditional Sailing Certificate after:

(1) Inspecting the cruise ship operator's properties and records, including, but are not limited to, its vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records;

(2) conferring with the cruise ship operator, responsible officials, third-party auditors, or other persons under the cruise ship operator's employ; and

(3) receiving information and written assurances from the cruise ship operator and/or its responsible officials that any deficiencies have been rectified and actions taken to ensure future compliance.

Administrative Review

(a) A cruise ship operator may appeal a denial of its application for a COVID–19 Conditional Sailing Certificate or a revocation or suspension of its COVID–19 Conditional Sailing Certificate based on specific factors particular to that operator.

(b) The cruise ship operator's appeal must be in writing, state the factual basis for the appeal, and be submitted to the CDC Director within 30 calendar days of the decision.

(c) The CDC Director's decision will be issued in writing and will constitute final agency action. Prior to deciding upon an appeal, the Director may further investigate the reasons for the denial, revocation, or suspension, including by conferring with the cruise ship operator, responsible officials, third-party auditors, or other persons under the cruise ship operator's employ.

Initial Phase COVID–19 Testing Requirements for Protection of Crew

CDC will take a phased approach to resuming passenger operations onboard cruise ships and considers adequate crew safeguards an integral part of its initial phases. Accordingly, it is further ordered:

Shoreside COVID–19 Laboratory Screening Testing of All Crew

(1) Within 60 days of the effective date of this Order,[19] cruise ship operators must collect clinical specimens from all crew currently onboard their cruise ships and have those specimens immediately transported and tested by a shoreside laboratory facility. This testing must be conducted by a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory using reverse transcriptase polymerase chain reaction (RT–PCR) tests that are approved, cleared, or authorized for emergency use by the U.S. Food and Drug Administration (FDA).

(2) To help ensure the validity of sampling, testing, and test results, cruise ship operators must contact CDC at *eocevent349@cdc.gov* at least 7 calendar days prior to collecting specimens and conducting testing. CDC must approve the cruise ship operator's selection of a CLIA-certified laboratory and the cruise ship operator's procurement of specimen collection kits. Include ''Laboratory Screening Testing of All Crew Onboard SHIP NAME'' in the subject line as part of your request for CDC approval.

(3) CDC's response to the cruise ship operator's email may include additional information regarding best practices that may assist cruise ship clinicians or public health staff in collecting and transporting crew specimens. CDC may also oversee the onboard collection of crew specimens through remote means allowing for visual observation.

(4) Cruise ship operators must report all laboratory results in aggregate to CDC through the Enhanced Data Collection (EDC) form.

Onboard COVID–19 Diagnostic Testing Capabilities for Symptomatic Travelers (Crew and Future Passengers)

(1) During this 60-day period, cruise ship operators in coordination with CDC must develop onboard testing capabilities to test all symptomatic travelers (crew and future passengers) for COVID–19 and close contacts. After this 60-day period, laboratory testing for every crew member must be conducted on a weekly basis or at such other intervals as required by CDC in technical instructions or orders.

(2) All cruise ships must procure rapid RT–PCR point-of-care equipment to test symptomatic travelers. This instrument must be CLIA-waived and have been evaluated on the FDA reference panel for SARS-CoV–2 and demonstrated a lower limit of detection correlating to higher sensitivity. Cruise ship operators must contact CDC prior to procuring this equipment. Antigen testing is not recommended at this time because it is more likely to miss cases of SARS-CoV–2 infection (*i.e.,* lower sensitivity) when compared to RT–PCR testing.

(3) Cruise ship medical clinic staff must be competent in specimen collection, be able to properly use testing equipment, follow all manufacturer's instructions, and have access to and use recommended personal protective equipment (PPE) for specimen collection and handling. CDC may ensure competency by conducting oversight of these practices through remote means allowing for visual observation. In addition, cruise ship operators must maintain onboard SARS-CoV–2 testing equipment to manufacturer's specifications.

(4) Once testing equipment has been obtained and cruise ship medical clinic staff are properly trained in its use, all symptomatic crew onboard the cruise ship must be tested for SARS-CoV–2

[19] For cruise ship operators with ships that have not been in U.S. waters during the period of the No Sail Order or voluntarily withdrew their ships, the 60-day period will begin upon: (1) CDC confirming to the cruise ship operator in writing that the operator has a complete and accurate NSO response plan, including having submitted to CDC a signed *Acknowledgment of No Sail Order Response Plan Completeness and Accuracy;* and (2) submission of the EDC form for the 28 days preceding the cruise ship's expected arrival in U.S. waters.

infection immediately upon notifying medical staff of symptom onset. These results must be reported to CDC in aggregate through the EDC form.

Shoreside COVID–19 Laboratory Screening Testing of All Embarking Crew

(1) On the day of crew members' embarkation, cruise ship operators must collect specimens for SARS-CoV–2 testing from all embarking land-based crew. Cruise ship operators must immediately transport the specimens to a CLIA-certified laboratory for testing.

(2) This laboratory must use an RT–PCR test that has been approved, cleared, or authorized for emergency use by FDA. Cruise ship operators must report results in aggregate to CDC through the EDC form. CDC must approve the cruise ship operator's selection of a CLIA-certified laboratory.

(3) All embarking land-based crew must be immediately quarantined onboard for 14 days. Those who test positive must be isolated until criteria are met for discontinuation of isolation according to the most current CDC guidance. CDC may also oversee the collection of specimens, or the quarantine or isolation of embarking crew, through remote means allowing for visual observation.

Continued Compliance With No Sail Order (NSO) Response Plans

(1) Cruise ship operators must continue to follow their cruise lines' complete, accurate, and acknowledged NSO response plans per the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (*i.e.,* ''No Sail Order response plan''), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)).

(2) Cruise ship operators must also continue to follow CDC's Interim Guidance for Mitigation of COVID–19 Among Cruise Ship Crew and COVID–19 Color-coding System for Cruise Ships, which may be modified or updated as needed. CDC will notify cruise ship operators of any updates. Ship-to-ship crew transfers and embarkations may continue to impact ships' color-coding status. For additional information about other public health preventive measures, such as social distancing, mask use, and cabin occupancy, refer to CDC's Interim Guidance.

Effective Date and Signature

This Order is effective upon signature and shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID–19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) November 1, 2021.

Authority: The authority for these orders is Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 CFR 70.2, 71.31(b), 71.32(b).

Dated: October 30, 2020.

Nina B. Witkofsky,

Acting Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2020–24477 Filed 10–30–20; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–20PA]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''DOP Cross-Site Program Implementation Evaluation of Overdose Data to Action Program'' to the Office of Management and Budget (OMB)for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on 06/15/2020 to obtain comments from the public and affected agencies. CDC did not receive public comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencie'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;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

DOP Cross-Site Program Implementation Evaluation of Overdose Data to Action Program—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Overdose Data to Action (OD2A) program is a comprehensive, national overdose prevention program developed by CDC. The purpose of the OD2A program is to support funded jurisdictions in obtaining high quality, complete, and timely data on opioid prescribing and overdoses, and to use those data to inform prevention and response efforts. OD2A funds a total of 66 recipients (state and local health departments) to implement surveillance and prevention strategies, through a three-year cooperative agreement.

This information collection review is focused on the tools needed to evaluate the unique OD2A program. This information collection includes key informant interviews (KII) and focus groups (FG). The information collection is unique and will be the first evaluation of the OD2A program. There are no other efforts that CDC knows of to obtain program information required to

demonstrate impact and improve implementation of OD2A. The purpose of this information collection is to assess the implementation and the effectiveness of the OD2A program activities and identify the conditions under which these activities are most effective, and for whom. The implementation evaluation will identify the barriers and facilitators associated with deploying several prevention activities targeting specific populations within specific jurisdictions.

Data collected from this evaluation will be used by the CDC to obtain valid information regarding how recipients operationalized and implemented their chosen prevention activities, to assess the impact of OD2A and different components of OD2A on the trajectory of the opioid epidemic, and through the provision of these data back to the recipients, to improve the implementation and impact of further OD2A prevention activities. There are no costs to the respondents other than their time. The total estimated annualized burden hours are 574.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Jurisdictions implementing OD2A program	Key Informant Interview Guides	181	1	1
	Focus Group Guides	165	1	1.5
	Permission to be Recorded	346	1	5/60
	Interview Recruitment Email	181	1	5/60
	Focus Group Recruitment Email	165	1	5/60
	Interview Recruitment Reminder Email	181	1	5/60
	Focus Group Recruitment Reminder Email ...	165	1	5/60
	Post-information Collection Follow up Email	346	1	5/60
	Program Manager Focus Group Recruitment Request Email.	165	1	5/60
	Program Manager Interview Recruitment Request Email.	181	1	5/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–24473 Filed 11–3–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–20OG]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Assessments of adults' professional experiences for improving programs to decrease sexual risk and related behaviors and adverse health outcomes among youth,'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 2, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assessments of adults' professional experiences for improving programs to decrease sexual risk and related behaviors and adverse health outcomes among youth—New—Division of Adolescent and School Health, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests approval for a new generic information collection package that supports collection of quantitative and qualitative information from adults who help implement programs and services designed to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy or influence related risk and protective factors; data will be collected for needs

assessment and program refinement. The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) conducts the assessment of program practices and health services to reduce sexual risk behaviors among adolescents and reduce adverse health outcomes of those risk behaviors.

NCHHSTP conducts behavioral and health service assessments and research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination and viral hepatitis control with national, state, and local partners. Adolescents are a population with specific developmental, health and social, and resource needs. Their health risk factors and access to health care is addressed as a primary mission by the Division of Adolescent and School Health (DASH), and adolescents are a population of interest for several other NCHHSTP divisions. The assessment and research conducted by NCHHSTP is one pillar upon which recommendations and guidelines are revised and updated. Recommendations and guidelines for adolescent sexual risk reduction require a foundation of scientific evidence. Assessment of programmatic practices for adolescents helps improve programs through better identification of strategies relevant to adolescents as a population as well as specific sub-groups of adolescents at highest risk for HIV and other STDs so that programs can be better tailored specifically for them.

Participants in data collection include adults (over 18 years old) who help implement or oversee programs to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among youth or influence related risk and protective factors. These participants may include adults in roles such as:

- School staff and administrators
- Staff in state and local education agencies
- Staff in state and local health agencies
- Staff in youth-serving community and national non-governmental organizations
- Community-based health care providers for adolescents
- School-based health care providers for students

The types of information collection activities included in this generic package are:

(1) Quantitative data collection conducted in-person on remotely through electronic (via computers, tablets, other mobile devices, etc.), telephone, or paper questionnaires to gather information about programmatic and service activities related to sexual risk reduction or related adverse health outcomes among youth. Questions relate to work-related experiences, training, context, duties, activities, and youths' health and service needs. Information may also be gathered on program implementers' demographic and social characteristics, program-related knowledge, attitudes, skills, and implementation practices.

(2) Qualitative data collection in-person or remotely through electronic, telephone, or paper means to gather information about program and service activities related to sexual risk reduction or prevention of related adverse health outcomes among youth. Qualitative data collection may involve focus groups and/or in-depth individual or group interviews. Interview and focus group guides may include questions about work-related experiences, training, context, duties, activities, and youths' health and service needs. Information may also be gathered on program implementers' demographic and social characteristics, program-related knowledge, attitudes, skills, and implementation practices. For adolescents, data collection instruments will include questions on demographic characteristics; experiences with programs and services to reduce the risk of HIV and other STD transmission; and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels.

The participants for this data collection are considered to be the ''implementers'' of the types of programs that are funded by CDC/DASH. Typically, CDC/DASH programs are intended to have direct impact on proximal indicators such as sexual health-related knowledge, attitudes, perceptions, and behaviors among youth, and although CDC/DASH programs are typically set in schools, they can be implemented by adults who work in a variety of school, community, and health-care roles.

Any data collection request put forward under this generic clearance will identify the programs and/or services to be informed or refined with the information from the collection and will include a cross-walk of data elements to the aspects of the program the project team seeks to inform or refine. Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data collection instruments will be pilot-tested, and will be culturally appropriate for the intended populations. All data collection procedures will receive review and approval by an Institutional Review Board for the Protection of Human Subjects and follow appropriate consent and assent procedures as outlined in the IRB-approved protocols, and these will be described in the individual information collection requests put forward under this generic package. Participation of respondents is voluntary. There is no cost to the participants other than their time.

The table below provides the estimated annualized response burden for up to 10 individual data collections per year under this generic clearance. Average burden per response is based on pilot testing and timing of quantitative and qualitative instrument administration during previous studies. Response times include the time to read and respond to consent forms and to read or listen to instructions. The proposed information collections combine for a total estimated annualized burden of up to 60,000 hours for respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adults helping with program implementation (*e.g.,* school or district staff, community partners, NGO staff).	Questionnaire	15,000	1	1
Adults helping with program implementation ..	Pre/Post Questionnaire	15,000	2	1
Adults helping with program implementation ..	Interview/focus group guide	4,000	1	1.5
Adults helping with program implementation ..	Pre/Post Interview/focus group guide	3,000	2	1.5

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–24475 Filed 11–3–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10744]

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 December 4, 2020.

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program—Contracting Forms; *Use:* The Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (''Medicare Modernization Act'' or ''MMA''). Section 302 of the MMA amended Section 1847 of the Social Security Act (the Act) to establish the competitive acquisition program and define program requirements.

Under the MMA, the DMEPOS Competitive Bidding Program was to be phased in so that competition under the program would first occur in 10 areas in 2007. The Centers for Medicare & Medicaid Services (CMS) completed the rulemaking process for the competitive acquisition of DMEPOS items and services in 42 CFR parts 411 and 414 published in the **Federal Register** Volume 72 on April 10, 2007. CMS conducted the Round 1 competition in 10 areas and for 10 DMEPOS product categories, and implemented the program on July 1, 2008. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), enacted on July 15, 2008, made limited changes to the Competitive Bidding Program, including termination of existing contracts that were in effect and a requirement to re-bid Round 1.

As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011. The Affordable Care Act (ACA), enacted on March 23, 2010, expanded the Round 2 competition by adding an additional 21 metropolitan statistical areas (MSAs), bringing the total MSAs for Round 2 to 91. The competition for Round 2 began in December 2011. CMS also began a competition for National Mail Order (NMO) of diabetes testing supplies at the same time as Round 2. The Round 2 and NMO contracts and prices were implemented on July 1, 2013.

The MMA requires the Secretary to recompete contracts not less often than once every three years. The Round 1 Rebid contract period for all product categories except mail-order diabetes testing supplies expired on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetes testing supplies ended on December 31, 2012.) The competition for the Round 1 Recompete began in August of 2012 and contracts and prices became effective on January 1, 2014. The Round 1 Recompete contract period expires on December 31, 2016. Round 1 2017 contracts will become effective on January 1, 2017 through December 31, 2018. Round 2 and NMO contracts and prices expired on June 30, 2016. Round 2 Recompete and the NMO Recompete contracts became effective on July 1, 2016, and expired on December 31, 2018. CMS will be implementing a consolidated round of competition to include all Round 1 2017 and Round 2 Recompete competitive bidding areas, referred to as Round 2021. Round 2021 will not include NMO, which will be competed again in future rounds of the program.

The forms included in this ICR were previously included in the ICR currently approved under 0938–1016. Due to the temporary gap in the DMEPOS Competitive Bidding Program, which started on January 1, 2019, we do not currently have any active PRA package for this specific collection of information (Form C, Subcontracting, Change of Ownerships, and Grandfathering). We are now seeking approval of a PRA package based on

estimates from previous rounds of the program (specifically Round 2 Recompete and Round 1 2017) and without reference to changes in burden. *Form Number:* CMS–10744 (OMB control number: 0938–New); *Frequency:* Occasionally (varies by form); *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 2,984; *Total Annual Responses:* 271,597; *Total Annual Hours:* 31,121. (For policy questions regarding this collection contact Julia Howard at 410–786–8645.)

Dated: October 30, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–24442 Filed 11–3–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10757]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On March 13, 2020, the President declared a national emergency in response to the public health emergency (PHE) caused by the SARS–CoV–2 virus, otherwise known as COVID–19. The CARES Act was published in response to the PHE that requires ''every laboratory that performs or analyzes a test that is intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19 shall report the results from each such test.'' The September 2, 2020 interim final rule with comment (CMS–3401–IFC) requires laboratories to report SARS–CoV–2 test results in a manner and frequency specified by the Secretary. Consistent with the CARES Act laboratory reporting requirements, CMS made modifications to the CLIA regulations to meet the SARS–CoV–2 test result reporting provisions related to the Secretary's Public Health Emergency declaration with respect to COVID–19.

DATES: Comments must be received by November 19, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted within 15 days in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed ICR. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR including the necessity and utility of the proposed ICR 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.

Contents

This notice sets out a summary of the use and burden associated with the following ICR. More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10757 CLIA Collection of Information Requirements Related to SARS–CoV–2 Test Results Reporting

Under the 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. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

Information Collection

1. Type of Information Collection Request: New collection (Request for a new OMB control number); *Title of Information Collection:* CLIA Collection of Information Requirements Related to SARS–CoV–2 Test Results Reporting; *Use:* In order to be in compliance with the new CLIA mandatory SARS–CoV–2 test results reporting requirements, laboratories will need to develop a mechanism to track, collect, and report test results as well as update policies and procedures. In addition, Accreditation Organizations (AOs) and Exempt States (ESs) will need to update laboratory standards to reflect the reporting requirements and update policies and procedures related to reporting laboratories that do not report test results as required.

The CDC has an information collection request (OMB Control Number 0920–1299) in order to collect laboratory data related to the COVID–19 Pandemic Response. The CMS package (ICR) is for laboratory implementation and CMS monitoring of compliance with the CMS–3401–IFC CLIA-certified laboratory reporting requirements.

The information collected by the Centers for Medicare and Medicaid Services (CMS) or its designee, such as a CMS agent or CMS approved laboratory accreditation organization, when conducting inspections will be used to determine a laboratory's compliance with the CLIA SARS–CoV–2 test result reporting requirements. During an on-site survey, the Condition-level laboratory requirement at 42 CFR 493.41 and 493.1100(a) are assessed for compliance. The information is used by CMS in determining appropriate Civil Money Penalties (CMPs) when laboratories fail to report as required. *Form Number:* CMS–10757 (OMB control number: 0938–NEW); *Frequency:* Daily; *Affected Public:* Private Sector Not-for-profit institutions and State, Local and Tribal Governments; *Number of Respondents:* 77,033; *Total Annual Responses:* 308,114; *Total Annual Hours:* 1,386,873 (For policy questions regarding this

collection contact Sarah Bennett at 410–786–3354.)

Dated: October 30, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–24435 Filed 11–3–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9126–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2020, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I. CMS Manual Instructions	Ismael Torres	(410) 786–1864
II. Regulation Documents Published in the FEDERAL REGISTER	Terri Plumb	(410) 786–4481
III. CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV. Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V. FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI. Collections of Information	William Parham	(410) 786–4669
VII. Medicare—Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII. American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786–2749
IX. Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786–7205
X. One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI. National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786–3365
XII. Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786–3365
XIII. Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV. Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV. Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786–3365
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for

purposes of publication in the **Federal Register**.

Dated: October 21, 2020.

Trenesha Fultz-Mimms,

Federal Register Liaison, Department of Health and Human Services.

BILLING CODE 4120–01–P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 6, 2019 (84 FR 59815), February 13, 2020 (85 FR 8282), April 24, 2020 (85 FR 23030) and August 12, 2020 (85 FR 48691). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2020)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP), use (CMS-Pub. 100-03) Transmittal No. 10337.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
10299	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

Medicare Benefit Policy (CMS-Pub. 100-02)	
10269	Billing for Home Infusion Therapy Services On or After January 1, 2021 Home Infusion Therapy Services General Requirements for Payment of Home Infusion Therapy Services Home Infusion Therapy Services Benefit is Separate from DME Benefit Qualified Home Infusion Therapy Suppliers Patient Eligibility for Home Infusion Therapy 320.4.1/Home Infusion Therapy Services for Homebound Patients Plan of Care Requirements Notification of Available Infusion Therapy Options Plan of Care Periodic Review and Provider Coordination Professional Services, Including Nursing Services, for Home Infusion Therapy Home Infusion Therapy Services Training and Education Remote Monitoring and Monitoring Services Home Infusion Therapy Drugs Determining Qualifying Home Infusion Drugs Payment for Home Infusion Therapy Services Home Infusion Drug Payment Categories Infusion Drug Administration Calendar Day and Unit of Single Payment 320.8.3/Initial Visits and Subsequent Visits for Home Infusion Therapy Services Medical Review
Medicare National Coverage Determination (CMS-Pub. 100-03)	
10337	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)
Medicare Claims Processing (CMS-Pub. 100-04)	
10201	October 2020 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
10202	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2021
10207	July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10210	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 3, Section 20 and 90.6 Payment Under Prospective Payment System (PPS) Diagnosis Related Groups (DRGs) Intestinal and Multi-Visceral Transplants
10211	Manual Update to Section 20.7 in Chapter 23 of Publication (Pub) 100-04
10213	Influenza Vaccine Payment Allowances - Annual Update for 2020-2021 Season
10214	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10215	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2020
10216	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10217	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10218	Change to the Payment of Allogeneic Stem Cell Acquisition Services
10221	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
10222	Updates in the Fiscal Intermediary Shared System (FISS) Inpatient Provider Specific Files (PSF)
10224	July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10225	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10229	Modify Edits in the Fee for Service (FFS) System When a Beneficiary has a Medicare Advantage (MA) Plan
10230	New Waived Tests
10232	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10233	Update to the (IOM) Publication 100-04, Medicare Claims Processing Manual, Chapter 23 – Fee Schedule Administration and Coding Requirements, Section 20.9 - Fee Schedule Administration and Coding Requirements National Correct Coding Initiative (NCCI Correct Coding Modifier Indicators and HCPCS Codes Modifiers Instructions for Codes with Modifiers (A/B MACs (B) Only) Appeals Procedure-to-Procedure Edits Medically Unlikely Edits Correct Coding Edit (CCE) File Record Format
10236	Update to the IOM Publication (Pub) 100-04, Medicare Claims Processing Manual, Chapters 1, 6, 8, 17, 20, 22, 24, and 31 Referencing the Active Universal Resource Locators (URLs) for the Washington Publishing Company (WPC) and the ASC X12 Organizations, and Updates to the HIPAA Eligibility Transaction System (HETS)
10242	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10244	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10246	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10247	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10249	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10251	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10253	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10254	Penalty for Delayed Request for Anticipated Payment (RAP) Submission – Implementation Addendum A Split Percentage Payment Grouper Links Assessment and Payment Request for Anticipated Payment (RAP Request for Anticipated Payment (RAP) HH PPS Claims

	Input/Output Record Layout Decision Logic Used by the Pricer on RAPs Decision Logic Used by the Pricer on Claims
10255	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10256	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10257	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10259	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10263	Influenza Vaccine Payment Allowances - Annual Update for 2020-2021 Season
10264	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10265	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10266	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10267	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10269	Billing for Home Infusion Therapy Services On or After January 1, 2021 Home Infusion Therapy Services Policy Coverage Requirements Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes Billing and Payment Requirements Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages CWF and MCS Editing Requirements
10270	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10272	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10273	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10274	Update to Osteoporosis Drug Codes Billable on Home Health Claims Osteoporosis Injections as HHA Benefit
10276	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10277	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10284	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10285	Instructions for Retrieving the January 2021 Opioid Treatment Program (OTP) Payment Rates Through the CMS Mainframe Telecommunications System
10288	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2020 Update
10290	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10293	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10296	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10297	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10298	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10305	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2020
10306	October 2020 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
10312	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2021
10313	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10314	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2021
10318	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10319	Removal of Contractor Requirement to Submit Electronic Data Interchange (EDI) Data into the Contractor Reporting of Operational and Workload Data (CROWD) System (Form 5)
10320	Updates to Chapter 23 - Fee Schedule Administration and Coding Requirements Description of Healthcare Common Procedure Coding System (HCPCS) Use and Maintenance of CPT-4 in HCPCS Local Codes Use and Acceptance of HCPCS Codes and Modifiers Deleted HCPCS Codes/Modifiers Payment, Utilization Review (UR), and Coverage Information on CMS Quarterly HCPCS Codes Update File Physician Fee Schedule Payment Policy Indicator File Record Layout
10321	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2021
10322	Claim Status Category and Claim Status Codes Update
10323	Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
10324	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
10325	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update

10326	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10328	January 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10329	Annual Clotting Factor Furnishing Fee Update 2021
10330	Instructions for Retrieving the January 2021 Medicare Physician Fee Schedule Database (MPFSDB) Files Through the CMS Mainframe Telecommunications System
10331	October 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10332	October 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.3
10334	October Quarterly Update for 2020 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
10337	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)
10338	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for FY 2021
10339	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10341	Internet Only Manual Update to Pub. 100-04, Chapter 16, Section 60.1.2 and Pub. 100-04, Chapter 26, Section 10.4, Item 19 Independent Laboratory Specimen Drawing Items 14-33 - Provider of Service or Supplier Information and 40.2.4.
10343	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 40.2.1 and 40.2.4.
10344	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10348	October 2020 Update of the Ambulatory Surgical Center (ASC) Payment System
10350	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10354	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10356	Update to the Medicare Claims Processing Manual Site of Service Payment Differential MPFSDB File Record Layout and Field Descriptions
10357	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 9, Section 70.7 and 70.8.
10358	Instructions for Downloading the Medicare ZIP Code File for January 2021
10360	Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
10371	Change to the Payment of Allogeneic
10373	October 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Medicare Secondary Payer (CMS-Pub. 100-05)	
10342	Update to the Model Admission Questions for Providers to Ask Medicare Beneficiaries Model Admission Questions to Ask Medicare Beneficiaries Documentation to Support the Admission Process
10359	Update to the Model Admission Questions for Providers to Ask Medicare Beneficiaries Model Admission Questions to Ask Medicare Beneficiaries Documentation to Support the Admission Process
Medicare Financial Management (CMS-Pub. 100-06)	
10203	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
10220	Notice of New Interest Rate for Medicare Overpayments and Underpayments -4th Qtr Notification for FY 2020
10226	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10319	Removal of Contractor Requirement to Submit Electronic Data Interchange (EDI) Data into the Contractor Reporting of Operational and Workload Data (CROWD) System (Form 5)
Medicare State Operations Manual (CMS-Pub. 100-07)	
	None
Medicare Program Integrity (CMS-Pub. 100-08)	
10209	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10219	Moving Chapter 15 (Medicare Enrollment) Manual Instructions in Publication (Pub.) 100-08 to Chapter 10 (Medicare Enrollment) Introduction to Medicare Provider Enrollment Definitions Provider and Supplier Types/Services Certified Providers and Certified Suppliers That Enroll Via the Form CMS-855A Suppliers That Enroll Via the Form CMS-855B Individual Practitioners That Enroll Via the Form CMS-855I Other Medicare Part B Services Suppliers That Enroll Via the Form CMS-855S Medicare Diabetes Prevention Program (MDPP) Suppliers/Providers/Suppliers Not Eligible to Participate
10226	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10227	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10228	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08
10234	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10235	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10345	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10

10347	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10353	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10 of Pub. 100-08, Modification of the Timeliness Standards
10355	Completion of Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08 Certified Providers and Suppliers That Enroll Via the Form CMS-855 Suppliers that Enroll Via the Form CMS-855B Individual Practitioners that Enroll Via the Form CMS-855I Other Medicare Part B Services Suppliers That Enroll Via the CMS-855S Medicare Enrollment: Contractor Processing Duties Appeals Process Other Medicare Contractor Duties Application Return, Rejection, and Denial Letters Denial Model Letters Revocation Letters Corrective Action Plan (CAP) Model Letters Reconsideration Request Model Letters Deactivation Model Letters Rebuttal Model Letters Revalidation Notification Letters Model Identity Theft Prevention Letter Model Documentation Request Letter Medicare Program Integrity Manual Chapter 15 – Reserved for Future Use
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
10303	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Medicare Prescription Drug Benefit (CMS-Pub. 100-18)	
	None
Demonstrations (CMS-Pub. 100-19)	
10206	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10208	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10260	Implementation of Nurse Practitioners Certifying Diabetic Shoe Orders Under the Primary Care First (PCF) Model
10281	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 2: FFS Payments and other claims-based adjustments
10282	Telehealth Expansion Benefit Enhancement under the Pennsylvania Rural Health Model (PARHM) – Implementation
10289	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10294	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10307	The Intravenous Immune Globulin (IVIG) Demonstration: Demonstration is ending on December 31, 2020
10327	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10336	Implementation of Nurse Practitioners Certifying Diabetic Shoe Orders Under the Primary Care First (PCF) Model
10351	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
One Time Notification (CMS-Pub. 100-20)	
10205	New Point of Origin Code for Transfer from a Designated Disaster Alternate Care Site
10212	Reprocessing of Fiscal Year (FY) 2019 and 2020 Inpatient Prospective Payment System (IPPS) Claims for Certain Hospitals
10223	Medicare Appeals System (MAS) Enhanced Web Services for Part A Medicare Administrative Contractors.
10231	Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) code 87426
10240	IDR Shared Systems (IDRSS) Reference File Request for the Fiscal Intermediary Shared System (FISS) Adjustment Reason Codes
10241	Reason Code Updates for the 2020 Annual Therapy Current Procedural Terminology (CPT) Codes in Change Request (CR) 11501
10245	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10248	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for January 2021
10250	Update the Combined Common Edits Module (CCEM) for Compatibility with JAVA Software Version 1.8 (also known as JAVA 8)
10252	COBOL Version 6.2 Upgrade - Phased Implementation for Fiscal Intermediary Shared System (FISS) and Multi Carrier System (MCS)
10258	Send Electronic Funds Transfer (EFT) Information from Provider Enrollment Chain and Ownership System (PECOS) to Multi-Carrier
10261	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--January 2021 Update
10271	Utility to Reprocess Bypassed Common Working File (CWF) Informational Unsolicited Responses (IURs)
10275	Correction to Editing Update for Vaccine Services
10278	Create a New Media Preference Indicator Custom Format and New eMedicare Correspondence Preference Indicator
10283	COBOL Version 6.2 Upgrade - Phased Implementation for ViPS Medicare System (VMS) and the Common Working File (CWF)

10286	User CR: ViPS Medicare System (VMS) - Create a Beneficiary Record Submitted with Medicare Beneficiary Identifier (MBI) Waiver Claims
10287	CR: ViPS Medicare System (VMS) - Enhancements to the Claim Edit Audit Trail Screen (BUDS05)
10291	Expand Retention of Claims History for Outpatient, Part B, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to 5 Years
10295	Shared System Support Hours for Application Programming Interfaces (APIs)
10300	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10301	Updates to Bills Pending Reports to Assist Medicare Administrative Contractors (MACs) with Monthly Status Report (MSR)
10302	Shared System Enhancement 2018: Rewrite Fiscal Intermediary Shared System (FISS) module FSSB6001, Common Working File (CWF) Unsolicited Response Function
10315	Updates to Nursing and Allied Health Education Medicare Advantage Payment Policies
10316	Revision to the Cost Report Acceptability Checklists - This CR Rescinds and Fully Replaces CR 10920.
10317	Update to the International Classification of Diseases, Tenth Revision (ICD-10) Diagnosis Codes for Vaping Related Disorder and Diagnosis and Procedure Codes for the 2019 Novel Coronavirus (COVID-19)
10333	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10352	Updates to Bills Pending Reports to Assist Medicare Administrative Contractors (MACs) with Monthly Status Report (MSR)
10361	Update to the Implementation of the Increased Payments for COVID-19 Discharges Under the Inpatient Prospective Payment System (IPPS) Under Section 3710 of the CARES Act
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
10340	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
State Payment of Medicare Premiums (CMS-Pub.100-24)	
4	New State Payment of Medicare Premiums, (SPMP)
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
10362	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

Addendum II: Regulation Documents Published in the Federal Register (July through September 2020)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: https://www.cms.gov/files/document/regs3q20qpu.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (July through September 2020)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (July through September 2020)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on

program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer	NCD 90.2	10346	09/11/2020	01/28/2020

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2020)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (July through September 2020)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (July through September 2020)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Arnot Ogden Medical Center 600 Roe Avenue Elmira, NY 14905	330090	07/14/2020	NY
McLeod Loris Seacoast Hospital 14000 Highway 9 East Little River, SC 29566 Other Information: dba McLeod Health Seacoast	420105	08/11/2020	SC
Orlando Health – South Seminole Hospital 555 State Road 434 Longwood, FL 32750	1184709057	09/22/2020	FL
The following facilities have editorial changes (in bold).			
FROM: Ingham Regional Medical Center **TO: McLaren Greater Lansing** 401 West Greenlawn Avenue Lansing, MI 48910	230167	09/22/2005	MI
FROM: St Mary's of Michigan **TO: Ascension St Mary's Hospital** 800 S. Washington Avenue Saginaw, MI 48601	230077	01/12/2006	MI

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2020)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2020)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2020)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at http://www.cms.gov . For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2020)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2020)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following facilities are new listings for this quarter.				
University Health Services, Inc d/b/a University Hospital 1350 Walton Way Augusta, GA 30901 Other information: Joint Commission ID # 564723-2020-VAD	110028	08/28/2020		GA

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
St. Elizabeth Healthcare 1 Medical Village Drive Edgewood, KY 41017 Other information: Joint Commission ID # 188468-2020-VAD	180035	08/12/2020		KY
AMITA Health Alexian Brothers Medical Center 800 Biesterfield Rd Elk Grove Village, IL 60007 Other information: DNV GL ID # 185936-2020-VAD	140258	07/21/2020		IL
Heart Hospital of Austin, A campus of St. David's Medical Center 3801 N. Lamar Blvd Austin, TX 78756 Other information: DNV GL ID # 181413-2020-VAD	450431	07/27/2020		TX
The following facilities have editorial changes (in bold).				
NYU Langone Hospitals 550 First Avenue New York, NY 10016 Other information: Joint Commission ID # 5820 Previous Re-certification Dates: 02/14/2012; 01/14/2014; 03/08/2016; 03/27/2018	330214	02/14/2012	**08/26/2020**	NY
University of Kentucky Hospital 800 Rose Street Lexington, KY 40536-0293 Other information: Joint Commission ID # 7760 Previous Re-certification Dates: 02/10/2009; 09/20/2011; 09/18/2013; 11/03/2015; 12/05/2017	180067	02/10/2009	**02/26/2020**	KY
Sutter Medical Center 2825 Capitol Ave Sacramento, CA 95816 Other information: Joint Commission ID # 2902 Previous Re-certification Dates: 10/20/2009; 09/22/2011; 10/17/2013; 10/27/2015; 11/07/2017	050108	10/20/2009	**03/04/2020**	CA

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2020)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2020)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures.

We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2020)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2020–24464 Filed 11–3–20; 8:45 am]

BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Refugee Data Submission System for Formula Funds Allocations (ORR–5) (OMB #0970–0043)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

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 extend approval for data collection using the current Refugee Data Submission System for Formula Funds Allocations (ORR–5) until January 31, 2021, and revise the current form for use after Fiscal Year (FY) 2020. The revised form will collect additional client-level data.

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: ORR–5 is designed to satisfy the statutory requirements of the Immigration and Nationality Act (INA). Section 412(a)(3) of INA (8 U.S.C. 1522(a)(3)) requires that the Director of ORR make a periodic assessment of the needs of refugees for assistance and services and the resources available to meet those needs. ORR proposes an extension with no changes to the current form until January 31, 2021, to ensure continuous information collection for FY 2020. ORR also proposes revisions to the current form for use after FY 2020. Revisions include collecting additional client-level data elements on the ORR–5 at multiple points in time, which will allow the ORR Director to better understand client goals, services utilized, and the outcomes achieved by the population ORR serves. New data elements include additional demographics, primary goals identified and referrals made to work toward self-sufficiency, progress made toward achieving said goals, and employment status of employable refugees 12 months post-enrollment. The data collected will inform evidence-based policy making and program design. These revisions also enable ORR and states to monitor implementation of the requirements put forth in ORR Policy Letter 19–07.

Respondents: States, Replacement Designees, and the District of Columbia.

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
Refugee Data Submission for Formula Funds Allocations (ORR–5)—Current (through January 31, 2021)	50	1	90	4,500	*1,500
Refugee Data Submission for Formula Funds Allocations (ORR–5)—Revised	50	3	140	21,000	7,000

*Burden is annualized over the full 3-year request period, but this form will be complete within the 1st year.

Estimated Total Annual Burden Hours: 8,500.

Authority: 8 U.S.C. 412(a)(3).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–24398 Filed 11–3–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0588]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by December 4, 2020.

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 0910–0614. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

OMB Control Number 0910–0614—Extension

Under the Public Health Service Act, the Department of Health and Human Services stockpiles medical products that are essential to the health security of the Nation (see 42 U.S.C. 247d–6b). This collection of medical products for use during national health emergencies, known as the Strategic National Stockpile (SNS), is to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

It may be appropriate for certain medical products that are or will be held in the SNS to be labeled in a manner that would not comply with certain FDA labeling regulations given their anticipated circumstances of use in an emergency. However, noncompliance with these labeling requirements could render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

Under §§ 201.26, 610.68, 801.128, and 809.11 (21 CFR 201.26, 610.68, 801.128, and 809.11), the appropriate FDA Center Director may grant a request for an exception or alternative to certain regulatory provisions pertaining to the labeling of human drugs, biological products, medical devices, and in vitro diagnostics that currently are or will be included in the SNS if certain criteria are met. The appropriate FDA Center Director may grant an exception or alternative to certain FDA labeling requirements if compliance with these labeling requirements could adversely affect the safety, effectiveness, or availability of products that are or will be included in the SNS. An exception or alternative granted under the regulations may include conditions or safeguards so that the labeling for such products includes appropriate information necessary for the safe and effective use of the product given the product's anticipated circumstances of use. Any grant of an exception or alternative will only apply to the specified lots, batches, or other units of medical products in the request. The appropriate FDA Center Director may also grant an exception or alternative to the labeling provisions specified in the regulations on his or her own initiative.

Under §§ 201.26(b)(1)(i) (human drug products), 610.68(b)(1)(i) (biological products), 801.128(b)(1)(i) (medical devices), and 809.11(b)(1)(i) (in vitro diagnostic products for human use) an SNS official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores such products that are or will be included in the SNS may submit, with written concurrence from a SNS official, a written request for an exception or alternative to certain labeling requirements to the appropriate FDA Center Director. Except when initiated by an FDA Center Director, a request for an exception or alternative must be in writing and must:

- Identify the specified lots, batches, or other units of the affected product;
- identify the specific labeling provisions under the regulations that are the subject of the request;
- explain why compliance with the specified labeling provisions could adversely affect the safety, effectiveness, or availability of the product subject to the request;
- describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product

given the anticipated circumstances of use of the product;

- provide copies of the proposed labeling of the specified lots, batches, or other units of the affected product that will be subject to the exception or alternative; and
- provide any other information requested by the FDA Center Director in support of the request.

If the request is granted, the manufacturer may need to report to FDA any resulting changes to the new drug application, biologics license application, premarket approval application, or premarket notification (510(k)) in effect, if any. The submission and grant of an exception or an alternative to the labeling requirements specified in the regulations may be used to satisfy certain reporting obligations relating to changes to product applications under §§ 314.70, 601.12, 814.39, or 807.81 (21 CFR 314.70 (human drugs), 601.12 (biological products), 814.39 (medical devices subject to premarket approval), or 807.81 (medical devices subject to 510(k) clearance requirements)). The information collection provisions in §§ 314.70, 601.12, 807.81, and 814.39 have been approved under OMB control numbers 0910–0001, 0910–0338, 0910–0120, and 0910–0231, respectively. On a case-by-case basis, the appropriate FDA Center Director may also determine when an exception or alternative is granted that certain safeguards and conditions are appropriate, such as additional labeling on the SNS products, so that the labeling of such products would include information needed for safe and effective use under the anticipated circumstances of use.

Respondents to this collection of information are entities that manufacture (including labeling, packing, relabeling, or repackaging), distribute or store affected SNS products. Based on data from fiscal years 2017, 2018, and 2019, FDA estimates an average of one request annually for an exception or alternative received by FDA. FDA estimates an average of 24 hours preparing each request. The average burden per response for each submission is based on the estimated time that it takes to prepare a supplement to an application, which may be considered similar to a request for an exception or alternative. To the extent that labeling changes not already required by FDA regulations are made in connection with an exception or alternative granted under the regulations, FDA is estimating one occurrence annually in the event FDA would require any additional labeling changes not already covered by FDA regulations. FDA estimates 8 hours to develop and revise the labeling to make such changes. The average burden per response for each submission is based on the estimated time to develop and revise the labeling to make such changes.

In the **Federal Register** of July 2, 2020 (85 FR 39914), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but was not responsive to the four information collection topics solicited and is therefore not addressed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	24	24
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	8	8
Total					32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Consistent with the PRA, our current estimate of the burden of the information collection is based on our evaluation over the past 3 years. However, in light of recent consumption of products from the SNS, we expect future adjustments may be necessary and invite specific comment in this regard.

Dated: October 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24427 Filed 11–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0487]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 4, 2020.

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 0910–0697. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD

20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

OMB Control Number 0910–0697—Extension

The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. 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 the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

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 following: 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 non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to 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.

Respondents to this collection of information cover a broad range of stakeholders who have specific characteristics related to certain products or services regulated by FDA. These stakeholders include members of the general public, healthcare professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction.

In the **Federal Register** of April 3, 2020 (85 FR 18989), we published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were 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 REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus groups	800	1	800	1.75	1,400
Customer comment cards/forms	1,325	1	1,325	*.25	331.25
Small discussion groups	800	1	800	1.75	1,400
Customer satisfaction surveys	12,000	1	12,000	†.33	3,960
Usability Studies	800	1	800	1.75	1,400
Total					8,491.25

* (15 minutes).
† (20 minutes).

In the 60-day notice published on April 3, 2020, the number of responses and number of burden hours did not match OMB approved inventory. This notice corrects the burden in table 1 of that notice. In addition, the burden for this collection of information has increased by 800 responses from 14,925 to 15,725 responses due to an inadvertent omission of responses of usability studies for this collection. This addition to responses will correct the number of responses for this collection. The burden hours in OMB's inventory will remain the same.

Dated: October 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24422 Filed 11–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0369]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements of our regulations implementing the Federal Import Milk Act (FIMA).

DATES: Submit either electronic or written comments on the collection of information by January 4, 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 January 4, 2021. The *https://www.regulations.gov* electronic filing system will accept

comments until 11:59 p.m. Eastern Time at the end of January 4, 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–2012–N–0369 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act.'' 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, 240–420–7500.

- 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, 240–420–7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Under the Federal Import Milk Act (FIMA)—21 CFR Part 1210

OMB Control Number 0910–0212—Extension

This information collection supports FDA regulations. Under FIMA (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F (21 U.S.C. 142).

Our regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of

tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.

Description of Respondents: Respondents include foreign dairy farms and plants engaged in transporting milk and/or cream into the United States. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.11	1996/Farm Inspection Report	1	200	200	1.5	300
1210.12	1995/Report of Physical Examination of Cows ..	1	1	1	0.5 (30 minutes)	0.5
1210.13	1994/Report of Tuberculin Tests of Cattle	1	1	1	0.5 (30 minutes)	0.5
1210.14	1997/Score Card for Sanitation Inspections of Milk Plants.	1	1	1	2	2
1210.20	1993/Application for Permit to Ship or Transport Milk and/or Cream into United States.	1	1	1	0.5 (30 minutes)	0.5
1210.23	1815/Certificate/Transmittal for an Application ...	1	1	1	0.5 (30 minutes)	0.5
Total	.....	.....	.....	.....	.....	304

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1210.15 Pasteurization; Equipment, and Methods	1	1	1	0.05 (3 minutes)	0.05

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. In the past, Form FDA 1815 has been submitted in lieu of these forms. Because we have not received any Forms FDA 1994 or 1995 in the last 3 years, we assume no more than one will be submitted annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by us (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by OMB under the PRA. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of business activities.

Based on a review of the information collection since our last OMB approval, we have decreased our burden estimate. The estimated number of respondents and hours per response are based on our experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. However, we have not received any responses in the last 3 years; therefore, we estimate that one or fewer to be submitted annually. Although we have not received any responses in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need for a milk importer.

Dated: October 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24428 Filed 11–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is hereby giving notice that the charter for the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has been renewed.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Officer for the ACBTSA, Senior Advisor for Blood and Tissue Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, 330 C Street SW, Suite L600, Washington, DC 20024. Phone: (202) 795–7608. Email: *ACBTSA@hhs.gov.*

SUPPLEMENTARY INFORMATION: The ACBTSA is a non-discretionary federal advisory committee. The ACBTSA is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service

(PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The ACBTSA advises, assists, consults with, and makes policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding broad responsibilities related to the safety of blood, blood products, tissues, and organs. For solid organs and blood stem cells, the Committee's work is limited to policy issues related to donor derived infectious disease complications of transplantation.

To carry out its mission, the ACBTSA provides advice to the Secretary through the Assistant Secretary for Health on a range of policy issues which includes: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (*e.g.,* product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues.

On October 9, 2020, the Secretary approved for the ACBTSA charter to be renewed. The new charter was effected and filed with the appropriate Congressional committees and the Library of Congress on October 9, 2020. Renewal of the Committee's charter gives authorization for the Committee to continue to operate until October 9, 2022.

A copy of the ACBTSA charter is available on the Committee's website at *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/charter/index.html.*

Dated: October 22, 2020.

James J. Berger,

DFO, Advisory Committee on Blood and Safety and Availability, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020–24404 Filed 11–3–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Appointment to the Tick-Borne Disease Working Group; Extension of Nomination Period

AGENCY: Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; extension of nomination period.

SUMMARY: The Office of the Assistant Secretary for Health published a document in the **Federal Register** on October 6, 2020 seeking nominations of non-federal public individuals who represent diverse scientific disciplines and views and are interested in being considered for appointment to the Tick-Borne Disease Working Group (TBDWG). Due to requests to extend the nomination period, this document is announcing a 30-day extension. The October 6 notice can be accessed at *https://www.govinfo.gov/content/pkg/FR-2020-10-06/pdf/2020-22062.pdf.*

DATES: To be assured consideration, nominations must be sent to the TBDWG email address at *tickbornedisease@hhs.gov* no later than 5:00 p.m. Eastern Standard Time on December 5, 2020.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, (202) 795–7608; *tickbornedisease@hhs.gov.*

Dated: October 29, 2020.

James Berger,

Senior Advisor for Blood and Tissue Policy, Designated Federal Officer, HHS Tick-Borne Disease Working Group and the Advisory Committee on Blood and Tissue Safety and Availability, Office of the Assistant Secretary for Health.

[FR Doc. 2020–24414 Filed 11–3–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below. Individuals who plan to participate and need special assistance, such as sign language interpretation or other 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 Neurological Disorders and Stroke Council.

Date: February 3–4, 2021.

Open: February 03, 2021, 1:00 p.m. to 6:00 p.m.

Agenda: Report by the Director, NINDS; Report by the Director, Division of Extramural Activities; and Administrative and Program Developments.

Open session will be videocast from this link: https://videocast.nih.gov/.

Closed: February 04, 2021, 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC Building, 6001 Executive Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert Finkelstein, Ph.D., Director of Extramural Research, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., Suite 3309, MSC 9531, Bethesda, MD 20892, (301) 496–9248, *finkelsr@ninds.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: *www.ninds.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 29, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–24395 Filed 11–3–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute On Drug Abuse; 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 Drug Abuse Special Emphasis Panel; Exploiting In Vivo or In Situ Imaging Approaches to Understand HIV-relevant Processes in the Context of Substance Use Disorders (R61/R33 Clinical Trials Optional).

Date: November 12, 2020.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5819, *gm145a@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 29, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–24396 Filed 11–3–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE ON DRUG ABUSE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDA.

Date: November 9, 2020.

Time: 8:45 a.m. to 4:45 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Drug Abuse, NIH Biomedical Research Center, 251 Bayview Boulevard, Baltimore, MD 21224 (Virtual Meeting).

Date: November 10, 2020.

Time: 8:00 a.m. to 3:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Drug Abuse, NIH Biomedical Research Center, 251 Bayview Boulevard, Baltimore, MD 21224 (Virtual Meeting)

Contact Person: Adrienne Snyder, Management Analyst, Office of the Scientific Director, NIH Biomedical Research Center, National Institute on Drug Abuse, 251 Bayview Blvd., Suite 200, Room 04A524, Baltimore, MD 21224, 443–740–2394, *adrienne.snyder@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the intramural review cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 29, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–24369 Filed 11–3–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY921000, L71220000.EU0000, LVTFK2099100 WYW–184983]

Notice of Intent/Notice of Realty Action: Proposed Resource Management Plan Amendment and Non-Competitive Direct Sale of Public Land in Johnson County, Wyoming

AGENCY: Bureau of Land Management.

ACTION: Notice of intent; notice of Realty Action.

SUMMARY: The Bureau of Land Management (BLM) proposes to amend the September 22, 2015, Buffalo Resource Management Plan (RMP) and prepare an associated Environmental Assessment (EA) to identify and allow the non-competitive (direct) sale of 1.13 acres of public lands in Johnson County, Wyoming, to William D. and Bonnie S. Ross. The purpose of the sale would be to resolve an inadvertent unauthorized use of public lands. The sale would be for no less than the appraised fair market value of $555. The sale is subject to the applicable provisions of Sections 203 of the Federal Land Policy and Management Act of 1976 (FLPMA), as amended, and the BLM land conveyance regulations. Section 203 of FLPMA requires the parcel to meet disposal criteria for sales in Section 202 of FLPMA, and specifically requires the BLM to identify parcels for disposal within the RMP or amend the RMP to establish the disposal criteria in order to dispose of the parcel.

DATES: Interested parties may submit comments regarding the proposed RMP amendment, classification of the land for disposal and the proposed direct sale by December 21, 2020.

ADDRESSES: Written comments concerning this plan amendment and direct sale may be submitted by mail to Field Manager, BLM, Buffalo Field Office, 1425 Fort St., Buffalo, Wyoming 82834 or electronically on BLM's ePlanning website, *https://go.usa.gov/xdFUQ*.

FOR FURTHER INFORMATION CONTACT: Denise Oliverius, Realty Specialist, BLM, Buffalo Field Office by phone at 307–684–1178 or by email at *doliveri@blm.gov*. Persons who use a

telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1–800–877–8339. The FRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours. Project information will also be available on the BLM's ePlanning website: *https://go.usa.gov/xdFUQ.*

SUPPLEMENTARY INFORMATION: In the 1960s, local landowners misinterpreted the boundaries of their private property and inadvertently built a home site that encroached onto public land. The BLM proposes to segregate the affected land, amend the relevant RMP, and offer the land for direct sale to resolve the issue. The BLM will examine the following described public lands located in Johnson, County, Wyoming, for disposal suitability under the authority of Sections 202 and 203 of FLPMA:

Sixth Principal Meridian, Wyoming

T. 44 N., R. 81 W.,
Sec. 30, parcel A.

The area described contains 1.13 acres.

Upon publication of this Notice in the **Federal Register**, the public land described above will be segregated from all forms of appropriation under the public land laws, including the mining laws, except for the sale provisions of the FLPMA. The segregation will terminate upon (1) issuance of a conveyance document; (2) publication in the **Federal Register** terminating the segregation; or (3) on November 4, 2022, unless extended by the BLM Wyoming State Director in accordance with 43 CFR 2711.1–2(d). Until completion of the sale, the BLM will no longer accept land use applications affecting the identified public land in accordance with 43 CFR 2807.15.

The BLM may sell a tract of public land as a result of approved land use planning if the sale of the tract meets the disposal criteria. The 2015 Buffalo RMP does not identify the 1.13 acres of public land in question as suitable for disposal. Therefore, to dispose of the tract, the BLM must amend the RMP to meet the requirements of FLPMA Section 203 through planning. If authorized, the underlying decision will amend the Buffalo RMP, establishing that ''such tract, because of its location or other characteristics, is difficult and uneconomic to manage as part of the public lands and is not suitable for management by another Federal department or agency.''

The BLM will analyze the parcel and develop an EA to evaluate the environmental effects of the proposed RMP amendment and the sale criteria under FLPMA Section 203(a)(3) and 43 CFR 2710.0–3(a)(3) to ensure the disposal of the tract will serve important public objectives, including but not limited to relieving BLM authority for a parcel of public land that, because of its location or other characteristics, is difficult and uneconomic to manage as part of the public lands and is not suitable for management by another Federal department or agency. After the BLM has analyzed public scoping comments and prepared the analysis, the EA will be available for a 30-day protest period.

The parcel being considered for direct sale is not required for any other Federal purpose. Regulations contained in 43 CFR 2710.0–6 (c)(3)(iii) and 2711.3–3(a)(5) make allowances for direct sales to resolve inadvertent unauthorized use or occupancy of public land. The BLM will consider selling this parcel if it is determined that the public interest would best be served by selling the 1.13-acre parcel to William D. and Bonnie S. Ross for the fair market value of at least $555 to resolve the inadvertent unauthorized use and ensure the federal government receives fair compensation for the sale of the parcel. The BLM has determined the parcel is not an access point for recreation in accordance with Secretary's Order 3373, *Evaluating Public Access in Bureau of Land Management Public Land Disposals and Exchanges.* Disposal of this tract will have no anticipated impacts on recreational access to adjacent tracts of publicly accessible lands.

The conveyance document, if issued, will contain the following reservations; excepting and reserving to the United States:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945);

2. All the mineral deposits in the lands so patented pursuant to the Act of October 21, 1976 (43 U.S.C. 1719), including, without limitation, substances subject to disposition under the general mining laws, the general mineral leasing laws, the Materials Act and the Geothermal Steam Act, and to it, its permittees, licensees, lessees, and mining claimants, the right to prospect for, mine and remove the minerals owned by the United States under applicable law an such regulations as the Secretary of the Interior may prescribe. This reservation includes necessary access and exit rights and the right to conduct all necessary and incidental activities including, without limitation, all drilling, underground, open pit or surface mining operations, storage and transportation facilities deemed reasonably necessary.

Unless otherwise provided by separate agreement with the surface owner, mining claimants, permittees, licensees and lessees of the United States shall reclaim disturbed areas to the extent prescribed by regulations issued by the Secretary of the Interior.

All causes of action brought to enforce the rights of the surface owner under the regulations above referred to shall be instituted against mining claimants, permittees, licensees and lessees of the United States; and the United States shall not be liable for the acts or omissions of its mining claimants, permittees, licensees and lessees.

3. An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy, or occupation on the patented lands.

The conveyance document, if issued, will be subject to all valid existing rights. The BLM will publish this notice in the *Buffalo Bulletin* newspaper once a week for three consecutive weeks. Comments will be accepted as discussed in the **ADDRESSES** section above.

Before including your address, phone number, email address, or other personally identifying information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so. Comments, including names and street addresses of respondents, will be available for public review at the BLM Buffalo Field Office during regular business hours, except holidays.

Any adverse comments regarding the sale will be reviewed by the BLM Wyoming State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action in response to such comments. In the absence of comments, this realty action will become the final determination of the Department of the Interior.

(Authority: 43 CFR 2711)

Kimber Liebhauser,

Acting State Director, Wyoming.

[FR Doc. 2020–24389 Filed 11–3–20; 8:45 am]

BILLING CODE 4310–22–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Chocolate Milk Powder and Packaging Thereof, DN 3504;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (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 United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.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 has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Meenaxi Enterprise Inc. on October 29, 2020. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain chocolate milk powder and packaging thereof. The complaint names as respondents: Bharat Bazar Inc. of Union City, CA; Madras Group Inc. d/b/a Madras Groceries of Sunnyvale, CA; Coconut Hill Inc. d/b/a Coconut Hill of Sunnyvale, CA; Organic Food Inc. d/b/a Namaste Plaza Indian Super Market of Fremont, CA; India Cash & Carry Inc. d/b/a India Cash & Carry of Sunnyvale, CA; New India Bazar Inc. d/b/a New India Bazar of San Jose, CA; Aapka Big Bazar of Jersey City, NJ; Siya Cash & Carry Inc. d/b/a Siya Cash & Carry of Jersey City, NJ; JFK Indian Grocery LLC d/b/a D-Mart Super Market of Jersey City, NJ; Trinethra Indian Super Markets of Newark, CA; Apna Bazar Cash & Carry Inc. d/b/a Apna Bazar Cash & Carry of Edison, NJ; Subzi Mandi Cash & Carry Inc. d/b/a Subzi Mandi Cash & Carry of Piscataway, NJ; Subhlaxmi Grocers of Piscataway, NJ; Patidar Cash & Carry Inc. d/b/a Patidar Cash & Carry of South Plainfield, NJ; Keemat Grocers of Sugarland, TX; KGF World Food Warehouse Inc. d/b/a World Food Mart of Houston, TX; Telfair Spices of Sugarland, TX; Indian Groceries and Spices Inc. d/b/a iShopIndia.com of Milwaukee, WI; Rani Foods LP d/b/a Rani's World Foods of Houston TX; Tathastu Trading LLC of South Plainfield, NJ; and Choice Trading LLC of Guttenberg, NJ. The complainant requests that the Commission issue a general exclusion order and cease and desist orders.

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3504'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews,

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: October 30, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–24480 Filed 11–3–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Active Optical Cables and Products Containing the Same, DN 3503;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (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 United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.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 has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Cosemi Technologies, Inc. on October 29, 2020. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain active optical cables and products containing the same. The complaint names as respondents: EverPro Technologies Company Ltd. of China; Fibbr Technologies of China; Logitech Inc. of Newark, CA; and Facebook Technologies, LLC of Menlo Park, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3503'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: October 29, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–24390 Filed 11–3–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–741]

Bulk Manufacturer of Controlled Substances Application: Navinta LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Navinta LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 4, 2021. Such persons may also file a written request for a hearing on the application on or before January 4, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on September 25, 2020, Navinta LLC 1499 Lower Ferry Road, Ewing, New Jersey 08618–1414, applied to be registered as an bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Levomethorphan	9210	II
Levorphanol	9220	II
Remifentanil	9739	II
Fentanyl	9801	II

The company plans to bulk manufacture active pharmaceutical ingredients (API) quantities of the listed controlled substances for validation purposes and the Food and Drug Administration's approval. No other activity for these drug codes is authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–24465 Filed 11–3–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–717]

Bulk Manufacturer of Controlled Substances Application: Cerilliant Corporation

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cerilliant Corporation has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 4, 2021. Such persons may also file a written request for a hearing on the application on or before January 4, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on August 6, 2020, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665–2402, applied to be registered as an bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
3-Fluoro-N-methylcathinone (3–FMC)	1233	I
Cathinone	1235	I
Methcathinone	1237	I
4-Fluoro-N-methylcathinone (4–FMC)	1238	I
Pentedrone (α-methylaminovalerophenone)	1246	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
4-Methyl-N-ethylcathinone (4–MEC)	1249	I
Naphyrone	1258	I

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

Controlled substance	Drug code	Schedule
N-Ethylamphetamine	1475	I
N,N-Dimethylamphetamine	1480	I
Fenethylline	1503	I
Aminorex	1585	I
4-Methylaminorex (cis isomer)	1590	I
Gamma Hydroxybutyric Acid	2010	I
Methaqualone	2565	I
JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	6250	I
SR–18 (Also known as RCS–8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	7008	I
ADB–FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7010	I
5-Fluoro-UR-144 and XLR11 [1-(5-Fluoro-pentyl)1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	7011	I
AB–FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7012	I
FUB–144 (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone)	7014	I
JWH–019 (1-Hexyl-3-(1-naphthoyl)indole)	7019	I
MDMB–FUBINACA (Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7020	I
FUB–AMB, MMB–FUBINACA, AMB–FUBINACA (2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3-methylbutanoate).	7021	I
AB–PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7023	I
THJ–2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	7024	I
5F–AB–PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluropentyl)-1H-indazole-3-carboximide)	7025	I
AB–CHMINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7031	I
MAB–CHMINACA (N-(1-amino-3,3dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7032	I
5F–AMB (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	7033	I
5F–ADB, 5F–MDMB–PINACA (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7034	I
ADB–PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7035	I
5F–EDMB–PINACA (ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7036	I
5F–MDMB–PICA (methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	7041	I
MDMB–CHMICA, MMB–CHMINACA (Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate).	7042	I
MMB–CHMICA, AMB–CHMICA (methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate)	7044	I
FUB–AKB48, FUB–APINACA, AKB48 N-(4-FLUOROBENZYL) (N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboximide).	7047	I
APINACA and AKB48 (N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	7048	I
5F–APINACA, 5F–AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	7049	I
JWH–081 (1-Pentyl-3-(1-(4-methoxynaphthoyl)indole)	7081	I
5F–CUMYL–PINACA, 5GT–25 (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide)	7083	I
5F–CUMYL–P7AICA (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide)	7085	I
4–CN–CUML–BUTINACA, 4–cyano–CUMYL–BUTINACA, 4–CN–CUMYL BINACA, CUMYL–4CN–BINACA, SGT–78 (1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide).	7089	I
SR–19 (Also known as RCS–4) (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	7104	I
JWH–018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I
JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	7122	I
UR–144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	7144	I
JWH–073 (1-Butyl-3-(1-naphthoyl)indole)	7173	I
JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I
AM2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indole)	7201	I
JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	7203	I
NM2201, CBL2201 (Naphthalen-1-yl1-(5-fluoropentyl)-1H-indole-3-carboxylate	7221	I
PB–22 (Quinolin-8-yl1-pentyl-1H-indole-3-carboxylate)	7222	I
5F–PB–22 (Quinolin-8-yl1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7225	I
4–MEAP (4-Methyl-alpha-ethylaminopentiophenone)	7245	I
N-Ethylhexedrone	7246	I
Alpha-ethyltryptamine	7249	I
CP–47, 497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol)	7297	I
CP–47, 497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)3-hydroxycyclohexyl-phenol)	7298	I
Lysergic acid diethylamide	7315	I
2C–T–7 (2,5-Dimethoxy-4-(n)-propylthiophenethylamine	7348	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Parahexyl	7374	I
Mescaline	7381	I
2C–T–2 (2-(4-Ethylthio-2,5-dimethoxyphenyl)ethanamine)	7385	I
3,4,5-Trimethoxyamphetamine	7390	I
4-Bromo-2,5-dimethoxyamphetamine	7391	I
4-Bromo-2,5-dimethoxyphenethylamine	7392	I
4-Methyl-2,5-dimethoxyamphetamine	7395	I
2,5-Dimethoxyamphetamine	7396	I
JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	7398	I
2,5-Dimethoxy-4-ethylamphetamine	7399	I
3,4-Methylenedioxyamphetamine	7400	I
5-Methoxy-3,4-methylenedioxyamphetamine	7401	I
N-Hydroxy-3,4-methylenedioxyamphetamine	7402	I
3,4-Methylenedioxy-N-ethylamphetamine	7404	I
3,4-Methylenedioxymethamphetamine	7405	I

Controlled substance	Drug code	Schedule
4-Methoxyamphetamine	7411	I
5-Methoxy-N-N-dimethyltryptamine	7431	I
Alpha-methyltryptamine	7432	I
Bufotenine	7433	I
Diethyltryptamine	7434	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I
4′-Chloro-alpha-pyrrolidinovalerophenone	7443	I
MPHP, 4′-Methyl-alpha-pyrrolidinohexiophenone	7446	I
N-Ethyl-1-phenylcyclohexylamine	7455	I
1-(1-Phenylcyclohexyl)pyrrolidine	7458	I
1-[1-(2-Thienyl)cyclohexyl]piperidine	7470	I
N-Benzylpiperazine	7493	I
4-MePPP (4-Methyl-alphapyrrolidinopropiophenone)	7498	I
2C–D (2-(2,5-Dimethoxy-4-methylphenyl)ethanamine)	7508	I
2C–E (2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine)	7509	I
2C–H 2-(2,5-Dimethoxyphenyl)ethanamine)	7517	I
2C–I 2-(4-iodo-2,5-dimethoxyphenyl)ethanamine)	7518	I
2C–C 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine)	7519	I
2C–N (2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine)	7521	I
2C–P (2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine)	7524	I
2C–T–4 (2-(4-Isopropylthio)-2,5-dimethoxyphenyl)ethanamine)	7532	I
MDPV (3,4-Methylenedioxypyrovalerone)	7535	I
25B–NBOMe (2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine)	7536	I
25C–NBOMe (2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine)	7537	I
25I–NBOMe (2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine)	7538	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Butylone	7541	I
Pentylone	7542	I
N-Ethypentylone, ephylone (1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one)	7543	I
α–PHP, alpha-Pyrrolidinohexanophenone	7544	I
alpha-pyrrolidinopentiophenone (α–PVP)	7545	I
alpha-pyrrolidinobutiophenone (α–PBP)	7546	I
Ethylone	7547	I
PV8, alpha-Pyrrolidinoheptaphenone	7548	I
AM–694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole)	7694	I
Acetyldihydrocodeine	9051	I
Benzylmorphine	9052	I
Codeine-N-oxide	9053	I
Desomorphine	9055	I
Codeine methylbromide	9070	I
Dihydromorphine	9145	I
Heroin	9200	I
Hydromorphinol	9301	I
Methyldesorphine	9302	I
Methyldihydromorphine	9304	I
Morphine methylbromide	9305	I
Morphine methylsulfonate	9306	I
Morphine-N-oxide	9307	I
Normorphine	9313	I
Pholcodine	9314	I
U–47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide)	9547	I
AH–7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I
MT–45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine))	9560	I
Acetylmethadol	9601	I
Allylprodine	9602	I
Alphacetylmethadol except levo-alphacetylmethadol	9603	I
Alphameprodine	9604	I
Alphamethadol	9605	I
Betacetylmethadol	9607	I
Betameprodine	9608	I
Betamethadol	9609	I
Betaprodine	9611	I
Isotonitazene	9614	I
Dipipanone	9622	I
Hydroxypethidine	9627	I
Noracymethadol	9633	I
Norlevorphanol	9634	I
Normethadone	9635	I
Trimeperidine	9646	I
Phenomorphan	9647	I
1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I

Controlled substance	Drug code	Schedule
Tilidine	9750	I
Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide)	9811	I
Para-Fluorofentanyl	9812	I
3-Methylfentanyl	9813	I
Alpha-methylfentanyl	9814	I
Acetyl-alpha-methylfentanyl	9815	I
N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide	9816	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Butyryl Fentanyl	9822	I
Para-fluorobutyryl fentanyl	9823	I
4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide)	9824	I
2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide	9825	I
Para-chloroisobutyryl fentanyl	9826	I
Isobutyryl fentanyl	9827	I
Beta-hydroxyfentanyl	9830	I
Beta-hydroxy-3-methylfentanyl	9831	I
Alpha-methylthiofentanyl	9832	I
3-Methylthiofentanyl	9833	I
Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide)	9834	I
Thiofentanyl	9835	I
Beta-hydroxythiofentanyl	9836	I
Para-methoxybutyryl fentanyl	9837	I
Ocfentanil	9838	I
Valeryl fentanyl	9840	I
N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide	9843	I
Cyclopropyl Fentanyl	9845	I
Cyclopentyl fentanyl	9847	I
Fentanyl related-compounds as defined in 21 CFR 1308.11(h)	9850	I
8Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Phenmetrazine	1631	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Nabilone	7379	II
1-Phenylcyclohexylamine	7460	II
Phencyclidine	7471	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Norfentanyl	8366	II
1-Piperidinocyclohexanecarbonitrile	8603	II
Alphaprodine	9010	II
Cocaine	9041	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Hydrocodone	9193	II
Levomethorphan	9210	II
Levorphanol	9220	II
Isomethadone	9226	II
Meperidine	9230	II
Meperidine intermediate–A	9232	II
Meperidine intermediate–B	9233	II
Meperidine intermediate–C	9234	II
Metazocine	9240	II
Methadone	9250	II
Methadone intermediate	9254	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Morphine	9300	II
Thebaine	9333	II
Levo-alphacetylmethadol	9648	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Thiafentanil	9729	II
Racemethorphan	9732	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II

Controlled substance	Drug code	Schedule
Carfentanil	9743	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to bulk manufacture small quantities of the listed controlled substances to make reference standards which will be distributed to its customers. No other activity for these drug codes is authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–24466 Filed 11–3–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act, the Comprehensive Environmental Response, Compensation, and Liability Act, and the Emergency Planning and Community Right-To-Know Act

On October 28, 2020, the Department of Justice filed a complaint and lodged a proposed Consent Decree with the United States District Court for the District of Arizona (''Court'') in the matter of *United States of America* v. *Apache Nitrogen Products, Inc.,* Civil Action No. 4:20–cv–00463–BGM (D. Ariz.).

The proposed Consent Decree resolves certain claims brought under Sections 112(r)(1) and 112(r)(7) of the Clean Air Act (''CAA''), 42 U.S.C. 7412(r)(1), (r)(7); Section 103 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9603; and Section 304 of the Emergency Planning and Community Right-to-Know Act (''EPCRA''), 42 U.S.C. 11004, at the chemical manufacturing facility that Apache Nitrogen Products, Inc. (''Apache Nitrogen'') owns and operates in Cochise County, Arizona. The claims alleged in the complaint and resolved in the proposed Consent Decree concern Apache Nitrogen's prevention and mitigation of accidental chemical releases. The Consent Decree requires Apache Nitrogen to perform safety improvements at its Cochise County, Arizona facility, including making improvements to Apache Nitrogen's preventive maintenance tracking system, conducting an audit of its process safety culture, and upgrading its emergency response plan to include installation of an anhydrous ammonia monitoring system and enhanced public notification. The Consent Decree also documents that the company has replaced or upgraded equipment to improve accident prevention. The Consent Decree requires Apache Nitrogen to pay a civil penalty of $1,500,000 to the United States.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America* v. *Apache Nitrogen Products, Inc.,* D.J. Ref. No. 90–5–2–1–10736/1. 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 email	*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: *https://www.usdoj.gov/enrd/consent-decrees.* 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 $15.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Lori Jonas,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–24482 Filed 11–3–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On October 29, 2020, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Colorado in the lawsuit entitled *United States of America, the State of Colorado, the Lower Arkansas Valley Water Conservancy District, and the Board of County Commissioners in the County of Pueblo* v. *the City of Colorado Springs, Colorado,* Civil Action No. 1:16–cv–02745–JLK.

The lawsuit seeks injunctive relief and civil penalties for violations of the Clean Water Act, 33 U.S.C. 1319(b) and (d), based on the City's violations of the terms and conditions of its National Pollutant Discharge Elimination System (''NPDES'') permit issued by the State of Colorado under Section 402(b) of the Clean Water Act, 33 U.S.C. 1342(b), for discharges of stormwater from the City's municipal separate storm sewer system, as well as for violations of the Colorado Water Quality Control Act, §§ 25–8–101 *et seq.* C.R.S.

The proposed Consent Decree resolves all litigation in this action. The proposed Consent Decree requires the City of Colorado Springs to implement city-wide injunctive relief to comply with its NPDES permit, perform $11 million of mitigation to offset the environmental harm caused by its alleged violations, and pay the United States a $1 million civil penalty. In addition, in lieu of receiving a civil penalty payment, the State of Colorado agrees that the City shall satisfy the State civil penalty through performance of a State approved supplemental environmental project valued at $1 million, to be performed by Intervenor Plaintiff the Lower Arkansas Valley Water Conservancy District.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States, et al.* v. *the City of Colorado Springs, Colorado,* Civil Action No. 1:16–cv–02745–JLK, DOJ number 90–5–1–1–11293. All comments must be submitted no later than 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 email	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: *https://www.justice.gov/enrd/consent-decrees.* 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 $42.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Jeffrey Sands,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–24430 Filed 11–3–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Information Advisory Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of three virtual meetings in December 2020.

SUMMARY: Notice is hereby given that the Workforce Information Advisory Council (WIAC or Advisory Council) will meet for three days, virtually. Information for public attendance at the virtual meetings will be posted at *www.dol.gov/agencies/eta/wioa/wiac/meetings* several days prior to each meeting date. The meetings will be open to the public.

DATES: The meetings will take place December 3, 2020, December 10, 2020, and December 17, 2020. Each meeting will begin at 1:00 p.m. EST and conclude at approximately 4:00 p.m. EST. Public statements and requests for special accommodations or to address the Advisory Council must be received three days prior to the meeting dates.

ADDRESSES: Information for public attendance at the virtual meetings will be posted at *www.dol.gov/agencies/eta/wioa/wiac/meetings* several days prior to each meeting date. If problems arise accessing the meetings, please contact Donald Haughton, Unit Chief in the Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, at 202–693–2784.

FOR FURTHER INFORMATION CONTACT: Steven Rietzke, Chief, Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–4510, 200 Constitution Ave. NW, Washington, DC 20210; Telephone: 202–693–3912. Mr. Rietzke is the WIAC Designated Federal Officer.

SUPPLEMENTARY INFORMATION:

Background: These meetings are being held pursuant to Sec. 308 of the Workforce Innovation and Opportunity Act of 2014 (WIOA) (Pub. L. 113–128), which amends Sec. 15 of the Wagner-Peyser Act of 1933 (29 U.S.C. 491–2). The WIAC is an important component of the WIOA. The WIAC is a federal advisory committee of workforce and labor market information experts representing a broad range of national, State, and local data and information users and producers. The WIAC was established in accordance with provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.) and will act in accordance with the applicable provisions of FACA and its implementing regulation at 41 CFR 102–3. The purpose of the WIAC is to provide recommendations to the Secretary of Labor (Secretary), working jointly through the Assistant Secretary for Employment and Training and the Commissioner of Labor Statistics, to address: (1) The evaluation and improvement of the nationwide workforce and labor market information (WLMI) system and statewide systems that comprise the nationwide system; and (2) how the Department and the States will cooperate in the management of those systems. These systems include programs to produce employment-related statistics and State and local workforce and labor market information.

The Department of Labor anticipates the WIAC will accomplish its objectives by: (1) Studying workforce and labor market information issues; (2) seeking and sharing information on innovative approaches, new technologies, and data to inform employment, skills training, and workforce and economic development decision making and policy; and (3) advising the Secretary on how the workforce and labor market information system can best support workforce development, planning, and program development. Additional information is available at *www.dol.gov/agencies/eta/wioa/wiac/meetings.*

Purpose: The WIAC is currently in the process of identifying and reviewing issues and aspects of the WLMI system and statewide systems that comprise the nationwide system and how the Department and the States will cooperate in the management of those systems. As part of this process, the Advisory Council meets to gather information and to engage in deliberative and planning activities to facilitate the development and provision of its recommendations to the Secretary in a timely manner.

Agenda: The tentative agenda for each meeting is as follows: (1) Comments on minutes from previous meeting, (2) continue review and discussion of WIAC recommendations from 2018, (3) continue discussion on identification of new recommendations, (4) presentations from WLMI subject matter experts for information gathering purposes, and (5) comment period for the general public. A detailed, finalized agenda will be available at *www.dol.gov/agencies/eta/wioa/wiac/meetings* shortly before the meetings commence.

The Advisory Council will open the floor for public comment at approximately 2:30 p.m. EST on each meeting date and last for approximately 10 minutes. However, that time may change at the WIAC chair's discretion.

Attending the meetings: Members of the public who require reasonable accommodations to attend any of the meetings may submit requests for accommodations via email to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line ''December 2020 WIAC Meeting Accommodations'' by the date indicated in the **DATES** section. Please include a specific description of the accommodations requested and phone number or email address where you may be contacted if additional information is needed to meet your request.

Public statements: Organizations or members of the public wishing to submit written statements may do so by mailing them to the person and address indicated in the **FOR FURTHER INFORMATION CONTACT** section by the date indicated in the **DATES** section or transmitting them as email attachments in PDF format to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line ''December 2020 WIAC Meeting Public Statements'' by the date indicated in the **DATES** section. Submitters may include their name and contact information in a cover letter for

mailed statements or in the body of the email for statements transmitted electronically. Relevant statements received before the date indicated in the **DATES** section will be included in the record of each meeting. No deletions, modifications, or redactions will be made to statements received, as they are public records. Please do not include personally identifiable information in your public statement.

Requests to Address the Advisory Council: Members of the public or representatives of organizations wishing to address the Advisory Council should forward their requests to the contact indicated in the **FOR FURTHER INFORMATION CONTACT** section, or contact the same by phone, by the date indicated in the **DATES** section. Oral presentations will be limited to 10 minutes, time permitting, and shall proceed at the discretion of the Advisory Council chair. Individuals with disabilities, or others who need special accommodations, should indicate their needs along with their request.

John Pallasch,

Assistant Secretary for Employment and Training Administration.

[FR Doc. 2020–24399 Filed 11–3–20; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of four petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petitions must be received by MSHA's Office of Standards, Regulations, and Variances on or before December 4, 2020.

ADDRESSES: You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Roslyn B. Fontaine, Deputy Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9557 (voice), *Noe.Song-Ae.A@dol.gov* (email), or 202–693–9441 (facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2020–017–C.

Petitioner: LCT Energy, LP, 938 Mt. Airy Drive, Suite 200, Johnstown, PA 15904.

Mine: Rustic Ridge No. 1 Mine, MSHA I.D. No. 36–10089, located in Westmoreland County, Pennsylvania.

Regulation Affected: 30 CFR 75.503 (Permissible electric face equipment; maintenance) and 18.35(a)(5)(i) (Portable (trailing) cables and cords).

Modification Request: The petitioner's alternative approach to 30 CFR 75.503 will allow for No. 2 AWG, 900-foot extended trailing cables on roof bolters. The petitioner requests a modification of the existing standard to permit an alternative method that will provide no less a degree of safety than that provided by the standard.

The petitioner states that:

(a) The petitioner is submitting a petition to use No. 2 AWG, 900-foot extended trailing cables for roof bolters to allow for access to the end of 600-foot room panels without having to move power.

(b) 30 CFR 75.333 allows temporary ventilation controls in mining rooms that are 600 feet in length. The petitioner is applying to use extended trailing cables to mine to the end of the 600-foot room, set for 2–3 shifts, without needing to move power. Coal seams at this mine average 42 inches to 48 inches, not having to move the power source limits the handling of cables. This will be safer and reduce physical injuries to miners such as muscle strain, shoulder, and back injuries. Additionally, this will limit the exposure of miners to electrical hazards.

(c) The petition applies to trailing cables, supplying 480 AC volt, three phase, alternating the roof bolting machine; the extended length trailing cable will be No. 2 AWG, three conductor round cable and are not to exceed 900 feet in length, with a 90 degree C insulation of either Type G–GC, Type G, Type G+GC.

(d) The components for short circuit protection will have interruption ratings that are in accordance with the maximum calculated fault currents available. Circuit breakers (including both in service and replacement) protecting No. 2 AWG extended trailing cables will have instantaneous trip units calibrated to trip at 649 amps. The breaker provider, Global Mine Service, has verified breaker settings, which are sealed and the settings cannot be altered. Permanent legible labels will be attached to the circuit breaker, identifying it as able to protect the trailing cables and maintained in such condition. The labels will let miners know that they should not change or alter sealed short circuit settings.

(e) The lowered trip setting for circuit breakers, 649 amps for 900 feet of #2 AWG cables, requested in this petitioner will be safer than the cable allowed in Table 8 and 9 of Part 18, which is for 800 amps for 700 feet of #2 AWG cable.

(f) Daily inspections, labeling of circuit breakers, training before and after implementation, will allow for safety equal to 30 CFR 75.503, as required.

The petitioner proposes the following:

(a) The trailing cables will be visually examined each production day by a person designated by the petitioner, to ensure that they are in safe operating

condition. If they are not in safe operating condition, they will not be used until properly repaired or removed. The instantaneous settings for the specially calibrated breakers will be checked to make sure that seals are not removed, tampered with, or do not exceed stipulated settings.

(b) Miner safety will be increased because of examinations of the breakers and trailing cables, ensuring that they are in safe condition. If any trailing cable is not in safe condition, it will not be used until repaired or removed from service. Instantaneous settings for specially calibrated breakers will be examined to ensure make sure that seals have not been removed, tampered with, or are beyond stipulated settings.

(c) Splices and repairs to the trailing cables for roof bolting machines will be conducted properly and according to instructions of the manufacturer of splicing and repair materials, which will comply with 30 CFR 75.603 and 75.604.

(d) Haulage roads and trailing cable storage areas will be situated, as an additional precaution, to lessen contact between the trailing cable with scoops, shuttle cars, and roof bolting machines (as in 30 CFR 75.606). Trailing cable anchors on cable reel equipment will be permanent, minimizing tensile forces on the trailing cables.

(e) Only enough cable will be on the cable reel to operate the current production shift in order to limit heat, and excess cable will be kept behind the anchor(s) on equipment that uses cable reels, preventing cable overheating.

(f) The petitioner's alternative method will not be conducted until all miners designated to examine the seals, verify short-circuit settings, and examine trailing cables for defects have received training.

(g) Listed equipment in this petition (No. 2 AWG, 900-foot extended trailing cables, short circuit interrupting devices, and circuit breakers) will comply with the Federal Mine Safety and Health Act of 1977 and 30 CFR part 75.

(h) The petitioner plans to submit to the District Manager revisions to 30 CFR part 48 training plan approved for this mine. Revisions will note specific training tasks for miners examining trailing cables and safe operating conditions. Training will include:

(1) hazards associated with setting the circuit interrupting devices too high to protect trailing cables;

(2) verifying that circuit interrupting devices are properly set and maintained, to protect trailing cables;

(3) mining and operating procedures to ensure that trailing cables are not damaged;

(4) protecting trailing cables against damage by overheating, excessive cable storing on cable reels, and adjusting cable stored behind cable anchors when tramming distances change; and

(5) procedures to visually examine trailing cables so that they are in safe operating condition (examinations include inspecting the cable, observing insulation, integrity of splices, nicks, and abrasions).

(i) Equipment in this petition will comply with the Federal Mine and Health Act of 1877 and 30 CFR 75, where applicable.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the standard.

Docket Number: M–2020–029–C.

Petitioner: Canyon Fuel Company, LLC, 597 South SR 24, Salina, UT 84654.

Mine: Sufco Mine, MSHA I.D. No. 42–00089, located in Sevier County, Utah.

Regulation Affected: 30 CFR 75.500 (Permissible electric equipment).

Modification Request: The petitioner is applying to use various non-MSHA approved Powered Air Purifying Respirators (PAPRs) equipment in lieu of the current standard, in or inby the last open crosscut.

The petitioner states that:

(a) The modification to the current standard is requested to allow for an alternative method of respiratory protection for longwall miners.

(b) The current 3M Airstream PAPR, the Mining Headgear-Mounted model, is approved by MSHA but is being discontinued by the manufacturer, 3M. The 3M Airstream model allows for constantly filtered air to flow, reducing exposure to respirable dust. There are no other MSHA-approved PAPRs.

(c) The petitioner is applying to allow for non-MSHA approved PAPRs to protect miners from exposure to respirable dust during regular mining operations in or inby the last open crosscut.

(d) This petition will allow longwall miners to use PAPRs in MMU 001–0 and MMU 007–0, giving miners the opportunity to reduce dust exposure, decreasing health risks.

As an alternative to the existing standard, the petitioner proposes the following:

(c) The petitioner proposes using the following intrinsically safe models:

(1) CleanSpace EX—full or half mask;

(2) CleaSpace2—Full or half mask, this is NIOSH approved and intrinsically safe;

(3) 3M Versaflo TR–800—certified under ANSI/UL 60079–11 standard for hazardous locations, it is intrinsically safe; and

(4) Non-battery powered 3M Ultimate FX full facepiece respirator mask.

(b) CleanSpace respirators use an air filtering, fan assisted pressure mask, which can be used in high dust environments. They are light and compact, require no servicing, are intrinsically safe, and have few parts. The 3M Versaflo TR–800 allows for increased movement in tight spaces, while protecting against airborne contaminates. It is easy to use, has interchangeable components for specific application, is intrinsically safe, has audible and visual alarms, multi-speed blower, long battery run times, charges quickly and is ANSI/UL 60079–11 certified, allowing it to be used in hazardous locations. The 3M Ultimate FX respirator utilizes a scotchguard protection lens, allowing liquids to bead up and be removed easily, a large lens provides visibility, it is comfortable and easy to use, the 3M cool flow valve allows for easier breathing, and particle filters help filter out various particulates.

(c) When not in operation, batteries for the PAPR models will be charged outby the last open crosscut.

(d) The following battery charger products will be used: 3M battery charger TR–641N or 3M 4-station battery charger TR–644–N.

(e) The 3M Versaflo TR–800 PAPR will exclusively use the 3M TR–830 battery pack.

(f) Miners will be trained on how to safely use and take care of PAPR units, per manufacturer instructions.

(g) The above instruments will be assessed for physical damage as well as the integrity of the case.

(h) If methane levels go above 1.0 percent, 30 CFR 57.22234 procedures will be followed.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the standard.

Docket Number: M–2020–030–C.

Petitioner: Canyon Fuel Company, LLC, 597 South SR 24, Salina, UT 84654.

Mine: Sufco Mine, MSHA I.D. No. 42–00089, located in Sevier County, Utah.

Regulation Affected: 30 CFR 75.507–1 (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner is applying to use various non-MSHA approved Powered Air Purifying Respirators (PAPRs) equipment in lieu of the current standard, in return air and outby the last open crosscut.

The petitioner states that:

(a) The modification to the current standard is requested to allow for an alternative method of respiratory protection for longwall miners.

(b) The current 3M Airstream PAPR, the Mining Headgear-Mounted model, is approved by MSHA but is being discontinued by the manufacturer, 3M. The 3M Airstream model allows for constantly filtered air to flow, reducing exposure to respirable dust. There are no other MSHA-approved PAPRs.

(c) The petitioner is applying to allow for non-MSHA approved PAPRs to protect miners from exposure to respirable dust during regular mining operations in return air and outby the last open crosscut.

(d) This petition will allow longwall miners to use PAPRs in MMU 001–0 and MMU 007–0, giving miners the opportunity to reduce dust exposure, decreasing health risks.

As an alternative to the existing standard, the petitioner proposes the following:

(d) The petitioner proposes using the following intrinsically safe models:

(5) CleanSpace EX—full or half mask;

(6) CleaSpace2—Full or half mask, this is NIOSH approved and intrinsically safe;

(7) 3M Versaflo TR–800—certified under ANSI/UL 60079–11 standard for hazardous locations, it is intrinsically safe; and

(8) Non-battery powered 3M Ultimate FX full facepiece respirator mask.

(b) CleanSpace respirators use an air filtering, fan assisted pressure mask, which can be used in high dust environments. They are light and compact, require no services, are intrinsically safe, and have few parts. The 3M Versaflo TR–800 allows for increased movement in tight spaces, while protecting against airborne contaminates. It is easy to use, has interchangeable components for specific application, is intrinsically safe, has audible and visual alarms, multi-speed blower, long battery run times, charges quickly and is ANSI/UL 60079–11 certified, allowing it to be used in hazardous locations. The 3M Ultimate FX respirator utilizes a scotchguard protection lens, allowing liquids to bead up and be removed easily, a large lens provides visibility, it is comfortable and easy to use, the 3M cool flow valve allows for easier breathing, and particle filters help filter out various particulates.

(c) When not in operation, batteries for the PAPR models will be charged outby the last open crosscut.

(d) The following battery charger products will be used: 3M battery charger TR–641N or 3M 4-station battery charger TR–644–N.

(e) The 3M Versaflo TR–800 PAPR will exclusively use the 3M TR–830 battery pack.

(f) Miners will be trained on how to safely use and take care of PAPR units, per manufacturer instructions.

(g) The above instruments will be assessed for physical damage as well as the integrity of the case.

(h) If methane levels go above 1.0 percent, 30 CFR 57.22234 procedures will be followed.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the standard.

Docket Number: M–2020–031–C.

Petitioner: Kimmel's Mining, Inc., 1744 E Grand Ave, Tower City, PA 17980.

Mine: Williamstown Mine No. 1, MSHA I.D. No. 36–09435, located in Dauphin County, PA.

Regulation Affected: 30 CFR 75.1506(c)(1) (Refuge alternatives).

Modification Request: The petitioner, which operates an anthracite mine, is requesting an alternative method to 30 CFR 75.1506(c)(1), based on the specific factors of the petitioner's mining operations. The alternative would provide no less than the same measure of protection afforded by the existing standard.

The petitioner states that:

(a) Due to the anthracite mining operations at Williamstown Mine No. 1, the petitioner is requesting an alternative to 30 CFR 75.1506(c)(1). The modification application is to allow miners to work and travel over 2,000 feet from the working face to the hoist mantrip.

As an alternative to the existing standard, the petitioner states the following:

(a) By foot, miners are less than 30 minutes from the working face and less than 10 minutes from the bottom of the slope.

(b) The mine does not have any seals.

(c) There is no history of detectable methane gas or oxygen deficient atmospheres at this mine.

(d) Anthracite coal mining is low in volatility, meaning rock dust is not applied in any anthracite underground mine.

(e) 30 pound fire extinguishers are kept at the working section, at all times.

(f) Wooden posts are used as the primary roof support, which are spaced on five foot centers. The coal seam mined has a thickness that is on average 36 to 42 inches. This makes it difficult to move a refuge structure. Moving such a prefabricated structure would cause damage to the structure, due to the type of roof support at this mine.

(g) The mine does not pump water and is located above the mine pool.

(h) There are over two escapeway portals to the surface at this mine.

(i) A drag run by a motor is the only mechanical equipment at the mine.

(j) The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the standard.

Roslyn Fontaine,

Deputy Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2020–24397 Filed 11–3–20; 8:45 am]

BILLING CODE 4520–43–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2021–003]

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: We have submitted the following generic information collection request (generic ICR) to the Office of Management and Budget (OMB) for approval to continue to collect feedback on our service delivery: ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.'' As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, we developed this generic ICR to cover all of our requests for feedback on our services. We invite your comments on this ICR.

DATES: Comments must be submitted December 4, 2020.

ADDRESSES: Send comments and recommendations on the proposed information collection in writing 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: Tamee Fechhelm, Paperwork Reduction Act Officer, by email at *tamee.fechhelm@nara.gov* or by telephone at 301.837.1694 with requests for additional information.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite the public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collections are necessary for NARA to properly perform its functions; (b) our estimates of the burden of the proposed information collections and their accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether these collections affect small businesses.

We will summarize any comments you submit and include the summary in our request for OMB approval. All comments will become a matter of public record. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information.

In this notice, we solicit comments concerning the following information collection. We published this information collection in the **Federal Register** on July 20, 2020 (85 FR 43880), for an initial 60-day public comment period. We received no comments in response.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB number: 3095–0070.

Abstract: This information collection provides a means to gather qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. By qualitative feedback, we mean information that provides useful insights into customers' or stakeholders' perceptions and opinions, but not statistical surveys that yield quantitative results that can be generalized to the population of study. Qualitative feedback provides insights into perceptions, experiences, and expectations, provides an early warning of issues with service, or focuses attention on areas where communication, training, or changes in operations might improve delivery of products or services. Collecting this information allows for ongoing, collaborative, and actionable communications between NARA and its customers and stakeholders. It also allows us to contribute feedback directly to improving program management.

We collect feedback in areas of service delivery such as timeliness, appropriateness, accuracy of information, plain language, courtesy, efficiency, and resolution of issues with service delivery. We use customer feedback to plan 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 NARA's services will be unavailable.

We will submit a collection for approval under this generic clearance only if it meets the following conditions:

- The collection is voluntary;
- The collection is low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and is low-cost for both the respondents and the Federal Government;
- The collection is non-controversial and does not raise issues of concern to other Federal agencies;
- It is targeted to solicit opinions from respondents who have experience with the program or may have experience with the program in the near future;
- It collects personally identifiable information (PII) only to the extent necessary and we will not retain it;
- We will use the information gathered only internally, for general service improvement and program management purposes, and do not intend to release it outside of the agency;
- We will not use the information gathered for substantially informing influential policy decisions; and
- 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 provides useful information, but it does 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 non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to 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, but do not fall under the current generic collection.

As a general matter, information collections under this generic collection request 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.

Current actions: We currently have 13 surveys or other activites that have been approved by OMB under this generic ICR, are ongoing, and will continue through the renewal period. Some of these surveys include the OGIS FOIA Program Compliance Review, NPRC Survey of Customer Satisfaction, and Training and Event Evaluations.

Type of review: Regular.

Affected public: Anyone who uses NARA's services, programs, or facilities, including requesting personnel records, requesting historical, genealogical, or other archival records, using research rooms, requesting research or asking research questions, ordering and receiving reproductions, using FOIA dispute resolution services, using records management services, working with records management schedules, renting facilities, attending exhibitions, events, or open houses, using learning centers or educational materials, attending training, etc. This can include individuals and households, businesses and organizations, or state, local, or tribal governments.

Estimated numbers: Below, we provide estimates on surveys or other activities under this information collection for the next three years:

Estimated annual number of surveys or other activities: 20.

Estimated total annual number of respondents: 225,000 (to the projected 20 surveys or other activities).

Average number of respondents per survey or other activity: 1,250.

Annual responses per respondent: 1.

Frequency of response: Once per request.

Average minutes per response: 10.

Burden hours: 37,500.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2020–24379 Filed 11–3–20; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–20–0023; NARA–2021–005]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: NARA must receive comments by December 21, 2020.

ADDRESSES: You may submit comments by either of the following methods. You must cite the control number, which appears on the records schedule in parentheses after the name of the agency that submitted the schedule.

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Mail:* Records Appraisal and Agency Assistance (ACR); National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, by email at *regulation_comments@nara.gov.* For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov,* by mail at the address above, or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule. We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Defense, Defense Counterintelligence and Security Agency, Adjudication Records (DAA–0446–2020–0001).

2. Department of Defense, Defense Counterintelligence and Security Agency, Customer Relationship Management and Personnel Vetting Records (DAA–0446–2020–0003).

3. Department of Energy, Agency-wide, Budgeting Records (DAA–0434–2020–0008).

4. Department of Energy, Western Area Power Administration, Asset Planning and Management Program Records (DAA–0201–2020–0009).

5. Department of Homeland Security, Agency-wide, Legal Records (DAA–0563–2019–0010).

6. Department of Justice, Drug Enforcement Administration, Inspection Records (DAA–0170–2017–0007).

7. Department of Labor, Mine Safety and Health Administration, Technical

Support Center Records (DAA–0433–2015–0002).

8. Department of Labor, Mine Safety and Health Administration, Records of Office of Standards, Regulations and Variances (DAA–0433–2020–0004).

9. Department of the Navy, Agency-wide, Logistics (DAA–NU–2019–0014).

10. Department of State, Office of the Executive Secretariat, Consolidated Schedule (DAA–0059–2020–0020).

11. Department of Transportation, Federal Aviation Administration, Traffic Resolution Advisory Monitoring System (DAA–0237–2020–0009).

12. Department of Transportation, Federal Aviation Administration, Quality Performance Management System (DAA–0237–2020–0010).

13. Department of Transportation, Federal Aviation Administration, Designee Case Files (DAA–0237–2020–0013).

14. Department of Transportation, Federal Aviation Administration, Automatic Dependent Surveillance and Broadcast Compliance Records (DAA–0237–2020–0026).

15. Department of Transportation, Federal Highway Administration, FHWA Oversight Construction Project Files (DAA–0406–2020–0004).

16. Securities and Exchange Commission, Office of Human Resources, Records of Senior Officials and Designees (DAA–0266–2020–0001).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2020–24381 Filed 11–3–20; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 20 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference or videoconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate.

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Sherry P. Hale, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *hales@arts.gov,* or call 202/682–5696.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of September 10, 2019, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

The upcoming meetings are:

Our Town (review of applications): This meeting will be closed.

Date and time: December 1, 2020; 11:00 a.m. to 1:30 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 1, 2020; 2:30 p.m. to 5:00 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 2, 2020; 11:00 a.m. to 1:30 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 2, 2020; 2:30 p.m. to 5:00 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 3, 2020; 11:30 a.m. to 1:30 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 3, 2020; 2:30 p.m. to 4:30 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 3, 2020; 11:00 a.m. to 1:30 p.m.

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: December 7, 2020; 1:00 p.m. to 3:00 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 8, 2020; 1:30 p.m. to 3:30 p.m.

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: December 8, 2020; 1:00 p.m. to 3:00 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 8, 2020; 11:30 a.m. to 1:30 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 8, 2020; 2:30 p.m. to 4:30 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 9, 2020; 11:30 a.m. to 1:30 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 9, 2020; 2:30 p.m. to 4:30 p.m.

Locals (review of applications): This meeting will be closed.

Date and time: December 10, 2020; 1:00 p.m. to 3:00 p.m.

Locals (review of applications): This meeting will be closed.

Date and time: December 10, 2020; 3:30 p.m. to 5:30 p.m.

Media (review of applications): This meeting will be closed.

Date and time: December 10, 2020; 2:30 p.m. to 4:30 p.m.

Museums (review of application): This meeting is closed.

Date and time: December 10, 2020; 11:30 a.m. to 1:30 p.m.

Media (review of applications): This meeting will be closed.

Date and time: December 15, 2020; 11:30 a.m. to 1:30 p.m.

Media (review of applications): This meeting will be closed.

Date and time: December 15, 2020; 2:30 p.m. to 4:30 p.m.

Dated: October 30, 2020.

Sherry P. Hale,

Staff Assistant, National Endowment for the Arts.

[FR Doc. 2020–24419 Filed 11–3–20; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–10; NRC–2020–0215]

Northern States Power Company; Prairie Island Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) reviewed an application by Northern States Power Company (NSPM) for amendment of Special Nuclear Materials License No. SNM–2506 which authorizes NSPM to receive, possess, store, and transfer spent nuclear fuel and associated radioactive materials. The amendment

sought to increase the maximum amount of spent fuel that may be possessed and stored at the Prairie Island Independent Spent Fuel Storage Installation (PI ISFSI) and approval of the construction of an additional concrete pad within the confines of the existing facility.

DATES: November 4, 2020.

ADDRESSES: Please refer to Docket No. NRC–2020–0215 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0215. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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.*
- *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: William Allen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6877; email: *William.Allen@nrc.gov.*

SUPPLEMENTARY INFORMATION: By application dated July 26, 2019 (ADAMS Accession No. ML19210D273), as supplemented April 29, 2020 and June 10, 2020 (ADAMS Accession Nos. ML20120A625 and ML20162A445 respectively), NSPM submitted to the NRC, in accordance with part 72 of title 10 of the *Code of Federal Regulations* (CFR), a request to amend Special Nuclear Materials License No. SNM–2506 for its PI ISFSI site located in Welch, Minnesota. License No. SNM–2506 authorizes NSPM to receive, possess, store, and transfer spent nuclear fuel and associated radioactive materials resulting from the operation of the PI Power Plant in an ISFSI at the power plant site for a term of 20 years. Specifically, the amendment proposed to increase the storage capacity of the PI ISFSI and to approve the design of a new storage pad to be built at the existing facility.

The NRC issued a letter dated October 28, 2019 (ADAMS Accession No. ML19301D285), notifying NSPM that the application was acceptable for review. In accordance with 10 CFR 72.16, a notice of docketing was published in the **Federal Register** on December 16, 2019 (84 FR 68491). The notice of docketing included an opportunity to request a hearing and to petition for leave to intervene. No requests for a hearing or petitions for leave to intervene were submitted.

The NRC prepared a safety evaluation report (ADAMS Accession No. ML20237F368) to document its review and evaluation of the amendment request. Also, in connection with this action, the NRC prepared an environmental assessment (EA) and a finding of no significant impact (FONSI). The notice of availability of the EA and FONSI for the PI ISFSI was published in the **Federal Register** on October 8, 2020 (85 FR 63588).

Upon completing its review, the NRC staff determined that the request complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), as well as the NRC's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment. The NRC approved and issued Amendment No. 11 to Special Nuclear Materials License No. SNM–2506, held by NSPM for the receipt, possession, transfer, and storage of spent fuel and associated radioactive materials at the PI ISFSI. Pursuant to 10 CFR 72.46(d), the NRC is providing notice of the action taken. Amendment No. 11 was effective as of the date of issuance.

Dated October 30, 2020.

For the Nuclear Regulatory Commission.

John B. McKirgan,

Chief, Storage and Transportation Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2020–24448 Filed 11–3–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0218]

Information Collection: Notices, Instructions and Reports to Workers: Inspection and Investigations

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Notices, Instructions and Reports to Workers: Inspection and Investigations.''

DATES: Submit comments by January 4, 2021. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0218. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0218 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–2020–0218. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2020–0218 on this website.

• *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 supporting statement is available in ADAMS under Accession No. ML20203M169.

• *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.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0218 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions 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, and 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. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Part 19 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Notices, Instructions and Reports to Workers: Inspection and Investigations.''

2. *OMB approval number:* 3150–0044.

3. *Type of submission:* Revision.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* As necessary in order that adequate and timely reports of radiation exposure be made to individuals involved in applicable NRC-licensed activities.

6. *Who will be required or asked to respond:* Licensees authorized to receive, possess, use, or transfer material licensed by the NRC.

7. *The estimated number of annual responses:* 1,899,235.

8. *The estimated number of annual respondents:* 19,500.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 579,661.

10. *Abstract:* 10 CFR part 19 establishes requirements for notices, instructions, and reports by licensees and regulated entities to individuals participating in NRC-licensed and regulated activities and options available to these individuals in connection with Commission inspections of licensees and regulated entities, and to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, Titles II and IV of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder. The regulations in this part also establish the rights and responsibilities of the Commission and individuals during interviews compelled by subpoena as part of the agency's inspections or investigations under Section 161c of the Atomic Energy Act of 1954, as amended, on any matter within the Commission's jurisdiction.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: October 30, 2020.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2020–24400 Filed 11–3–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. EA–20–006, EA–20–007; NRC–2020–0244]

In the Matter of Tennessee Valley Authority, Chattanooga, TN

AGENCY: Nuclear Regulatory Commission.

ACTION: Order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an Order Imposing Civil Penalty in the amount of $606,942 to Tennessee Valley Authority (TVA). The NRC determined that four violations of NRC's employee protection regulation occurred as identified during two investigations completed on October 3, 2019, and January 21, 2020, by the NRC's Office of Investigations (OI) relating to activities at the TVA. In the first investigation, the NRC determined that a former employee was first subjected to an investigation and then placed on administrative leave on May 25, 2018, in part, for engaging in protected activity. In the second investigation, the NRC determined that a second former employee was subjected to an investigation, placed on paid administrative leave on October 15, 2018, and terminated on January 14, 2019, in part, for engaging in the protected activity. The order is effective on the date of issuance.

DATES: The Order was issued on October 29, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0244 when contacting the NRC about the availability of

information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0244. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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.* Order EA–20–006, EA–20–007, issued to TVA on October 29, 2020, is available in ADAMS under Accession No. ML20297A544.
- *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: Ian Gifford, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–287–9216, email: *Ian.Gifford@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated: October 29, 2020.

For the Nuclear Regulatory Commission.

George A. Wilson,

Director, Office of Enforcement.

United States of America Nuclear Regulatory Commission

In the Matter of TENNESSEE VALLEY AUTHORITY, CHATTANOOGA, TENNESSEE

Docket Numbers: 05000259, 05000260, 05000296, 05000327, 05000328, 05000390, 05000391

License Numbers: DPR–33, DPR–52, DPR–68, DPR–77, DPR–79, NPF–90, NPF–96

EA–20–006, EA–20–007

Order Imposing Civil Monetary Penalty

I

Tennessee Valley Authority (TVA) holds Browns Ferry Units 1, 2, and 3 License Nos. DPR–33, DPR–52, and DPR–68 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), on December 20, 1973, June 28, 1974, and July 2, 1976, respectively. The units are located on the Licensee's site in Athens, Alabama. TVA holds Sequoyah Units 1 and 2 License Nos. DPR–77 and DPR–79 issued by the NRC pursuant to 10 CFR part 50, on September 17, 1980, and September 15, 1981, respectively. The units are located on the Licensee's site in Soddy-Daisy, Tennessee. TVA holds Watts Bar Units 1 and 2 License Nos. NPF–90 and NPF–96 issued by the NRC pursuant to 10 CFR part 50, on February 7, 1996, and October 22, 2015, respectively. The units are located on the Licensee's site in Spring City, Tennessee. The licenses authorize the operation of these facilities in accordance with the conditions specified therein.

II

Two investigations were completed on October 3, 2019 (2–2018–033), and January 21, 2020 (2–2019–015), by the NRC Office of Investigations (OI). The results of these investigations indicated that the Licensee had not conducted its activities in full compliance with NRC requirements, specifically, 10 CFR 50.7, ''Employee Protection.''

A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated August 24, 2020. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee violated, and the amount of the civil penalty proposed for the violations.

The Licensee responded to the Notice in a letter dated September 23, 2020. In its response, the Licensee denied all four violations and stated that, if the NRC continues to believe that the violations occurred, then at a minimum the NRC should reduce the severity level of the alleged violations and commensurately reduce the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has, as set forth in the Appendix to this Order, determined that the violations occurred as stated and that the penalty proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *it is hereby ordered that:*

The Licensee pay a civil penalty in the amount of $606,942 within 30 days of the date of this Order, in accordance with NUREG/BR–0254. In addition, at the time payment is made, the Licensee shall submit a statement indicating when and by what method payment was made to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738.

V

In accordance with 10 CFR 2.202, ''Orders,'' TVA must, and any other person adversely affected by this Order may, submit an answer to this Order within 30 days of the date of the Order. In addition, TVA and any other person adversely affected by this Order may request a hearing on this Order within 30 days of the date of the Order. Where good cause is shown, consideration will be given to extending the time to answer or request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *https://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the

participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a hearing is requested by a licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained. In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 30 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. If payment has not been made by the time specified above, the matter may be referred to the Attorney General for collection.

For the Nuclear Regulatory Commission.

GEORGE A. WILSON,

Director, Office of Enforcement.

Dated this 29th day of October 2020.

[FR Doc. 2020–24392 Filed 11–3–20; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Information Collection Request Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: Comments should be addressed to Virginia Burke, FOIA/Privacy Act Officer. Virginia Burke can be contacted by email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke at Peace Corps address above; telephone at (202) 692–1887.

SUPPLEMENTARY INFORMATION:

Title: Report of Dental Examination.
OMB Control Number: 0420–0546.
Type of Request: Revision.
Affected Public: Individuals/Physicians.
Respondents Obligation to Reply: Voluntary.
Respondents: Potential and current volunteers.

BURDEN TO THE PUBLIC

a. Estimated number of respondents (applicants/dentists).	7,000/7,000.
b. Estimated average burden per response (applicants/dentists).	90 minutes/45 minutes.
c. Frequency of response (applicants/dentists).	One time.
d. Annual reporting burden (applicants/dentists).	10,500/5,250.

General Description of Collection: The Peace Corps Office of Medical Services is responsible for the collection of Applicant dental information, using the Report of Dental Exam ''Dental Exam'' form. The Dental Exam form is completed by the Applicant's examining dentist. The results of the examinations are used to ensure that Applicants for Volunteer service will, with reasonable accommodation, be able to serve in the Peace Corps without jeopardizing their health.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on October 29, 2020.

Virginia Burke,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2020–24446 Filed 11–3–20; 8:45 am]

BILLING CODE 6051–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: Comments should be addressed to Virginia Burke, FOIA/Privacy Act Officer. Virginia Burke can be contacted by email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke at Peace Corps address above; telephone at (202) 692–1887.

SUPPLEMENTARY INFORMATION:

Title: Durable Medical Equipment (DME) (PC–2161).
OMB Control Number: 0420–0559.
Type of Request: New information collection.
Affected Public: Individuals.
Respondents Obligation to Reply: Voluntary.
Respondents: Potential and current volunteers.

BURDEN TO THE PUBLIC

a. Estimated number of respondents (applicants/physicians).	77/77.
b. Estimated average burden per response (applicants/physicians).	15 minutes/10 minutes.
c. Frequency of response (applicants/physicians).	One time.
d. Annual reporting burden (applicants/physicians).	19 hours/13 hours.

General Description of Collection: Durable Medical Equipment (DME) is any equipment that provides therapeutic benefits to a patient in need because of certain medical conditions and/or illness. They consist of items that are primarily and customarily used to serve a medical purpose; are not useful to a person in the absence of illness or injury; are ordered or prescribed by a physician; are reusable; can stand repeated use, and are appropriate for use in the home. Other devices covered in this guidance include prosthetic equipment (cardiac pacemakers), hearing aids, orthotic items (artificial devices such as braces and splints), and prostheses (artificial body parts). The information collected will assist in the determination of Peace Corps eligibility. If eligible, it will assist with ongoing care during service. All applicants to the Peace Corps must have a medical clearance that will determine their ability to serve in a particular country.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on October 30, 2020.

Virginia Burke,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2020–24451 Filed 11–3–20; 8:45 am]

BILLING CODE 6051–01–P

PEACE CORPS

Information Collection Request Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: Comments should be addressed to Virginia Burke, FOIA/Privacy Act Officer. Virginia Burke can be contacted by email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke at Peace Corps address above; telephone at (202) 692–1887.

SUPPLEMENTARY INFORMATION:

Title: Peace Corps Report of Physical Examination (PC 1790S).
OMB Control Number: 0420–0549.
Type of Request: Revision.
Affected Public: Individuals/Physicians.
Respondents Obligation to Reply: Voluntary.

Respondents: Potential and current volunteers.

BURDEN TO THE PUBLIC

a. Estimated number of respondents (applicants/Physicians).	5,100/5,100.
b. Estimated average burden per response (applicants/Physicians).	90 min/45 min.
c. Frequency of response (applicants/Physicians).	One time.
d. Annual reporting burden (applicants/Physicians).	7,650 hours/3,825 hours.

General Description of Collection: The information in this form will be used by the Peace Corps Office of Medical Services to determine whether an Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems and, if so, to establish the level of medical and other support, if any, that may be required to reasonably accommodate the Applicant. The information in this form is also used as a baseline assessment for the Peace Corps Medical Officers overseas who are responsible for the Volunteer's medical care. Finally, the Peace Corps may use the information in this form as a point of reference in the event that, after completion of the Applicant's service as a Volunteer, he or she makes a worker's compensation claim under the Federal Employee Compensation Act (FECA).

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on October 29, 2020.

Virginia Burke,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2020–24447 Filed 11–3–20; 8:45 am]

BILLING CODE 6051–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: Comments should be addressed to Virginia Burke, FOIA/Privacy Act Officer. Virginia Burke can be contacted at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke at Peace Corps address above; telephone at (202) 692–1887.

SUPPLEMENTARY INFORMATION:

Title: Health History Form.

OMB Control Number: 0420–0510.

Type of Request: Revison.

Affected Public: Individuals.

Respondents Obligation to Reply: Voluntary.

Respondents: Potential and current volunteers.

BURDEN TO THE PUBLIC

a. Estimated number of respondents.	23,000.
b. Estimated average burden per response.	45 minutes.
c. Frequency of response	One Time.
d. Annual reporting burden ...	17,250 hours.

General Description of Collection: The information collected is required for consideration for Peace Corps Volunteer service. The information in the Health History Form, will be used by the Peace Corps Office of Medical Services to determine whether an Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems and, if so, to establish the level of medical and programmatic support, if any, that may be required to reasonably accommodate the Applicant.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on October 30, 2020.

Virginia Burke,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2020–24445 Filed 11–3–20; 8:45 am]

BILLING CODE 6051–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–23 and CP2021–24]

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:* November 6, 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

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.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2021–23 and CP2021–24; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 176 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 29, 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:* November 6, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–24421 Filed 11–3–20; 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).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 85 FR 69375, 2 November 2020.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, November 4, 2020 at 2:00 p.m.

CHANGES IN THE MEETING: The following item will not be considered during the Open Meeting on Wednesday, November 4, 2020:

2. The Commission will consider whether to issue an order granting exemptive relief from Sections 8 and 15(a)(1) of the Securities Exchange Act of 1934 and Rules 3b–13(b)(2), 8c–1, 10b–10, 15a–1 and 15c2–1 thereunder in connection with the revision of the definition of ''security'' to encompass security-based swaps; declining to extend exemptive relief from Rules 10b–16 and 15c2–5; and determining the expiration date for a temporary exemption from Section 29(b) of the Securities Exchange Act of 1934 in connection with registration of security-based swap dealers and major security-based swap participants.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: November 2, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–24613 Filed 11–2–20; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34080; 812–15144]

First Eagle Credit Opportunities Fund, et al.

October 30, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c), and 18(i) of the Act, under sections 6(c) and 23(c) of the Act for an exemption from rule 23c-3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d-1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares and to impose asset-based service and distribution fees, and early withdrawal charges (''EWCs'').

APPLICANTS: First Eagle Credit Opportunities Fund (the ''Initial Fund''), First Eagle Investment Management, LLC (the ''Adviser'') and FEF Distributors, LLC (the ''Distributor'').

FILING DATES: The application was filed on July 22, 2020.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request, by email. Hearing requests should be received by the Commission by 5:30 p.m. on November 30, 2020 and should be accompanied by proof of service on the applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: David O'Connor, First Eagle Investment Management, LLC, *David.OConnor@feim.com.*

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, at (202) 551–6773 or David J. Marcinkus, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Initial Fund is a newly organized Delaware statutory trust that is registered under the Act and will operate as a non-diversified, closed-end management investment company. The Initial Fund will operate as an ''interval

fund'' pursuant to rule 23c-3 under the Act and intends to continuously offer its shares.

2. The Adviser is a Delaware limited liability partnership registered as an investment adviser under the Investment Advisers Act of 1940. The Adviser will serve as investment adviser to the Initial Fund. The Adviser expects to enter into a sub-advisory agreement with First Eagle Alternative Credit, LLC (the ''Sub-Adviser''), pursuant to which the Sub-Adviser will serve as the sub-adviser to the Initial Fund. The Sub-Adviser is a Delaware limited liability company that is registered as an investment adviser under the Investment Advisers Act of 1940 and is an indirect wholly-owned subsidiary of the Adviser.

4. The Distributor is registered with the Commission as a broker-dealer under the Securities Exchange Act of 1934 (the ''Exchange Act''), and will act as the distributor of the Initial Fund.

5. Applicants seek an order to permit the Initial Fund to issue multiple classes of shares, each having its own fee and expense structure, and to impose asset-based distribution and service fees, and EWCs.

6. Applicants request that the order also apply to any continuously offered registered closed-end management investment company that has been previously organized or that may be organized in the future for which the Adviser or the Distributor or any entity controlling, controlled by, or under common control with the Adviser or the Distributor, or any successor in interest to any such entity,[1] acts as investment adviser or principal underwriter, respectively, and which operates as an interval fund pursuant to rule 23c-3 under the Act or provides periodic liquidity with respect to its shares pursuant to rule 13e-4 under the Exchange Act (each, a ''Future Fund'' and together with the Initial Fund, the ''Funds'').[2]

7. The Initial Fund will make a continuous public offering of its shares. Applicants state that additional offerings by any Fund relying on the order may be on a private placement or public offering basis. Shares of the Funds will not be listed on any securities exchange, nor quoted on any quotation medium. The Funds do not expect there to be a secondary trading market for their shares.

8. If the requested relief is granted, the Initial Fund may offer classes of shares in addition to its initial share class, with each class having its own fee and expense structure. The terms of any additional classes may differ from the initial class pursuant to and in compliance with rule 18f–3 under the Act.

10. Applicants state that shares of a Fund may be subject to a repurchase fee at a rate of no greater than 2% of the shareholder's repurchase proceeds if the interval between the date of purchase of the shares and the valuation date with respect to the repurchase of those shares is less than one year. Any repurchase fee will apply equally to all classes of shares of a Fund, consistent with section 18 of the Act and rule 18f–3 thereunder. Further, applicants represent that to the extent a Fund determines to waive, impose scheduled variations of, or eliminate any repurchase fee, it will do so consistently with the requirements of rule 22d–1 under the Act as if the repurchase fee were a CDSL (defined below) and as if the Fund were an open-end investment company and the Fund's waiver of, scheduled variation in, or elimination of, any such repurchase fee will apply uniformly to all shareholders of the Fund regardless of class.

11. Applicants state that the Initial Fund will adopt a fundamental policy to repurchase a specified percentage of its shares (no less than 5% and not more than 25%) at net asset value on a periodic basis. Such repurchase offers will be conducted pursuant to rule 23c–3 under the Act.[3] Each Future Fund will likewise adopt a fundamental investment policy in compliance with rule 23c–3 and make periodic repurchase offers to its shareholders, or provide periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Exchange Act. Any repurchase offers made by the Funds will be made to all holders of shares of each such Fund.

12. Applicants represent that any asset-based service and/or distribution fees for each class of shares will comply with the provisions of FINRA Rule 2341 (''Sales Charge Rule'').[4] Applicants also represent that each Fund will disclose in its prospectus the fees, expenses, and other characteristics of each class of shares offered for sale by the prospectus, as is required for open-end multiple class funds under Form N–1A. As is required for open-end funds, each Fund will disclose its expenses in shareholder reports, and describe any arrangements that result in breakpoints in or elimination of sales loads in its prospectus.[5] In addition, applicants will comply with applicable enhanced fee disclosure requirements for fund of funds, including registered funds of hedge funds.[6]

13. Each of the Funds will comply with any requirements that the Commission or FINRA may adopt regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements, as if those requirements applied to each Fund. In addition, each Fund will contractually require that any distributor of the Fund's shares comply with such requirements in connection with the distribution of such Fund's shares.

14. Applicants state that each Fund may impose an EWC on shares submitted for repurchase that have been held less than a specified period and may waive the EWC for certain categories of shareholders or transactions to be established from time to time. Applicants state that each of the Funds will apply the EWC (and any waivers or scheduled variations of the EWC) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act as if the Fund was an open-end investment company.

15. Each Fund operating as an interval fund pursuant to rule 23c–3 under the Act may offer its shareholders an exchange feature under which the shareholders of the Fund may, in connection with the Fund's periodic repurchase offers, exchange their shares of the Fund for shares of the same class

[1] A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] Any Fund relying on this relief in the future will do so in compliance with the terms and conditions of the application. Applicants represent that each entity presently intending to rely on the requested relief is listed as an applicant.

[3] Applicants submit that rule 23c–3 and Regulation M under the Exchange Act permit an interval fund to make repurchase offers to repurchase its shares while engaging in a continuous offering of its shares pursuant to rule 415 under the Securities Act of 1933.

[4] Any reference to the Sales Charge Rule includes any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority (''FINRA'').

[5] *See* Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release) (requiring open-end investment companies to disclose fund expenses in shareholder reports); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release) (requiring open-end investment companies to provide prospectus disclosure of certain sales load information).

[6] Fund of Funds Investments, Investment Company Act Rel. Nos. 26198 (Oct. 1, 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). See also Rules 12d1–1, *et seq.* of the Act.

of (i) registered open-end investment companies or (ii) other registered closed-end investment companies that comply with rule 23c–3 under the Act and continuously offer their shares at net asset value, that are in the Fund's group of investment companies (collectively, ''Other Funds''). Shares of a Fund operating pursuant to rule 23c–3 that are exchanged for shares of Other Funds will be included as part of the amount of the repurchase offer amount for such Fund as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–3 under the Act, as if the Fund were an open-end investment company subject to rule 11a–3. In complying with rule 11a–3, each Fund will treat an EWC as if it were a contingent deferred sales load (''CDSL'').

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(a)(2) of the Act makes it unlawful for a closed-end investment company to issue a senior security that is a stock unless certain requirements are met. Applicants state that the creation of multiple classes of shares of the Funds may violate section 18(a)(2) because the Funds may not meet such requirements with respect to a class of shares that may be a senior security.

2. Section 18(c) of the Act provides, in relevant part, that a registered closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of Shares of a Fund proposed herein may result in Shares of a class having ''priority over [another] class as to . . . payment of dividends,'' and being deemed a ''senior security,'' because shareholders of different classes may pay different distribution fees, different shareholder services fees, and any other expense. Accordingly, applicants state that the creation of multiple classes of Shares of a Fund with different fees and expenses may be prohibited by section 18(c).

3. Section 18(i) of the Act provides, in relevant part, that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of shares of the Funds may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(a)(2), 18(c) and 18(i) to permit the Funds to issue multiple classes of shares.

5. Applicants submit that the proposed allocation of expenses relating to distribution and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit a Fund to facilitate the distribution of its securities and provide investors with a broader choice of shareholder services. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Early Withdrawal Charges

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company shall purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c–3 under the Act permits an interval fund to make repurchase offers of between five and twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act permits an interval fund to deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under section 6(c), discussed above, and section 23(c)(3) from rule 23c–3 to the extent necessary for the Funds to impose EWCs on shares of the Funds submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the EWCs they intend to impose are functionally similar to CDSLs imposed by open-end investment companies under rule 6c–10 under the Act. Rule 6c–10 permits open-end investment companies to impose CDSLs, subject to certain conditions. Applicants note that rule 6c–10 is grounded in policy considerations supporting the employment of CDSLs where there are adequate safeguards for the investor and state that the same policy considerations support imposition of EWCs in the interval fund context. In addition, applicants state that EWCs may be necessary for the distributor to recover distribution costs. Applicants represent that any EWC imposed by the Funds will comply with rule 6c–10 under the Act as if the rule were applicable to closed-end investment companies. The Funds will disclose EWCs in accordance with the requirements of Form N–1A concerning CDSLs.

Asset-Based Service and Distribution Fees

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of (or principal underwriter for) a registered investment company, or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

2. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants

request an order under section 17(d) and rule 17d–1 under the Act to the extent necessary to permit the Funds to impose asset-based service and distribution fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its shares through asset-based service and distribution fees.

3. For the reasons stated above, applicants submit that the exemptions requested under section 6(c) are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) will be consistent with the protection of investors and will insure that applicants do not unfairly discriminate against any holders of the class of securities to be purchased. Finally, applicants state that the Funds' imposition of asset-based service and distribution fees is consistent with the provisions, policies, and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Each Fund relying on the order will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, 22d–1, and, where applicable, 11a–3 under the Act, as amended from time to time, as if those rules applied to closed-end management investment companies, and will comply with the Sales Charge Rule, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2020–24469 Filed 11–3–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34081]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

October 30, 2020.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of October 2020. A copy of each application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the SEC by 5:30 p.m. on November 24, 2020, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary at *Secretarys-Office@sec.gov*.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*.

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Assistant Director, at (202) 551–6413 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549–8010.

Angel Oak Financial Institutions Income Term Trust [File No. 811–23327]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Date: The application was filed on August 4, 2020, and amended on October 23, 2020.

Applicant's Address: stephen.cohen@dechert.com.

CC Real Estate Income Fund [File No. 811–23109]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On August 6, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $2,649 incurred in connection with the liquidation were paid by the applicant or applicant's investment adviser. Applicant also has retained $18,038 for the purpose of paying outstanding obligations.

Filing Date: The application was filed on August 18, 2020.

Applicant's Address: Clifford.cone@cliffordchance.com.

CC Real Estate Income Fund-ADV [File No. 811–23260]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On August 6, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $316 incurred in connection with the liquidation were paid by the applicant or applicant's investment adviser. Applicant also has retained $4,962 for the purpose of paying outstanding obligations.

Filing Date: The application was filed on August 18, 2020.

Applicant's Address: Clifford.cone@cliffordchance.com.

CC Real Estate Income Fund-T [File No. 811–23133]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On August 6, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $1,483 incurred in connection with the liquidation were paid by the applicant. Applicant also has retained $13,603 for the purpose of paying outstanding obligations.

Filing Date: The application was filed on August 18, 2020, and amended on October 23, 2020.

Applicant's Address: Clifford.cone@cliffordchance.com.

Cushing Energy Income Fund [File No. 811–22593]

Summary: Applicant, a closed-end investment company, seeks an order

declaring that it has ceased to be an investment company. The applicant has transferred its assets to Cushing MLP & Infrastructure Total Return Fund and, on May 29, 2020, made a final distribution to its shareholders based on net asset value. Expenses of $119,536 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on June 1, 2020.

Applicant's Address: Kevin.Hardy@skadden.com.

Goldman Sachs Private Markets Fund 2018 (A) LLC [File No. 811–23300]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on August 23, 2019, and amended on August 14, 2020.

Applicant's Address: william.bielefeld@dechert.com.

Goldman Sachs Private Markets Fund 2018 (B) LLC [File No. 811–23302]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on August 23, 2019, and amended on August 14, 2020.

Applicant's Address: william.bielefeld@dechert.com.

Goldman Sachs Private Markets Fund 2018 LLC [File No. 811–23301]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on August 23, 2019, and amended on August 14, 2020.

Applicant's Address: william.bielefeld@dechert.com.

Icon Funds [File No. 811–07883]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to SCM Trust, and on June 30, 2020, July 9, 2020, and September 24, 2020, made final distributions to its shareholders based on net asset value. Expenses of $246,000 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on September 29, 2020.

Applicant's Address: bcallahan@iconadvisers.com.

Independence Variable Annuity Separate Account [File No. 811–05232]

Summary: Applicant, a unit investment trust, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Date: The application was filed on July 13, 2020.

Applicant's Address: Susan.Lazzo@sunlife.com.

Jackson Variable Series Trust [File No. 811–22613]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Date: The application was filed on September 18, 2020.

Applicant's Address: emily.bennett@jackson.com.

JNL Variable Fund LLC [File No. 811–09121]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to JNL Series Trust, and on April 27, 2020 made a final distribution to its shareholders based on net asset value. Expenses of $13,655.50 incurred in connection with the reorganization were paid by the applicant's investment advisor.

Filing Date: The application was filed on September 18, 2020.

Applicant's Address: emily.bennett@jackson.com.

Legg Mason Permal Alternatives Fund Inc. [File No. 811–22537]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on September 20, 2019, and amended on October 9, 2020.

Applicant's Address: George.Hoyt@franklintempleton.com.

Pine Grove Alternative Institutional Fund [File No. 811–22860]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On August 1, 2019, and June 4, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $48,100 incurred in connection with the liquidation were paid by the applicant's investment adviser.

Filing Dates: The application was filed on July 14, 2020, and amended on October 19, 2020.

Applicant's Address: zac.tackett@apexfs.com.

Reliastar Life Ins Co of NY Variable Annuity Funds A B & C [File No. 811–02579]

Summary: Applicant, a unit investment trust, seeks an order declaring that it has ceased to be an investment company. No expenses were incurred in connection with the liquidation.

Filing Dates: The application was filed on October 21, 2019, and amended on September 21, 2020.

Applicant's Address: anngharaad.reid@voya.com.

Victory Institutional Funds [File No. 811–21584]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On April 26, 2019, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of $2,500 incurred in connection with the reorganization were paid by the applicant. Applicant has also retained $287 for the purpose of paying outstanding liabilities.

Filing Dates: The application was filed on October 9, 2019, and amended on August 28, 2020.

Applicant's Address: cdyer@vcm.com, and *ewagner@vcm.com*.

Western Asset Opportunistic Income Fund Inc. [File No. 811–22787]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on September 20, 2019, and amended on October 9, 2020.

Applicant's Address: George.Hoyt@franklintempleton.com.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2020–24481 Filed 11–3–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34079; File No. 812–15121]

New York Life Insurance and Annuity Corporation, et al; Notice of Application

October 30, 2020.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice.

Notice of application for an order approving the substitution of certain securities pursuant to Section 26(c) of the Investment Company Act of 1940, as amended (the ''1940 Act'').

APPLICANTS: New York Life Insurance and Annuity Corporation (''NYLIAC''), NYLIAC Variable Annuity Separate Account—I (''VA I''), NYLIAC Variable Annuity Separate Account—II (''VA II''), NYLIAC Variable Annuity Separate Account—III (''VA III''), NYLIAC Variable Annuity Separate Account—IV (''VA IV''), NYLIAC Variable Universal Life Separate Account—I (''VUL I''), NYLIAC Corporate Sponsored Variable Universal Life Separate Account—I (''Corporate VUL I''), NYLIAC Private Placement Variable Universal Life Separate Account—I (''Private VUL I''), and NYLIAC Private Placement Variable Universal Life Separate Account—II (''Private VUL II'') (each, a ''Separate Account'' and together, the ''Separate Accounts''). NYLIAC and the Separate Accounts are collectively the ''Applicants.''

SUMMARY OF APPLICATION: Applicants seek an order pursuant to Section 26(c) of the 1940 Act, approving the substitution of shares issued by certain investment certain investment portfolios (the ''Existing Portfolios'') for the shares of certain investment portfolios of registered investment companies (the ''Replacement Portfolios''), held by the Separate Accounts as investment options for certain variable life insurance policies and variable annuity contracts (such policies and contracts, the ''Contracts'') issued by NYLIAC (the ''Proposed Substitutions'').

FILING DATE: The application was filed on April 8, 2020 and was amended on July 24, 2020, October 23, 2020, October 26, 2020, and October 27, 2020.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on November 19, 2020 and should be accompanied by proof of service on the Applicants in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Erica E. Carrig, Esq., New York Life Insurance and Annuity Corporation, 51 Madison Avenue, New York, NY 10010 and Richard Choi, Esq., Carlton Fields, P.A., 1025 Thomas Jefferson St. NW, Suite 400 West, Washington, DC 20007.

FOR FURTHER INFORMATION CONTACT: Thankam A. Varghese, Senior Counsel at (202) 551–6446 or Parisa Haghshenas, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an Applicant using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

Applicants' Representations

1. NYLIAC is a Delaware stock life insurance company. NYLIAC is an indirect wholly-owned subsidiary of New York Life Insurance Company, a mutual life insurance company. NYLIAC serves as the depositor of the Separate Accounts, which are segregated asset accounts NYLIAC that fund the Contracts.

2. Each Separate Account, except for Private VUL I and Private VUL II, is registered under the 1940 Act as a unit investment trust.[1] Each Separate Account meets the definition of ''separate account'' contained in Section 2(a)(37) of the 1940 Act. Interests under the Contracts, except for Contracts issued through Private VUL I and Private VUL II, are registered under the Securities Act of 1933.[2] Each Account is divided into subaccounts, each of which invests exclusively in the securities of an underlying insurance-dedicated mutual fund (''Portfolio''). The application sets forth the registration statement file numbers for the Contracts and the Separate Accounts, with the exceptions of Private VUL I and Private VUL II.

3. The Contracts include the variable annuity contracts and the variable universal life policies. The Contracts may be issued as individual or group Contracts. Contract owners and participants in group Contracts (each a ''Contract Owner'' and collectively, the ''Contract Owners'') may allocate some or all of their Contract value to one or more Subaccounts that are available as investment options under the Contracts.

4. Each Contract permits its owner to transfer all or a portion of the Contract value from one Subaccount to another at any time, subject to certain policy limitations, as well as potential restrictions if NYLIAC determines that such transfers may disadvantage or potentially harm the rights and interests of other policy holders. No sales charges applies to any such transfer of Contract value among Subaccounts. None of the Contracts currently assess a transfer charge, and no transfer charges will apply in connection with the Proposed Substitutions.

5. Under the Contracts, NYLIAC reserves the right to substitute, for the shares of a Portfolio held in any Subaccount, the shares of another Portfolio. NYLIAC, on behalf of itself and its Separate Accounts, proposes to substitute shares of one Portfolio for that of another Portfolio by replacing the shares of four Existing Portfolios that are held in Subaccounts of their Separate Accounts with shares of the corresponding Replacement Portfolios as shown in the table below. NYLIAC states that the proposed Substitutions are part of an ongoing effort to make their Contracts more attractive to existing and prospective Contract Owners. Additional information for

[1] Private VUL I and Private VUL II are exempt from registration under the 1940 Act pursuant to Sections 3(c)(1) and 3(c)(7) thereof.

[2] Contracts issued through Private VUL I and Private VUL II are sold without registration under the 1933 Act in reliance on the private offering exemption of Section 4(2) of the 1933 Act and Regulation D thereunder.

each Existing Portfolio and the corresponding Replacement Portfolio, including investment objectives, principal investment strategies, principal risks, and performance, as well as the fees and expenses of each Existing Portfolio and its corresponding Replacement Portfolio, can be found in the application.

Substitution	Existing portfolio	Replacement portfolio
1	MainStay VP Indexed Bond Portfolio—Initial Class	Fidelity VIP Bond Index Portfolio—Initial Class.
	MainStay VP Indexed Bond Portfolio—Service Class	Fidelity VIP Bond Index Portfolio—Service Class 2.
2	Victory Variable Insurance Diversified Stock Fund—Class A Shares.	MainStay VP MacKay S&P 500 Index Portfolio—Initial Class.
	Victory Variable Insurance Diversified Stock Fund—Class A Shares.	MainStay VP MacKay S&P 500 Index Portfolio—Service Class.
3	LVIP SSgA International Index Fund—Standard Class	Fidelity VIP International Index Portfolio—Initial Class.
4	Invesco VI American Value Fund—Series I	MFS VIT III Mid Cap Value Portfolio—Initial Class.
	Invesco V.I. America Value Fund—Series II	MFS VIT III Mid Cap Value Portfolio—Service Class.

6. Applicants state that the Proposed Substitutions will be described in supplements to the applicable prospectuses for the Contracts filed with the Commission or in other supplemental disclosure documents (collectively, ''Supplements'') and delivered to all affected Contract Owners at least 30 days before the date the Proposed Substitution is effected (the ''Effective Date''). Each Supplement, among other things, will advise Contract Owners that for 30 days before the Effective Date, Contract Owners are permitted to transfer all of or a portion of their Contract value that out of any Subaccount investing in the Existing Portfolios to any other available Subaccounts offered under their Contracts without the transfer being counted as a transfer for purposes of transfer limitations and fees that would otherwise be applicable under the terms of the Contracts.

7. Applicants will send the Supplements and the summary prospectuses to all existing Contract Owners at least 30 days prior to the Effective Date. The Contract prospectus and Supplement, and the summary prospectuses for the Replacement Portfolios will be delivered to purchasers of new Contracts.

8. In addition to the Supplement distributed to Contract Owners, within five business days after the Effective Date, Contract Owners will be sent a written confirmation of the completed Proposed Substitutions in accordance with Rule 10b–10 under the Securities Exchange Act of 1934. The confirmation statement will include or be accompanied by a statement that reiterates the free transfer rights disclosed in the Supplement.

9. The Proposed Substitutions will take place at the Existing and Replacement Portfolios' relative per share net asset values determined on the Effective Date in accordance with Section 22 of the 1940 Act and Rule 22c–1 thereunder. The Proposed Substitutions will be effected by having each applicable Existing Portfolio Subaccount redeem its Existing Portfolio shares in cash on the Effective date at net asset value per share and purchase shares of the corresponding Replacement Portfolio at net asset value per share calculated on the same date. The Proposed Substitutions will be effective by redeeming shares of an Existing Portfolio for cash and using the cash to purchase shares of the Replacement Portfolio.

10. NYLIAC or an affiliate will pay all expenses and transaction costs of the Proposed Substitutions. No costs of the Substitutions will be borne directly or indirectly by Contract Owners. Affected Contract Owners will not incur any fees or charges as a result of the Proposed Substitutions, nor will their rights or the obligations of NYLIAC under the Contracts be altered in any way. The Proposed Substitutions will not cause the fees and charges under the Contracts currently being paid by Contract Owners to be greater after the Proposed Substitutions than before the Proposed Substitutions. The charges for optional living benefit riders may change from time to time and any such changes would be unrelated to the Proposed Substitutions. No fees will be charged on the transfer made on the Effective Date because the Proposed Substitutions will not be treated as a transfer for the purpose of assessing transfer charges or, if applicable, for determining the number of remaining permissible transfers in a Contract year.

11. In addition, with respect to Proposed Substitution 2, Applicants represent that New York Life Investment Management LLC (the ''Manager'') will enter into a written contract with the MainStay VP MacKay S&P 500 Index Portfolio whereby during the two years following the Effective Date the annual net operating expenses of the MainStay VP MacKay S&P 500 Index Portfolio will not exceed the annual net operating expenses of the Victory VI Diversified Stock Fund for the fiscal year ended December 31, 2019.

12. Applicants represent that with respect to Proposed Substitution 4, for a period of two (2) years commencing on the Effective Date and for those Contracts with assets allocated to the Invesco VI American Value Fund on the Effective Date, NYLIAC will, no later than the last business day of each fiscal quarter, make a corresponding reduction in Separate Account (or Subaccount) expenses to the extent that the annual net operating expenses of MFS VIT III Mid Cap Value Portfolio for such period exceeds, on an annualized basis, the total annual net operating expenses of the Invesco VI American Value Fund for fiscal year 2019. The Applicants further agree that separate account charges of any Subaccounts investing in the Proposed Substitution 2 and 4 Replacement Portfolios for any Contract Owner on the Effective Date will not be increased at any time during the two year period following the Effective Date.

Legal Analysis

1. Applicants request that the Commission issue an order pursuant to Section 26(c) of the 1940 Act approving the Substitutions. Section 26(c) of the 1940 Act prohibits any depositor or trustee of a unit investment trust that invests exclusively in the securities of a single issuer from substituting the securities of another issuer without the approval of the Commission. Section 26(c) provides that such approval shall be granted by order of the Commission, if the evidence establishes that the substitution is consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

2. Applicants submit that each of the Substitutions is constituent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act. In particular, Applicants point to the following:

(a) The Contracts permit the Proposed Substitutions, subject to Commission approval and compliance with applicable laws, upon appropriate notice;

(b) the prospectuses for the Contracts contain appropriate disclosure of these rights;

(c) the Proposed Substitutions will be described in the Supplements delivered to all affected Contract Owners 30 days before the Effective Date;

(d) the Supplements will advise Contract Owners that 30 days before the Effective Date through 30 days following the Substitution Date, Contract Owners are permitted to transfer all or a portion of their Contract value out of any Subaccount investing in the Existing Portfolios to any other available Subaccounts offered under their Contracts without the transfer being counted as a transfer for purposes of transfer limitations and fees that would otherwise be applicable under the terms of the Contracts;

(e) each Replacement Portfolio and its corresponding Existing Portfolio have similar or substantially similar investment objectives, principal investment strategies, and principal risks; [3] and

(f) the total net operating expenses of each Replacement Portfolio will be the same or lower than those of the corresponding Existing Portfolio for at least two years following the Substitution Date.

Applicants assert that, based on the terms noted above, and subject to the conditions set forth below, the Proposed Substitutions do not raise the concerns underlying section 26(c) of the 1940 Act.

3. Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. The Proposed Substitutions will not be effected unless NYLIAC determines that: (a) The Contracts allow the substitution of shares of registered open-end investment companies in the manner contemplated by the application; (b) the Proposed Substitutions can be consummated as described in the Application under applicable insurance laws; and (c) any regulatory requirements in each jurisdiction where the Contracts are qualified for sale have been complied with to the extent necessary to complete the Proposed Substitutions.

2. NYLIAC or its affiliates will pay all expenses and transaction costs of the Proposed Substitutions, including legal and accounting expenses, any applicable brokerage expenses and other fees and expenses. No fees or charges will be assessed to the Contract Owners to effect the Proposed Substitutions.

3. The Proposed Substitutions will be effected at the relative net asset values of the respective shares in conformity with section 22(c) of the 1940 Act and rule 22c–1 thereunder without the imposition of any transfer or similar charges by Applicants. The Proposed Substitutions will be effected without change in the amount or value of any Contracts held by affected Contract Owners.

4. The Proposed Substitutions will in no way alter the tax treatment of affected Contract Owners in connection with their Contracts, and no tax liability will arise for affected Contract Owners as a result of the Proposed Substitutions.

5. The rights or obligations of the Applicants under the Contracts of affected Contract Owners will not be altered in any way. The Proposed Substitutions will not adversely affect any riders under the Contracts since each Replacement Portfolio is an allowable Investment Option for use with such riders.

6. Affected Contract Owners will be permitted to make at least one transfer of Contract value from the Subaccount investing in the Existing Portfolio (before the Effective Date) or the Replacement Portfolio (after the Effective Date) to any other available investment option under the Contract without charge for a period beginning at least 30 days before the Effective Date through at least 30 days following the Effective Date. Except as described in any market timing/short-term trading provisions of the relevant prospectus, the NYLIAC will not exercise any right it may have under the Contract to impose restrictions on transfers between the subaccounts under the Contracts, including limitations on the future number of transfers, for a period beginning at least 30 days before the Effective Date through at least 30 days following the Effective Date.

7. All affected Contract Owners will be notified, at least 30 days before the Effective Date about: (a) The intended substitution of the Existing Portfolios with the Replacement Portfolios; (b) the intended Effective Date; and (c) information with respect to transfers as set forth in Condition 6 above. In addition, NYLIAC will also deliver, at least 30 days before the Effective Date, a prospectus for each applicable Replacement Portfolio.

8. NYLIAC will deliver to each affected Contract Owner within five (5) business days of the Effective Date a written confirmation which will include: (a) A confirmation that the Substitutions were carried out as previously notified; (b) a restatement of the information set forth in the Pre-Substitution Notice; and (c) before and after account values.

9. In addition, with respect to Proposed Substitution 2 the Manager will enter into a written contract with the MainStay VP MacKay S&P 500 Index Portfolio whereby during the two years following the Effective Date the annual net operating expenses of the MainStay VP MacKay S&P 500 Index Portfolio will not exceed the annual net operating expenses of the Victory VI Diversified Stock Fund for the fiscal year ended December 31, 2019. With respect to Proposed Substitution 4, for a period of two (2) years commencing on the Effective Date and for those Contracts with assets allocated to the Invesco VI American Value Fund on the Effective Date, NYLIAC will, no later than the last business day of each fiscal quarter, make a corresponding reduction in Separate Account (or Subaccount) expenses to the extent that the annual net operating expenses of MFS VIT III Mid Cap Value Portfolio for such period exceeds, on an annualized basis, the total annual net operating expenses of the Invesco VI American Value Fund for fiscal year 2019. The Applicants further agree that separate account charges of any Subaccounts investing in the Proposed Substitution 2 and 4 Replacement Portfolios for any Contract Owner on the Effective Date will not be increased at any time during the two year period following the Effective Date.

10. With respect to Proposed Substitutions 1, 3 and 4, the Applicants will not receive, for three years from the Effective Date, any direct or indirect benefits paid by the applicable Replacement Portfolios, their advisers or underwriters (or their affiliates), in connection with assets attributable to Contracts affected by the applicable Substitutions, at a higher rate than the Applicants have received from the corresponding Existing Portfolio, its advisers or underwriters (or their affiliates), including without limitation Rule 12b–1 fees, shareholder service, administration, or other service fees, revenue sharing, or other arrangements in connection with such assets. Proposed Substitutions 1, 3 and 4, and the selection of the applicable Replacement Portfolios was not motivated by any financial consideration paid or to be paid to NYLIAC or its affiliates by the

[3] Applicants cite to prior Commission orders under Section 26(c) for similar substitutions in support of their request.

applicable Replacement Portfolios, their advisers, underwriters or their affiliates.

For the Commission, by the Division of Investment Management, under delegated authority.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2020–24449 Filed 11–3–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90286; File No. SR–NYSEArca–2020–80]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the Alger Mid Cap 40 ETF and Alger 25 ETF Under Rule 8.900–E, Managed Portfolio Shares

October 29, 2020.

On September 1, 2020, NYSE Arca, Inc. (''NYSE Arca'') 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 of the Alger Mid Cap 40 ETF and Alger 25 ETF under Rule 8.900–E (Managed Portfolio Shares). The proposed rule change was published for comment in the **Federal Register** on September 21, 2020.[3] On October 7, 2020, NYSE Arca filed Amendment No. 1 to the proposed rule change.[4] The Commission has received no comments on the proposal.

Section 19(b)(2) of the Act [5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 5, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates December 20, 2020 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2020–80).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2020–24377 Filed 11–3–20; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89869 (September 15, 2020), 85 FR 59354.

[4] Amendment No. 1, which amended and replaced the proposed rule change in its entirety, is available on the Commission's website at: *https://www.sec.gov/comments/sr-nysearca-2020-80/srnysearca202080.htm.*

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2020–0056]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2020–0056].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than January 4, 2021. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Help America Vote Act—0960–0706. Public Law 107–252, the Help America Vote Act of 2002, mandates that States verify the identities of newly registered voters. When newly registered voters do not have driver's licenses or State-issued ID cards, they must supply the last four digits of their Social Security number to their local State election agencies for verification. The election agencies forward this information to their State Motor Vehicle Administration (MVA), and the State MVA inputs the data into the American Association of MVAs, a central consolidation system that routes the voter data to SSA's Help America Vote Verification (HAVV) system. Once SSA's HAVV system confirms the identity of the voter, the information returns along the same route in reverse until it reaches the State election agency. The respondents are the State MVAs seeking to confirm voter identities.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
HAVV	48	87,332	4,191,936	2	139,731	* $17.94	** $2,506,774

* We based this figure on average local government information and records clerk's salary shown on the Bureau of Labor Statistic's website (*https://www.bls.gov/oes/current/oes434199.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Incoming and Outgoing Intergovernmental Personnel Act Assignment Agreement—5 CFR part 334—0960–0792. The Intergovernmental Personnel Act (IPA) mobility program provides for the temporary assignment of civilian personnel between the Federal Government and State and local governments; colleges and universities; Indian tribal governments; federally funded research and development centers; and other eligible organizations. The Office of Personnel Management (OPM) created a generic form, the OF–69, for agencies to use as a template when collecting information for the IPA assignment. The OF–69 collects specific information about the agreement including: (1) The enrolled employee's name, Social Security number, job title, salary, classification, and address; (2) the type of assignment; (3) the reimbursement arrangement; and (4) an explanation as to how the assignment benefits both SSA and the non-federal organization involved in the exchange. OPM directs agencies to use their own forms for recording these agreements. So, SSA modified the OF–69 to meet our needs, creating the SSA–187 for incoming employees and the SSA–188 for outgoing employees. SSA collects information on the SSA–187 and SSA–188 to document the IPA assignment, and to act as an agreement between the agencies. Respondents are personnel from State and local governments; colleges and universities; Indian tribal governments; federally funded research and development centers; and other eligible organizations who participate in the IPA exchange with SSA.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Non-Federal employee	3	1	30	2	* $50.00	** $100
Non-Federal employer signers	12	1	5	1	* 50.00	** 50
Totals	15			3		** 150

* We based this figure on averaging the average of Postsecondary Education Administrators and Executive Branch Management Analysts hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes119033.htm* & *https://www.bls.gov/oes/current/oes131111.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than December 4, 2020. Individuals can obtain copies of these OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. Statement Regarding Contributions—20 CFR 404.360–404.366 and 404.736—0960–0020. SSA uses Form SSA–783 to collect information regarding a child's current sources of support when determining the child's entitlement to Social Security benefits. We request this information from adults acting on behalf of the child claimants who can provide SSA with any sources of support or substantial contributions for the child. These adults inform the claims representative as part of the initial benefits process. If the individual capable of providing the information does not accompany the child claimant, we mail the SSA–783 to the individual for completion, or if the person has access to a computer, we will refer them to SSA's website. The respondents are individuals providing information about a child's sources of support.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–783	2,352	1	15	588	* $25.72	** 24	*** $39,326

* We based this figure on the average hourly wage for all occupations in May 2019 as reported by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*).

** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Statement of Income and Resources—20 CFR 416.207, 416.301–416.310, 416.704, and 416.708—0960–0124. SSA collects information about income and resources for Supplemental Security Income (SSI) claims and redeterminations on the SSA–8010–BK. SSA uses the information to make initial or continuing eligibility determinations for SSI claimants or recipients who are subject to deeming. The respondents are people whose income and resources SSA may deem (consider to be available) to SSI applicants or recipients.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–8010–BK (Intranet)	1,855,340	1	20	618,447	* $10.73	** 24	*** $14,599,056
SSA–8010–BK (Paper)	61,380	1	20	20,460	* 10.73	** 24	*** 482,979
Totals	1,916,720	.....	.....	638,907	.....	.....	*** 15,082,035

* We based this figure on average DI payments based on SSA's current FY 2020 data (*https://www.ssa.gov/legislation/2020Fact%20Sheet.pdf*).

** We based this figure on the average FY 2020 wait times for field offices, based on our current management information data.

*** This figure does not represent actual costs that we are imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. Medical Permit Parking Application—41 CFR 102–71.20 & 102–74.305—0960–0624. SSA employees and contractors with a qualifying medical condition who park at SSA-owned and leased facilities may apply to receive a medical parking permit. SSA uses three forms for this program: (1) SSA–3192, the Application and Statement, which an individual completes when first applying for the medical parking space; (2) SSA–3193, the Physician's Report, which the applicant's physician completes to verify the medical condition; and (3) SSA–3194, Renewal Certification, which medical parking permit holders complete to verify their continued need for the permit. The respondents are SSA employees and contractors seeking medical parking permits, and their physicians.

Note: Because SSA employees are Federal workers exempt from the requirements of the Paperwork Reduction Act, the burden below is only for SSA contractors and physicians (of both SSA employees and contractors).

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–3192	390	1	30	195	* $44.07	** $8,594
SSA–3193	465	1	90	698	* 44.07	** 30,761
SSA–3194	82	1	5	7	* 44.07	** 308
Totals	937	.....	.....	900	.....	** 39,663

* We based this figure on averaging the average of Office Physicians and Executive Branch Management Analysts hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes291123.htm* & *https://www.bls.gov/oes/current/oes131111.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. Request for Evidence from Doctor and Request for Evidence from Hospital—20 CFR 404 Subpart P and 20 CFR 416 Subpart I—0960–0722. Sections 223(d)(5) and 1614(a)(3)(H)(i) of the Social Security Act require claimants to furnish medical evidence of their disability when filing a disability claim. SSA uses Forms HA–66 and HA–67 to request evidence from medical sources, which claimants identify as having information relative to their impairments, or ability to do work-related activities. In addition to accepting manual paper responses, SSA sends a barcode with the HA–66 and HA–67, allowing respondents to fax the information directly into the electronic claims folder rather than submitting it manually. SSA uses the information to determine eligibility for benefits, and to pay medical sources for furnishing the information. The respondents are medical sources, doctors, and hospitals that evaluate the claimants.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
HA–66—Paper Version	3,060	22	15	16,830	$40.21	** $676,734
HA–66—;Electronic Version (ERE or barcode)	8,940	22	15	49,170	40.21	* 1,977,126
HA–67—Paper Version	3,060	22	15	16,830	40.21	** 676,734
HA–67—Electronic Version (ERE or barcode)	8,940	22	15	49,170	40.21	** 1,977,126
Totals	24,000			132,000		** 5,307,720

* We based this figure on average Healthcare Practitioners and Technical Occupations hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes290000.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

5. Social Security's Public Credentialing and Authentication Process—20 CFR 401.45 and Part 402—0960–0789.

Background

Authentication is the foundation for secure, online transactions. Identity authentication is the process of determining, with confidence, that someone is who he or she claims to be during a remote, automated session. It comprises three distinct factors: Something you know; something you have; and something you are. Single-factor authentication uses one of the factors, and multi-factor authentication uses two or more of the factors.

SSA's Public Credentialing and Authentication Process

SSA offers consistent authentication across SSA's secured online services. We allow our users to request and maintain only one User ID, consisting of a self-selected username and password, to access multiple Social Security electronic services. Designed in accordance with the OMB Memorandum M–04–04 and the National Institute of Standards and Technology (NIST) Special Publication 800–63, this process provides the means of authenticating users of our secured electronic services and streamlines access to those services.

SSA's public credentialing and authentication process:

- Issues a single User ID to anyone who wants to do business with the agency and meets the eligibility criteria;
- Partners with an external Identity Services Provider (ISP) to help us verify the identity of our online customers;
- Complies with relevant standards;
- Offers access to some of SSA's heaviest, but more sensitive, workloads online while providing a high level of confidence in the identity of the person requesting access to these services;
- Offers an in-person process for those who are uncomfortable with or unable to use the internet process;
- Balances security with ease of use; and
- Provides a user-friendly way for the public to conduct extended business with us online instead of visiting local servicing offices or requesting information over the phone. Individuals have real-time access to their Social Security information in a safe and secure web environment.

Public Credentialing and Authentication Process Features

We collect and maintain the users' personally identifiable information (PII) in our Central Repository of Electronic Authentication Data Master File Privacy Act system of records, which we published in the **Federal Register** (75 FR 79065). The PII may include the users' name; address; date of birth; Social Security number (SSN); phone number; and other types of identity information [*e.g.,* address information of persons from the W–2 and Schedule Self Employed forms we receive electronically for our programmatic purposes as permitted by 26 U.S.C. 6103(l)(1)(A)]. We may also collect knowledge-based authentication data, which is information users establish with us or that we already maintain in our existing Privacy Act systems of records.

We retain the data necessary to administer and maintain our e-Authentication infrastructure. This includes management and profile information, such as blocked accounts; failed access data; effective date of passwords; and other data allowing us to evaluate the system's effectiveness. The data we maintain also may include archived transaction data and historical data.

We use the information from this collection to identity proof and authenticate our users online, and to allow them access to their personal information from our records. We also use this information to provide second factor authentication. We are committed to expanding and improving this process so we can grant access to additional online services in the future.

Offering online services is not only an important part of meeting SSA's goals, but is vital to good public service. In increasing numbers, the public expects to conduct complex business over the internet. Ensuring SSA's online services are both secure and user-friendly is our priority.

We awarded a competitively bid contract to an ISP, Equifax, to help us verify the identity of our online customers. We use this ISP, in addition to our other authentication methods, to help us prove, or verify, the identity of our customers when they are completing online or electronic transactions with us.

Social Security's Authentication Strategy

We remain committed to enhancing our online services using authentication processes that balance usability and security. We will continue to research and develop new authentication tools while monitoring the emerging threats.

The following are key components of our authentication strategy:

- Enrollment and Identity Verification—Individuals who meet the following eligibility requirements may enroll:
  - Must have a valid email address;
  - Must have a valid Social Security number (SSN);
  - Must have a domestic address of record (includes military addresses); and
  - Must be at least 18 years of age.

We collect identifying data and use SSA and ISP records to verify an individual's identity. Individuals have

the option of obtaining an enhanced, stronger, User ID by providing certain financial information (*e.g.,* Medicare wages, self-employed earnings, or the last eight digits of a credit card number) for verification. We also ask individuals to answer out-of-wallet questions so we can further verify their identities. Individuals who are unable to complete the process online can present identification at a field office to obtain a User ID.

- Establishing the User Profile—The individual self-selects a username and password, both of which can be of variable length and alphanumeric. We provide a password strength indicator to help the individual select a strong password. We also ask the individual to choose challenge questions for use in restoring a lost or forgotten username or password.
- Provide a Second Factor—We ask the individual to provide a text message enabled cell phone number or an email address. We consider the cell phone number or email address the second factor of authentication. We send a security code to the individual's selected second factor. We require the individual to confirm its receipt by entering the security code online. Subsequently, each time the individual attempts to sign in to his or her online account, we will also send a message with a one-time security code to the individual's selected second factor. The individual must enter the security code along with his or her username and password. The code is valid for only 10 minutes. If the individual does not enter the code within 10 minutes, the code expires, and the individual must request another code.
- Enhancing the User ID—If individuals opt to enhance or upgrade their User IDs, they must provide certain financial information for verification. We mail a one-time-use upgrade code to the individual's verified residential address. When the individual receives the upgrade code in the mail, he or she can enter this code online to enhance the security of the account. With extra security, we continue to require the individuals to sign in using their username, password, and a one-time security code we send to their second factor email address or cell phone number (whichever the users listed in their account).
- Sign in and Use—Our authentication process provides an individual with a User ID for access to our sensitive online Social Security services. Second factor authentication requires the individual to sign in with a username, password, and a one-time security code sent to the individual's selected second factor. SSA expanded its existing capabilities to require second factor authentication for every online sign in. We also allow for maintenance of the second factor options. An individual who forgets the password can reset it automatically without contacting SSA.

Social Security's Enrollment Process

The enrollment process is a one-time only activity. SSA requires the individuals to agree to the ''Terms of Service'' detailed on our website before we allow them to begin the enrollment process. The ''Terms of Service'' inform the individuals what we will and will not do with their personal information, and the privacy and security protections we provide on all data we collect. These terms also detail the consequences of misusing this service.

To verify the individual's identity, we ask the individual to give us minimal personal information, which may include:

- Name;
- SSN;
- Date of birth;
- Address—mailing and residential;
- Telephone number;
- Email address;
- Financial information;
- Cell phone number; and
- Selecting and answering password reset questions.

We send a subset of this information to the ISP, who then generates a series of out-of-wallet questions back to the individual. The individual must answer all or most of the questions correctly before continuing in the process. The exact questions generated are unique to each individual.

This collection of information, or a subset of it, is mandatory for respondents who want to do business with SSA via the internet. We collect this information via the internet on SSA's public-facing website. We also offer an in-person identification verification process for individuals who cannot, or are not willing, to register online. For this process, the individual must go to a local SSA field office and provide identifying information. We do not ask for financial information with the in-person process.

We only collect the identity verification information one time, when the individual registers for a credential. We ask for the User ID (username and password) every time an individual signs in to our automated services. If individuals opt for the enhanced or upgraded account, they also either receive an email message or a text message on their cell phones (this serves as the second factor for authentication) each time they sign in.

The respondents are individuals who choose to use the internet or Automated Telephone Response System to conduct business with SSA.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
Internet Registration	7,875,448	1	8	1,050,060	* $25.72		*** $27,007,543
Internet Sign-Ins	53,985,814	1	1	899,764	* 25.72		*** 23,141,930
Intranet Registration (RCS)	2,295,983	1	8	306,131	* 25.72	** 24	*** 31,494,757
Totals	64,157,245			2,255,955			*** 81,644,230

* We based this figures on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_stru.htm*).

** We based this figure on the average FY 2020 wait times for field offices, based on our current management information data.

*** This figure does not represent actual costs that we are imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: October 30, 2020.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2020–24479 Filed 11–3–20; 8:45 am]

BILLING CODE 4191–02–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 43 (Sub-No. 191X); Docket No. AB 33 (Sub-No. 337X)]

Illinois Central Railroad Company—Abandonment Exemption—in Jefferson County, Ill.; Union Pacific Railroad Company—Abandonment Exemption—in Jefferson County, Ill.

Illinois Central Railroad Company (IC) and Union Pacific Railroad Company (UP) (collectively, the Railroads) jointly filed a verified notice of exemption under 49 CFR part 1152, subpart F—*Exempt Abandonments* to abandon approximately 100 feet of jointly owned railroad line extending from milepost 10.53 to milepost 10.55 at the railroad bridge overpass (the Bridge) of State Route 148 (County Road 600E), south of the Village of Waltonville in Jefferson County, Ill. (the Line). The Line traverses U.S. Postal Service Zip Codes 62894 and 62833.[1]

The Railroads have certified that: (1) No local traffic has moved over the Line for at least two years; (2) any overhead traffic could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7 and 1105.8 (notice of environmental and historic report), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

Any employee of the Railroads adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[2] the exemptions will be effective on December 4, 2020, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues [3] must be filed by November 13, 2020. Formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2) and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by November 16, 2020.[4] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by November 24, 2020.

A copy of any petition filed with the Board should be sent to IC's representative, Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208; and UP's representative, Jeremy M. Berman, Union Pacific Railroad Company, 1400 Douglas Street, Stop 1580, Omaha, NE 68179.

If the verified notice contains false or misleading information, the exemptions are void ab initio.

The Railroads have filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by November 9, 2020. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or interim trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), the Railroads shall file a notice of consummation with the Board to signify that they have exercised the authority granted and fully abandoned the Line. If consummation has not been effected by the Railroads' filing of a notice of consummation by November 4, 2021, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Decided: October 29, 2020.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2020–24590 Filed 11–3–20; 8:45 am]

BILLING CODE 4915–01–P

[1] The Railroads state that, after abandonment, they plan to salvage the Line, and the Bridge will be removed to permit the Illinois Department of Transportation to undertake a road improvement project on State Route 148.

[2] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[3] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemptions' effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemptions' effective date.

[4] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0416]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Dealer's Aircraft Registration Application

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 April 23, 2020. The collection involves submission of an AC Form 8050–5, Dealer's Aircraft Registration Certificate Application, by companies or individuals to obtain a Dealer's Aircraft Registration Certificate, which allows operation of an aircraft instead of obtaining a permanent aircraft registration certificate. The information collection is necessary for a dealer to operate an aircraft without a permanent aircraft registration certificate and to comply with statutory and regulatory requirements.

DATES: Written comments should be submitted by December 4, 2020.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory

Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Bonnie Lefko by email at: *bonnie.lefko@faa.gov;* phone: 405–954–7461.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0024.

Title: Dealer's Aircraft Registration Certificate Application.

Form Numbers: AC Form 8050–5.

Type of Review: Renewal.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 23, 2020 (85 FR 22783). All aircraft must be registered before being flown. Obtaining a dealer's registration certificate allows the holder of that certificate to operate aircraft in lieu of obtaining a permanent aircraft registration certificate. Any individual or company engaged in manufacturing, distributing, or selling aircraft who wants to operate aircraft with a dealer's certificate may apply. Applicants complete the AC Form 8050–5, Dealer's Aircraft Registration Certificate Application. A dealer's certificate is valid for one year from the issuance date. A dealer must re-apply annually to maintain their certificate.

Respondents: Companies or individuals engaged in manufacturing, distributing, or selling aircraft.

Frequency: Annually to maintain a certificate.

Estimated Average Burden per Response: 45 minutes.

Estimated Total Annual Burden: During FY 2019, the FAA received 3,670 applications for dealer's certificates for a total annual burden of 2,753 hours.

Issued in Oklahoma City, OK, on October 30, 2020.

Bonnie Lefko,

Program Analyst, Civil Aviation Registry, Aircraft Registration Branch, AFB–711.

[FR Doc. 2020–24409 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Permanent Closure

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration received written notice from the Alaska Department of Transportation (AKDOT) advising that infrastructure associated with Juneau, Alaska Seaplane Base (5Z1) in Harris Harbor was permanently removed and that 5Z1 is permanently closed.

DATES: The permanent closure of the seaplane base is retroactively effective.

FOR FURTHER INFORMATION CONTACT: Molly Fierro, Compliance Manager, Federal Aviation Administration, Alaskan Region Airports District Office, 222 W 7th Avenue, Anchorage, AK 99513. Telephone Number: (907) 271–5439/FAX Number: (907) 271–2851.

SUPPLEMENTARY INFORMATION: Ownership of infrastructure associated with 5Z1 (Harris Harbor) was transferred to the City of Borough of Juneau (CBJ) in 2003. As the docks were no longer being utilized, the CBJ removed the infrastructure in September of 2020. The FAA hereby retroactively publishes the AKDOTs and CBJs notice of permanent closure of the Juneau Seaplane Base in Harris Harbor (5Z1) in accordance with 49 U.S.C 46319(b).

Issued in Anchorage, Alaska.

Kristi A. Warden,

Director, Airports Division, FAA, Alaskan Region.

[FR Doc. 2020–24372 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–1046]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Federal Aviation Regulation Part 119—Certification: Air Carriers and Commercial Operators

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. Organizations that desire to become or remain certified as air carriers or commercial operators are mandated to report information to the FAA. The information collected reflects requirements necessary under parts 135, 121, and 125 to comply with Federal Aviation Regulation part 119—Certification: Air Carriers and Commercial Operators. The FAA will use the information it collects and reviews to ensure compliance and adherence to regulations and, if necessary, to take enforcement action on violators of the regulations.

DATES: Written comments should be submitted by January 4, 2021.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field)

By mail: Sandra Ray, Federal Aviation Administration, Policy Integration Branch AFS–270, 1187 Thorn Run Road, Suite 200, Coraopolis, PA 15108

By fax: 412–239–3063.

FOR FURTHER INFORMATION CONTACT: Steve Hanes by email at: *steven.a.hanes@faa.gov;* phone: 517–260–9179.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency

will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0593.

Title: Federal Aviation Regulation part 119—Certification: Air Carriers and Commercial Operators.

Form Numbers: N/A.

Type of Review: Renewal of an information collection.

Background: The request for clearance reflects requirements necessary under parts 135, 121, and 125 to comply with part 119. The FAA will use the information it collects and reviews to ensure compliance and adherence to regulations and, if necessary, to take enforcement action on violators of the regulations.

Respondents: 1695 Air Carrier and Commercial Operators.

Frequency: Varies per requirement.

Estimated Average Burden per Response: 5,174.5 Hours.

Estimated Total Annual Burden: $155,016.73.

Issued in Washington, DC, on October 29, 2020.

Sandra L. Ray,

Aviation Safety Inspector, FAA, Policy Integration Branch, AFS–270.

[FR Doc. 2020–24371 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2020–0024]

Agency Information Collection Activities: Notice of Request for Extension of Currently Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for extension of currently approved information collection.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) for approval of a new (periodic) information collection. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on November 19, 2020. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by December 4, 2020.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 2020–0024 by any of the following methods:

For access to 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: Steven Frankel, (202) 366–9649 or Beatriz Hernandez (202) 366–3126, Office of the Chief Financial Officer, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Request Form for Fund Transfers to Other Agencies and Among Title 23 Programs.

OMB Control Number: 2125–0620.

Background: The Fixing America's Surface Transportation (FAST) Act, Public Law 114–94, continues the ability of States to transfer highway funds to other States and agencies and among programs/projects. These authorities are codified in sections 104 and 126 of title 23, United States Code, as amended by the FAST Act. Transferability under the FAST Act is generally similar to that allowed under previous authorization acts such as the Moving Ahead for Progress in the 21st Century Act (MAP–21) and the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU). This notice establishes requirements for initiating the transfer of apportioned funds (funds distributed among States and programs by statutory formula) to carry out these provisions of law. The types of transfers affected by this notice are:

a. Transfer of funds from a State to the FHWA pursuant to U.S.C. Title 23, § 104(f)(3);

b. Transfer of funds from a State to a Federal Agency other than FHWA;

c. Transfer of funds from a State to another State;

d. Transfer of funds from FHWA to Federal Transit Administration pursuant to U.S.C. Title 23, § 104(f)(1);

e. Transfer of funds between programs pursuant to U.S.C. Title 23, § 126; and,

f. Transfer of funds between projects.

The State initiating the fund transfer must fill out a FHWA Funds Transfer Request form. This transfer form (FHWA–1575C) submitted for approval is similar to the currently approved transfer forms (FHWA–1575 and FHWA–1576) that have been utilized for the past five years. The main improvement is that this transfer form combines what were previously two forms (one for transfers within State or to another State and one for transfers to other agencies) into a single form. The new FHWA–1575C transfer form includes drop-down boxes that will allow States to select the type of transfer and other information. This new form will streamline that transfer request process for States by allowing them to use the single form for all types of transfers of apportioned funds rather than having to select the appropriate form. Information required to fill out a transfer form will include the requester's contact information; a description of the program/project the transfer will come from and go to, the fiscal year, the program code, a demo ID or an urban area when applicable, and the amount to be transferred. The form must be approved by the applicable State Department of Transportation and concurred on by the correlating FHWA Division Office.

Respondents: 50 State Transportation Departments, the District of Columbia, and Puerto Rico.

Frequency: As Needed.

Estimated Average Burden per Response: 15 minutes.

Estimated Total Annual Burden Hours: It is estimated that a total of 2,000 responses will be received annually, which would equal a total annual burden of 500 hours.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: October 30, 2020.

Michael Howell,

Information Collection Officer.

[FR Doc. 2020–24438 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2020–0023]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the

Federal Register by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by January 4, 2021.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 2020–0023 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Allen Greenberg, *Allen.Greenberg@dot.gov* or 202–366–2425, Office of Transportation Management, Federal Highway Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Data Collection for Smartphone Travel Incentives Study.

Background: This study seeks to gain a deeper understanding of the factors influencing individual travel decisions at different times and for a range of trip purposes. Of primary interest is learning about participants weighing of travel options that have differing congestion impacts and, if participants consider but do not ultimately choose an option with low congestion impacts, to engage in a discovery process to ascertain the degree to which certain types and levels of encouragement and incentives could influence decision making. Such knowledge will help FHWA and state and local transportation departments to offer transportation services and engage the public in ways that minimize congestion and better serve travelers.

Up to 7,500 volunteers, in total, would be recruited from up to 15 cities to participate in this study for a period of not more than two years for the purpose of testing the impacts of a range of personal interventions on travel behavior. Participants may be surveyed at the beginning of the study. Such a general survey may include questions related to demographics (to ensure population representation and to learn about different views and impacts on different population segments); travel preferences and habits; familiarity and comfort with and views about different transportation modes; and perceptions of travel related trade-offs.

Through a smartphone application, trips would be tracked with user consent, and strong user privacy protocols would be followed. A small control group would occasionally be surveyed about their travel opinions and preferences, but otherwise would just have their travel observed without intervention. A hierarchy of engagement techniques would be deployed for other participants, starting first with information, followed by prompts to take an action, and then with incentives. Messages, action prompts, and incentives would be designed to encourage users to make more system-efficient travel choices. By continuously observing travel behaviors, changes in behavior may be linked to specific engagement techniques.

The first stage of information engagement would entail providing users ''information tiles'' where the general advantages to users of shifting travel times and/or modes that would reduce their congestion impacts on the system are highlighted to them. The second stage of information engagement would entail providing users ''action tiles'' where very specific actions they could take, reflective of recent travel choices they had made, would be shown on the smartphone application along with the associated benefits to them (*e.g.,* anticipated travel time-savings for shifting departure time to 30 minutes earlier than normal, or one or two specific bus departure times and routes that may serve as a reasonable substitute for a drive-alone trip and allow the participant to use his or her commute time more efficiently). After either the first or second stage of information engagement, participants may soon thereafter be given a very brief in-app, follow-up survey asking about whether they would be willing to consider trying the alternative or alternatives. The degree of additional surveying a participant would face would be based on their responses to information engagement, with those who are less responsive being queried more frequently. If neither of these information-providing techniques leads to an observed travel behavior change, an ''incentive treatment'' would then be tested.

The incentive treatment may entail a participant being presented one or more additional travel choices that would reduce congestion as compared to the participant repeating an earlier-observed travel departure time or mode, or a user being asked to declare a second and perhaps even a third choice travel option, and if either or both of their second or third choice is more system efficient than the first choice, ascertaining what level of incentive the user would require to make the switch.

To understand the strength of participant preferences, and to ascertain the level of incentive required to change the order of preferences, a reverse auction mechanism with a randomly generated award (RGA) amount (limited to, say, between 1 cent and $10) may be deployed. In this instance, a user would be queried about their willingness to accept (WTA) payment requirement amount to move from their first choice to their second choice and/or to their third choice travel mode(s) or departure time, if these choices would cause less congestion than their first choice. If the user's WTA compensation requirement is lower than the RGA payment amount, then they would be given the RGA payment in exchange for shifting to their second or third choice travel mode or departure time. If the RGA payment amount is lower than their WTA compensation requirement, then the user would continue with his or her first choice and receive no award.

The above approach is particularly advantageous from a data gathering standpoint, as the users communicate their precise WTA compensation to make a change for each trip, rather than the WTA having to be estimated/modeled after the user responds to being given different award offers over many different trips. With such an unfamiliar approach, users would need to be taught how the awards work and convinced (correctly) that bidding their actual WTA is always the best strategy. To ensure that users understand how such bidding may work, they may be asked ''quiz type'' questions after the strategy is described and corrected if user responses indicate a lack of understanding.

When users make a change in travel mode or departure time in response to the study, an in-app micro survey around the specific trip taken may be administered, such as to confirm travel mode(s), to discern satisfaction, and to assess if users believe that in the future they will repeat any travel choice change that they had made.

So that the choice set presented is personally relevant to individuals, users may be enabled/encouraged to customize the output from their app to exclude choices/services that they never want to use (whether riding bikeshare if

they are not able to or comfortable bicycling, driving their own car if they do not own one, using vehicles from a carsharing company if they have not and do not plan to sign up for such a service, or taking the bus if they simply refuse to do so under any circumstance). Further, machine learning could enable the application to present options the user is more likely to see as attractive under specific trip circumstances (*e.g.,* focusing on transit for commute trips while TNC options for late-night trips).

The application might add a proactive feature to enable and encourage users to indicate within the app their desired travel destination(s), departure time, and mode. Such a feature may be especially important to learn more about users whose trip patterns are quite varied, thereby making it difficult for the study team to predict what trips might be repeated and thus what specific messages should be communicated and for what trips WTA incentives should be offered. Here, participants planning to travel at a time or in a manner that would mean they will be substantially contributing to congestion would be randomly assigned to one of a few different groups within the study. The ''no treatment'' group within the proactive feature might just receive an in-app response note saying: ''Thanks for letting us know. Have a good trip.'' The study interest in this group is to ascertain whether the trip is taken as planned. The proactive feature would not include an ''information tile'' group, as it would not be expected that someone with a specific travel intention would make a change after a somewhat generic positive statement is communicated about an alternative without the needed practical details about using the alternative for the specific trip also being presented. There would be an ''action tile'' treatment group that would be presented with a range of travel departure and mode choice alternatives that would have reduced congestion impacts to what the user indicated was his or her travel plan, along with costs and estimated travel times associated with the different alternatives. Perhaps, too, users would be provided within the app the ability to book such a trip, such as with a transportation network company (TNC) or through the organization of a real-time carpool. The action tiles presented to this group may be tailored to individuals based upon their previous survey responses and/or reported/observed travel behaviors. A third group would also be presented the information about trip alternatives contained in the action tiles, and then would be assigned to the WTA survey and treatment, as described above.

Learnings about the effects of the various treatments on individual travel decisions would expand the knowledge and tools available to policy makers to further engage travelers by providing information and offering incentives that are shown to yield more system-efficient travel choices. This will enable an assessment of the expected impacts of city or metropolitan level policy scenarios to encourage the use of apps that offer real-time travel information about a range of alternatives, and provide incentives such as through public-private partnerships (PPPs) that encourage travel choices that reduce congestion.

Respondents: As noted above, up to 7,500 total field-test participants nationwide would be recruited from up to 15 cities.

Frequency: One time collecton.

Estimated Average Burden per Response: Approximately 20 minutes prior to field testing, 1 hour and 30 minutes during field testing and 15 minutes as the participant exits field-testing. Approximately 2 hours and 5 minutes per participant in total is anticipated over the 2-year study.

Estimated Total Annual Burden Hours: Approximately 15,625 hours in total is estimated. Significantly, many travel options presented to participants will save them time over alternatives (especially if trip times are shifted to avoid congestion), and thus many participants are expected to experience net time savings. All participation is voluntary, and some participants will be offered compensation.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: October 30, 2020.

Michael Howell,

Information Collection Officer.

[FR Doc. 2020–24437 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2019–0287]

Driver Qualification Files: Application for Exemption; Knight-Swift Transportation Holdings, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition; granting of application of exemption.

SUMMARY: FMCSA announces its decision to grant, with conditions, Knight-Swift Transportation Holdings, Inc.'s (Knight-Swift) application for an exemption from the requirement that motor carriers rely on the motor vehicle record (MVR) of their drivers holding a commercial driver's license (CDL) as proof of the driver's medical qualifications when the driver undergoes a new medical exam during the initial period of employment as a condition of employment. Knight-Swift would rely on the medical long form for newly hired drivers and then rely on the MVR when the subsequent annual review of the driving record is performed. FMCSA analyzed the exemption application and public comments and determined that the applicant would achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

DATES: The exemption is effective December 4, 2020. The exemption expires November 4, 2025.

ADDRESSES:

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit 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. The on-line Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year.

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: Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of

Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325. 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

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, ''FMCSA–2018–0347 in the ''Keyword'' box and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., 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.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from the Federal Motor Carrier Safety Regulations. FMCSA shall establish terms and conditions for each exemption to ensure that it will likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. 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 the safety analyses and the public comments 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 Agency's decision must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the granting or denial, and, if granted, the specific person or class of persons receiving the exemption and the regulatory provision or provisions from which the exemption is granted. The notice must specify the effective period of the exemption (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

Knight-Swift has adopted a company policy of requiring all newly hired drivers to undergo a complete medical examination. Knight-Swift explains that it believes this policy combats medical fraud and ensures that the driver is medically qualified at the time of hiring. This medical examination upon hiring is not required by the FMCSRs (unless the driver's current medical certificate has expired) but it triggers the requirement of 49 CFR 391.51(b)(7(ii) that Knight-Swift obtain the results of that examination from the SDLA in the form of an updated MVR. Knight-Swift objects to the cost and inconvenience of obtaining the MVR a second time when it recently obtained the MVR pursuant to hiring as required by 49 CFR 391.23(a)(1). It asserts that it is pointless to obtain ''information that in most cases we have already verified within the previous few days.'' Knight-Swift seeks an exemption from the requirement to obtain a new MVR when the medical examination triggering the requirement was of a newly hired Knight-Swift driver.

Knight-Swift provided data to support their exemption application and this data is included in the docket for this application. The provided data included a sample pool of 5,722 newly hired Knight-Swift drivers with valid 2-year medical cards. After undergoing Knight-Swift's hiring process, 19% of the sample pool drivers were downgraded to a 1-year certification and 2.1% were disqualified. Knight-Swift did not indicate whether it knew if these drivers (those holding a CDL) provided the new certification to the SDLAs issuing their licenses.

IV. Method To Ensure an Equivalent Level of Safety

To ensure an equivalent level of safety, Knight-Swift proposes to include in the driver qualification file the newly hired driver's medical examination report in lieu of obtaining a second MVR.

V. Public Comments

On December 23, 2019, FMCSA published notice of Knight-Swift's application and requested comments (84 FR 68287). Three comments were received from individuals and all opposed granting the exemption. Michael Millard, made the following statement: ''To extend the exemption to such a large base of drivers would basically nullify the need for any carrier to pull Commercial Driver's Licensing Information System (CDLIS) with the medical status on the driver's CDLIS report potentially resulting in multiple carriers following suit.'' Art Meyer made the following opposing argument ''I would highly recommend that this exemption not go through as I am a fleet manager and it never ceases to amaze me that the driver has not certified his medical card with the State and is thus driving on a downgraded D.L. We all should have to follow the rules no matter how big or how small a company we are and to file to [*sic*] not have to follow the rules tells me why we see so many Swift wrecks on the highways and social media that we do.'' Lastly, Jean Publiee argued that Knight-Swift should not be granted an exemption and emphasized that full documentation of a driver should be required.

VI. FMCSA Decision

The FMCSA believes Knight-Swift's exemption application has merit and with necessary terms and conditions, will allow the applicant to achieve a level of safety equivalent to what is required under the current safety regulations, provided Knight-Swift complies with the imposed terms and conditions. Under current regulations, CMV drivers required to have a commercial driver's license (CDL) or a commercial learner's permit (CLP) are required to provide the SDLA with the original or a copy of the medical examiner's certificate (MEC) (49 CFR 383.71(h)(1) and (3)). This includes an initial MEC and ''each *subsequently issued* medical examiner's certificate''. SDLAs are required to post this information to the driver's CDLIS driver record within 10 calendar days (49 CFR 383.73(o)(1)). If the driver does not provide an MEC to the SDLA, either at the time of a licensing transaction, when the MEC provided expires or is voided, or after obtaining a subsequently issued MEC, then the SDLA must within 10 calendar days change the driver's status in the CDLIS driver record to ''not certified'' (49 CFR 383.73(o)(2)). If this status change occurs, the driver is no longer physically qualified to operate a CMV that requires a CDL or CLP (49 CFR 391.41(a)(2)). The SDLA must notify the CDL or CLP holder of the status as ''not certified'' and begin the process of downgrading the license, to be completed within 60 days (49 CFR 383.73(o)(4)).

In addition, within 30 days after employing a CMV driver, motor carriers are required to obtain the motor vehicle record from the current licensing SDLA and place a copy in the driver's driver qualification file (49 CFR 391.23(a)(1)

and (b)). For drivers required to have a CDL or CLP to operate a CMV, the CDLIS motor vehicle record must be obtained and must show that the driver was properly certified as physically qualified (49 CFR 391.23(m)(2) and (3)). The driver's updated MVR showing that he or she was properly certified as physically qualified by submitting the MEC to the SDLA, must be retained in the driver qualification file. This is the requirement for which Knight-Swift is requesting an exemption. A CDL driver who is ''without medical certification status information on the CDLIS motor vehicle record is designated 'not-certified' to operate a CMV in interstate commerce'' (49 CFR 391.51(b)(7(ii)). From the MVR, the carrier can verify both that the driver is currently physically qualified and that the driver has a valid CDL that is in effect.

The carrier reviews the MVR as required under the current regulations and the record provides proof that the prospective employee has both a valid CDL and medical certification. The proof of the medical certification comes from the medical certificate issued by a healthcare provider on the National Registry, as long as it has been provided to the SDLA and is entered on the CDLIS driver record.

Knight-Swift has implemented a process through which each newly hired driver must undergo a medical examination by one of its healthcare professionals listed on the National Registry. For all drivers receiving a new medical certificate, the information would be provided to the SDLA for the driver's State of domicile so that the certificate would then serve as the most up-to-date information captured on the MVR. And because the initial MVR obtained for the newly hired driver no longer reflects the most recent medical examination, the carrier needs an exemption. To provide an equivalent level of safety under the requested exemption, Knight-Swift will be required to obtain from the driver proof that the subsequently issued medical examiner's certificate issued as a result of the new examination required by Knight-Swift has been provided to the SDLA. Instead of the MVR, Knight-Swift can obtain other proof for inclusion in the driver qualification file, such as a receipt from the SDLA, a certification from the driver that the subsequently issued certificate has been provided to the SDLA, or any other reliable proof that such action has occurred.

The FMCSA believes that under these unique circumstances, allowing Knight-Swift to rely on its records of medical certificates for the first year of employment for newly hired drivers would not compromise safety or enforcement of the medical certification requirements for CDL holders. First, the carrier has reviewed the MVR to ensure that each newly hired driver has a valid CDL and the carrier is aware of convictions for traffic offenses that have been posted to the MVR, if the prospective employees have exhibited safety performance problems. Second, Knight-Swift's review of the MVR indicates the newly hired CDL holders were medically certified prior to seeking employment at the company, and the company is aware of the expiration date of that medical certification. The subsequent medical examination provides an extra level of safety assurance for the company by having its own medical examiner verify that each newly hired driver meets FMCSA's physical qualifications standards. Compliance with the condition for obtaining proof that the subsequently issued medical certificate was provided to the SDLA will also ensure that the driver's CDL remains valid. In the event a driver does not pass the company-mandated physical examination, the driver is not allowed to operate CMVs for Knight-Swift until the medical issue(s) are resolved.

In regards to enforcement of the medical certification requirements by Federal or State personnel, they would continue to review the driving record electronically to identify the most up-to-date medical certificate. After the medical certificate prepared by the Knight-Swift medical examiner has been provided to the SDLA, Federal and State personnel would then be able to obtain the information as the most recent assessment of the driver's medical qualification status and the validity of the CDL or CLP.

The Agency believes Knight-Swift's policy of requiring newly hired drivers to undergo a medical exam, although the drivers have a valid medical exam reflected on their MVR at the time of hire, is likely to achieve an equivalent or greater than level of safety than would be achieved absent such exemption.

VII. Terms and Conditions

FMCSA grants Knight-Swift an exemption from the medical certification requirements in 49 CFR 391.51(b)(7)(ii) to permit the company to use newly hired drivers without having to obtain a MVR that reflects the latest medical certification status during the first year of employment. Knight-Swift is subject to the following terms and conditions:

(1) Knight-Swift must maintain the initial MVR reviewed prior to hiring the driver showing the driver was medically certified by a healthcare professional on the Agency's National Registry of Certified Medical Examiners;

(2) The medical examiner's report the company will rely upon for the first year of employment must be prepared by a healthcare professional on the Agency's National Registry of Certified Medical Examiners and be available for inspection by Federal or State enforcement personnel during an investigation or compliance review;

(3) Knight-Swift must obtain reliable proof that the new medical examiner's certificate was provided by the driver to the SDLA and include such proof in the driver qualification file.

VIII. Preemption of State Laws and Regulations

During the period this exemption is in effect, no State shall enforce any law or regulation that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption (49 U.S.C. 31315(d)).

IX. Notification to FMCSA

Knight-Swift must provide a quarterly report to FMCSA concerning newly hired drivers who are downgraded from a 2-year medical certificate to a shorter duration certificate, or medically disqualified upon completion of the company-mandated medical examination. The report must provide:

- Driver's full name;
- CDL number and State of issuance;
- Medical examiner's name and FMCSA-issued National Registry identification number for the examination recorded on the MVR prior to the Knight-Swift medical exam.
- Examination date and expiration date for the medical exam noted on the MVR;
- Knight-Swift medical examiner's name and FMCSA-issued National Registry identification number.
- Knight-Swift examination date and expiration date for the medical exam.

The report must be transmitted electronically in a manner to protect drivers' Personally Identifiable Information (PII).

Termination

FMCSA does not believe this exemption would result in Knight-Swift or any of its newly hired drivers experiencing a decrease in safety performance. Interested parties possessing information that would otherwise show that the exemption has resulted in a lower level of safety than what would be observed absent the exemptions should immediately notify FMCSA.

The Agency will evaluate any information submitted and, if safety is being compromised or if the continuation of this exemption is inconsistent with 49 U.S.C. 31315(b)(4), FMCSA will immediately take steps to revoke the exemption.

James W. Deck,

Deputy Administrator.

[FR Doc. 2020–24472 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0148]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel CURRENT SEA (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0148 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0148 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0148, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Russell Haynes, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone 202–366–3157, Email *Russell.Haynes@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CURRENT SEA is:

—*Intended Commercial Use of Vessel:* ''Carrying up to 12 passengers for day trips, weekend charters, and full week charters''

—*Geographic Region Including Base of Operations:* ''FLORIDA RHODE ISLAND MASSACHUSETTS MAINE'' (Base of Operations: Naples, FL)

—*Vessel Length and Type:* 49′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0148 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2020–0148 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage 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.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: October 30, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–24406 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0147]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel GYPSY SOUL (Motor Yacht); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0147 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0147 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0147, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Russell Haynes, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone 202–366–3157, Email *Russell.Haynes@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel GYPSY SOUL is:

—*Intended Commercial Use of Vessel:* ''Luxury yacht charters''

—*Geographic Region Including Base of Operations:* ''Illinois'' (Base of Operations: Chicago, IL)

—*Vessel Length and Type:* 45′ Motor Yacht

The complete application is available for review identified in the DOT docket as MARAD–2020–0147 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2020–0147 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage 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.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121

* * * * *

Dated: October 30, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–24408 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0150]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MOOREACREW (Trawler); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no

more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0150 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0150 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0150, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Russell Haynes, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone 202–366–3157, Email *Russell.Haynes@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MOOREACREW is:

—*Intended Commercial Use of Vessel:* ''Vessel will conduct high end crewed, sunset, day, and overnight charter, inshore and coastal.''
—*Geographic Region Including Base of Operations:* ''California, Oregon and Washington'' (Base of Operations: Channel Islands, CA)
—*Vessel Length and Type:* 70′ Trawler

The complete application is available for review identified in the DOT docket as MARAD–2020–0150 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2020–0150 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage 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.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: October 30, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–24410 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0151]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel OCEAN A (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0151 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0151 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0151, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Russell Haynes, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone 202–366–3157, Email *Russell.Haynes@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel OCEAN A is:

—*Intended Commercial Use of Vessel:* ''Vessel will primarily be used for crewed charters of 6 passengers or less.''

—*Geographic Region Including Base of Operations:* ''Maryland, Florida, South Carolina.'' (Base of Operations: Annapolis, MD)

—*Vessel Length and Type:* 53.8′ Motor Vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0151 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2020–0151 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage 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.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

Dated: October 30, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2020–24412 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0149]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel DAUNTLESS (Sailing Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0149 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0149 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0149, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you

if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Russell Haynes, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone 202–366–3157, Email *Russell.Haynes@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel DAUNTLESS is:

—*Intended Commercial Use of Vessel:* ''CONDUCT SAILING CHARTERS 7–10 NIGHT TRIPS SAILING TO VARIOUS DESTINATIONS ALONG US. EAST COAST AND US. GULF COAST.''

—*Geographic Region Including Base of Operations:* ''MAINE, NEW HAMPSHIRE, MASSACHUSETTS, RHODE ISLAND, CONNECTICUT, NEW JERSEY, DELAWARE, MARYLAND, VIRGINIA, NORTH CAROLINA, SOUTH CAROLINA, GEORGIA, FLORIDA, ALABAMA, MISSISSIPPI, LOUISIANA, TEXAS, PUERTO RICO'' (Base of Operations: Annapolis, MD)

—*Vessel Length and Type:* 49′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0149 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2020–0149 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage 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.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * *

Dated: October 30, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–24407 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0145]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MS BRAVEHEART (Motor Yacht); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0145 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0145 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0145, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments

received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Russell Haynes, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone 202–366–3157, Email *Russell.Haynes@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MS BRAVEHEART is:

—*Intended Commercial Use of Vessel:* ''Intended use of this Vessel is to provide Yacht cruises on the water Ways of the San Diego Bay area. They will be dally and evening passenger cruisers for sightseeing, and use of the waterways.

This will be operated exclusively under bare boat Cruise vessels criteria. The maximum per Coast Guard will be 12 passengers plus Crew Of three.''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: San Diego, CA)

—*Vessel Length and Type:* 50′ Motor Yacht

The complete application is available for review identified in the DOT docket as MARAD–2020–0145 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2020–0145 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage 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.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: October 30, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–24411 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0127]

Deepwater Port License Application: Blue Marlin LLC (BMOP)

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of application.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce they have received an application for the licensing of a deepwater port and that the application contains information sufficient to commence processing. This notice summarizes the applicant's plans and the procedures that will be followed in considering the application.

DATES: The Deepwater Port Act of 1974, as amended, requires at least one public hearing on this application to be held in the designated Adjacent Coastal State(s) not later than 240 days after publication of this notice, and a decision on the application not later than 90 days after the final public hearing(s).

ADDRESSES: The public docket for the BMOP deepwater port license application is maintained by the U.S. Department of Transportation, Docket Management Facility, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

The license application is available for viewing at the *Regulations.gov* website: *http://www.regulations.gov* under docket number MARAD–2020–0127.

We encourage you to submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* If you submit your comments electronically, it is not necessary to also submit a hard copy. If you cannot submit material using *http://www.regulations.gov,* please contact either Mr. William Nabach, USCG or Dr. Efrain Lopez, MARAD, as listed in the following **FOR FURTHER INFORMATION CONTACT** section of this document. This section provides alternate instructions for submitting written comments. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted. Anonymous comments will be

accepted. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. The Federal Docket Management Facility's telephone number is 202–366–9317 or 202–366–9826, the fax number is 202–493–2251.

FOR FURTHER INFORMATION CONTACT: Mr. William Nabach, U.S. Coast Guard, telephone: 202–372–1437, email: *William.A.Nabach2@uscg.mil,* or Dr. Efrain Lopez, Maritime Administration, telephone: 202–366–9761, email: *Efrain.Lopez@dot.gov.* For questions regarding viewing the Docket, call Docket Operations, telephone: 202–366–9317 or 202–366–9826.

SUPPLEMENTARY INFORMATION:

Receipt of Application

On October 1, 2020, MARAD and USCG received an application from Blue Marlin Offshore Port LLC (BMOP) for Federal authorizations required for a license to own, construct, and operate a deepwater port for the export of oil as authorized by the Deepwater Port Act of 1974, as amended, 33 U.S.C. 1501 *et seq.* (the Act), and implemented under 33 Code of Federal Regulations (CFR) Parts 148, 149, and 150. After a coordinated completeness review by MARAD, the USCG, and other cooperating Federal agencies, the application is deemed complete and contains information sufficient to initiate processing.

Background

The Act defines a deepwater port as any fixed or floating manmade structure other than a vessel, or any group of such structures, that are located beyond State seaward boundaries and used or intended for use as a port or terminal for the transportation, storage, and further handling of oil or natural gas for transportation to, or from, any State. A deepwater port includes all components and equipment, including pipelines, pumping or compressor stations, service platforms, buoys, mooring lines, and similar facilities that are proposed as part of a deepwater port to the extent they are located seaward of the high-water mark.

The Secretary of Transportation delegated to the Maritime Administrator authorities related to licensing deepwater ports (49 CFR 1.93(h)). Statutory and regulatory requirements for processing applications and licensing appear in 33 U.S.C. 1501 *et seq.* and 33 CFR part 148. Under delegations from, and agreements between, the Secretary of Transportation and the Secretary of Homeland Security, applications are jointly processed by MARAD and USCG. Each application is considered on its merits.

In accordance with 33 U.S.C. 1504(f) for all applications, MARAD and the USCG, working in cooperation with other involved Federal agencies and departments, shall comply with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*). The Federal Energy Regulatory Commission (FERC), the U.S. Environmental Protection Agency (EPA), the U.S. Army Corps of Engineers (USACE), the National Oceanic and Atmospheric Administration (NOAA), the Bureau of Ocean Energy Management (BOEM), the Bureau of Safety and Environmental Enforcement (BSEE), and the Pipeline and Hazardous Materials Safety Administration (PHMSA), among others, participate in the processing of deepwater port applications and assist in the NEPA process as described in 40 CFR 1500–1508. Each agency may participate in scoping and/or other public meeting(s) and may adopt the MARAD/USCG prepared environmental impact review for purposes of their jurisdictional permitting processes, to the extent applicable. Comments related to this deepwater port application addressed to the EPA, USACE, or other Federal agencies should note the Federal docket number, MARAD–2020–0127. Each comment will be incorporated into the Department of Transportation (DOT) docket and considered as the environmental impact analysis is developed to ensure consistency with the NEPA process.

All connected actions, permits, approvals and authorizations will be considered during the processing of BMOP's deepwater port license application.

MARAD, in issuing this Notice of Application pursuant to 33 U.S.C. 1504(c), must designate as an ''Adjacent Coastal State'' any coastal state which (A) would be directly connected by pipeline to a deepwater port as proposed in an application, or (B) would be located within 15 nautical miles of any such proposed deepwater port (see 33 U.S.C. 1508(a)(1)). Pursuant to the criteria provided in the Act, Louisiana and Texas are the designated Adjacent Coastal States for this application. Other states may request from the Maritime Administrator designation as an Adjacent Coastal State in accordance with 33 U.S.C. 1508(a)(2).

The Act directs that at least one public hearing take place for each Adjacent Coastal State, in this case, Louisiana and Texas. Additional public meetings may be conducted to solicit comments for the environmental analysis to include public scoping meetings, or meetings to discuss the Draft and Final environmental impact documents prepared in accordance with NEPA.

MARAD, in coordination with the USCG, will publish additional **Federal Register** notices with information regarding these public meeting(s) and hearing(s) and other procedural milestones, including the NEPA environmental impact review. The Maritime Administrator's decision, and other key documents, will be filed in the public docket at docket number MARAD–2020–0127.

The Deepwater Port Act imposes a strict timeline for processing an application. When MARAD and USCG determine that an application is complete (*i.e.,* contains information sufficient to commence processing), the Act directs that all public hearings on the application be concluded within 240 days from the date the Notice of Application is published.

Within 45 days after the final hearing, the Governors of the Adjacent Coastal States, in this case the Governors of Louisiana and Texas, may notify MARAD of their approval, approval with conditions, or disapproval of the application. If such approval, approval with conditions, or disapproval is not provided to the Maritime Administrator by that time, approval shall be conclusively presumed. MARAD may not issue a license without the explicit or presumptive approval of the Governors of the Adjacent Coastal States. During this 45-day period, the Governors may also notify MARAD of inconsistencies between the application and States programs relating to environmental protection, land and water use, and coastal zone management. In this case, MARAD may condition the license to make it consistent with such state programs (33 U.S.C. 1508(b)(1)). MARAD will not consider written approvals or disapprovals of the application from the Governors of the Adjacent Coastal States until after the final public hearing is complete and the 45-day period commences.

The Maritime Administrator must render a decision on the application within 90 days after the final hearing.

In accordance with section 33 U.S.C. 1504(d), MARAD is required to designate an application area for a deepwater port application intended to transport oil. Section 1504(d)(2) provides MARAD the discretion to establish a reasonable application area constituting the geographic area in which only one deepwater port may be

constructed and operated. MARAD has consulted with USCG in developing BMOP's application area and designates an application area encompassing the deepwater port that is a circle having a radius of no less than three-and-three-tenths (3.30) nautical miles centered at BMOP's existing WC 509 platform, latitude N 28°26′00.01″ and longitude W 93°00′15.23″. Any person interested in applying for the ownership, construction, and operation of a deepwater port within this designated application area must file with MARAD (see **FOR FURTHER INFORMATION CONTACT**) a notice of intent to file an application for the construction and operation of a deepwater port not later than 60 days after the date of publication of this notice, and shall submit a completed application no later than 90 days after publication of this notice.

Should a favorable record of decision be rendered and license be issued, MARAD may include specific conditions related to design, construction, operations, environmental permitting, monitoring and mitigations, and financial responsibilities. If a license is issued, USCG in coordination with other agencies as appropriate, would review and approve the deepwater port's engineering, design, and construction; operations/security procedures; waterways management and regulated navigation areas; maritime safety and security requirements; risk assessment; and compliance with domestic and international laws and regulations for vessels that may call on the port. The deepwater port would be designed, constructed and operated in accordance with applicable codes and standards.

In addition, installation of pipelines and other structures may require permits under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act, which are administered by the USACE.

Permits from the EPA may also be required pursuant to the provisions of the Clean Air Act, as amended, and the Clean Water Act, as amended.

Summary of the Application

BMOP is proposing to construct, own, and operate a deepwater port terminal in the Gulf of Mexico to export domestically produced crude oil. Use of the deepwater port would include the loading of various grades of crude oil at flow rates of up to 80,000 barrels per hour (bph). The BMOP deepwater port would allow for up to one (1) Very Large Crude Carrier (VLCC) or other crude oil carrier per catenary anchor leg mooring (CALM) and connect with the deepwater port via floating connecting crude oil hoses. The maximum frequency of loading VLCCs or other crude oil carriers would be approximately 2 million barrels per day (1,920,000), 365 days per year.

The overall project would consist of offshore and marine components as well as onshore components as described below.

The BMOP deepwater port offshore and marine components would consist of the following:

- Two (2) new CALM Buoys installed, one in WC 508 (CALM Buoy No. 1) and the other in EC 263(CALM Buoy No. 2). The CALM Buoys will be anchored to the seafloor via an engineered mooring system capable of accommodating mooring forces exerted by a VLCC or other large seafaring vessels during loading operations. Two 24-inch diameter floating hoses will be connected to each CALM Buoy. The hoses will be approximately 1,500 feet long and used for loading operations.
- Two new PLEMs installed and anchored on the seafloor. Two 24-inch undersea flexible hoses will be connected to each PLEM and associated CALM Buoy.
- Two Crude Oil Loading Pipelines, approximately 4,710 feet long to PLEM/CALM Buoy No. 1 and 6,085 feet long to PLEM/CALM Buoy No. 2, installed from the WC 509 Platform Complex to the PLEM and CALM locations, one for each PLEM and CALM Buoy. The pipelines will be installed with the top of pipe at least three feet below the natural seafloor.
- New MLV on WC 148 Platform;
- Two new 36-inch risers connected to the Crude Oil Loading Pipelines on WC 509B Platform;
- New control room on WC 509B Platform;
- Three new pig barrels, one on the WC 509A Platform and two on WC 509B Platform;
- Meter station for crude oil on the WC 509B Platform;
- New living quarters (LQ) and heliport on the WC 509C Platform;
- Surge valves and tank on the WC 509B Platform; and
- New ancillary equipment for the 509 Platform (*e.g.,* power generators, instrument/utility air system, fuel tanks, ac units, freshwater makers, firewater system, seawater and freshwater system, sewage treatment unit, fuel gas system, diesel system, closed drain system, open drain system, hydraulic power unit, hypochlorite system, cranes, communications tower and system, radar) to support operation of the offshore facilities.
- Safety Zone—The Applicant is requesting that the USCG Captain of the Port establish a Safety Zone around the entire DWP operations area. The Safety Zone will only be open to entry for VLCCs or other crude oil carriers prepared for connection for loading of crude oil, and the necessary service vessels supporting that process.
- Anchorage area—Existing USCG-designated anchorage areas will be utilized for VLCCs (or other crude carriers) awaiting mooring at a CALM Buoy or if they must disconnect from the CALM Buoys for safety reasons.
- Support vessel mooring area—A designated Service Vessel Mooring Area will be established in proximity to the offshore WC 509 facilities.

The BMOP deepwater port onshore storage and supply components would consist of the following:

- Temporary pre-fabrication yards—Component fabrication will occur at multiple existing fabrication facilities within the GOM coastal region.
- Support facilities—Facilities within the GOM coastal region providing support for offshore operations and maintenance activities (*e.g.,* helicopters, supply vessels, work boats, equipment suppliers, and maintenance workers).

For more information on the BMOP deepwater port project, you can visit the *Regulations.gov* website: *http://www.regulations.gov* under docket number MARAD–2020–0127.

Privacy Act

The electronic form of all comments received into the Federal Docket Management System can be searched by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). The DOT Privacy Act Statement can be viewed in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, pages 19477–78) or by visiting *http://www.regulations.gov.*

Authority: 33 U.S.C. 1501, *et seq.;* 49 CFR 1.93(h).

Dated: October 30, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–24468 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0146]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel BORROW AND BUILD (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0146 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0146 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0146, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Russell Haynes, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone 202–366–3157, Email *Russell.Haynes@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel BORROW AND BUILD is:

—*Intended Commercial Use of Vessel:* ''Bareboat Charters''
—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: Marina Del Rey, CA)
—*Vessel Length and Type:* 58′ Motor Vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0146 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2020–0146 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage 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.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: October 30, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–24405 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

United States Mint

Establish Pricing for 2020 United States Mint Numismatic Products

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is establishing a price for two new United States Mint numismatic products in accordance with the table below:

Product	2020 retail price
2020 United States Mint Ornament	$29.95
2020 Mighty Minters™ Ornament ..	27.95

FOR FURTHER INFORMATION CONTACT: Cathy Olson, Marketing Specialist, Sales and Marketing; United States Mint; 801 9th Street NW; Washington, DC 20220; or call 202–354–7519.

Authority: 31 U.S.C. 9701

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2020–24415 Filed 11–3–20; 8:45 am]

BILLING CODE 4810–37–P

DEPARTMENT OF THE TREASURY

United States Mint

Citizens Coinage Advisory Committee Public Meeting

ACTION: Notice of meeting.

Pursuant to United States Code, Title 31, section 5135(b)(8)(C), the United States Mint announces the Citizens Coinage Advisory Committee (CCAC) teleconference public meeting scheduled for November 17, 2020.

Date: November 17, 2020.

Time: 11:00 a.m. to 1 p.m.

Location: This meeting will occur via teleconference. Interested members of the public may dial in to listen to the meeting at (888) 330–1716; Access Code: 1137147.

Subject: Review and discussion of obverse and reverse candidate designs for the Congressional Gold Medals honoring Katherine Johnson and Dr. Christine Darden in accordance with the Hidden Figures Congressional Gold Medal Act.

Interested persons should call the CCAC HOTLINE at (202) 354–7502 for the latest update on meeting time and access information.

The CCAC advises the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals; advise the Secretary of the Treasury with regard to the events, persons, or places to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made; and makes recommendations with respect to the mintage level for any commemorative coin recommended.

For members of the public interested in listening in to the provided call number, this is a reminder that the public attendance is for listening purposes only. Any member of the public interested in submitting matters for the CCAC's consideration is invited to submit them by email to *info@ccac.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Warren, United States Mint Liaison to the CCAC; 801 9th Street NW; Washington, DC 20220; or call 202–354–7208.

(Authority: 31 U.S.C. 5135(b)(8)(C))

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2020–24413 Filed 11–3–20; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 85 Wednesday,
No. 214 November 4, 2020

Part II

Securities and Exchange Commission

17 CFR Part 240
Procedural Requirements and Resubmission Thresholds Under Exchange Act Rule 14a–8; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–89964; File No. S7–23–19]

RIN 3235–AM49

Procedural Requirements and Resubmission Thresholds Under Exchange Act Rule 14a–8

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: We are adopting amendments to certain procedural requirements and the provision relating to resubmitted proposals under the shareholder-proposal rule in order to modernize and enhance the efficiency and integrity of the shareholder-proposal process for the benefit of all shareholders. The amendments to the procedural rules: Amend the current ownership requirements to incorporate a tiered approach that provides three options for demonstrating a sufficient ownership stake in a company—through a combination of amount of securities owned and length of time held—to be eligible to submit a proposal; require certain documentation to be provided when a proposal is submitted on behalf of a shareholder-proponent; require shareholder-proponents to identify specific dates and times they can meet with the company in person or via teleconference to engage with the company with respect to the proposal; and provide that a person may submit no more than one proposal, directly or indirectly, for the same shareholders' meeting. The amendments to the resubmission thresholds revise the levels of shareholder support a proposal must receive to be eligible for resubmission at the same company's future shareholders' meetings from 3, 6, and 10 percent to 5, 15, and 25 percent, respectively.

DATES: The final rules are effective January 4, 2021, except for amendatory instruction 2.b adding § 240.14a–8(b)(3), which is effective January 4, 2021 through January 1, 2023. See Section III for further information on transitioning to the final rules.

FOR FURTHER INFORMATION CONTACT: Matt McNair, Senior Special Counsel in the Office of Chief Counsel, at (202) 551–3500, Division of Corporation Finance, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: We are adopting amendments to 17 CFR 240.14a–8 (''Rule 14a–8'') under the Securities Exchange Act of 1934 [15 U.S.C. 78a *et seq.*] (''Exchange Act'').

Table of Contents

I. Introduction

A. Background

Rule 14a–8 requires companies that are subject to the federal proxy rules to include shareholder proposals in companies' proxy statements to shareholders, subject to certain procedural and substantive requirements.[1] By giving any shareholder-proponent the ability to have a proposal included in the company's proxy statement to all shareholders, Rule 14a–8 enables eligible shareholder-proponents to easily present their proposals to all other shareholders, and to have proxies solicited for their proposals, at little or no expense to themselves.

This form of engagement among shareholder-proponents, other shareholders, and companies has benefits for shareholder-proponents as well as companies and their shareholders. However, the costs of processing, analyzing, and voting on the proponent's proposal largely are borne by the company and its shareholders. Accordingly, the mechanism for shareholder-proponents to require inclusion of their proposals in companies' proxy materials is not without limits. Rule 14a–8 permits a company to exclude a shareholder proposal from its proxy statement if the proposal fails to meet any of several specified procedural or substantive requirements, or if the shareholder-proponent does not satisfy certain eligibility or procedural requirements. All of these requirements are generally designed to ensure that the ability under Rule 14a–8 for a shareholder to have a

[1] Unless otherwise noted, references to ''shareholder proposal,'' ''shareholder proposals,'' ''proposal,'' or ''proposals'' refer to submissions made in reliance on Rule 14a–8.

proposal included alongside management's in the company's proxy materials—and thus to draw on resources and to command the time and attention of the company and other shareholders—is not inappropriately used. Over the years, the Commission has amended the shareholder-proposal rule as necessary to protect against such use and protect the integrity of the process.[2] The most recent significant amendments were adopted over 35 years ago in 1983.

On November 5, 2019, we proposed amendments to the procedural requirements and resubmission thresholds under Rule 14a–8 as part of our ongoing focus on modernizing and improving the proxy voting process.[3] We noted at that time concerns with certain aspects of the shareholder-proposal rule, which had not been reviewed by the Commission in more than 20 years.[4] We also noted that shareholders' ability to communicate with issuers and other shareholders through various channels has evolved significantly in response to technological advancements and developing market practices. As a result of these developments, shareholders now have more tools at their disposal to engage with a company's board and management in a manner that may be more efficient and less costly for all parties than the Rule 14a–8 process.

In light of the above, we proposed amendments to the shareholder-proposal rule to: (1) Amend the criteria that a shareholder must satisfy to be eligible to have a proposal included in a company's proxy statement; (2) modify the rule limiting the number of proposals that may be submitted for a particular company's shareholders' meeting (the ''one-proposal rule'') to establish that a single person may not submit multiple proposals at the same shareholders' meeting, whether the person submits a proposal as a shareholder or as a representative of a shareholder; and (3) revise the levels of shareholder support a proposal must receive to be eligible for resubmission at the same company's future shareholders' meetings.[5]

We received many comment letters in response to the Proposing Release.[6] After taking into consideration these public comments, as well as the feedback received as part of the Commission's 2018 Roundtable on the Proxy Process (the ''Proxy Process Roundtable''),[7] we are adopting the amendments substantially as proposed with the exception of the Momentum Requirement (defined below), which we are not adopting. The amendments are intended to modernize and enhance the efficiency and integrity of the shareholder-proposal process for the benefit of all shareholders, including to help ensure that a shareholder-proponent has demonstrated a meaningful ''economic stake or investment interest'' in a company before the shareholder may draw on company resources to require the inclusion of a proposal in the company's proxy statement, and before the shareholder may use the company's proxy statement to command the attention of other shareholders to consider and vote on the proposal.[8]

II. Final Amendments

A. Ownership Requirements

1. Proposed Rule Amendments

i. Ownership Thresholds

Rule 14a–8(b) requires a shareholder that wishes to have a proposal included in a company's proxy materials to have continuously held at least $2,000 in market value, or 1 percent, of a company's securities entitled to vote on the proposal for at least one year as of the date the shareholder submits the proposal.

In the Proposing Release, we proposed to modify the current one-year minimum holding period associated with the $2,000 ownership threshold to require continuous ownership for at least three years and to add two alternative ownership thresholds. As proposed, a shareholder would be eligible to submit a proposal if the shareholder had continuously held at least:

- $2,000 of the company's securities entitled to vote on the proposal for at least three years;
- $15,000 of the company's securities entitled to vote on the proposal for at least two years; or
- $25,000 of the company's securities entitled to vote on the proposal for at least one year.

Under the proposed amendment, a shareholder could satisfy any one of these thresholds to be eligible to submit a proposal.

ii. Percentage Test

We also proposed to eliminate the one-percent test in the rule because this test has not historically been utilized. In addition, we understand that the vast majority of shareholders who use Rule 14a–8 do not hold one percent or more of a company's shares.[9]

iii. Aggregation

We also proposed to amend the rule to prohibit shareholders from aggregating their securities with other shareholders for the purpose of meeting the applicable minimum ownership thresholds to submit a Rule 14a–8 proposal. Under the proposal, shareholders would continue to be permitted to co-file or co-sponsor shareholder proposals as a group if each shareholder-proponent in the group met

[2] The Commission has expressed concern over the years that Rule 14a–8 is susceptible to misuse. In 1948, the Commission adopted three new bases for exclusion to ''relieve the management of harassment in cases where [shareholder] proposals are submitted for the purpose of achieving personal ends rather than for the common good of the issuer and its security holders.'' *See* Notice of Proposal to Amend Proxy Rules, Release No. 34–4114 (July 6, 1948) [13 FR 3973 (July 14, 1948)], at 3974. In 1953, the Commission amended the shareholder-proposal rule to allow companies to omit the name and address of the shareholder-proponent to ''discourage the use of this rule by persons who are motivated by a desire for publicity rather than the interests of the company and its security holders.'' *See* Notice of Proposed Amendments to Proxy Rules, Release No. 34–4950 (Oct. 9, 1953) [18 FR 6646 (Oct. 20, 1953)], at 6647. In amending the resubmission basis for exclusion in 1983, the Commission noted that commenters ''felt that it was an appropriate response to counter the abuse of the security holder proposal process by certain proponents who make minor changes in proposals each year so that they can keep raising the same issue despite the fact that other shareholders have indicated by their votes that they are not interested in that issue.'' *See* Amendments to Rule 14a–8 Under the Securities Exchange Act of 1934 Relating to Proposals by Security Holders, Release No. 34–20091 (Aug. 16, 1983) [48 FR 38218 (Aug. 23, 1983)], at 38221 (''1983 Adopting Release''). In addressing the personal-grievance basis for exclusion in 1982, the Commission noted that ''[t]here has been an increase in the number of proposals used to harass issuers into giving the proponent some particular benefit or to accomplish objectives particular to the proponent.'' *See* Proposed Amendments to Rule 14a–8, Release No. 34–19135 (Oct. 14, 1982) [47 FR 47420 (Oct. 26, 1982)], at 47427 (''1982 Proposing Release'').

[3] *See* Procedural Requirements and Resubmission Thresholds under Exchange Act Rule 14a–8, Release No. 34–87458 (Nov. 5, 2019) [84 FR 66458 (Dec. 4, 2019)] (''Proposing Release'').

[4] *See* Amendments To Rules On Shareholder Proposals, Release No. 34–40018 (May 21, 1998) [63 FR 29106 (May 28, 1998)] (''1998 Adopting Release'').

[5] *See* Proposing Release, *supra* note 3.

[6] *See generally* letters submitted in connection with the Proposing Release, *available at https://www.sec.gov/comments/s7-23-19/s72319.htm.* Unless otherwise specified, all references in this release to comment letters are to those relating to the Proposing Release.

[7] On November 15, 2018, Commission staff held a roundtable on the proxy process, which included a panel discussion on Rule 14a–8 and the shareholder-proposal process. The shareholder-proposal panelists expressed their views on the application of Rule 14a–8 and shared their experiences with shareholder proposals and the related benefits and costs involved for companies and shareholders. In connection with the Proxy Process Roundtable, the staff invited members of the public to provide their views on the proxy process via written comments, which are available at *https://www.sec.gov/comments/4-725/4-725.htm.*

[8] *See* 1983 Adopting Release, *supra* note 2.

[9] *See* Proposing Release at 66464 n.58.

one of the proposed eligibility requirements.

iv. Lead-Filer Designation

The Proposing Release also addressed whether co-filers, or co-sponsors, should be required to identify a lead filer and specify whether such lead filer is authorized to negotiate with the company and withdraw the proposal on behalf of the other co-filers. Although we did not propose to require this practice in our rules, we requested comment on whether we should revise the rules to require co-filers to identify a lead filer and authorize the lead filer to negotiate the withdrawal of the proposal on behalf of the other co-filers.

2. Comments on the Proposed Rule Amendments

i. Ownership Thresholds

The proposal generated a wide range of responses among commenters. Commenters that supported the revised ownership thresholds generally indicated that a tiered approach would help address concerns related to the shareholder-proposal process while maintaining an avenue of communication for shareholders of various investment sizes.[10] Several commenters also indicated that satisfaction of the proposed thresholds would help demonstrate that a shareholder-proponent has a meaningful ownership interest in the company that will receive the proposal.[11]

Many commenters questioned the need and/or rationale for the proposed amendment to the ownership requirements.[12] For example, several commenters disagreed with the discussion in the Proposing Release [13] positing that an investor's holding period is a meaningful indicator of a shareholder's interest in a company, or that a longer holding period may make it more likely that a proposal will reflect a greater interest in the company and its shareholders rather than promote a personal interest or publicize a general cause.[14] Other commenters questioned whether the proposed thresholds were commensurate with the rate of inflation or appreciation in the capital markets.[15]

Many commenters that opposed the proposed ownership thresholds expressed concern about their potential effect on the ability of shareholders with smaller investments to submit proposals.[16] Several commenters also expressed the view that shareholders with smaller investments play an important role in the shareholder-proposal process and may submit proposals that other shareholders support.[17] In addition, some expressed concern about these investors' ability to satisfy the proposed ownership thresholds without compromising portfolio diversification.[18]

Some commenters expressed the view that, while shareholders that are unable to submit proposals are able to pursue alternative avenues of engagement with management and other shareholders, these alternatives are not as effective as shareholder proposals.[19] For example, these commenters suggested that there are inherent weaknesses with using social media as a method of engagement,[20] or that alternative engagement methods do not allow shareholders to solicit the views of the entire shareholder base.[21]

A number of commenters suggested adjustments or alternative approaches to the proposed ownership requirements. Some commenters that were supportive of the proposed tiered approach recommended raising the initial $2,000 threshold for inflation and/or periodically adjusting each of the proposed ownership thresholds for inflation going forward.[22] Several commenters that opposed the proposed ownership requirements indicated that they would not object to adjusting the existing $2,000 threshold for inflation.[23] Other commenters expressed support for a single threshold at an amount higher than $2,000.[24] One commenter suggested adopting thresholds of $5,000, $10,000, and $15,000, depending on the holding period.[25] Another commenter suggested tying eligibility to the size of an investor's total investment portfolio by applying the existing thresholds to investors with a total investment portfolio of less than $1 million and the proposed thresholds to those with a total investment portfolio in excess of $1 million.[26] Another commenter found merit to a tiered approach, but suggested an alternative in which shareholders meeting a three-year holding period would be permitted to submit a proposal regardless of investment amount.[27]

Several commenters offered views that were specific to the proposed holding periods. One commenter urged us to ''consider changing the duration of the ownership requirement so as to

[10] *See, e.g.,* letters from Center for Capital Markets Competitiveness dated January 31, 2020; Senator Kevin Cramer dated July 28, 2020; Energy Infrastructure Council dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; International Bancshares Corporation dated January 23, 2020; Investment Company Institute dated February 3, 2020; National Association of Manufacturers dated February 3, 2020.

[11] *See* letters from Center for Capital Markets Competitiveness dated January 31, 2020; Fidelity Management & Research LLC dated February 3, 2020; International Bancshares Corporation dated January 23, 2020.

[12] *See, e.g.,* letters from CalSTRS dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; RK Invest Law, PBC dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[13] *See* Proposing Release at 66463.

[14] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; RK Invest Law, PBC dated February 3, 2020.

[15] *See, e.g.,* letters from CalPERS dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[16] *See, e.g.,* letters from Benedictine Sisters of Chicago dated January 23, 2020; Senator Sherrod Brown dated August 21, 2020; John Chevedden dated January 31, 2020; Christian Brothers Investment Services, Inc. dated January 21, 2020; Connecticut State Treasurer dated January 31, 2020; Council of Institutional Investors et al. dated July 29, 2020; Senator Tammy Duckworth dated January 30, 2020; James McRitchie dated November 5, 2019; James McRitchie dated July 21, 2020; Shareholder Rights Group dated June 10, 2020.

[17] *See, e.g.,* letters from John Chevedden dated July 13, 2020; John Chevedden dated July 20, 2020; Christian Brothers Investment Services, Inc. dated January 21, 2020; Council of Institutional Investors et al. dated July 29, 2020; Senator Tammy Duckworth dated January 30, 2020; Form Letter Type A; Illinois State Treasurer dated January 16, 2020; James McRitchie dated July 21, 2020.

[18] *See, e.g.,* Council of Institutional Investors dated January 30, 2020; NorthStar Asset Management, Inc. dated February 3, 2020; Shareholder Commons dated January 31, 2020; Shareholder Rights Group dated February 3, 2020; US SIF dated January 31, 2020. *See also* Recommendation of the SEC Investor Advisory Committee (IAC) Relating to SEC Guidance and Rule Proposals on Proxy Advisors and Shareholder Proposals dated January 24, 2020 (''Recommendation of the IAC'').

[19] *See, e.g.,* letters from Lucian A. Bebchuk dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Council of Institutional Investors et al. dated July 29, 2020; James McRitchie dated February 2, 2020; New York State Comptroller dated February 3, 2020; NorthStar Asset Management, Inc. dated February 3, 2020.

[20] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; James McRitchie dated February 2, 2020; New York State Comptroller dated February 3, 2020.

[21] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; James McRitchie dated February 2, 2020.

[22] *See* letters from Business Roundtable dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; FedEx Corporation dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020; Society for Corporate Governance dated February 3, 2020.

[23] *See* letters from CalPERS dated February 3, 2020; CFA Institute dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; James McRitchie dated February 2, 2020; Shareholder Rights Group dated February 3, 2020.

[24] *See* letters from CT Hagberg LLC dated February 3, 2020 (suggesting a single threshold of $5,000); Jing Zhao dated February 3, 2020 (suggesting a single threshold of $2,500).

[25] *See* letter from Van Brenner dated November 21, 2019.

[26] *See* letter from John Taylor dated November 14, 2019.

[27] *See* letter from Josh Feldblyum dated November 30, 2019.

better reflect the significant changes to holding periods during the years since the one-year requirement was established.'' [28] Another commenter expressed the view that the current one-year holding period is appropriate in light of the average holding periods of individual and institutional investors.[29] Another commenter recommended adopting a three-year holding period for all shareholder-proponents because, in the commenter's view, such a holding period ''would demonstrate a serious commitment to a company's long-term success and should discourage proposals focused on short-term changes.'' [30] Other commenters suggested that the holding period should be aligned with the Internal Revenue Code, which treats an asset as a long-term capital asset if held for more than one year and is thus taxed at capital gain rather than ordinary tax rates.[31] Other commenters expressed the view that a shareholder's holding period may not accurately capture the nature of an investor's investment stake as the length of time held may not necessarily be indicative of the shareholder's future investment intent.[32] One of these commenters suggested that the Commission instead explore a requirement that a shareholder-proponent ''attest that the holder will maintain ownership of at least $2,000 of shares . . . for at least one year after the annual meeting,'' or a requirement that companies disclose a shareholder-proponent's name and holdings ''so that shareholders could make their own determinations if they believe a stake is too small.'' [33] Another commenter supported the proposed three-year holding requirement at the $2,000 threshold, but stated that further study was necessary to understand the implications of the $25,000 ownership requirement.[34]

One commenter sought clarification as to whether share lending would be deemed to interrupt the period of continuous ownership.[35]

ii. Percentage Test

Several commenters supported [36] and two opposed [37] eliminating the one-percent ownership test. In addition, one commenter opposed the adoption of an ownership requirement based solely on a percentage of shares owned,[38] while another supported such a requirement.[39]

iii. Aggregation

Several commenters supported the proposed amendment related to shareholders' ability to aggregate their holdings,[40] while others opposed it.[41] One commenter stated that the proposed amendment would be premature without first studying the effects of any newly adopted ownership thresholds.[42] This commenter also suggested that a prohibition on aggregation would be inconsistent with the Commission's beneficial ownership rules as well as certain other state law provisions.[43] The commenters that supported the proposed amendment stated that allowing aggregation would undermine the principle underlying the ownership requirements.[44] Many commenters that opposed the proposed amendment stated that such a limitation would have a more pronounced effect on shareholders with smaller investments.[45] One of these commenters stated that aggregation among shareholders is an indication of their long-term investment interest.[46] Another of these commenters suggested that a group of shareholders that collectively satisfies an ownership requirement is not functionally different than a single shareholder that satisfies the requirement.[47] This commenter also stated the view that a proposal submitted by a group of shareholders aggregating their holdings may be ''more worthy of consideration'' than a proposal submitted by a single shareholder because it ''involves coordination of support [among] multiple shareholders.'' [48] Another commenter said that up to five

[28] *See* letter from CalPERS dated February 3, 2020 (stating that ''the average stock holding period spanned several years'' when the Commission first adopted an ownership requirement, whereas today ''the average stock holding period in the U.S. is under nine months'') (citing Ted Maloney & Robert Almeida, Jr., Lengthening the Investment Time Horizon (MFS Investment Management 2019), *available at https://www.mfs.com/content/dam/mfs-enterprise/mfscom/insights/2019/November/mfse_time_wp/mfse_time_wp.pdf*).

[29] *See* letter from AFL–CIO dated February 3, 2020.

[30] *See* letter from The Vanguard Group, Inc. dated February 3, 2020.

[31] *See* letters from Jantz Management LLC dated January 21, 2020; James McRitchie dated December 28, 2019; James McRitchie dated December 29, 2019; James McRitchie dated January 21, 2020; James McRitchie dated July 21, 2020; Tom Shaffner dated December 17, 2019.

[32] *See* letters from Council of Institutional Investors dated January 30, 2020; Pension Investment Association of Canada dated January 23, 2020.

[33] *See* letter from Council of Institutional Investors dated January 30, 2020.

[34] *See* letter from Washington State Investment Board dated January 22, 2020.

[35] *See* letter from Baillie Gifford & Co. dated February 3, 2020.

[36] *See* letters from CFA Institute dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Manhattan Institute for Policy Research dated February 3, 2020; James McRitchie dated February 2, 2020; National Association of Manufacturers dated February 3, 2020; John Taylor dated November 14, 2019.

[37] *See* letters from Local Authority Pension Fund Forum dated February 3, 2020; Jena Martin dated February 3, 2020.

[38] *See* letter from John Taylor dated November 14, 2019.

[39] *See* letter from Don E. Sprague dated November 15, 2019.

[40] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Exxon Mobil Corporation dated February 3, 2020; International Bancshares Corporation dated January 23, 2020; Manhattan Institute for Policy Research dated February 3, 2020; National Association of Manufacturers dated February 3, 2020.

[41] *See, e.g.,* letters from Amazon Employees for Climate Justice dated February 3, 2020; American Baptist Home Mission Societies dated January 31, 2020; Baillie Gifford & Co. dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; Christian Brothers Investment Services, Inc. dated January 21, 2020; Church Investor Group dated January 29, 2020; CT Hagberg LLC dated February 3, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Franciscan Sisters of Allegany, NY dated January 29, 2020; International Corporate Governance Network dated December 4, 2019; North American Securities Administrators Association, Inc. dated February 3, 2020; Oneida Trust Enrollment Committee dated February 3, 2020; Tom Shaffner dated December 17, 2019; Singing Field Foundation dated January 31, 2020; Sisters of St. Ursula dated January 23, 2020; Sisters of the Order of St. Dominic dated January 24, 2020; State Board of Administration of Florida dated February 3, 2020.

[42] *See* letter from Professor James D. Cox et al. dated February 2, 2020.

[43] *Id.* Another commenter also expressed the view that the proposed rule would be inconsistent with ''other SEC rules that allow (and sometimes require) aggregation of shares held by different shareholders'' in the context of different regulatory objectives such as when shareholders collectively owning more than five percent of a class of equity securities of a registrant act as a ''group'' for purposes of the disclosure requirements of Section 13(d) of the Exchange Act. *See* letter from Council of Institutional Investors et al. dated July 29, 2020.

[44] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Exxon Mobil Corporation dated February 3, 2020; International Bancshares Corporation dated January 23, 2020; Manhattan Institute for Policy Research dated February 3, 2020; National Association of Manufacturers dated February 3, 2020.

[45] *See, e.g.,* letters from Amazon Employees for Climate Justice dated February 3, 2020; American Baptist Home Mission Societies dated January 31, 2020; Baillie Gifford & Co. dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; Christian Brothers Investment Services, Inc. dated January 21, 2020; Church Investor Group dated January 29, 2020; CT Hagberg LLC dated February 3, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Franciscan Sisters of Allegany, NY dated January 29, 2020; International Corporate Governance Network dated December 4, 2019; North American Securities Administrators Association, Inc. dated February 3, 2020; Oneida Trust Enrollment Committee dated February 3, 2020; Tom Shaffner dated December 17, 2019; Singing Field Foundation dated January 31, 2020; Sisters of St. Ursula dated January 23, 2020; Sisters of the Order of St. Dominic dated January 24, 2020.

[46] *See* letter from First Affirmative Financial Network, LLC dated January 24, 2020.

[47] *See* letter from Tom Shaffner dated December 17, 2019.

[48] *Id.*

shareholders should be allowed to aggregate their holdings.[49]

iv. Lead-Filer Designation

Several commenters supported a rule requiring the designation of a lead filer where co-filers submit a proposal.[50] Of these commenters, several supported a requirement that co-filers delegate to the lead filer the ability to negotiate with respect to, and withdraw, the proposal to reduce administrative burdens on companies.[51]

Other commenters opposed the idea of requiring the designation of a lead filer.[52] Two of these commenters explained that such a requirement is unnecessary as co-filers already tend to designate a lead filer.[53] One of the commenters indicated that such a requirement could lead to more shareholder proposal submissions and suggested that, if such a requirement were adopted, companies should be required to disclose the lead filer and all co-filers in their proxy statements to foster engagement and provide investors with additional information related to their vote.[54]

3. Final Rule Amendments

i. Ownership Thresholds

After considering the comments received, we are adopting the amendments as proposed. Under new Rule 14a–8(b), a shareholder will be eligible to submit a Rule 14a–8 proposal if the shareholder demonstrates continuous ownership of at least:

- $2,000 of the company's securities entitled to vote on the proposal for at least three years;
- $15,000 of the company's securities entitled to vote on the proposal for at least two years; or
- $25,000 of the company's securities entitled to vote on the proposal for at least one year.[55]

The Commission has previously indicated that the required dollar amount and holding period should be calibrated such that a shareholder has some meaningful ''economic stake or investment interest'' in a company—and therefore is more likely to put forth proposals reflecting an interest in the company and its shareholders than to use the proxy process to promote a personal interest or general cause—before the shareholder may draw on company and shareholder resources to require the inclusion of a proposal in the company's proxy statement, and before the shareholder may use the company's proxy statement to command the time and attention of other shareholders to consider and vote on the proposal.[56] We believe this longstanding statement of the Commission's perspective continues to appropriately capture the various interests that should be considered when calibrating the eligibility of shareholder-proponents to access the proxy statement at little or no cost to themselves.

As we explained in the Proposing Release, we believe that holding $2,000 worth of a company's stock for a single year, a threshold that was last substantively reviewed and updated by the Commission in 1998,[57] does not appropriately ensure that the shareholder has a sufficiently meaningful stake in a company today. As the table below demonstrates, the $2,000 threshold, adjusted for inflation, is equivalent to $3,183 in 2020 dollars.[58] Moreover, using the cumulative growth of the Russell 3000 Index as a proxy for the average increase in companies' market values, a $2,000 investment in that index in 1998 would be worth approximately $9,489 today.[59] Furthermore, we estimate that the market capitalization of the largest 100 issuers in the S&P 500 Index (the companies that on a per-issuer basis receive a disproportionate number of shareholder proposals[60]) has grown by 164 percent since 1998, and a $2,000 stake would be worth approximately $5,280 today.[61] We believe that the increases in inflation and market value have contributed, in part, to the need to revisit the $2,000/one-year ownership threshold and to recalibrate the relationship between the amount of stock owned and the requisite holding period to reflect a more appropriate economic stake or investment interest.

OWNERSHIP THRESHOLD COMPARISON

Threshold established in 1998	1998 Threshold adjusted for inflation	Change in Russell 3000 Index	Change in largest 100 issuers in S&P 500 Index
$2,000	$3,183	$9,489	$5,280

[49] *See* letter from State Board of Administration of Florida dated February 3, 2020.

[50] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Exxon Mobil Corporation dated February 3, 2020; General Motors Company dated February 25, 2020; James McRitchie dated February 2, 2020; National Association of Manufacturers dated February 3, 2020; Society for Corporate Governance dated February 3, 2020; State Board of Administration of Florida dated February 3, 2020.

[51] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Exxon Mobil Corporation dated February 3, 2020; National Association of Manufacturers dated February 3, 2020; Society for Corporate Governance dated February 3, 2020.

[52] *See* letters from Local Authority Pension Fund Forum dated February 3, 2020; New York State Comptroller dated February 3, 2020; John Taylor dated November 14, 2019.

[53] *See* letters from Local Authority Pension Fund Forum dated February 3, 2020; New York State Comptroller dated February 3, 2020.

[54] *See* letter from New York State Comptroller dated February 3, 2020.

[55] Due to market fluctuations, the value of a shareholder's investment in a company may vary throughout the applicable holding period before the shareholder submits the proposal. In order to determine whether the shareholder satisfies the relevant ownership threshold, the shareholder should look at whether, on any date within the 60 calendar days before the date the shareholder submits the proposal, the shareholder's investment is valued at the relevant threshold or greater. *See* 1983 Adopting Release, *supra* note 2. For these purposes, companies and shareholders should determine the market value by multiplying the number of securities the shareholder continuously held for the relevant period by the highest selling price during the 60 calendar days before the shareholder submitted the proposal. For purposes of this calculation, it is important to note that a security's highest selling price is not necessarily the same as its highest closing price.

[56] *See* 1983 Adopting Release, *supra* note 2.

[57] *See* 1998 Adopting Release.

[58] $3,183 = $2,000 × 1.5915 (cumulative rate of inflation between May 1998 and July 2020, using the CPI inflation calculator, *available at https://data.bls.gov/cgi-bin/cpicalc.pl?cost1=11%2C600.00&year1=201011&year2=201906*).

[59] $9,489 = $2,000 × 4.744 (cumulative rate of growth of the Russell 3000 index between May 1998 and July 2020, which is the most recent date with available data, assuming dividends are reinvested). Data is retrieved from Compustat Daily Updates—Index Prices.

[60] In 2019, out of a total of 371 shareholder proposals voted on, *see* Sullivan & Cromwell, 2019 Proxy Season Review, Part I (July 13, 2019), *available at https://www.sullcrom.com/files/upload/SC-Publication-2019-Proxy-Season-Review-Part-1-Rule-14a-8-Shareholder-Proposals.pdf* (''Sullivan & Cromwell Report''), 187 were voted on at S&P 100 companies, *see* David Bell, *Silicon Valley and S&P 100: A Comparison of 2019 Proxy Season Results,* Dec. 27, 2019, *available at https://corpgov.law.harvard.edu/2019/12/07/silicon-valley-and-sp-100-a-comparison-of-2019-proxy-season-results/.*

[61] $5,280 = $2,000 × (1+1.64) (cumulative rate of growth in the market capitalization of the largest 100 issuers in the S&P 500 Index between May 1998 and May 2019, which is the most recent date with available data). Data is retrieved from Compustat Annual Updates—Security Monthly.

In making this assessment and recalibration, we recognize that the amount of stock owned is not the only way to demonstrate an interest in a company, particularly for smaller investors. In many cases, the length of time owning the company's securities may be a more meaningful indicator that a shareholder has a sufficient interest that warrants use of the company's proxy statement. A shareholder's demonstrated long-term investment interest in a company may make it more likely that the shareholder's proposal will reflect a greater interest in the company and its shareholders, rather than an intention to use the company and the proxy process to promote a personal interest or publicize a general cause. We believe having a longer holding period is particularly important if the dollar value of the ownership interest is minimal, including in terms of a company's market capitalization, and may help address concerns related to misuse of the shareholder-proposal process, while ensuring that smaller investors have access to the proxy statements of companies in which they have a demonstrated continuing interest.

We also recognize that shareholders' ability to communicate with issuers and other shareholders has evolved in response to technological advancements and developing market practices since our rules were last amended. As a result, shareholders now have more tools at their disposal to engage with a company's board and/or management, as well as their fellow shareholders, in a manner that may be more efficient and less costly for all parties than the Rule 14a–8 process. Thus, shareholders that do not meet the relevant one-, two-, or three-year holding period (and related $25,000, $15,000, or $2,000 continuous ownership threshold), and for some limited period of time would not be eligible to require a company to include a proposal in its proxy statement, can nevertheless raise important issues with companies and other shareholders through alternative avenues with greater ease than in the past.

In establishing the amended thresholds, we also have considered the costs to the company and its shareholders associated with management's consideration of a proposal and/or its inclusion in the company's proxy statement, as well as the direct costs to other shareholders. In the Proposing Release, we cited several cost estimates for companies provided by market participants ranging from $50,000 to $150,000 per proposal associated with this process and estimated that the proposed amendments to the ownership thresholds could result in aggregate annual cost savings of up to $69.8 million per year for all Russell 3000 companies.[62] In response to the Proposing Release, several commenters provided us with estimates of the costs associated with a company's receipt of a shareholder proposal ranging from approximately $20,000 to $150,000.[63] The costs to non-proponent shareholders of considering shareholder proposals are difficult to quantify but in aggregate are estimated to be significant, including in comparison to the costs borne by shareholder-proponents.[64] Because Rule 14a–8 enables individual shareholders to shift to the company and other shareholders the significant cost of processing, analyzing, and voting their proposals, we believe the Commission's longstanding perspective that ownership thresholds should be calibrated so that a shareholder-proponent's economic stake or investment interest in the company is more likely to demonstrate an alignment of interest with the company's other shareholders continues to be appropriate.

Taking into account the above factors, the new thresholds will require a more appropriate demonstrated ''economic stake or investment interest'' in a company before the shareholder may draw on company and shareholder resources to require the inclusion of a proposal in the company's proxy statement, and before the shareholder-proponent may use the company's proxy statement to command the time and attention of other shareholders to analyze and vote on the proposal.[65] Each of these factors is described in greater detail below.

While the current $2,000 threshold will remain the same to preserve the ability of long-term shareholders owning a relatively small amount of shares to continue to utilize Rule 14a–8, these investors will be required to hold the securities for at least three years to be eligible to submit a proposal. In light of the smaller investment amount required under this ownership tier, we believe that a longer holding period is warranted to demonstrate a sufficient investment interest in a company before being able to draw on company and shareholder resources for the purpose of including a proposal in the company's proxy statement. Investors who currently are eligible to submit proposals under the current $2,000 threshold/one-year minimum holding period, but currently do not satisfy the new requirements, will continue to be eligible to submit proposals through the expiration of the transition period that extends for all annual or special meetings held prior to January 1, 2023, provided they continue to hold at least $2,000 of a company's securities.

To help put these thresholds in context, the following table shows them as a percentage of market value as of April 2020 for the S&P 500 Index

[62] *See* Proposing Release at 66502.

[63] *See* letters from Business Roundtable dated February 3, 2020 (noting that ''[a]lthough many member companies reported that it was difficult to quantify the costs of shareholder proposals, several reported costs ranging from $50,000 to $100,000 or more per proposal. In addition, a number of companies noted that their costs for first-time proposals are generally higher than those incurred for resubmitted proposals''); CalPERS dated February 3, 2020 (''Fortunately, the most substantial shareholder proposal work product is included in the no-action correspondence on the SEC's website and does not reflect a value anywhere near $150,000 per submission. During no-action fights, many proposals are disposed of fairly quickly and easily by referencing the appropriate exclusion. Companies actually pay less than $20,000 in marginal costs for the work product displayed on the SEC website.''); Center for Capital Markets Competitiveness dated January 31, 2020 (noting that ''[t]he Commission cited commenters who estimated that the average cost of responding to a proposal for inclusion in the company's proxy statement can cost anywhere from $87,000 to $150,000 per proposal. Our members report that this is a fair estimate for a typical proposal, though some outliers (such as ones involving multiple rounds of correspondence with a proponent and the Commission) may exceed the high end of the range.''); John Coates and Barbara Roper dated January 30, 2020 (noting that the Commission's paperwork burden analysis uses ''a much lower figure, based on direct company information: 'A July 2009 survey of Business Roundtable companies, in which 67 companies responded . . . indicated that the average burden for a company associated with printing and mailing a single shareholder proposal is 20 hours with associated costs of $18,982.' While this much lower estimate may not comprehensively reflect all costs, it is a relevant datum for estimating cost savings, and is at least in tension with the SEC's assertion that $50,000 is a 'lower bound' on costs.''); Exxon Mobil Corporation dated February 3, 2020 (estimating the direct cost of each shareholder proposal included in its proxy statement ''to be at least $100,000''); General Motors Company dated February 25, 2020 (stating that a cost estimate of $87,000 to $150,000 is ''directionally accurate''); Society for Corporate Governance dated February 3, 2020 (providing the results of a survey of its members in which one respondent reported a cost of $109,792 (including the cost of seeking no-action relief) with respect to a proposal received in 2018 that was ultimately withdrawn, and a cost of $133,587 with respect to a proposal in 2019 that was ultimately included in the company's proxy statement). For additional discussion of these cost estimates, *see infra* note 332 and accompanying text.

[64] *See infra* Section V.D.2.

[65] One commenter sought clarification regarding the effect of share lending. *See* letter from Baillie Gifford & Co. dated February 3, 2020. The rule will not prohibit share lending or otherwise require investors to maintain a net-long position. We note that the rule has not historically imposed such a requirement, and we are not aware of any concerns with respect to these practices by shareholder-proponents at this time.

constituents and May 2020 for the Russell 3000 Index constituents: [66]

Registrant	$2,000 threshold as a percentage of market value	$15,000 threshold as a percentage of market value	$25,000 threshold as a percentage of market value
Largest Registrant in the S&P 500 Index	0.0000002	0.0000012	0.0000020
Smallest Registrant in the S&P 500 Index	0.0001	0.0009	0.0015
Smallest Registrant in the Russell 3000 Index	0.0021	0.016	0.026

Although the ownership thresholds are still very low as a percentage of market value, we believe that maintaining the $2,000 threshold and extending the holding period to three years, and adding new thresholds with one- and two-year holding periods, provides for a framework that is more effectively calibrated to the potentially varying interests of shareholder-proponents, companies, and other shareholders and, as a result, a shareholder-proponent that meets one of them will have demonstrated a sufficient ''economic stake or investment interest'' in a company before being able to draw on company and other shareholder resources for the purpose of including a proposal in the company's proxy statement. While we considered the alternative of simply raising the dollar amount of securities required to be held for one year, we were cognizant of the effect such an increase may have on investors with smaller investments, including those with a demonstrated long-term economic stake or investment interest in the company. We also considered adopting a single ownership threshold with a three-year holding period, but we believe that shorter holding periods are appropriate where a shareholder-proponent's demonstrated investment interest is greater in amount. Accordingly, we are retaining a $2,000 ownership threshold while adjusting the related holding period and adopting alternative thresholds for investors that have held their shares for shorter periods of time.

For the reasons discussed above and in the Proposing Release, such as the costs incurred by other shareholders and companies and the availability of alternative communication channels, we do not believe that a one-year holding period is indicative of a sufficient investment interest where the amount invested is less than $25,000. We also do not find commenters' analogy to the Internal Revenue Code's treatment of capital assets compelling in light of the differing objectives of the Internal Revenue Code and the shareholder-proposal rule.[67] At the same time, we also do not find compelling the suggestion of a different commenter that a three-year holding period for all shareholder-proponents is necessary to demonstrate a ''serious commitment to a company's long-term success.'' [68] We believe that holding periods of less than three years are sufficient where the economic stake is greater.

Two commenters suggested that any adjustments to the one-year holding period should be informed by the holding periods of investors generally.[69] In the Proposing Release, we noted our review of academic studies and other data on share ownership duration generally.[70] In establishing the amended holding periods, and in response to these commenters, we further reviewed holding period data.[71] We note, however, that academic studies and data regarding holding periods for smaller investors reflect a static assessment of general eligibility in the context of the current one-year minimum holding period and, therefore, do not account for changes in investment amounts and holding periods for the historically limited group of smaller investors that are interested in submitting proposals that may result from the amendments.[72] We believe that where the amount invested is relatively small, an investor's holding period provides a meaningful indicator of the shareholder-proponent's investment interest in the company. As such, where the amount invested is less than $25,000 but greater than $15,000, we believe that a holding period of two years is appropriate. Where the amount invested is less than $15,000 but greater than $2,000, we believe that the three-year holding period is appropriate.[73]

Although we agree with the view of certain commenters that the length of time a shareholder has held a company's securities may not necessarily determine future investment intent,[74] we believe that it provides a meaningful indication as to the nature of the investment. Thus, we believe that it is appropriate to place greater emphasis on the length of continuous stock ownership when the economic stake is less and vice versa. Moreover, in response to a commenter, we considered whether to adopt an eligibility requirement based on a shareholder-proponent's statement that it will maintain a minimum investment in the company's securities for some period of time after the shareholders' meeting for which a proposal is submitted.[75] However, we believe that a shareholder-proponent with a limited economic stake should first demonstrate a meaningful investment interest in a company before drawing on company and shareholder resources to require the inclusion of a proposal in the company's proxy statement, and before using the company's proxy statement to command the time and attention of other shareholders to consider and vote on the proposal. In our view, requiring

[66] Data for the S&P 500 constituents is retrieved from CRSP and data for the Russell 3000 constituents is retrieved from *Market Capitalization Ranges,* FTSE Russell Market, *https://www.ftserussell.com/research-insights/russell-reconstitution/market-capitalization-ranges* (last visited Jun. 17, 2020). The largest registrant in the Russel 3000 index is the same as in the S&P 500 Index.

[67] *See* letters from Jantz Management LLC dated January 21, 2020; James McRitchie dated December 28, 2019; James McRitchie dated December 29, 2019; James McRitchie dated January 21, 2020; James McRitchie dated July 21, 2020; Tom Shaffner dated December 17, 2019.

[68] *See* letter from The Vanguard Group, Inc. dated February 3, 2020.

[69] *See supra* notes 28 and 29.

[70] *See* Proposing Release at 66490 n.195.

[71] *See infra* note 320 and accompanying text.

[72] The ratio of shareholder-proponents whose proposals appeared in proxy statements during 2018 (*i.e.,* 170) to the number of direct and indirect investors in companies subject to the proxy rules (*i.e.,* 65 million) is roughly equal to three shareholder-proponents per million investors.

[73] There may be a relation between duration of ownership and the propensity of a shareholder to submit a proposal.

[74] *See* letters from Council of Institutional Investors dated January 30, 2020; Pension Investment Association of Canada dated January 23, 2020.

[75] *See* letter from Council of Institutional Investors dated January 30, 2020 (''[T]he SEC should explore benefits and costs of a forward-looking regime, for example requiring the shareholder to attest that the holder will maintain ownership of at least $2,000 of shares (as valued at submission date) for at least one year after the annual meeting.'').

a company to include a shareholder proposal in its proxy statement before a proponent has demonstrated a sufficient economic stake or investment interest would be inconsistent with the purpose of the ownership requirement and could render the shareholder-proposal process subject to abuse. Accordingly, we do not believe that such an approach is appropriate.

In response to the same commenter, we also considered whether to eliminate the ownership threshold and adopt a requirement that companies disclose a shareholder-proponent's name and holdings ''so that shareholders could make their own determinations if they believe a stake is too small.'' [76] Because a determination by shareholders regarding a proponent's investment stake would occur only after a proposal had been included in the company's proxy statement and voted upon, companies and their shareholders could bear the burdens associated with a proposal submitted by a proponent whose stake is ultimately determined to be too small by the company's shareholders. For this reason, we believe that such an approach would be inconsistent with the purpose of the ownership requirement and could render the shareholder-proposal process subject to abuse. Accordingly, we are not adopting such an approach.

In establishing the amended thresholds, we also gave careful consideration to the effects any new thresholds may have on the ability of shareholders with smaller investments to submit proposals. We acknowledge, as several commenters asserted, that smaller shareholders can raise issues that other shareholders support.[77] The amendments we are adopting today do not preclude smaller shareholders from participating in the shareholder-proposal process.[78] As discussed above, the rule will continue to be available to shareholders that own at least $2,000 of a company's securities. We recognize, however, that the increased holding period will likely have some effect on the timing of submissions by those shareholders who could have relied on the current $2,000/one-year ownership threshold if they do not yet meet the three-year holding period (or the alternative eligibility thresholds). Specifically, shareholders that crossed the $2,000 ownership threshold for more than one year but less than three years (and do not satisfy the $15,000/two-year or $25,000/one-year thresholds) will need to postpone submitting a shareholder proposal until they have satisfied the requisite three-year holding requirement (or the alternative eligibility thresholds). We do not consider this increase in the holding period to be an undue burden on the ability to participate in the shareholder-proposal process, especially in light of the significant costs for other shareholders and the company involved in this method of shareholder engagement.[79]

We also note that, while these shareholder-proponents will be unable to require a company to include a proposal in its proxy statement until the shareholder has held the securities for the requisite three-year period, they will not be precluded from raising matters that are important to them through alternative avenues of engagement. Today's investors are able to engage with companies and other investors in a variety of ways, including via email, video conference calls, one-on-one ''sunny day'' meetings, shareholder surveys, and e-forums.[80] Although we recognize these alternative channels are different than a shareholder proposal, we understand that companies today are more responsive to shareholder requests to engage through alternative channels than when our rules were last amended.[81] Moreover, raising these issues through one-on-one engagement with management may produce better outcomes than submitting shareholder proposals.[82] In addition, we note that shareholders engage directly with each other through various channels, and, accordingly, an issue that is sufficiently important to the broader shareholder base could be brought to the company's attention by other shareholders, including those that are eligible to submit a shareholder proposal. We also note that the proxy rules allow shareholders, including those that have held shares for less than one year, to conduct their own proxy solicitations in accordance with those rules.

For the reasons discussed above, we believe that the amended thresholds appropriately capture the various interests that should be considered when calibrating the eligibility of shareholder-proponents to access a company's proxy statement at little or no cost to the shareholder-proponent. As such, we are not incorporating the suggestions of certain commenters, such as adjusting the thresholds to $5,000, $10,000, or $15,000;[83] eliminating a minimum dollar investment for shareholders meeting a three-year holding period;[84] establishing thresholds that are contingent on the size of an investor's total investment portfolio;[85] or subjecting the thresholds to future inflation adjustments.[86] Although we recognize that a minimum amount of stock owned is not the only way to demonstrate a current and continued investment interest in a company, we do not believe that eliminating a minimum dollar investment for shareholders meeting a three-year holding period would be consistent with the concept of demonstrating a meaningful economic stake or investment interest in a company prior to submitting a shareholder proposal. In addition, although we appreciate that the thresholds will represent different proportional investments relative to each shareholder's total investment portfolio—*e.g.,* they will represent a larger proportional investment where portfolio size is smaller and vice versa—we believe thresholds that vary based on the size of an investor's total investment

[76] *Id.*

[77] *See, e.g.,* letters from Christian Brothers Investment Services, Inc. dated January 21, 2020; Council of Institutional Investors et al. dated July 29, 2020; Senator Tammy Duckworth dated January 30, 2020; Form Letter Type A; Illinois State Treasurer dated January 16, 2020; James McRitchie dated July 21, 2020.

[78] *Cf.* letter from Fidelity Management & Research LLC dated February 3, 2020 (noting that the commenter ''reviewed all shareholder proposals received by and voted on by Fidelity mutual funds for the past six years and found that the vast majority of these proposals would still have satisfied the eligibility criteria under the new tiered submission thresholds'').

[79] *See infra* Section V.D.

[80] *See* Matteo Tonello & Matteo Gatti, *Board-Shareholder Engagement Practices,* Harvard L. Sch. F. on Corp. Governance (Dec. 30, 2019), *available at https://corpgov.law.harvard.edu/2019/12/30/board-shareholder-engagement-practices/;* Cleary Gottlieb Steen & Hamilton LLP, *Shareholder Engagement Trends and Considerations* (Jan. 10, 2020), *available at https://www.clearygottlieb.com/news-and-insights/publication-listing/shareholder-engagement-trends-and-considerations;* Donna Fuscaldo, *Say Gives Retail Investors A Voice And Tesla Listens,* FORBES (Feb. 19, 2019), *https://www.forbes.com/sites/donnafuscaldo/2019/02/19/say-gives-retail-investors-a-voice-and-tesla-listens/. See also* letter from Business Roundtable dated February 3, 2020.

[81] *See, e.g.,* letter from Business Roundtable dated February 3, 2020.

[82] *See* T.Rowe Price, *Sustainable Investing* (April 2020), *available at https://www.troweprice.com/content/dam/trowecorp/Pdfs/ESG_2019_AnnualReport-Global_30_April_2020_Final.pdf* (''Our experience after many years of assessing ESG issues as part of our investment process is that direct, one-on-one engagement with companies produces better outcomes than shareholder resolutions.'').

[83] *See* letter from Van Brenner dated November 21, 2019.

[84] *See* letter from Josh Feldblyum dated November 30, 2019.

[85] *See* letter from John Taylor dated November 14, 2019.

[86] *See* letters from Business Roundtable dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; FedEx Corporation dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020; Society for Corporate Governance dated February 3, 2020.

portfolio would be difficult to administer. For example, such a requirement could necessitate a shareholder's submission and a company's verification of voluminous amounts of documentation for the purpose of demonstrating and ascertaining the size of the shareholder's total investment portfolio in order to ascertain the applicable ownership threshold. Thus, we are not adopting thresholds that vary based on the size of a proponent's total investment portfolio. We also are not adopting a provision that would require periodic future inflation adjustments. We believe that such a mechanism is unnecessary at this time in light of the tiered approach being adopted.

Although some commenters raised concerns about the effects the new thresholds could have on portfolio diversification, they did not provide data about costs or the likelihood of occurrence. They also did not provide data addressing the percentage of smaller investors that maintain a diversified portfolio or the diversification of holdings of the relatively smaller subset of such investors that submit shareholder proposals. While we acknowledge that, in theory, some shareholders may not be able to satisfy the three-year ownership requirement without affecting portfolio diversification decisions to some degree, we believe the appropriate allocation of capital, taking into account various factors, including portfolio diversification and the importance of submitting a proposal for inclusion in a company's proxy statement, is something for the investor to determine. We also note that the three different ownership thresholds in the final rules will afford shareholders some flexibility in determining how to allocate capital while considering whether qualifying to submit a proposal in a shorter timeframe is in the shareholder-proponent's interest. In those situations where a shareholder decides not to alter portfolio diversification, we note that an issue that is sufficiently important to the broader shareholder base may be brought to the company's attention by other shareholders, including those that are eligible to submit a shareholder proposal.

ii. Percentage Test

As proposed, the amended rule will not include a component based on a percentage of shares owned. We believe that each of the revised thresholds represents a meaningful economic stake or investment interest such that a separate percentage-based threshold is unnecessary. We also believe that shareholders would be unlikely to rely on such a threshold in light of the new thresholds and that the amendment will avoid administrative complexities that could result from a percentage-based test. We also note that commenters who addressed it generally supported eliminating the current percentage ownership test.[87] Accordingly, we are not adopting a percentage-based component.

iii. Aggregation

As proposed, aggregation of holdings for purposes of meeting the ownership requirements will not be permitted. Instead, each shareholder must satisfy one of the three ownership thresholds to be eligible to submit or co-file a proposal.[88] Although the Commission allowed shareholders to aggregate their holdings when it first adopted ownership thresholds in 1983, it did not provide reasons for doing so. Consistent with the views of several commenters, we believe that allowing shareholders to aggregate their securities to meet the new thresholds would undermine the goal of ensuring that each shareholder who wishes to use a company's proxy statement to advance a proposal has a sufficient economic stake or investment interest in the company.[89] We recognize this limitation could affect the ability of shareholders with smaller investments to submit shareholder proposals, but as explained above, we believe each shareholder-proponent should have a meaningful ownership stake in a company before being permitted to draw on company resources to include a proposal in the company's proxy statement as well as draw on the time, attention, and other resources of non-proponent shareholders.[90]

Moreover, we do not agree with the commenter who suggested that a group of shareholders that collectively, but not individually, satisfies an ownership requirement is functionally the same as a single shareholder that satisfies the requirement.[91] Although the total dollar amount may be the same under either scenario, we do not believe that group ownership (where each member of the group does not individually satisfy one of the ownership requirements) represents an equivalent economic stake or investment interest as a single shareholder who satisfies the ownership requirements. Accordingly, we do not believe a group comprising shareholders, where each member of the group does not individually satisfy one of the ownership requirements, will have demonstrated a sufficient ownership interest to be eligible to submit a proposal. For similar reasons, we do not agree with commenters who suggested that aggregated holdings are indicative of a long-term investment interest,[92] or that a proposal submitted by a group of shareholders aggregating their holdings is ''more worthy of consideration'' than a proposal submitted by a single shareholder.[93] In our view, the more relevant consideration for these purposes is not the number of shareholder-proponents, but rather, whether each such proponent has a meaningful economic stake in the company. Accordingly, aggregation will not be permitted under the final amendments.[94]

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[87] *See* letters from CFA Institute dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Manhattan Institute for Policy Research dated February 3, 2020; James McRitchie dated February 2, 2020; National Association of Manufacturers dated February 3, 2020; John Taylor dated November 14, 2019.

[88] Shareholders whose shares are held in joint tenancy may submit proposals individually or jointly. However, the one-proposal limit will apply collectively to all persons having an interest in the same shares. *See* Adoption of Amendments Relating to Proposals by Security Holders, Release No. 34–12999 (Nov. 22, 1976) [41 FR 52994 (Dec. 3, 1976)] (''1976 Adopting Release'').

[89] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Exxon Mobil Corporation dated February 3, 2020; International Bancshares Corporation dated January 23, 2020; Manhattan Institute for Policy Research dated February 3, 2020; National Association of Manufacturers dated February 3, 2020.

[90] In articulating the need for an ownership requirement in prior releases, the Commission has explained that shareholders who submit proposals should have a specified ''economic stake'' or ''investment interest'' in the company. *See* 1983 Adopting Release, *supra* note 2. *See also* Amendments to Rules on Shareholder Proposals, Release No. 34–39093 (Sep. 18, 1997) [62 FR 50682 (Sep. 26, 1997)] (noting that ''[o]ne purpose of the requirement is to curtail abuse of the rule by requiring that those who put the company and other shareholders to the expense of including a proposal in proxy materials have had a continuous investment interest in the company.''). In parts of this release, we use ''ownership stake'' in lieu of ''economic stake'' because we believe an ownership stake represents a type of economic stake.

[91] *See* letter from Tom Shaffner dated December 17, 2019.

[92] *See* letter from First Affirmative Financial Network, LLC dated January 24, 2020.

[93] *See* letter from Tom Shaffner dated December 17, 2019.

[94] We do not agree with the commenter who suggested that the amendment is premature and that we should first study the effects of the new ownership thresholds. *See* letter from Professor James D. Cox et al. dated February 2, 2020. As stated above, we do not believe that group ownership (where the group comprises shareholders none of whom individually meets one of the ownership requirements) represents a sufficient economic or investment interest to require inclusion of a proposal in a company's proxy statement. This view applies regardless of how frequently shareholders might elect to aggregate and, therefore, we do not believe it is necessary to first study the effects of the new ownership thresholds prior to adopting the amendment. We also do not agree with this and

iv. Lead-Filer Designation

Although shareholders will not be able to aggregate their holdings under the amendment, they will continue to be permitted to co-file proposals as a group if each shareholder-proponent in the group meets an eligibility requirement.[95] However, we are not adopting rules requiring co-filers to identify a lead filer or specify whether the lead filer is authorized to negotiate a withdrawal on behalf of the co-filers. As several commenters observed, such a requirement does not appear necessary at this time as co-filers already tend to designate a lead filer.[96] Nevertheless, we continue to believe that, as a best practice, co-filers should clearly state in their initial submittal letter to the company that they are co-filing the proposal with other proponents and identify the lead filer, specifying whether such lead filer is authorized to negotiate with the company and withdraw the proposal on behalf of the other co-filers.[97]

B. Proposals Submitted on Behalf of Shareholders

1. Proposed Rule Amendment

We proposed to add a new eligibility requirement to Rule 14a–8 that would require shareholders that use a representative to submit a proposal for inclusion in a company's proxy statement to provide documentation that:

- Identifies the company to which the proposal is directed;
- Identifies the annual or special meeting for which the proposal is submitted;
- Identifies the shareholder-proponent and the designated representative;
- Includes the shareholder's statement authorizing the designated representative to submit the proposal and/or otherwise act on the shareholder's behalf;
- Identifies the specific proposal to be submitted;
- Includes the shareholder's statement supporting the proposal; and
- Is signed and dated by the shareholder.

2. Comments on the Proposed Rule Amendment

The proposed amendment generated a wide range of responses. Some commenters expressed the view that the proposed requirements were appropriate,[98] while others opposed them.[99] Several commenters stated that the proposed representations would help clarify the relationship between the shareholder-proponent and the representative with minimal burden to shareholders.[100] Other commenters recommended adding additional informational requirements regarding a shareholder-proponent's motives for submitting a proposal.[101] One of these commenters suggested revisions to the rule text that would require: (i) The proposal text to be embedded in the authorization letter, (ii) the shareholder-proponent to sign the authorization letter no later than the date the proposal is submitted, and (iii) the authorization letter to specify that the representative is authorized to revise the proposal and/or supporting statement.[102] Several commenters stated that representatives should not be permitted to submit proposals on behalf of shareholders, although two of these commenters seemed supportive of the proposed requirements in the absence of such a prohibition.[103]

Of commenters that were opposed to the proposed amendment, several expressed the view that the proposed informational requirements could interfere with the principles of agency under state law and/or a representative's ability to carry out its fiduciary duties.[104] For example, some commenters expressed concern that the proposed amendment would intrude on the agency relationship by requiring the shareholder-proponent to pre-authorize the form and content of a shareholder proposal prior to its submission,[105] or by requiring written authorization that

another commenter's suggestion that the amendment is at odds with other aspects of corporate and/or securities laws under which aggregation of holdings is permitted or required. We note that the primary examples cited by the commenter were the subject of a 5% ownership requirement, whereas the ownership requirements under the amended thresholds are considerably lower—*i.e.,* $2,000, $15,000, and $25,000. In light of the relatively low ownership requirements under the amendment, we do not believe the ability to aggregate is necessary or appropriate. As previously stated, aggregate holdings at these ownership levels would not represent a sufficient economic or investment interest and could undermine the purpose of the ownership requirement. In addition, we do not agree with the commenter's suggestion that the amendment is inconsistent with the beneficial ownership provisions under the federal securities laws, which, among other things, require any ''group'' of beneficial holders owning more than five percent of a security registered under Section 12 of the Exchange Act to file a Schedule 13D or Schedule 13G. We note that the objectives of the beneficial ownership reporting requirements fundamentally differ from those of the shareholder-proposal rule.

[95] Under Section 13(d) and Section 13(g), a ''group'' is formed when two or more persons act together for the purpose of acquiring, holding, voting, or disposing of the securities. Congress created the ''group'' concept to prevent persons who seek to pool their voting or other interests in the securities of an issuer from evading the Section 13(d) or 13(g) obligations because no one person owns more than five percent of the securities. To the extent co-filers are acting together (or in concert with others) for the purpose of voting in favor of their proposals they should consider whether such activity constitutes a ''group'' for purposes of Section 13(d) and Section 13(g).

[96] *See* letters from Local Authority Pension Fund Forum dated February 3, 2020; New York State Comptroller dated February 3, 2020.

[97] We remind co-filers that ambiguities in the nature of coordination on a proposal's submission could prompt companies to seek exclusion under Rule 14a–8(i)(11). Specifically, if two or more shareholder-proponents submit substantially duplicative proposals but fail to clearly indicate that they intend to co-file or co-sponsor the proposal, the later-received proposal may be susceptible to exclusion under Rule 14a–8(i)(11).

[98] *See* letters from British Columbia Investment Management Corporation dated February 3, 2020; Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; CFA Institute dated February 3, 2020; Corporate Governance Coalition for Investor Value dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; General Motors Company dated February 25, 2020; Nareit dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020; National Association of Manufacturers dated February 3, 2020; School Sisters of Notre Dame Cooperative Investment Fund received January 24, 2020; Tom Shaffner dated December 17, 2019; Sisters of the Order of St. Dominic dated January 24, 2020; Southwestern Energy Company dated February 3, 2020.

[99] *See* letters from AFL–CIO dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; CalPERS dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Figure 8 Investment Strategies dated January 31, 2020; Illinois State Treasurer dated January 16, 2020; International Brotherhood of Teamsters dated February 3, 2020; Local Authority Pension Fund Forum dated February 3, 2020; James McRitchie dated February 2, 2020; Paul M. Neuhauser dated February 3, 2020; New York City Comptroller dated February 3, 2020; North Berkeley Wealth Management dated January 31, 2020; Shareholder Rights Group dated March 18, 2020; State Board of Administration of Florida dated February 3, 2020; John Taylor dated November 14, 2019; Trillium Asset Management dated February 3, 2020; Worker Owner Council of the Northwest dated February 3, 2020.

[100] *See* letters from Business Roundtable dated February 3, 2020; CFA Institute dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020.

[101] *See* letters from Center for Capital Markets Competitiveness dated January 31, 2020; Corporate Governance Coalition for Investor Value dated February 3, 2020; Nareit dated February 3, 2020; Southwestern Energy Company dated February 3, 2020.

[102] *See* letter from Southwestern Energy Company dated February 3, 2020.

[103] *See* letters from CT Hagberg LLC dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020.

[104] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; As You Sow dated February 3, 2020; CalPERS dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Figure 8 Investment Strategies dated January 31, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Brotherhood of Teamsters dated February 3, 2020; Worker Owner Council of the Northwest dated February 3, 2020.

[105] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; Shareholder Rights Group dated March 18, 2020.

is not required under state law.[106] Some commenters also stated that an amendment requiring this information is unnecessary because the information is often already provided.[107] Commenters also raised concerns about the effects the proposed requirements could have on entities, such as asset managers, that must act through agents.[108]

In response to a request for comment, two commenters stated that a representative's ability to deliver evidence of the shareholder-proponent's ownership sufficiently demonstrates the representative's authority to submit a proposal on a shareholder's behalf,[109] while two others stated that it does not sufficiently demonstrate such authorization.[110]

3. Final Rule Amendment

We are adopting the amendment as proposed, but with a modification in response to commenters that clarifies that the shareholder-proponent must identify the specific topic of the proposal, rather than the specific language of the proposal, to be submitted. The rule will require shareholders that use a representative to submit a proposal for inclusion in a company's proxy statement to provide documentation that:

- Identifies the company to which the proposal is directed;
- Identifies the annual or special meeting for which the proposal is submitted;
- Identifies the shareholder submitting the proposal and the shareholder's designated representative;
- Includes the shareholder's statement authorizing the designated representative to submit the proposal and otherwise act on the shareholder's behalf;
- Identifies the specific topic of the proposal to be submitted;
- Includes the shareholder's statement supporting the proposal; and
- Is signed and dated by the shareholder.

As discussed in the Proposing Release, companies receive proposals under Rule 14a–8 from individuals and entities that may not qualify to submit proposals at a particular company in their own name, but arrange to serve as a representative to submit a proposal on behalf of individuals or entities that have held a sufficient number of shares for the requisite amount of time.[111]

We also understand that shareholders may wish to use a representative for a number of reasons, including to obtain assistance from someone who has more experience with the shareholder-proposal process or as a matter of administrative convenience. Often, the shareholder has an established relationship with the representative (*e.g.,* the shareholder has previously used the representative to submit proposals on his or her behalf, or the representative serves as the shareholder's investment adviser). In practice, the representative typically submits the proposal to the company on the shareholder's behalf along with necessary documentation, including evidence of ownership (typically in the form of a broker letter) and the shareholder's written authorization for the representative to submit the proposal and act on the shareholder's behalf. After the initial submission, the representative often speaks for and acts on the shareholder's behalf in connection with the matter. When a representative speaks and acts for a shareholder, there may be a question as to whether the shareholder has a genuine and meaningful interest in the proposal, or whether the proposal is instead primarily of interest to the representative, with only an acquiescent interest by the shareholder.[112]

We believe that these amendments will help safeguard the integrity of the shareholder-proposal process and the eligibility restrictions by making clear that representatives are authorized to so act, and by providing a meaningful degree of assurance as to the shareholder-proponent's identity, role, and interest in a proposal that is submitted for inclusion in a company's proxy statement. We also believe that these requirements will reduce some of the administrative burdens associated with confirming a shareholder's role in the shareholder-proposal process and that the burden on shareholder-proponents of providing this information will be minimal; in fact, we note that much of it is often already provided.

Although much of this information is already provided in accordance with staff guidance,[113] we do not agree with commenters who suggested that current practices obviate the need for an amendment.[114] We believe that an amendment will promote consistency among shareholder-proponents and provide greater clarity to those seeking to rely on the rule. In addition, we believe it is important that the documentation include the shareholder's statement authorizing the designated representative to submit the proposal and otherwise act on the shareholder's behalf, as well as the shareholder's statement supporting the proposal, neither of which is addressed in staff guidance. At this time, however, we do not believe that any of the additional informational requirements suggested by commenters are necessary to demonstrate a shareholder-proponent's identity, role, and interest in a proposal and, accordingly, we are not adding any additional requirements.

We do not expect these requirements will interfere with a shareholder-proponent's ability to use an agent, or prevent representatives who act as fiduciaries from carrying out their fiduciary duties. Although shareholder-proponents who elect to submit a proposal through a representative will be required to provide additional information about their submissions, the rule will not prevent them from using representatives in accordance with state law. Moreover, the rule's requirement to disclose this information is only a condition on the ability of a shareholder-proponent, under federal law, to submit a proposal for inclusion in a company's proxy statement. The rule does not substantively alter the agency relationship between a shareholder and a representative. Thus, we do not agree with the commenter who stated that the proposed amendment ''interferes with state agency law by requiring that shareholders provide express and specific authorization of the designated representative to submit a shareholder proposal.'' [115] Furthermore, in response to commenters who suggested that the amendment would intrude on a shareholder-proponent's ability to use an agent by requiring the shareholder-

[106] *See, e.g.,* letter from AFL–CIO dated February 3, 2020.

[107] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; CalPERS dated February 3, 2020; James McRitchie dated February 2, 2020.

[108] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; International Brotherhood of Teamsters dated February 3, 2020; International Corporate Governance Network dated December 4, 2019; Paul M. Neuhauser dated February 3, 2020; New York City Comptroller dated February 3, 2020.

[109] *See* letters from Council of Institutional Investors dated January 30, 2020; James McRitchie dated February 2, 2020.

[110] *See* letters from Exxon Mobil Corporation dated February 3, 2020; Southwestern Energy Company dated February 3, 2020.

[111] *See* Proposing Release at 66465–66466.

[112] *See, e.g.,* Baker Hughes Inc., SEC No-Action Letter 2016 WL 722853 (Feb. 22, 2016) (investment adviser failed to provide documentation sufficient to ascertain the shareholder's identity, role, or interest in the proposal); Chevron Corp., SEC No-Action Letter 2014 WL 262988 (Apr. 4, 2014) (same).

[113] *See* Staff Legal Bulletin No. 14I (Nov. 1, 2017).

[114] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; CalPERS dated February 3, 2020; James McRitchie dated February 2, 2020.

[115] *See* letter from AFL–CIO dated February 3, 2020.

proponent to pre-authorize the form and content of a shareholder proposal prior to its submission,[116] we have revised the rule text to state that the shareholder-proponent must identify the specific topic (as opposed to the text) of the proposal to be submitted. Likewise, we do not believe that the rule will interfere with a representative's ability to act as a fiduciary or satisfy any applicable fiduciary obligations. Rather, the rule is intended to help shareholders and companies more clearly understand the nature and scope of the relationship between a shareholder-proponent and his or her representative.

In addition, we agree with those commenters who expressed the view that a representative's ability to obtain a broker letter from the shareholder's broker does not offer a sufficient degree of assurance as to the shareholder-proponent's identity, role, and interest in a proposal.[117] Although the ability to obtain a broker letter will generally require the shareholder's authorization, the scope of such authorization may not be evident. In this situation, it may be unclear whether a shareholder is aware of or has authorized the submission of the specific proposal to a particular company. The new requirements will provide a greater degree of certainty with respect to these issues with minimal burden on the shareholder-proponent.

Furthermore, we are clarifying in response to commenters [118] that, where a shareholder-proponent is an entity, and thus can act only through an agent, compliance with the amendment will not be necessary if the agent's authority to act is apparent and self-evident such that a reasonable person would understand that the agent has authority to act. For example, compliance generally would not be necessary where a corporation's CEO submits a proposal on behalf of the corporation, where an elected or appointed official who is the custodian of state or local trust funds submits a proposal on behalf of one or more such funds, where a partnership's general partner submits a proposal on behalf of the partnership, or where an adviser to an investment company submits a proposal on behalf of an investment company. On the other hand, compliance would be required where the agency relationship is not apparent and self-evident. For example, compliance would be required where an investment adviser submits a proposal on behalf of a client that is a shareholder. A private relationship between a third-party investment adviser and the adviser's client would not be apparent or self-evident because these private relationships are generally governed by private contractual arrangements where the scope of the principal-agent relationship does not as a matter of course extend to representation with respect to the submission of proposals. Additionally, there are inherent difficulties in ascertaining the scope of such a relationship, as investment advisers can provide a wide range of services to their clients,[119] which may or may not include shareholder advocacy on the client's behalf.[120]

C. The Role of the Shareholder-Proposal Process in Shareholder Engagement

1. Proposed Rule Amendment

We proposed to amend Rule 14a–8(b) to add a shareholder engagement component to the current eligibility criteria, which would require a statement from each shareholder-proponent that he or she is able to meet with the company in person or via teleconference no less than 10 calendar days, nor more than 30 calendar days, after submission of the shareholder proposal. Under the proposal, shareholders would also be required to include their contact information as well as business days and specific times that they are available to discuss the proposal with the company.

2. Comments on the Proposed Rule Amendment

We received numerous comments on the proposed amendment regarding a shareholder-proponent's statement of ability to engage with the company. Some commenters supported the proposed amendment,[121] while others opposed such a requirement.[122] Of those that opposed the proposed amendment, several expressed the view that such a requirement would not make companies more likely to engage with shareholders.[123] Some commenters also questioned the basis for and appropriateness of the 10 to 30 calendar-day window,[124] or suggested that requiring a statement of availability would impose a burden on shareholders.[125]

Several commenters raised questions about certain technical aspects of the proposal, such as whether the times specified for engagement should be during the company's normal business hours,[126] and when the 10 to 30

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[116] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; Shareholder Rights Group dated March 18, 2020.

[117] *See* letters from Exxon Mobil Corporation dated February 3, 2020; Southwestern Energy Company dated February 3, 2020.

[118] *See* letters from AFL–CIO dated February 3, 2020; International Brotherhood of Teamsters dated February 3, 2020; International Corporate Governance Network dated December 4, 2019; Paul M. Neuhauser dated February 3, 2020; New York City Comptroller dated February 3, 2020.

[119] *See* Regulation Best Interest: The Broker-Dealer Standard of Conduct, Release No. 34–86031 (June 5, 2019) [84 FR 33318 (July 12, 2019)], at 33319.

[120] An investment adviser may advise multiple clients who submit their own shareholder proposals, as long as the adviser complies with the one-proposal limitation. *See infra* Section II.D.3.

[121] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; CFA Institute dated February 3, 2020; Church Investor Group dated January 29, 2020; Energy Infrastructure Council dated February 3, 2020; International Corporate Governance Network dated December 4, 2019; Nareit dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020; National Association of Manufacturers dated February 3, 2020; Pension Investment Association of Canada dated January 23, 2020; Robeco dated January 16, 2020; Society for Corporate Governance dated February 3, 2020.

[122] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; As You Sow dated February 3, 2020; Boston Common Asset Management dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; CalPERS dated February 3, 2020; Ceres et al. dated February 3, 2020; John Chevedden dated January 30, 2020; Christian Brothers Investment Services, Inc. dated January 21, 2020; Council of Institutional Investors dated January 30, 2002; Figure 8 Investment Strategies dated January 31, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Harrington Investments, Inc. dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Brotherhood of Teamsters dated February 3, 2020; Local Authority Pension Fund Forum dated February 3, 2020; Maryknoll Sisters of St. Dominic, Inc. dated January 17, 2020; Paul M. Neuhauser dated February 3, 2020; New York City Comptroller dated February 3, 2020; New York State Comptroller dated February 3, 2020; Nia Impact Capital dated February 2, 2020; NorthStar Asset Management, Inc. dated February 3, 2020; Pension Investment Association of Canada dated January 23, 2020; Paul Rissman dated January 15, 2020; Rockefeller Asset Management dated January 31, 2020; Segal Marco Advisors dated February 3, 2020; Shareholder Rights Group dated February 3, 2020; Singing Field Foundation dated January 31, 2020; State Board of Administration of Florida dated February 3, 2020; John Taylor dated November 14, 2019; Trillium Asset Management dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020; Worker Owner Council of the Northwest dated February 3, 2020.

[123] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Local Authority Pension Fund Forum dated February 3, 2020; New York State Comptroller dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[124] *See, e.g.,* letters from As You Sow dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020.

[125] *See, e.g.,* letters from Boston Trust Walden et al. dated January 27, 2020; John Chevedden dated January 30, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[126] *See* letters from Center for Capital Markets Competitiveness dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Society for Corporate Governance dated February 3, 2020.

calendar-day period starts to run where co-filers submit their proposals on different dates.[127] One commenter stated that shareholder-proponents should be available to discuss the proposal, but encouraged the Commission to provide clarity as to whether the shareholder-proponent must identify a minimum number of dates and/or times that the proponent would be available to discuss the proposal, or whether the dates and/or times offered must be convenient to the company.[128] This commenter also suggested that a lack of clarity on these points could result in unnecessary no-action requests.[129]

A number of commenters stated that companies also should be required to be available to engage with the shareholder-proponent and/or to state that they attempted to engage with the proponent prior to submitting a no-action request.[130] Two commenters that were supportive of an engagement-related mechanism suggested that, instead of stating their availability to engage, shareholder-proponents should include a statement with their submission as to whether they attempted to engage with the company prior to submitting the proposal.[131] Another commenter indicated that a statement of general availability would be preferable.[132] Other commenters expressed the view that shareholder-proponents should be required to make a good-faith effort to meet with a company after stating their availability to engage,[133] or that there should be a penalty for failing to engage.[134] Another commenter suggested that where the shareholder-proponent is different from the lead filer, the lead filer should be required to participate in the engagement.[135]

A number of commenters expressed concern about the requirement that the contact information and availability be the shareholder-proponent's, and not that of the shareholder's representative (if the shareholder uses a representative).[136] Some of these commenters suggested that this requirement would disadvantage shareholder-proponents who require a representative's assistance in utilizing and/or navigating the shareholder-proposal process.[137] Other commenters suggested that this requirement could have a chilling effect on shareholder-proposal submissions because shareholder-proponents may not feel comfortable engaging with companies themselves.[138] One commenter also expressed concern about a shareholder's private telephone number or email address being made public through the no-action process.[139] Another commenter indicated that the proposed amendment could indirectly raise costs on shareholders.[140]

3. Final Rule Amendment

We are adopting the amendment largely as proposed, but with some modifications in response to comments received. We believe that encouraging company-shareholder engagement through this new requirement will be beneficial both to shareholders and to companies. As we explained in the Proposing Release, while Rule 14a–8 provides a means for shareholder-proponents to advance proposals and solicit proxies from other shareholders, the rule is only one of many mechanisms for shareholders to engage with companies and their fellow shareholders and to advocate for the measures they propose. While other forms of engagement may sometimes accomplish a shareholder's interest in communicating with a company and its other shareholders without the burdens associated with including a proposal in a company's proxy statement, we understand that shareholder proposals are at times used as the sole method of engaging with companies even if the company is willing to discuss, and possibly resolve, the matter with the shareholder.[141] In those cases, Rule 14a–8 may result in a shareholder burdening other shareholders and the company with a proxy vote that may have been avoided had meaningful prior engagement taken place.[142] We believe that having shareholder-proponents state their availability to discuss their proposal will facilitate dialogue between shareholders and companies in

[127] *See* letter from Council of Institutional Investors dated January 30, 2020.

[128] *See* letter from International Corporate Governance Network dated December 4, 2019. Another commenter also sought clarification on the ramifications of a shareholder being unable to meet on one of the dates the shareholder identifies. *See* letter from Boston Trust Walden et al. dated January 27, 2020.

[129] *See* letter from International Corporate Governance Network dated December 4, 2019.

[130] *See* letters from AFL–CIO dated February 3, 2020; CalPERS dated February 3, 2020; Ceres et al. dated February 3, 2020; Church Investor Group dated January 29, 2020; Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Illinois State Treasurer dated January 16, 2020; International Brotherhood of Teamsters dated February 3, 2020; International Corporate Governance Network dated December 4, 2019; Local Authority Pension Fund Forum dated February 3, 2020; Loring, Wolcott & Coolidge dated January 31, 2020; James McRitchie dated February 2, 2020; Mercy Investment Services dated January 31, 2020; New York City Comptroller dated February 3, 2020; NorthStar Asset Management, Inc. dated February 3, 2020; Pension Investment Association of Canada dated January 23, 2020; Tom Shaffner dated December 17, 2019; Shareholder Rights Group dated February 3, 2020; State Board of Administration of Florida dated February 3, 2020; Trillium Asset Management dated February 3, 2020; US SIF dated January 31, 2020; Worker Owner Council of the Northwest dated February 3, 2020.

[131] *See* letters from Baillie Gifford & Co. dated February 3, 2020; Stewart Investors dated January 30, 2020.

[132] *See* letter from James McRitchie dated February 2, 2020.

[133] *See* letter from National Association of Manufacturers dated February 2, 2020.

[134] *See* letters from Center for Capital Markets Competitiveness dated January 31, 2020; Nasdaq, Inc. dated February 3, 2020.

[135] *See* letter from Society for Corporate Governance dated February 3, 2020.

[136] *See* letters from Emily Aldridge dated January 31, 2020; Jennifer Astone dated January 17, 2020; Kate Barron-Alicante dated January 31, 2020; Jane Bulnes-Fowles dated February 3, 2020; Brian Canning January 31, 2020; Harvey Christensen dated January 28, 2020; Christian Brothers Investment Services, Inc. dated January 21, 2020; Clean Yield Asset Management dated February 3, 2020; Sara Culotta dated February 3, 2020; Daughters of Charity of St. Vincent de Paul dated January 30, 2020; John Eing dated January 31, 2020; Nancy Faris dated January 27, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Global Affairs Associates, LLC dated February 3, 2020; Gorge Sustainable Investing dated December 27, 2019; Green America et al. dated January 29, 2020; Patricia Hathaway dated January 31, 2020; Andrew Howard dated December 14, 2019; Neela Hummel dated January 31, 2020; Andrew Ish dated February 2, 2020; Brent Kessel dated January 31, 2020; Laird Norton Family Foundation dated January 28, 2020; Lynnea C. Lane dated February 3, 2020; James McRitchie dated February 2, 2020; Margaret Miars dated December 13, 2019; Thomas Miars dated December 13, 2019; Anne Miller dated January 23, 2020; Laura Morganelli dated January 31, 2020; Oneida Trust Enrollment Committee dated February 3, 2020; Pension Investment Association of Canada dated January 23, 2020; Rhia Ventures dated January 31, 2020; Cheryl Ritenbaugh dated January 17, 2020; Rockefeller Asset Management dated January 31, 2020; The Arntz Family Foundation dated January 14, 2020; The Pension Board—United Church of Christ, Inc. dated January 29, 2020; Upcyclers Network dated January 17, 2020; US SIF dated January 31, 2020; Luci Walker dated December 9, 2019; Barbara J. Wolf dated January 31, 2020; Ann W. Woll dated January 18, 2020.

[137] *See, e.g.,* letters from Boston Trust Walden et al. dated January 27, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Singing Field Foundation dated January 31, 2020.

[138] *See, e.g.,* letters from As You Sow dated February 3, 2020; Paul Rissman dated January 15, 2020.

[139] *See* letter from James McRitchie dated February 2, 2020.

[140] *See* Recommendation of the IAC, *supra* note 18.

[141] We recognize that some shareholder-proponents use a shareholder proposal as a way to open a dialogue with management and not with the objective of having the matter go to a vote. *See* Transcript of the Roundtable on the Proxy Process (Nov. 15, 2018) (''Roundtable Transcript''), *available at https://www.sec.gov/files/proxy-round-table-transcript-111518.pdf,* comments of Michael Garland, Assistant Comptroller, Corporate Governance and Responsible Investment, Office of the Comptroller, New York City.

[142] We acknowledge that engagement outside the shareholder-proposal process can also result in burdens on companies, but our rules do not mandate that such activity occur.

the shareholder-proposal process, and may lead to more efficient and less costly resolution of these matters. Company-shareholder engagement can thus be an efficient alternative to the shareholder-proposal process. We understand that proactive company engagement with shareholders has increased in recent years,[143] and that shareholders frequently do not submit, or ultimately withdraw, their proposals as a result of company-shareholder engagement.[144]

Under the amendment, shareholder-proponents will be required to provide the company with a written statement that they are able to meet with the company in person or via teleconference at specified dates and times that are no less than 10 calendar days, nor more than 30 calendar days, after submission of the proposal.[145] For example, for a proposal submitted on October 1, the shareholder-proponent would be required to identify dates of availability between October 11 and October 31.[146] Although some commenters questioned the basis for this window of availability,[147] we believe that it is appropriate for several reasons. While we recognize the point made by commenters that some companies may choose not to engage until after the deadline for submitting proposals or later,[148] we believe that encouraging engagement shortly after submission can lead to swifter resolution of these matters and obviate the need for a no-action request. In this regard, we note that where a proposal is submitted at or near a company's deadline for receiving proposals, the company will have a relatively short amount of time to prepare and submit a no-action request.[149] Thus, early engagement may help avoid the time and expense of the no-action process. Nevertheless, the amended rule will not permit shareholders to identify availability earlier than 10 days after the proposal's submission, so that the company will have sufficient time to consider the proposal prior to engagement taking place.[150] In addition, shareholders may have a better sense of what their availability will be 10 to 30 days after submitting the proposal compared with longer periods. Moreover, shareholders have some degree of flexibility in choosing when to submit a proposal prior to the submission deadline and therefore can do so when they are more likely to have greater availability.

Shareholder-proponents will also be required to provide their contact information[151] and identify specific business days and times (*i.e.,* more than one date and time) that they are available to discuss the proposal.[152] In response to commenters, we are modifying the final rule to clarify that the times specified should be during the regular business hours of the company's principal executive offices.[153] If these hours are not disclosed in the company's proxy statement,[154] the shareholder-proponent should identify times between 9:00 a.m. and 5:30 p.m. on business days in the time zone of the company's principal executive offices. If a company is not available to engage with the shareholder-proponent on the specific date(s) or time(s) originally identified by the shareholder-proponent, engagement may take place at a different date and/or time, provided that it is acceptable to both the shareholder-proponent and company. If the shareholder-proponent's availability changes, the company should be notified and alternative date(s) and time(s) should be provided to the company.

We do not agree with the commenter who suggested that providing a general statement of the shareholder-proponent's availability would be preferable to identifying specific dates and times.[155] While a general statement of availability could indicate a shareholder-proponent's willingness to engage, the identification of specific dates and times would add certainty as to the shareholder-proponent's availability, and we believe that engagement may be more likely to occur where the company knows the

[143] *See* letters in response to the Proxy Process Roundtable from Business Roundtable dated June 3, 2019; Chevron Corporation dated August 20, 2019; Society for Corporate Governance dated November 9, 2018.

[144] Company-shareholder engagement with respect to shareholder proposals frequently leads to withdrawn proposals. *See, e.g.,* letters in response to the Proxy Process Roundtable from Everence Financial dated December 6, 2018 (''[A]n increasing number of resolutions end up being withdrawn by the proponent because of conversations between [the proponent] and the company.''); Praxis Mutual Funds dated December 6, 2018 (same); Principles for Responsible Investment dated November 14, 2018 (''[A] growing number of shareholder proposals are withdrawn due to corporate management developing workable solutions with investors.''). *See also* Proposing Release at 66478 fig.2.

[145] The contact information and availability will have to be the shareholder's, and not that of the shareholder's representative (if the shareholder uses a representative). The amendment, however, does not preclude a representative from participating in any discussions between the company and the shareholder. The proposal's date of submission is the date the proposal is postmarked or transmitted electronically. In the event the proposal is hand delivered, the submission date would be the date of hand delivery.

[146] Companies that intend to seek exclusion under Rule 14a–8(b) based on a shareholder-proponent's failure to provide some or all of this information must notify the proponent of the specific defect(s) within 14 calendar days of receiving the proposal so that the shareholder-proponent has an opportunity to cure the defect(s), and the shareholder-proponent is required to respond to this notice within 14 days. *See* 17 CFR 240.14a–8(f)(1). Where a company sends a deficiency notice for the purpose of requesting identification of a shareholder-proponent's availability to engage, the shareholder-proponent must identify dates of the shareholder-proponent's availability that are within the remaining 10- to 30-day window. For example, where a proposal is submitted on October 1, the company's deficiency notice is received by the shareholder-proponent on October 15, and the shareholder-proponent responds to the deficiency notice by email on October 20, the shareholder-proponent would be required to identify business days between October 21 and October 31 that the shareholder-proponent is available to discuss the proposal.

[147] *See, e.g.,* letters from As You Sow dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; New York City Comptroller dated February 3, 2020.

[148] *See, e.g.,* letters from Boston Trust Walden et al. dated January 27, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[149] For a regularly-scheduled meeting, the deadline for submitting proposals is ''120 calendar days before the date of the company's proxy statement released to shareholders in connection with the previous year's annual meeting.'' *See* 17 CFR 240.14a–8(e)(2). A company that intends to exclude a proposal ''must file its reasons with the Commission no later than 80 calendar days before it files its definitive proxy statement and form of proxy with the Commission.'' If a proposal is received at or near the 120-day deadline and the company intends to file its definitive proxy statement at or near the anniversary of the prior year's proxy filing date, the company will generally have approximately 40 days from receiving the proposal to notify the Commission of its intention to exclude the proposal.

[150] Although the rule will require shareholder-proponents to identify their availability within the 10- to 30-day window, the parties can arrange to engage on a date that is not within that window.

[151] In response to one commenter's concern regarding the potential for a shareholder's private contact information to be made publicly available through the no-action process, *see* letter from James McRitchie dated February 2, 2020, we note that Commission staff removes personally identifiable information from no-action requests and related correspondence before making these materials publicly available on the Commission's website.

[152] Where shareholders elect to co-file a proposal, all co-filers must either: (1) Agree to the same dates and times of availability or (2) identify a single lead filer who will provide dates and times of the lead filer's availability to engage on behalf of all co-filers.

[153] *See* letters from Center for Capital Markets Competitiveness dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Society for Corporate Governance dated February 3, 2020.

[154] The Commission's proxy rules do not require issuers to disclose this information, but companies may choose to do so to facilitate shareholder engagement with respect to shareholder proposals. If an issuer chooses to disclose this information, we suggest that it appear alongside the deadline for submitting proposals.

[155] *See* letter from James McRitchie dated February 2, 2020.

shareholder-proponent's availability in advance.

The contact information and availability must be the shareholder-proponent's, and not that of the shareholder's representative, if any.[156] We do not agree with commenters who suggested that this requirement will disadvantage shareholder-proponents who require a representative's assistance in navigating the shareholder-proposal process.[157] We believe that a shareholder-proponent who elects to require a company to include a proposal in its proxy statement, requiring the company and other shareholders to bear the related costs, should be willing and available to discuss the proposal with the company and not simply rely on its representative to do so. At least one commenter suggested that shareholders could incur greater costs as a result of the proposed amendment,[158] but we believe any cost will be de minimis given that engagement can take place through inexpensive means, such as teleconference calls.

We also believe that the ability to engage directly with the shareholder-proponent may encourage greater dialogue between the shareholder and the company, and may lead to more efficient and less costly resolution of these matters. As explained in the Proposing Release, however, shareholder-proponents may seek assistance and advice from lawyers, investment advisers, or others to help them draft shareholder proposals and navigate the shareholder-proposal process.[159] The shareholder-proponent's representative also may participate in any discussions between the company and the shareholder.[160] Thus, shareholder-proponents will be able to continue to seek and utilize the assistance of a representative.

Other than providing the clarifications discussed above, we are not making any changes to what we proposed. For example, we are not adopting a requirement suggested by commenters that shareholder-proponents include a statement with their submission as to whether they attempted to engage with the company prior to submitting the proposal.[161] The company will already know whether the shareholder attempted to engage prior to submission and the statement suggested by the commenter would not be available to other shareholders. Thus, there would be minimal value associated with providing such a statement.[162] To the extent engagement takes place prior to a proposal's submission, the new rule will encourage further dialogue between the shareholder-proponent and company after submission. In addition, although some commenters stated that shareholders should be required to make a good-faith effort to meet with a company after stating their availability to engage,[163] or that there should be a penalty for failing to engage,[164] the rule will not impose requirements governing specific engagement activities between the shareholder-proponent and the company.

Under the new rule, companies will not be required to engage with a shareholder-proponent or to state that they attempted to engage with the shareholder-proponent prior to submitting a no-action request, as some commenters suggested.[165] Because companies and their shareholders bear the burdens associated with including a shareholder proposal in their proxy materials, or seeking no-action relief to exclude such proposals, we believe companies are sufficiently incentivized to pursue less costly forms of engagement.

In light of a shareholder-proponent's election to use a company's proxy statement and other resources to solicit proxies for his or her proposal, we believe it is appropriate to require shareholder-proponents to state their availability to discuss the proposal with the company. Although some commenters questioned whether such a requirement would make it more likely that companies would choose to engage with shareholders,[166] we believe that the amendment is likely to eliminate certain frictions in the engagement process, thereby making it easier for companies to contact shareholders and, in turn, increasing the likelihood that engagement will occur.

D. One-Proposal Limit

1. Proposed Rule Amendment

We proposed an amendment to Rule 14a–8(c) to apply the one-proposal rule to ''each person'' rather than ''each shareholder'' who submits a proposal, so that the amended rule would state, ''Each person may submit no more than one proposal, directly or indirectly, to a company for a particular shareholders' meeting. A person may not rely on the securities holdings of another person for the purpose of meeting the eligibility requirements and submitting multiple proposals for a particular shareholders' meeting.'' In the Proposing Release, we explained that under the proposed amendment, a shareholder-proponent would not be permitted to submit one proposal in its own name and simultaneously serve as a representative to submit a different proposal on another shareholder's behalf for consideration at the same meeting. Similarly, we explained that a representative would not be permitted to submit more than one proposal to be considered at the same meeting, even if the representative were to submit each proposal on behalf of different shareholders.

2. Comments on the Proposed Rule Amendment

We received a number of comments on the proposed rule amendment. Commenters that expressed support for the proposed amendment indicated that such an amendment is necessary to

[156] Where a shareholder-proponent is an entity, and thus can act only through an agent, and the agent's authority to act is apparent and self-evident such that a reasonable person would understand that the agent has authority to act on the entity's behalf, the contact information and availability may be that of the agent. *Cf. supra* Section II.B.3.

[157] *See, e.g.,* letters from Boston Trust Walden et al. dated January 27, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Singing Field Foundation dated January 31, 2020.

[158] *See* Recommendation of the IAC, *supra* note 18.

[159] *See* Proposing Release at 66468.

[160] *See supra* note 145.

[161] *See* letters from Baillie Gifford & Co. dated February 3, 2020; Stewart Investors dated January 30, 2020.

[162] One commenter expressed the view that this information ''would allow other shareholders to assess the attitude of the proponent and the company to the issue and to engagement generally.'' *See* letter from Baillie Gifford & Co. dated February 3, 2020. However, it is unclear how other shareholders would learn of this information absent imposing a new disclosure requirement on issuers, which we are not inclined to do at this time.

[163] *See* letter from National Association of Manufacturers dated February 2, 2020.

[164] *See* letters from Center for Capital Markets Competitiveness dated January 31, 2020; Nasdaq, Inc. dated February 3, 2020.

[165] *See* letters from AFL–CIO dated February 3, 2020; CalPERS dated February 3, 2020; Ceres et al. dated February 3, 2020; Church Investor Group dated January 29, 2020; Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Illinois State Treasurer dated January 16, 2020; International Brotherhood of Teamsters dated February 3, 2020; International Corporate Governance Network dated December 4, 2019; Local Authority Pension Fund Forum dated February 3, 2020; Loring, Wolcott & Coolidge dated January 31, 2020; James McRitchie dated February 2, 2020; Mercy Investment Services dated January 31, 2020; New York City Comptroller dated February 3, 2020; NorthStar Asset Management, Inc. dated February 3, 2020; Pension Investment Association of Canada dated January 23, 2020; Tom Shaffner dated December 17, 2019; Shareholder Rights Group dated February 3, 2020; State Board of Administration of Florida dated February 3, 2020; Trillium Asset Management dated February 3, 2020; US SIF dated January 31, 2020; Worker Owner Council of the Northwest dated February 3, 2020.

[166] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Local Authority Pension Fund Forum dated February 3, 2020; New York State Comptroller dated February 3, 2020.

prevent proponents from avoiding the one-proposal limit by submitting proposals on behalf of other shareholders.[167] However, a number of commenters that opposed the proposed amendment stated that it would interfere with a shareholder's ability to use a representative under state law and/or interfere with a representative's ability to effectively represent its clients.[168] For example, some of these commenters stated that the proposed amendment could prevent a shareholder-proponent from using his or her preferred representative if that representative has already submitted a proposal to the same company on behalf of another client,[169] prevent a representative from being able to represent a client in the shareholder-proposal process,[170] raise costs for shareholder-proponents,[171] or affect the competitive advantage of representatives that specialize in active engagement.[172] Another commenter stated that the proposed amendment ''may limit the ability of institutional investors to select the agent of their own choosing to represent them for shareholder engagement purposes.'' [173]

Other commenters sought clarification with respect to the proposed rule's intended operation, or suggested modifications to the proposed amendments. For example, some commenters questioned whether the proposal would affect a representative's ability to present proposals on behalf of multiple shareholder-proponents at the shareholder meeting.[174] One of these commenters also sought clarification on whether the proposed rule's reference to ''person'' means a natural person or encompasses discrete entities made up of or employing multiple natural persons, and whether co-filers of a single proposal would be precluded from using the same representative.[175] Another commenter suggested a modification to the proposed amendment that would require shareholders to certify that a proposal was submitted of their own accord and not at the request or solicitation of a representative that already submitted (or is considering submitting) a proposal to the same company.[176] This commenter stated that ''[s]uch a certification would provide greater assurance that representatives are not actively soliciting multiple proposals and reduce the chances for abuse.'' [177]

3. Final Rule Amendment

We are adopting the amendment as proposed. As the Commission explained when it adopted the one-proposal restriction in 1976, the submission of multiple proposals by a single proponent ''constitute[s] an unreasonable exercise of the right to submit proposals at the expense of other shareholders'' and also may ''tend to obscure other material matters in the proxy statement of issuers, thereby reducing the effectiveness of such documents.'' [178] At the time the one-proposal limitation was adopted, the Commission explained that it was ''aware of the possibility that some proponents may attempt to evade the new limitations through various maneuvers, such as having other persons whose securities they control submit . . . proposals each in their own names.'' [179] To combat this type of abuse, the Commission clarified that the limitation ''will apply collectively to all persons having an interest in the same securities (*e.g.,* the record owner and the beneficial owner, and joint tenants).'' [180]

We continue to believe that this one-proposal limit is appropriate. In our view, the Commission's stated reasoning for the one-proposal limit applies equally to representatives who submit proposals on behalf of shareholders they represent. We believe permitting representatives to submit multiple proposals for the same shareholders' meeting can give rise to the same concerns about the expense and obscuring effect of including multiple proposals in the company's proxy materials, thereby undermining the purpose of the one-proposal limit.

Accordingly, the new rule will state that each person may submit no more than one proposal, directly or indirectly, to a company for a particular shareholders' meeting. It also will state that a person may not rely on the securities holdings of another person for

[167] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Senator Kevin Cramer dated July 28, 2020; Energy Infrastructure Council dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; General Motors Company dated February 25, 2020; International Bancshares Corporation dated January 23, 2020; Manhattan Institute for Policy Research dated February 3, 2020; Nareit dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020; National Association of Manufacturers dated February 3, 2020; Robeco dated January 16, 2002; Society for Corporate Governance dated February 3, 2020.

[168] *See* letters from AFL–CIO dated February 3, 2020; Emily Aldridge dated January 31, 2020; American Baptist Home Mission Societies dated January 31, 2020; Jennifer Astone dated January 17, 2020; As You Sow dated February 3, 2020; Kate Barron-Alicante dated January 31, 2020; Boston Trust Walden et al. dated January 31, 2020; Boston Trust Walden et al. dated January 27, 2020; British Columbia Investment Management Corporation dated February 3, 2020; Jane Bulnes-Fowles dated February 3, 2020; CalPERS dated February 3, 2020; Brian Canning dated January 31, 2020; Ceres et al. dated February 3, 2020; Christian Brothers Investment Services, Inc. dated January 21, 2020; Colorado Public Employees' Retirement Association dated February 3, 2020; Professor James D. Cox, et al. dated February 2, 2020; East Bay Municipal Utility District Employees' Retirement System dated January 15, 2020; John Eing dated January 31, 2020; Harold Erdman dated February 3, 2020; Figure 8 Investment Strategies dated January 31, 2020; Franciscan Sisters of Allegany, NY dated January 29, 2020; Global Affairs Associates, LLC dated February 3, 2020; Harrington Investments, Inc. dated February 3, 2020; Neela Hummel dated January 31, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Brotherhood of Teamsters dated February 3, 2020; Andrew Ish dated February 2, 2020; Jayce Jordan dated January 17, 2020; Brent Kessel dated January 31, 2020; Laird Norton Family Foundation dated January 28, 2020; Local Authority Pension Fund Forum dated February 3, 2020; James McRitchie dated February 2, 2020; James McRitchie dated July 21, 2020; Mercy Investment Services, Inc. dated January 31, 2020; Laura Morganelli dated January 31, 2020; National Conference on Public Employee Retirement Systems dated February 3, 2020; Paul M. Neuhauser dated February 3, 2020; North American Securities Administrators Association, Inc. dated February 3, 2020; Pension Investment Association of Canada dated January 23, 2020; PNM Shareholders for a Responsible Future dated February 3, 2020; Paul Rissman dated January 15, 2020; Cheryl Ritenbaugh dated January 17, 2020; School Sisters of Notre Dame Cooperative Investment Fund received January 24, 2020; Segal Marco Advisors dated February 3, 2020; Shareholder Rights Group dated February 3, 2020; Sisters of St. Ursula dated January 23, 2020; Sisters of the Order of St. Dominic dated January 24, 2020; State Board of Administration of Florida dated February 3, 2020; The Arntz Family Foundation dated January 15, 2020; The Pension Board—United Church of Christ, Inc. dated January 29, 2020; Trillium Asset Management dated February 3, 2020; Upcyclers Network dated January 17, 2020; Barbara J. Wolf dated January 31, 2020; Ann W. Woll dated January 18, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[169] *See* letters from AFL–CIO dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; Professor James D. Cox et al. dated February 2, 2020; James McRitchie dated February 2, 2020; Paul M. Neuhauser dated February 3, 2020; Shareholder Rights Group dated June 10, 2020.

[170] *See* letters from Segal Marco Advisors dated February 3, 2020; Trillium Asset Management dated February 3, 2020.

[171] *See* letters from Tom Shaffner dated December 17, 2019; Trillium Asset Management dated February 3, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[172] *See* letter from Shareholder Rights Group dated February 3, 2020.

[173] *See* Recommendation of the IAC, *supra* note 18.

[174] *See* letters from AFL–CIO dated February 3, 2020; As You Sow dated February 3, 2020; Boston Trust et al. Walden dated January 31, 2020; CalPERS dated February 3, 2020; Domini Impact Investments dated February 3, 2020; New York City Comptroller dated February 3, 2020; New York State Comptroller dated February 3, 2020; PNM Shareholders for a Responsible Future dated February 3, 2020; Shareholder Rights Group dated February 3, 2020; Unitarian Universalist Association dated January 28, 2020.

[175] *See* letter from Boston Trust Walden et al. dated January 27, 2020.

[176] *See* letter from Society for Corporate Governance dated February 3, 2020.

[177] *Id.*

[178] *See* 1976 Adopting Release, *supra* note 88.

[179] *Id.*

[180] *Id.* This limitation will continue to apply under the adopted amendments.

the purpose of meeting the eligibility requirements and submitting multiple proposals for a particular shareholders' meeting. Under the new rule, a shareholder-proponent will not be permitted to submit one proposal in his or her own name and simultaneously serve as a representative to submit a different proposal on another shareholder's behalf for consideration at the same meeting. Likewise, a representative will not be permitted to submit more than one proposal to be considered at the same meeting, even if the representative were to submit each proposal on behalf of different shareholders. Using the rule in this way undermines the one-proposal limit. The amended rule text will more effectively apply the one-proposal limit to shareholders and representatives of shareholders.

While some commenters expressed concern about the effect the amended rule could have on a shareholder's ability to use a representative or a representative's ability to effectively represent its clients,[181] the amendment is not intended to prevent shareholders from seeking assistance and advice from lawyers, investment advisers, or others to help them draft shareholder proposals and navigate the shareholder-proposal process, nor do we believe it would interfere with a representative's ability to effectively represent its clients. The ability to provide such assistance to more than one shareholder is not affected. However, to the extent that the provider of such services submits a proposal, either as a proponent or as a representative, it will be subject to the one-proposal limit and will not be permitted to submit more than one proposal in total to the same company for the same meeting. In addition, we do not believe, as suggested by commenters,[182] that the amended rule will raise costs to a meaningful degree for shareholder-proponents or otherwise unduly restrict their options in selecting a representative because, while in some cases shareholder-proponents may need to submit a proposal on their own, they can otherwise enjoy all of the benefits of being represented by a representative of their choosing. For example, if a shareholder's representative of choice is unable to submit a proposal for the shareholder, because it has already made a submission on behalf of another client, the representative could still assist the shareholder with drafting the proposal, advising on steps in the submission process, and engaging with the company. For similar reasons, we do not agree that the rule will affect the competitive advantage of representatives that specialize in active engagement.[183] Nor do we agree that state agency law should govern the number of proposals a representative may submit on behalf of proponents when proponents and agents seek to make use of the opportunities afforded by the federal proxy rules.[184]

Some commenters questioned whether the amendment, which addresses the submission of proposals, would affect a representative's ability to present proposals on behalf of multiple shareholder-proponents at the same shareholders' meeting.[185] In order for shareholder-proponents who have submitted a proposal for inclusion in a company's proxy statement to remain eligible to do so at the same company within the following two years, shareholder-proponents must appear at the meeting and present their proposal.[186] However, a shareholder-proponent may satisfy this requirement by employing a representative who is qualified under state law to present the proposal on the proponent's behalf. The amendment is not intended to limit a representative's ability to present proposals on behalf of multiple shareholders at the same shareholders' meeting. The conduct of shareholder meetings, including how proposals are presented, is generally governed by state law, and does not raise the same concerns that are raised by a proponent's use of a company's proxy statement under the federal proxy rules. We believe that compliance with the substantive eligibility requirements of amended Rule 14a–8(c) will appropriately address the concerns we have with respect to the one-proposal limit, and we do not believe that the designation of a representative for the purpose of presenting a proposal at the shareholder meeting raises similar concerns.[187]

In response to certain commenters,[188] we note that under the final amendment, entities and all persons under their control, including employees, will be treated as a ''person'' for purposes of the amendment. As such, if an investment adviser at Advisory Firm A submits a proposal on behalf of a shareholder-proponent to Company Y, neither that investment adviser nor any other adviser at Advisory Firm A would be permitted to submit a proposal on behalf of a different shareholder-proponent at Company Y for the same meeting. However, the amendment will not prohibit a single representative from representing multiple co-filers in connection with the submission of a single shareholder proposal. Where multiple shareholders co-file a proposal, the company receives only one proposal and, therefore, the submission does not raise the types of concerns that Rule 14a–8(c) is intended to address.

We are not adopting a commenter's suggestion to require shareholders to certify that the proposal has been submitted of their own accord and not at the request or solicitation of a representative that already has submitted (or is considering submitting) a proposal to the same company.[189] We believe that the representations in Rule 14a–8(b)(1)(iv) will provide a meaningful degree of assurance as to the shareholder-proponent's identity, role, and interest in a proposal that is submitted for inclusion in a company's proxy statement and that, therefore, the certification suggested by the commenter is unnecessary.

E. Resubmission Thresholds

1. Proposed Rule Amendment

We proposed to amend the resubmission thresholds under Rule 14a–8(i)(12); specifically, we proposed to replace the thresholds of 3, 6, and 10 percent with thresholds of 5, 15, and 25 percent, respectively. Under the

[181] *See supra* note 168.

[182] *See* letter from Trillium Asset Management dated February 3, 2020. *See also* Recommendation of the IAC, supra *note* 18.

[183] *Cf.* letter from Shareholder Rights Group dated February 3, 2020.

[184] *See* letter from CalPERS dated February 3, 2020.

[185] *See* letters from AFL–CIO dated February 3, 2020; As You Sow dated February 3, 2020; Boston Trust Walden et al. dated January 31, 2020; CalPERS dated February 3, 2020; Domini Impact Investments dated February 3, 2020; New York City Comptroller dated February 3, 2020; New York State Comptroller dated February 3, 2020; PNM Shareholders for a Responsible Future dated February 3, 2020; Shareholder Rights Group dated February 3, 2020; Unitarian Universalist Association dated January 28, 2020.

[186] 17 CFR 240.14a–8(h).

[187] The Commission has previously stated that allowing a representative to present a proposal on a shareholder's behalf ''should provide greater assurance that the proposal will be presented at the meeting and that the proposal will be presented by a well-informed person.'' *See* 1982 Proposing Release, *supra* note 2. Thus, it may be important at a shareholders' meeting to ensure that a proposal is presented in accordance with state law by a well-informed person, and the use of a representative for this purpose with respect to multiple proposals does not ''constitute an unreasonable exercise of the right to submit proposals at the expense of other shareholders'' or ''tend to obscure other material matters in the proxy statement of issuers, thereby reducing the effectiveness of such documents.'' *Cf.* 1976 Adopting Release, *supra* note 88.

[188] *See* letter from Boston Trust Walden et al. dated January 27, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[189] *See* letter from Society for Corporate Governance dated February 3, 2020.

proposed amendment, a shareholder proposal would be excludable from a company's proxy materials if it addressed substantially the same subject matter as a proposal, or proposals, previously included in the company's proxy materials within the preceding five calendar years if the most recent vote occurred within the preceding three calendar years and the most recent vote was:

- Less than 5 percent of the votes cast if previously voted on once;
- Less than 15 percent of the votes cast if previously voted on twice; or
- Less than 25 percent of the votes cast if previously voted on three or more times.

We did not propose changes to the ''substantially the same subject matter'' test, which focuses on the substantive concerns addressed by a proposal rather than the ''specific language or actions proposed to deal with those concerns,'' [190] or the duration of the cooling-off period. We did, however, seek comment on whether a change to the ''substantially the same subject matter'' standard was necessary or appropriate in light of the proposed amendments to the resubmission thresholds and whether to amend the duration of the cooling-off period.[191]

2. Comments on the Proposed Rule Amendment

Commenters expressed a wide range of views on the proposed rule amendment. Commenters that expressed support for the proposed amendment indicated that it would reduce the burden on shareholders and companies associated with resubmitted proposals and allow for exclusion of proposals that are unlikely to earn majority support in the near term.[192] Several commenters that were supportive of the proposed amendment expressed a preference for resubmission thresholds that are higher than those that were proposed.[193] A few of these commenters indicated that higher thresholds would be preferable in light of the influence proxy voting advice businesses have in the shareholder voting process.[194]

A number of commenters expressed concern that the new thresholds would stifle or delay adoption of shareholder-initiated reforms to the extent shareholder support develops gradually over time.[195] Other commenters expressed the view that the current resubmission thresholds are effective even though they may not have the same effect on resubmissions as when initially adopted.[196]

Two commenters that expressed concern about the effects of the proposed thresholds suggested alternative thresholds of 3, 10, and 15 percent or 5, 10, and 15 percent, respectively, if the Commission decided to revise the thresholds.[197] Another commenter stated that thresholds of 5, 7, and 10 percent would be preferable to the proposed thresholds.[198]

A number of commenters expressed the view that the proposed amendment would have a more pronounced effect at companies with dual-class voting structures,[199] and several commenters recommended adopting alternative vote-counting methodologies for companies with these voting structures.[200]

Several commenters expressed the view that the level of shareholder support is not the sole or most appropriate measure or indication of a proposal's success.[201] These

[190] *See* Proposing Release at 66471 n.115 (citing 1983 Adopting Release).

[191] *See* Proposing Release at 66473.

[192] *See* letters from American Securities Association dated February 3, 2020; Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Senator Kevin Cramer dated July 28, 2020; Energy Infrastructure Council dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; FedEx Corporation dated February 3, 2020; Fidelity Management & Research LLC dated February 3, 2020; Senator Phil Gramm dated January 29, 2020; International Bancshares Corporation dated February 3, 2020; Investment Company Institute dated February 3, 2020; Manhattan Institute for Policy Research dated February 3, 2020; Nareit dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020; National Association of Manufacturers dated February 3, 2020; Society for Corporate Governance dated February 3, 2020.

[193] *See* letters from Business Roundtable dated February 3, 2020 (supporting thresholds at 6%, 15%, and 30%); Exxon Mobil Corporation dated February 3, 2020 (supporting thresholds at 10%, 25%, and 50%); FedEx Corporation dated February 3, 2020 (supporting thresholds at 6%, 15%, and 30%); General Motors Company dated February 25, 2020 (supporting thresholds at 6%, 15%, and 30%); Nasdaq, Inc. dated February 3, 2020 (supporting thresholds at 6%, 15%, and 30%); Society for Corporate Governance dated February 3, 2020 (supporting thresholds at 6%, 15%, and 30%).

[194] *See* letters from Business Roundtable dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; Society for Corporate Governance dated February 3, 2020.

[195] *See, e.g.,* letters from ACTIAM dated November 21, 2019; AFL–CIO dated February 3, 2020; ARGA Investment Management dated December 12, 2019; BC Target Benefit Pension Plan dated November 28, 2019; Senator Sherrod Brown dated August 21, 2020; CalPERS dated February 3, 2020; Congregation of St. Basil dated December 15, 2019; Council of Institutional Investors et al. dated July 29, 2020; Dominican Sisters of Springfield Illinois dated January 9, 2020; Form Letter Type A; Franciscan Sisters of Allegany, NY dated December 9, 2019; Franciscan Sisters of Perpetual Adoration dated December 6, 2019; International Corporate Governance Network dated December 4, 2019; Jesuit Conference of Canada and the United Stated dated December 2, 2019; Lancaster Theological Seminary dated November 19, 2019; Maryknoll Fathers and Brothers dated December 5, 2019; Maryland and USA Northeast Province of the Society of Jesus dated December 19, 2019; Miller/Howard Investments dated January 3, 2020; New York State Comptroller dated February 3, 2020; Northwest Coalition for Responsible Investment dated January 27, 2020; Province of St. Joseph of the Capuchin Order dated December 9, 2019; Shareholder Rights Group dated January 6, 2020; Shareholder Rights Group dated June 10, 2020; Sisters of Bon Secours USA dated January 10, 2020; Sisters of Charity of the Blessed Virgin Mary dated November 21, 2019; Sisters of Mount St. Scholastica dated November 26, 2019; Sisters of the Precious Blood dated November 25, 2019; Ursuline Convent of the Sacred Heart, Toledo, OH dated November 26, 2019; Zevin Asset Management dated November 27, 2019. Some of these commenters cited proposals dealing with board declassification, climate change, and human rights risks as examples of proposals that took time to garner broader shareholder support. *See, e.g.,* letters from ACTIAM dated November 21, 2019; BC Target Benefit Pension Plan dated November 28, 2019; Congregation of St. Basil dated December 15, 2019; Franciscan Sisters of Perpetual Adoration dated December 6, 2019; Lancaster Theological Seminary dated November 19, 2019; Maryknoll Fathers and Brothers dated December 5, 2019; Province of St. Joseph of the Capuchin Order dated December 9, 2019; Sisters of Bon Secours USA dated January 10, 2020; Sisters of Charity of the Blessed Virgin Mary dated November 21, 2019; Sisters of Mount St. Scholastica dated November 26, 2019; Sisters of the Precious Blood dated November 25, 2019; Zevin Asset Management dated November 27, 2019. For example, some commenters noted that proposals addressing declassified boards received less than 10% support in 1987 and 81% in 2012, and proposals addressing climate change received less than 5% support in 1998 and now receive ''substantial, and even majority shareholder votes.'' *See, e.g.,* letters from ACTIAM dated November 21, 2019; AEquo et al. dated January 28, 2020; Church Investment Group dated January 29, 2020; Rockefeller Asset Management dated January 31, 2020.

[196] *See, e.g.,* letter from Segal Marco Advisors dated February 3, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[197] *See* letters from CalPERS dated February 3, 2020; Washington State Investment Board dated January 22, 2020.

[198] *See* letter from British Columbia Investment Management Corporation dated February 3, 2020.

[199] *See* letters from AFL–CIO dated February 3, 2020; Boston Trust Walden et al. dated January 31, 2020; CFA Institute dated February 3, 2020; Connecticut State Treasurer dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Council of Institutional Investors et al. dated July 29, 2020; Representative Bill Foster et al. dated January 31, 2020; Friends Fiduciary Corporation dated February 2, 2020; Illinois State Treasurer dated January 16, 2020; International Brotherhood of Teamsters dated February 3, 2020; International Corporate Governance Network dated December 4, 2019; Loring, Wolcott & Coolidge dated January 31, 2020; New York State Comptroller dated February 3, 2020; Shareholder Association for Research & Education dated January 30, 2020; Trillium Asset Management dated February 3, 2020.

[200] *See* letters from AFL–CIO dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Corporate Governance Network dated December 4, 2019; New York State Comptroller dated February 3, 2020; NorthStar Asset Management, Inc. dated February 3, 2020.

[201] *See, e.g.,* letters from CalPERS dated February 3, 2020; Center for Political Accountability dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; New York City Comptroller dated February 3, 2020; UAW Retiree Medical

Continued

commenters suggested that a proposal may be considered successful if it leads to a settlement with management—regardless of shareholder support—or raises management's awareness about an issue.[202] Two commenters suggested adopting an exception that would apply in the event of a change in circumstances that would warrant resubmission.[203]

3. Final Rule Amendment

After considering the comments, we are adopting the amendment as proposed. Under amended Rule 14a–8(i)(12), a shareholder proposal will be excludable from a company's proxy materials if it addresses substantially the same subject matter as a proposal, or proposals, previously included in the company's proxy materials within the preceding five calendar years if the most recent vote occurred within the preceding three calendar years and the most recent vote was:

- Less than 5 percent of the votes cast if previously voted on once;
- Less than 15 percent of the votes cast if previously voted on twice; or
- Less than 25 percent of the votes cast if previously voted on three or more times.[204]

In the Proposing Release, we expressed a concern that the current resubmission thresholds of 3, 6, and 10 percent do not adequately distinguish between proposals that are more likely to obtain broader or majority support upon resubmission and those that are not.[205] As such, we were concerned that the thresholds may not be functioning effectively to relieve companies and their shareholders of the obligation to consider, and spend resources on, matters that had previously been voted on and rejected by a substantial majority of shareholders without sufficient indication that a proposal could gain traction among the broader shareholder base in the near future. As a result, company and shareholder resources may end up being used to consider and vote on matters that are unlikely to be supported by shareholders. In the Proposing Release, we also noted that ''the current thresholds may not have the same effect today on resubmissions as they did when they were initially adopted.'' [206] Several commenters questioned the relevance of the rate of exclusion over time.[207] While the resubmission thresholds are not calibrated to achieve a specific rate of exclusion, we remain concerned that the current resubmission thresholds do not adequately distinguish between proposals that have a realistic prospect of obtaining broader or majority support in the near term and those that do not. The final amendments to the resubmission thresholds are intended to better achieve this purpose.

We recognize that some proposals may benefit from resubmission, among other factors, to obtain broader or majority support. However, we do not believe that companies and other shareholders should repeatedly bear the costs of proposals that have not demonstrated the potential of obtaining broader or majority support in the near term absent a significant change in circumstances. Moreover, if a proposal fails to generate meaningful support on its first submission, and is unable to generate significantly increased support upon resubmission, it is unlikely that the proposal will earn the support of a majority of shareholders in the near term.[208] Thus, in our view, a proposal that is unable to obtain the support of at least 1 in 20 shareholders on the first submission, 3 in 20 on the second submission, or 1 in 4 by the third submission should be subject to a temporary cooling-off period to help ensure that the inclusion of such proposals does not result in undue burdens on shareholders and companies. After the temporary cooling-off period, the proposal could once again be submitted to the company.

We recognize that initial levels of shareholder support may not always predict how shareholders will vote on an issue in the future. Nevertheless, we remain concerned that obtaining support of 3, 6, or 10 percent on a first, second, or third submission, respectively, does not demonstrate sufficient shareholder support, or a sufficient increase toward greater support, to warrant resubmission. Under the current thresholds, at least 90 percent of proposals remain eligible for resubmission.[209] These resubmitted proposals have been permitted even though, according to our analysis, only approximately 6.5 percent of proposals that fail to win majority support the first time go on to pass in a subsequent attempt.[210] Accordingly, it appears that under the current thresholds, the vast majority of shareholder proposals remain eligible for resubmission regardless of their likelihood of gaining broader or majority shareholder support, at least in the near term, requiring companies and shareholders to continually expend resources and consider proposals with minimal likelihood of success. In contrast, the new thresholds are designed to serve as better indicators of a proposal's path toward potentially greater shareholder support.

We note that some commenters indicated that achieving majority support is not the sole or most appropriate way to measure the success of a proposal.[211] In this regard, we believe that the new thresholds may also serve as better indicators of the likelihood that a proposal will result in an agreement between the company and the shareholder-proponent or raise management's awareness of an issue. For example, one observer posited that ''[t]hirty-percent support is the level at which many boards take note of a proposal topic'' and that ''at 50% support, if the board is deemed to take insufficient action in response, many investors will consider voting against incumbent directors at the next annual meeting.'' [212] We believe a proposal that satisfies the new thresholds will more likely be on a path toward broader support and, therefore, may be more likely to result in an agreement between the company and the shareholder-

Benefits Trust dated January 30, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[202] *Id.*

[203] *See* letters from Baillie Gifford & Co. dated February 3, 2020; Hal S. Scott dated January 6, 2020.

[204] When calculating the voting results for purposes of applying this rule, only votes for and against a proposal should be included in the calculation. Abstentions and broker non-votes should not be included. In addition, voting results should not be rounded up for purposes of determining whether the resubmission thresholds have been met. For example, a voting result of 4.85% should not be rounded up to 5%.

[205] *See* Proposing Release at 66470–66471.

[206] *Id.* at 66471.

[207] *See supra* note 196.

[208] Based on our review of shareholder proposals that received a majority of the votes cast between 2011 and 2018, approximately 90% received such support on the first submission. Of the remaining 10%, 60% received 40% or more of the votes cast on the initial submission. *See* Proposing Release at Section IV.B.3.iv.

[209] *See* Proposing Release at tbl.3.

[210] One commenter questioned the appropriateness of the baseline of 6.5%, stating, ''The willingness of boards to implement proposals that a majority of shareholders will support means that the total universe of majority vote proposals is unobservable. Accordingly, the 6.5 percent of resubmitted proposals that go on to receive majority support is the wrong baseline for consideration.'' *See* letter from AFL–CIO dated February 3, 2020. The baseline represents observable data and we believe it would be speculative to categorize implemented proposals that had not received majority support as ''majority vote'' proposals.

[211] *See, e.g.,* letters from CalPERS dated February 3, 2020; Center for Political Accountability dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; New York City Comptroller dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[212] *See* Jamie Smith, *Five Takeaways from the 2019 Proxy Season,* EY Center for Board Matters, July 23, 2019, at 7, *available at https://assets.ey.com/content/dam/ey-sites/ey-com/en_us/topics/cbm/ey-cbm-2019-proxy-season-preview.pdf.*

proponent or raise management's awareness of an issue. Moreover, we do not believe that a proposal must be resubmitted year after year to gain broader shareholder support or result in an agreement between the company and the shareholder-proponent.

While some commenters suggested higher or lower resubmissions thresholds, such that the amendments would potentially exclude more or fewer shareholder proposals, and recognizing that, for a particular proposal, any generally applicable threshold has the potential to be over- or under-inclusive, we believe the proposed amendments appropriately calibrate the resubmission criteria, taking into account the costs to companies and shareholders of responding to proposals that do not garner significant shareholder support and are unlikely to do so in the near future and the benefits to companies and their shareholders of facilitating an individual shareholder's ability to engage with a company and other shareholders on successive occasions through the shareholder-proposal process.

The amendments represent a modest increase to the initial resubmission threshold, and more significant increases to the second and third thresholds. As a result, there will be a 10 percentage point spread between the first and second threshold and between the second and third threshold. We believe that the more significant revisions to the second and third thresholds are appropriate due to the fact that a proposal will have already been considered by shareholders two or three times before becoming subject to these thresholds.

The increase to the initial resubmission threshold from 3 to 5 percent will allow for exclusion of proposals that are very unlikely to earn majority support upon resubmission and is intended to serve as a better indicator of proposals that are more likely to obtain majority support than the current threshold. Based on our analysis of the proposals that ultimately garnered majority support from 2011 to 2018, 90 percent did so on the first submission, and more than half of the proposals that were resubmitted garnered more than 40 percent on the first submission.[213] Of those that did not garner more than 40 percent on the first submission but subsequently obtained majority support, nearly all garnered support of at least 5 percent on the first submission.[214] While we recognize that there have been a few instances in which proposals that have failed to receive at least 5 percent of the votes cast have gone on to garner majority support, these instances appear to be infrequent and may be the result of factors other than or in addition to the resubmission.[215]

The increase to the second and third resubmission thresholds to 15 and 25 percent, respectively, are also intended to establish thresholds that are better indicators of proposals that have the possibility of obtaining broader or majority support in the near term than the current thresholds. We believe that proposals receiving these levels of support will have better demonstrated a sustained level of shareholder interest and a broadening of shareholder support to warrant management and shareholder consideration upon resubmission. We note that these thresholds are set significantly below the average and median support for initial submissions of 34 and 30 percent, respectively.[216] In addition, of resubmitted proposals that ultimately obtain majority support, the overwhelming majority garner more than 15 percent on their second submission and more than 25 percent on their third submission. Based on our review of shareholder proposals that received a majority of the votes cast on a second or subsequent submission between 2011 and 2018, 95 percent received support greater than 15 percent on the second submission, and 100 percent received support greater than 25 percent on the third or subsequent submission.[217] In addition, of the 22 proposals that obtained majority support on their third or subsequent submissions, approximately 95 percent received support of over 15 percent on their second submission, and 100 percent received support of over 25 percent on their third or subsequent submission.[218] Thus, as with the initial resubmission threshold, we expect that these thresholds will permit exclusion of proposals that are unlikely to garner broader or majority support in the near term.

Overall, we believe that the amended resubmission thresholds would reduce the costs associated with management's and shareholders' repeated consideration of these proposals and their recurrent inclusion in the proxy statement while maintaining shareholders' ability to submit proposals and engage with companies on matters of interest to shareholders. We also believe that the new resubmission thresholds may lead to the submission of proposals that will evoke greater shareholder interest in, and foster more meaningful engagement between, management and shareholders, as the thresholds will incentivize shareholders to submit proposals on matters that resonate with a broader shareholder base to avoid exclusion under the rule.

While we acknowledge the concern expressed by some commenters that the new resubmission thresholds could delay consideration of shareholder-initiated ideas or reforms,[219] we do not believe that the new thresholds will stifle such activity because failure to achieve these levels of support will not act as a permanent bar from the proxy statement. Instead, shareholders will be able to resubmit substantially similar proposals for inclusion in the proxy statement after a temporary cooling-off period. In addition, while shareholder-proponents will not be permitted to use a company's proxy statement to require a shareholder vote during the cooling-off period, engagement with the company and other shareholders can continue during that time, and proponents can continue to use other methods to seek to broaden support for their ideas.

The thresholds reflect a careful and appropriate calibration of the

[213] *See* Proposing Release at Section IV.B.3.iv.

[214] *Id.*

[215] Based on our review of shareholder proposals that received a majority of the votes cast on a second or subsequent submission between 2011 and 2018, only 2% of the proposals that have failed to receive at least 5% of the votes cast have gone on to garner majority support. *See* Proposing Release at Section IV.B.3.iv.

[216] *See* Proposing Release at 66472.

[217] *Id.*

[218] *Id.* at n.123.

[219] *See, e.g.,* letters from ACTIAM dated November 21, 2019; AFL–CIO dated February 3, 2020; ARGA Investment Management dated December 12, 2019; BC Target Benefit Pension Plan dated November 28, 2019; CalPERS dated February 3, 2020; Congregation of St. Basil dated December 15, 2019; Council of Institutional Investors et al. dated July 29, 2020; Dominican Sisters of Springfield Illinois dated January 9, 2020; Form Letter Type A; Franciscan Sisters of Allegany, NY dated December 9, 2019; Franciscan Sisters of Perpetual Adoration dated December 6, 2019; International Corporate Governance Network dated December 4, 2019; Jesuit Conference of Canada and the United Stated dated December 2, 2019; Lancaster Theological Seminary dated November 19, 2019; Maryknoll Fathers and Brothers dated December 5, 2019; Maryland and USA Northeast Province of the Society of Jesus dated December 19, 2019; Miller/Howard Investments dated January 3, 2020; New York State Comptroller dated February 3, 2020; Northwest Coalition for Responsible Investment dated January 27, 2020; Province of St. Joseph of the Capuchin Order dated December 9, 2019; Shareholder Rights Group dated January 6, 2020; Sisters of Bon Secours USA dated January 10, 2020; Sisters of Charity of the Blessed Virgin Mary dated November 21, 2019; Sisters of Mount St. Scholastica dated November 26, 2019; Sisters of the Precious Blood dated November 25, 2019; Ursuline Convent of the Sacred Heart, Toledo, OH dated November 26, 2019; Zevin Asset Management dated November 27, 2019.

resubmission criteria, taking into account the costs to companies and shareholders of responding to proposals that do not garner significant shareholder support (and are unlikely to do so in the near future) and the benefits to companies and their shareholders of facilitating an individual shareholder's ability to engage in the shareholder-proposal process on successive occasions. We note that, under the new rule, those proposals that are least likely to garner broad or majority shareholder support will be subject to exclusion, while the vast majority of proposals will remain eligible for resubmission.[220]

We are not adopting any changes to the vote-counting methodology used to determine whether a proposal is eligible for resubmission. We believe that it is most appropriate to treat votes in favor of a proposal in the same manner as the company when it tabulates votes and determines whether a proposal has achieved majority support. Calculating votes in this manner will help ensure that other shareholders and companies do not continue to bear the burdens associated with proposals that are unlikely to obtain majority support and/or be implemented by management. In addition, because issuers are not required to disclose voting results separately based on affiliate status or share class, proponents would be unable to readily ascertain whether the relevant resubmission thresholds have been satisfied if alternative vote-counting methodologies were adopted.[221] Accordingly, we are not adopting alternative vote-counting methodologies. We also are not adopting an exception to the rule that would allow an otherwise excludable proposal to be resubmitted if there were material developments that suggested a resubmitted proposal may garner significantly more votes than when previously voted on. There was little support among commenters for this type of mechanism, and we believe it would be difficult in many cases to determine how the intervening developments would affect shareholders' voting decisions and therefore difficult to apply such a provision in practice.

F. Momentum Requirement

1. Proposed Rule Amendment

In addition to proposing new resubmission thresholds of 5, 15, and 25 percent, we proposed to add a new provision to Rule 14a–8(i)(12) to allow companies to exclude proposals dealing with substantially the same subject matter as proposals previously voted on by shareholders three or more times in the preceding five calendar years that would not otherwise be excludable under the 25 percent threshold if (i) the most recently voted on proposal received less than a majority of the votes cast and (ii) support declined by 10 percent or more compared to the immediately preceding shareholder vote on the matter (the ''Momentum Requirement'').

In the Proposing Release, we explained that this requirement would have relieved management and shareholders from having to repeatedly consider, and bear the costs related to, matters for which shareholder interest had declined.[222] We also noted that it would have applied only to matters that had been previously voted on three or more times in the preceding five years, giving shareholder-proponents a number of years to advocate for, and the broader shareholder base ample opportunity to consider, the matters raised.[223]

2. Comments on the Proposed Rule Amendment

We received a number of comments on the proposed amendment. Commenters that expressed support for the proposal stated that such a requirement would relieve management and shareholders from having to repeatedly consider, and bear the costs related to, matters for which shareholder interest had declined.[224]

Many commenters objected to the proposed amendment with a number of them expressing concern that, under the proposed amendment, a proposal that gets higher overall support (*e.g.,* 44 percent) compared to another proposal may be excluded if it experiences a decline in support of 10 percent or more, whereas a proposal receiving lower support (*e.g.,* 27 percent) that does not experience a decline in support of 10 percent or more would not be excludable.[225] Another commenter indicated that 25 percent support sends a strong signal that shareholders are concerned about an issue and warrants resubmission.[226] Some commenters also stated that the Momentum Requirement would add complexity to the rule.[227] Another commenter called for additional explanation and justification for the proposed amendment.[228]

Several commenters suggested modifications to the proposed amendment. Some commenters recommended requiring a decline in shareholder support greater than 10 percent.[229] Two commenters suggested requiring shareholder support to increase for a proposal to remain

[220] Of the proposals resubmitted between 2011 and 2018, we estimate that approximately 85% would have been eligible for resubmission under the proposed resubmission thresholds. *See* Proposing Release at tbl.9. In 2018 alone, we estimate that the final amendments to the resubmission thresholds would have resulted in 5% of voted proposals being excludable.

[221] *Cf.* Item 5.07 of Form 8–K [17 CFR 249.308] (requiring disclosure of votes cast for, against, or withheld (in the case of director elections), as well as the number of abstentions and broker non-votes as to each matter voted upon); Rule 30e–1(b)(3) [17 CFR 270.13e–1(b)(3)] (similar).

[222] *See* Proposing Release at 66473.

[223] *Id.*

[224] *See* letters from American Securities Association dated February 3, 2020; Business Roundtable dated February 3, 2020; Corporate Governance Coalition for Investor Value dated February 3, 2020; International Bancshares Corporation dated January 23, 2020; Manhattan Institute for Policy Research dated February 3, 2020; Nasdaq, Inc. dated February 3, 2020; National Association of Manufacturers dated February 3, 2020.

[225] *See* letters from 444S Foundation et al. dated January 31, 2020; AFL–CIO dated February 3, 2020; Zehra R. Asghar dated February 3, 2020; As You Sow dated February 3, 2020; Kam Bellamy dated February 3, 2020; Samuel Bonsey dated February 3, 2020; Boston Trust Walden et al. dated January 31, 2020; Ghislaine Boulanger dated January 30, 2020; Andrew Boyd dated January 29, 2020; David Bragin dated February 1, 2020; Lisa Brick dated January 31, 2020; British Columbia Investment Management Corporation dated February 3, 2020; Marshall Brooks dated February 5, 2020; Thomas Buckner dated February 3, 2020; Laura J. Campos dated January 14, 2020; Canadian Coalition for Good Governance dated February 3, 2020; Hilary Clark dated February 3, 2020; Delbert Coonce dated January 30, 2020; Council of Institutional Investors dated January 30, 2020; Professor James D. Cox et al. dated February 2, 2020; Domini Impact Investments dated February 3, 2020; Christopher Hormel dated January 30, 2020; Artemis Joukowsky dated January 29, 2020; Mona Kanin dated January 29, 2020; Joyce Kutz dated February 1, 2020; Anna Lefer Kuhn dated February 3, 2020; Hanna Mahon dated January 31, 2020; Helene B. Marsh dated January 28, 2020; New York State Comptroller dated February 3, 2020; Judith Norell dated January 29, 2020; Angela Ocone dated February 3, 2020; Hayden Reilly dated January 29, 2020; Sarah Rose dated January 29, 2020; Hiroko Sakurazawa dated February 2, 2020; Elizabeth Schnee dated January 29, 2020; Ellen Seh dated January 28, 2020; Sarah Sills dated January 29, 2020; Emmanuel R. Sturman dated January 30, 2020; Jed Sturman dated February 1, 2020; Marilyn and Emanual Sturman dated January 30, 2020; Richard Teitelbaum dated February 2, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020; US SIF dated January 31, 2020; Peter Vandermark dated January 29, 2020; Julie & Steve Woodward dated January 29, 2020; Wright-Ingraham Institute dated February 3, 2020.

[226] *See* letter from International Corporate Governance Network dated December 4, 2019.

[227] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; CalPERS dated February 3, 2020; Canadian Coalition for Good Governance dated February 3, 2020; NorthStar Asset Management, Inc. dated February 3, 2020; Stewart Investors dated January 30, 2020; US SIF dated January 31, 2020.

[228] *See* Recommendation of the IAC, *supra* note 18.

[229] *See, e.g.,* letters from Baillie Gifford & Co. dated February 3, 2020 (suggesting a 25% decline); Investment Company Institute dated February 3, 2020 (suggesting a 30% decline).

eligible for resubmission upon a third or subsequent submission in five years,[230] and another commenter recommended requiring a 10 percent increase in shareholder support to remain eligible for resubmission.[231] One commenter that opposed the Momentum Requirement stated that the rule, if adopted, should include ''an exception in the event of a material change in the company's situation between the previous vote and the filing deadline.'' [232]

3. Final Rule Amendment

After considering the comments, we are not adopting the proposed amendment. We agree with commenters that the Momentum Requirement, as proposed, could at least in theory lead to anomalous results because, for example, under the proposed amendment, a proposal that gets higher overall support (*e.g.,* 44 percent) compared to another proposal may be excluded if it experiences a decline in support of 10 percent or more, whereas a proposal receiving lower support (*e.g.,* 27 percent) that does not experience a decline in support of 10 percent or more would not be excludable. In addition, we agree with commenters that the Momentum Requirement, as proposed, could render the resubmission basis for exclusion unnecessarily complex. Finally, we note that further consideration of a momentum requirement may be appropriate once the Commission has had an opportunity to evaluate its experience with the revised resubmission thresholds.

G. Other Matters

1. Response to Constitutional Objections

Several commenters raised First Amendment objections to the proposed amendments to the rule's procedural requirements.[233] We do not believe their arguments have merit. For decades, Rule 14a–8 has provided a procedural mechanism, subject to neutral eligibility criteria, for shareholders to submit proposals to companies for the company to include in its own proxy statement at the company's expense. The amendments do not disturb the basic functioning of this longstanding mechanism, but merely enhance existing limits on the ability of shareholders to make use of it. Because this mechanism ''govern[s] speech by a corporation *to itself,*'' it ''do[es] not limit the range of information that the corporation''—or shareholders—''may contribute to the public debate.'' [234] Rather, it simply ''allocate[s] shareholder property between management and certain groups of shareholders.'' [235] The amendments do not restrict shareholders from speaking out on any issue, or from communicating their views to management by any means at their own expense. Nor do they prevent shareholders from seeking and relying on the assistance of others in doing so. Even to the extent a shareholder may have a First Amendment right to engage in internal corporate speech with other shareholders, any such right would not be infringed by the Commission's decision to limit the circumstances in which other shareholders must subsidize that speech.[236]

Furthermore, the amendments do not impose content-based or viewpoint-based limitations on the kinds of proposals a shareholder may submit for inclusion in a company's proxy statement. The amendments reasonably limit access to a company's proxy statement based on content-neutral and viewpoint-neutral criteria designed to appropriately consider the ability of a shareholder-proponent to put forth proposals for shareholder consideration, on the one hand, and the costs to the company and other shareholders associated with the inclusion of such proposals in the company's proxy statement, on the other.

2. Proposals Submitted to Open-End Investment Companies

In the Proposing Release, the Commission requested comment on whether any special eligibility provision should be made for shareholder proposals submitted to open-end investment companies since, unlike other issuers, open-end investment companies generally do not hold shareholder meetings annually.[237] In some cases, years may pass between the submission of a shareholder proposal and the next shareholder meeting. Due to the passage of time that may occur before an open-end investment company holds a shareholder meeting, the submission may no longer reflect the interests of the shareholder-proponent or may be in need of updating, or the proponent may no longer own the requisite amount of shares to require the company to include a proposal in its proxy statement. In response to these issues, we asked whether we should consider any special provisions to the effect that a proposal would expire after the passage of a specified amount of time, unless the shareholder-proponent reaffirmed the proposal.

Several commenters responded to the request for comment. Two commenters suggested that a provision such as what was described in the request for comment could ease the administrative burden for investment companies.[238] Another commenter stated that it could support a requirement for reconfirmation of the proponent's interest, ''as long as the procedural requirements are well designed and not geared only to suppressing voicing of dissent.'' [239] A separate commenter expressed concern about ''adding additional process requirements'' with respect to submissions at open-end investment companies.[240]

At this time, we are not adopting a requirement that shareholder-proponents reaffirm their interest in a proposal submitted to an open-end investment company after the passage of a specified amount of time. We note that few commenters supported such a provision. We also understand that open-end investment companies currently may seek to obtain a shareholder-proponent's reaffirmation in such situations before including a proposal in their proxy statements and that where they are unable to confirm a shareholder-proponent's continuing ownership interest, the staff may agree that such proposals may be excluded from the proxy statement.[241] We may, however, revisit this issue in the future if it becomes necessary to do so.

3. Commission and Staff Role in the Rule 14a–8 Process

In the Proposing Release, we requested comment on whether the Rule 14a–8 process generally works well and whether the Commission and staff's role in the process should be altered.[242] For

[230] *See* letters from General Motors Company dated February 25, 2020; Society for Corporate Governance dated February 3, 2020.

[231] *See* letter from Exxon Mobil Corporation dated February 3, 2020.

[232] *See* letter from Council of Institutional Investors dated January 30, 2020. *See also* letters from Baillie Gifford & Co. dated February 3, 2020; Hal S. Scott dated January 6, 2020, *supra* note 203.

[233] *See* letters from CalPERS dated February 3, 2020; Shareholder Rights Group dated February 3, 2020; Shareholder Rights Group dated March 18, 2020; Ellen L. Weintraub, Commissioner, Federal Election Commission dated February 3, 2020.

[234] *Pacific Gas & Electric Co.* v. *Public Utilities Comm'n of California,* 475 U.S. 1, 14 n.10 (1986).

[235] *Id.*

[236] Cf. *Regan* v. *Taxation with Representation,* 461 U.S. 540, 549 (1983).

[237] *See* Proposing Release at 66465.

[238] *See* letters from Fidelity Management & Research LLC dated February 3, 2020; Investment Company Institute dated February 3, 2020.

[239] *See* letter from Council of Institutional Investors dated January 30, 2020.

[240] *See* letter from Investors Against Genocide dated February 14, 2020.

[241] *See, e.g.,* Fidelity Management & Research Co., SEC No-Action Letter 2015 WL 4911599 (Aug. 12, 2015).

[242] *See* Proposing Release at 66465.

example, we asked whether the Commission staff should continue to review proposals companies wish to exclude, or whether the Commission should instead review these proposals. We also asked whether there is a different structure that might better serve the interests of companies and shareholders, and whether states are better suited to establish a framework governing the submission and consideration of shareholder proposals.

Several commenters responded to these requests for comment.[243] Most commenters seemed generally supportive of the Commission and staff's involvement in the process, but several expressed criticism of certain aspects of the no-action process.[244] For example, one commenter expressed the view that, while the no-action process generally works well and is less costly than alternatives, frequent changes in staff positions can increase uncertainty and costs for issuers and proponents.[245] Another commenter argued the rule lacks a clear statutory mandate.[246] Another commenter seemed supportive of Commission and staff involvement in the process, but stated that the vast majority of its members ''do not believe the [staff's] 'no-action' letter process is administered in a consistent and transparent manner.'' [247] This commenter suggested that the Commission consider alternatives to improve consistency, such as ''considering whether the 'no-action' letter process should be converted into an SEC advisory opinion process, whereby the SEC would issue opinions on major policy issues rather than issuing 'no-action' letters,'' or revising the no-action process ''to allow for enhanced review and oversight mechanisms to achieve greater consistency.'' [248] This commenter also suggested other modifications to the shareholder-proposal rule.[249]

Two commenters suggested that the shareholder-proposal process should be allowed to be governed by state law and a company's bylaws.[250] One of these commenters indicated that such a mechanism would allow for greater flexibility on a company-by-company basis, taking into consideration a company's shareholder base, and that dispute resolution at the state-court level could allow a consistent body of law to develop ''as opposed to conflicting decisions in different federal courts.'' [251] The other commenter suggested that companies should have the option to elect a system governed by state law, which could improve market efficiency, but expressed the view that ''most publicly traded companies would opt for the stable expectations of sticking with the SEC default rule'' rather than a state-law option at least in the near term.[252] Another commenter questioned whether ''state governments are better equipped to establish a framework for submission and consideration of shareholder proposals,'' and expressed the view that a shareholder-proposal process governed by state law would increase administrative and legal costs for shareholders and companies, as well as state governments.[253] A separate commenter also objected to the notion of allowing the shareholder-proposal process to be governed by state law, and expressed the view that the staff's no-action process ''is superior to litigation of differences over inclusion of shareholder proposals.'' [254]

The primary purpose of seeking public comment on these issues was to gain a better understanding of commenters' views regarding the current role of the Commission and staff in the shareholder-proposal process and to solicit input with respect to possible areas for improvement. While we did not receive many comments in response to the requests for comment, the comments received were helpful in evaluating at a high level what generally works well and whether the Commission and staff's role in the process should be altered.

We acknowledge commenters' concerns regarding the need for a consistent application of Rule 14a–8. As the Commission has previously stated, ''the staff's views on certain issues may change from time-to-time, in light of re-examination, new considerations, or changing conditions which indicate that its earlier views are no longer in keeping with the objectives of Rule 14a–8.'' [255] We continue to believe that changes in staff views may be necessary on occasion. For this reason, and although the staff strives to apply the rule in a consistent and transparent manner, participants in the shareholder-proposal process ''should not consider the prior enforcement positions of the staff on proposals submitted to other issuers to be dispositive of identical or similar proposals submitted to them.'' [256]

As noted above, one commenter suggested that greater oversight by the Commission could help with consistency and transparency.[257] As the Commission has previously stated, ''The Commission does not engage in any formal proceedings in connection with shareholder proposal matters, nor has it adopted any formal procedures in that regard.'' [258] While we are not adopting such formal proceedings at this time, we note that the staff may seek the Commission's views on certain matters related to Rule 14a–8, including certain changes in staff positions.[259]

With respect to the commenters that supported companies' ability to elect a shareholder-proposal process governed by state law or a company's bylaws, we note that shareholder voting rights are governed by state rather than federal law and that shareholder-proponents must own shares entitled to vote on their proposals.[260] We further note that a shareholder proposal must be a proper subject for action under state law to be eligible for inclusion in a company's proxy statement.[261] Thus, while Rule 14a–8 provides a federal process for proxy voting and solicitation with respect to a shareholder proposal, matters of corporate organization such as voting rights and whether a proposal

[243] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Exxon Mobil Corporation dated February 3, 2020; Local Authority Pension Fund Forum dated February 3, 2020; Manhattan Institute for Policy Research dated February 3, 2020; James McRitchie dated February 2, 2020; National Association of Manufacturers dated February 3, 2020; New York State Comptroller dated February 3, 2020; State Board of Administration of Florida dated February 3, 2020; John Taylor dated November 14, 2019.

[244] *See* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Local Authority Pension Fund Forum dated February 3, 2020; James McRitchie dated February 2, 2020; National Association of Manufacturers dated February 3, 2020; New York State Comptroller dated February 3, 2020; John Taylor dated November 14, 2019.

[245] *See* letter from New York State Comptroller dated February 3, 2020.

[246] *See* letter from Manhattan Institute for Policy Research dated February 3, 2020.

[247] *See* letter from Business Roundtable dated February 3, 2020.

[248] *Id.*

[249] *Id.*

[250] *See* letters from Exxon Mobil Corporation dated February 3, 2020; Manhattan Institute for Policy Research dated February 3, 2020.

[251] *See* letter from Exxon Mobil Corporation dated February 3, 2020.

[252] *See* letter from Manhattan Institute for Policy Research dated February 3, 2020.

[253] *See* letter from New York State Comptroller dated February 3, 2020.

[254] *See* letter from Council of Institutional Investors dated January 30, 2020.

[255] *See* Statement of Informal Procedures for the Rendering of Staff Advice with Respect to Shareholder Proposals, Release No. 34–12599 (July 7, 1976) [41 FR 29989 (July 20, 1976)], at 29990 (''Statement of Informal Procedures'').

[256] *Id.*

[257] *See* letter from Business Roundtable dated February 3, 2020.

[258] *See* Statement of Informal Procedures, *supra* note 255.

[259] *See* 17 CFR 202.1(d).

[260] *See* Rule 14a–8(b)(1).

[261] *See* Rule 14a–8(i)(1).

is a proper subject for action remain governed by state law.

Although we are not implementing changes in these areas at this time, we will consider the comments received in connection with any future rulemaking or modifications to the no-action process.

III. Transition Matters

The final amendments will become effective 60 days after they are published in the **Federal Register** and will apply to any proposal submitted for an annual or special meeting to be held on or after January 1, 2022. However, a shareholder that has continuously held at least $2,000 of a company's securities entitled to vote on the proposal for at least one year as of January 4, 2021, and continuously maintains at least $2,000 of such securities from January 4, 2021 through the date he or she submits a proposal, will be eligible to submit a proposal to such company, and need not satisfy the amended share ownership thresholds under Rule 14a–8(b)(1)(i)(A)—(C), for an annual or special meeting to be held prior to January 1, 2023.[262] A shareholder relying on this transition provision must follow the procedures set forth in Rule 14a–8(b)(2) to demonstrate that the shareholder (i) continuously held at least $2,000 of the company's securities entitled to vote on the proposal for at least one year as of January 4, 2021 [263] and (ii) continuously held at least $2,000 of such securities from January 4, 2021 through the date the proposal is submitted to the company. The shareholder will also be required to provide the company with a written statement that the shareholder intends to continue to hold at least $2,000 of such securities through the date of the shareholders' meeting at which the proposal will be considered. This temporary provision will expire on January 1, 2023.

IV. Other Matters

If any of the provisions of these rules, or the application thereof to any person or circumstance, is held to be invalid, such invalidity shall not affect other provisions or application of such provisions to other persons or circumstances that can be given effect without the invalid provision or application.

Pursuant to the Congressional Review Act,[264] the Office of Information and Regulatory Affairs has designated these amendments as a ''major rule,'' as defined by 5 U.S.C. 804(2).

V. Economic Analysis

We are mindful of the costs and benefits of the rule amendments. The discussion below addresses the economic effects of the amendments, including their anticipated costs and benefits, as well as their likely effects on efficiency, competition, and capital formation.[265] We also analyze the potential costs and benefits of reasonable alternatives to the amendments. Where possible, we have attempted to quantify the costs, benefits, and effects on efficiency, competition, and capital formation expected to result from the final rule amendments.

We have provided both a qualitative assessment and, where feasible, quantified estimates of the potential effects of the rule amendments. We also have incorporated data and other information provided by commenters to assist in the analysis of the economic effects of the rule amendments. However, as explained in more detail below, because we do not have, have not received, and, in certain cases, do not believe we can reasonably obtain data that may inform certain economic effects, we are unable to quantify those effects. We further note that even in cases where we have some data or have received some data regarding certain economic effects, the quantification of these effects is particularly challenging due to the number of assumptions that we would need to make to estimate the benefits and costs of the rule amendments.

For example, on August 14, 2020, a preliminary draft analysis (''Preliminary Staff Analysis'') conducted by Commission staff in October 2019 using certain data obtained from Broadridge Financial Solutions, Inc. (''Broadridge'') was placed in the public comment file for the Proposing Release.[266] As noted in the Proposing Release and discussed in the memorandum accompanying the Preliminary Staff Analysis, the data supplied by Broadridge suffered from significant limitations. In noting certain limitations in the Proposing Release, we encouraged commenters to submit additional data to the public comment file.[267]

We concur with the conclusions of the Commission's Chief Economist set forth in the August 14, 2020 memorandum accompanying the Preliminary Staff Analysis. Despite the staff's attempts to analyze the data set, as a result of its significant limitations, neither the data set nor the associated Preliminary Staff Analysis could be used to reliably assess the potential impact of our rule amendments on retail shareholders.

A. Introduction

We are amending certain procedural requirements of—and the provision relating to resubmitted proposals under—Rule 14a–8, the shareholder-proposal rule. The Commission has conducted various forms of outreach over the years on the proxy process, including hosting the Proxy Process Roundtable and soliciting public input on both the Rule 14a–8 ownership thresholds and the costs of submitting shareholder proposals.[268] That input informed our economic analysis in the Proposing Release and this release. We also requested comment on the estimates and data in the Proposing Release to help us refine our economic analysis. We considered all of this information thoroughly, leveraging our decades of experience with Rule 14a–8, when evaluating the effects of the rule amendments.

After carefully reviewing all of the comments received, we supplemented our analysis to investigate certain issues raised by commenters. We are adopting the rule amendments substantially as proposed and, based on our analysis of the available evidence and data, and our consideration of the comments received, our primary conclusions about the likely economic effects of the rule amendments have not changed substantively. The benefits of the rule are largely attributable to direct cost savings for companies that may process fewer shareholder proposals annually

[262] *See* Rule 14a–8(b)(1)(i)(D).

[263] To determine whether a shareholder satisfies this ownership threshold, the shareholder should look at whether, on any date within the 60 calendar days before January 4, 2021, the shareholder's investment is valued at $2,000 or greater. *See supra* note 55. Aggregation will not be allowed for purposes of determining compliance with this temporary provision.

[264] 5 U.S.C. 801 *et seq.*

[265] Section 3(f) of the Exchange Act, Section 2(b) of the Securities Act of 1933, and Section 2(c) of the Investment Company Act require us, when engaging in rulemaking that requires us to consider or determine whether an action is necessary or appropriate in (or, with respect to the Investment Company Act, consistent with) the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. Additionally, Section 23(a)(2) of the Exchange Act requires us, when making rules or regulations under the Exchange Act, to consider, among other matters, the impact that any such rule or regulation will have on competition and states that the Commission shall not adopt any such rule or regulation which will impose a burden on competition that is not necessary or appropriate in furtherance of the Exchange Act.

[266] Memorandum Regarding Analysis of Data Provided by Broadridge Financial Solutions, Inc. (Aug. 14, 2020) (''Memorandum''), Appendix A, *available at https://www.sec.gov/comments/s7-23-19/s72319-7645492-222330.pdf.*

[267] *See* Proposing Release at 66498 n.245; Memorandum.

[268] *See supra* Section I.A.

and certain benefits to shareholders directly, as well as through their ownership in companies, derived from an ability to focus on shareholder proposals that are more likely to garner majority-voting support. The costs of the rule are attributable to certain costs to shareholder-proponents in navigating the new thresholds and becoming eligible to submit proposals under the new thresholds, as well as any costs that would arise if the final rules result in the exclusion of shareholder proposals that otherwise would have garnered majority support or garnered majority support more quickly. We discuss the benefits and costs of the rule amendments in detail in Sections V.D and V.E below.

Some commenters concurred with our assessment of the effects of the proposed rule amendments [269] while other commenters raised concerns with our analysis and conclusions in the Proposing Release.[270] Before addressing specific comments in more detail throughout the Economic Analysis, we address certain overarching issues raised by commenters.

First, a number of commenters expressed the view that the Commission had not identified an economic need for the rule amendments because the economic analysis in the Proposing Release did not document a market failure or other basis for the amendments. For example, some commenters argued that the decreasing trend in the number of submitted proposals, the increasing trend in the average voting support for certain proposals, and the fact that most companies do not receive any proposals during any given year suggests that there is no economic justification for the rule amendments.[271] As a general matter, we believe it is appropriate for the Commission to engage in retrospective review, including revisiting our rules on shareholder proposals, to ensure that they are functioning as intended. As discussed in the Proposing Release, certain aspects of the shareholder-proposal rule—including the ownership thresholds—had not been reviewed by the Commission in more than 20 years prior to the Proposing Release. As part of that review, we observed that (1) the overwhelming majority of shareholder proposals are submitted by a very small number of proponents and (2) a significant number of proposals that are eligible to be resubmitted under the current resubmission thresholds continue to receive low levels of support from fellow shareholders.[272] Because, in part, shareholder proposals impose direct and opportunity costs on shareholders and indirect costs on shareholders through their ownership in companies, the Commission has long held the view that it is appropriate to condition eligibility for those that submit shareholder proposals pursuant to Rule 14a–8 on indicia of an alignment of interest with non-proponent shareholders and to provide for a cooling-off period for proposals that receive low levels of support.[273] In addition, shareholders' ability to communicate with companies and other shareholders has evolved due to technological advancements and developing market practices. As a result, shareholders now have more tools at their disposal to engage with a company's board and management, as well as other shareholders, in ways that may be more efficient for all parties than under the Rule 14a–8 process. The amendments we are adopting are designed to revise the thresholds to better ensure that the significant attendant burdens for other shareholders and companies associated with the inclusion of such proposals in the company's proxy statement are incurred in connection with those proposals that are (i) submitted by shareholders with an economic stake or investment interest in the company that demonstrates a reasonably sufficient alignment of interest with non-proponent shareholders and (ii) with respect to resubmissions, more likely to receive support from fellow shareholders and, accordingly, are more likely to lead to an action that is approved by its shareholders.[274]

Second, some commenters argued that the Proposing Release did not consider all of the potential benefits of various shareholder proposals and thus did not adequately analyze the costs of the amendments to companies and, as a result, to their shareholders, that could result from the exclusion of shareholder proposals.[275] We recognize that shareholder proposals may bring benefits to companies and their shareholders and that the potential loss of those benefits resulting from the exclusion of certain proposals that are not otherwise proposed by other shareholders would be a cost of the rule. Thus, to the extent that the final rule amendments may exclude proposals that may bring benefits to companies and their shareholders, we qualitatively describe the cost that may arise. We do not focus on specific types of shareholder proposals or attempt to quantify whether excluded proposals would have resulted in economically beneficial changes, as suggested by some commenters.[276] As a threshold matter, under state corporate law, those evaluations are properly left to the company's owners—the shareholders. In addition, our regulation of shareholder proposals under Rule 14a-8 has not been, nor would it be under the final

[269] *See, e.g.,* letters from American Securities Association dated February 3, 2020; Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Compass Lexecon dated December 23, 2019.

[270] *See, e.g.,* letters from Lucian A. Bebchuk dated February 3, 2020; CalPERS dated February 3, 2020; John Coates and Barbara Roper dated January 30, 2020; Shareholder Rights Group dated January 6, 2020.

[271] *See, e.g.,* letters from As You Sow dated February 3, 2020; CalPERS dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Richard A. Liroff dated January 28, 2020; Local Authority Pension Fund Forum dated February 3, 2020; James McRitchie dated February 2, 2020; Presbyterian Church dated January 28, 2020; Tom Shaffner dated December 17, 2019; Shareholder Rights Group dated January 6, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020; US SIF dated January 31, 2020. *See also* Recommendation of the IAC, *supra* note 18. Some other commenters also raised concerns about amending the resubmission thresholds. In particular, commenters argued that the low number of excludable proposals under current resubmission thresholds does not imply that the resubmission thresholds are currently too low because proponents now tend to modify resubmitted proposals to increase the voting support they receive, proponents engage in more outreach than in the past which improves voting outcomes, and more active participation of proxy voting advice businesses and institutional investors can improve voting outcomes ultimately resulting in low numbers of excludable resubmitted proposals. In addition, some commenters argued that the rule amendments are unnecessary because shareholders already are unlikely to resubmit proposals that garner low levels of support. *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Principles for Responsible Investment dated February 3, 2020; Segal Marco Advisors dated February 3, 2020. Nevertheless, we believe that shareholder proposals impose direct and opportunity costs on shareholders and companies, and the amended resubmission thresholds are designed to decrease those costs by imposing a cooling-off period for proposals that receive low levels of support.

[272] Under the current thresholds, at least 90% of proposals remain eligible for resubmission. These resubmitted proposals have been permitted even though, according to our analysis, previously only approximately 6.5% of proposals that fail to win majority support the first time achieve majority support in a subsequent attempt. *See supra* notes 209 and 210 and accompanying text.

[273] *See supra* Section II.A.3 and II.E.3.

[274] *See supra* note 2 and accompanying text.

[275] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Lucian A. Bebchuk dated February 3, 2020; Center for Political Accountability dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Richard A. Liroff dated January 28, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[276] *See infra* note 426. *See also infra* Section V.E.2.

amendments,[277] designed to judge the economic value of any particular shareholder proposal, or intended to take a position on the merits of any shareholder proposal topic.[278] By way of example, it would be inappropriate and outside of our regulatory remit to make a determination that any particular proposal, for example one that has been disapproved by 90 percent of a company's voting shareholders, would have been beneficial (or costly) to those shareholders as it is the shareholders who ultimately determine the value of a proposal to a particular company. Rather, the rule focuses on setting thresholds at which it is appropriate for a shareholder proposal—regardless of its substance—to be included in the company's proxy materials at the expense of the other shareholders (directly and indirectly as owners of the company), either as an initial submission, or as a resubmission.

Moreover, even if the statutory remit and historic approach of the Commission to such matters were to change fundamentally, focus on the potential economic effects of specific types of shareholder proposals would be inherently speculative, as it would require us to opine on the merits, and estimated costs and benefits, of proposals—or categories of proposals—without knowing sufficient details of the proposals or the companies for which they are advanced. Moreover, there are significant methodological and empirical challenges to quantifying whether excluded proposals would have resulted in economically beneficial changes to the company, including the difficulty of assessing whether a particular proposal would be beneficial to a particular company, for example because any decision driven by such a proposal would be part of an overarching array of decisions that collectively affect the company's business and prospects. It is also difficult to disentangle the effect of shareholder proposals from other effects such as the effect of direct communication of shareholders with management. A proposal that is subject to a cooling-off period may be approved in the future or, instead of waiting, shareholders who supported the proposal may use other methods to engage with the company on the issue. Consequently, the marginal cost of not allowing a shareholder proposal that would have benefited the company to go forward during the cooling-off period may be quite low. In addition, the relevant data does not exist and existing data cannot be generalized to estimate the benefits of shareholder proposals across a broad set of those proposals.[279]

Finally, some commenters criticized the data and method used to estimate the benefits of the proposed rule amendments, which we primarily expect to come in the form of cost savings to shareholders directly and through their ownership in companies.[280] As a response to these comments, we discuss in more detail below the limitations associated with our estimates of those savings, including that we are unable to predict how shareholder-proponents might modify their behavior in response to the final amendments. We also have revised our cost savings analysis to take into account the additional cost estimates provided by commenters.[281]

The economic analysis proceeds as follows. Section V.B discusses the baseline against which we will measure the costs and benefits of the rule amendments and the effects of the rule amendments on efficiency, competition and capital formation. Section V.C provides our estimate of the reduction in the number of shareholder proposals as a result of the rule amendments. As discussed in more detail below, the net effect of the rule amendments will be the result of a combination of factors as there will likely be an increase in the number of excludable proposals from the baseline, but any such increase in the number of excludable proposals as a result of the changes to the initial submission thresholds may be mitigated by changes in proponent behavior as a response to the rule amendments. Any shareholder that meets the current initial submission threshold (*e.g.,* holding $2,000 of company stock for at least one year), but does not already meet the length of holding or other thresholds under the amended rule and desires to submit a proposal can hold onto the company stock until it satisfies the three-year holding period or can otherwise adjust his or her holdings to meet the amended thresholds. As this discussion illustrates, the changes in shareholder-proponent behavior, in particular, in the areas of investment amount and holding period, and the effects thereof are difficult to quantify, including as a result of the relatively small percentage of shareholders that submit shareholder proposals. Section V.D discusses the benefits, costs, and effects on efficiency, competition, and capital formation of the rule amendments by type of affected party. In particular, Section V.D.1 discusses the effects of the rule amendments on companies that receive shareholder proposals, Section V.D.2 discusses the effects of the rule amendments on the non-proponent shareholders of those companies, and Section V.D.3 discusses the effects of the rule amendments on shareholder-proponents. Finally, Section V.E discusses other effects of the rule that were raised by commenters,[282] and Section V.F discusses reasonable alternatives to the amendments.

B. Economic Baseline

The baseline against which we measure the costs, benefits, and the impact on efficiency, competition, and capital formation of the final rule amendments consists of the current regulatory framework[283] and the current practices for shareholder proposal submissions.[284] The final amendments

[277] For purposes of the economic analysis, we use the term ''final amendments'' to refer collectively to the amendments to Rules 14a–8(b), 14a–8(c), and 14a–8(i)(12).

[278] *See* Statement of Informal Procedures, *supra* note 255 (stating that the Commission has no interest in the merits of particular security holder proposals and that its ''sole concern is to insure that public investors receive full and accurate information about all security holder proposals that are to, or should, be submitted to them for their action''). This is consistent with the federal securities laws' general approach to public company disclosure, which eschews merit-based regulation and instead focuses on the need to provide information material to investment and voting decisions.

[279] *See infra* Section V.E.2.

[280] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; As You Sow dated February 3, 2020; Better Markets dated February 3, 2020; CalPERS dated February 3, 2020; John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020; Impax Asset Management dated January 20, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Brotherhood of Teamsters dated February 3, 2020; Richard A. Liroff dated January 28, 2020; Paul M. Neuhauser dated February 3, 2020; Segal Marco Advisors dated February 3, 2020; Tom Shaffner dated December 17, 2019; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[281] *See infra* Section V.D.1.i.

[282] Section V.E also discusses additional baseline considerations raised by commenters.

[283] *See* Proposing Release at 66474 for a detailed description of state laws, corporate bylaws prepared under state law, and federal securities laws that jointly govern the shareholder-proposal process.

[284] *See* Proposing Release at 66476 for a detailed description of current market practices related to shareholder proposals, including general trends documenting the number of shareholder proposals and voting support over time, the distribution of ownership across shareholder-proponents, disclosures associated with the use of a representative, and shareholder proposal resubmissions.

We believe that the 2018 data used in the Proposing Release to describe the economic baseline is representative of current market practices surrounding the shareholder-proposal process because 2018 was a year of low market stress and 2018 data are recent. Our review of industry publications also suggests that the 2018 proxy season is largely representative of recent proxy seasons, including the 2019 proxy season

Continued

to Rule 14a–8(b), Rule 14a–8(c), and Rule 14a–8(i)(12) will affect all companies subject to the federal proxy rules that receive shareholder proposals, shareholders of these companies, and the proponents of these proposals.[285] We discuss each one of these affected parties below.

1. Companies

The final amendments will affect companies that expect to receive shareholder proposals. For each shareholder proposal a company receives, the company will incur costs to consider the proposal. For each shareholder proposal that meets the eligibility criteria, a company will incur costs associated with its response, which could include engaging with the proponent, including the proposal in the company's proxy statement, or submitting a no-action request to Commission staff.[286] Although not required, no-action letters are submitted by most companies seeking to exclude shareholder proposals from their proxy statements.[287] For the proposals that are not eligible for submission under Rule 14a–8, the company may incur the costs associated with submitting a no-action request to Commission staff. More specifically, the costs that companies incur include, to the extent applicable, costs to: (i) Review the proposal and address issues raised in the proposal (including time dedicated by internal legal, corporate governance, communications, and investor relations staff, law firms and other service providers, subject matter experts, executive management, and the board of directors on evaluating each proposal); (ii) engage in discussions with the proponent(s); (iii) print and distribute proxy materials, and tabulate votes on the proposal; (iv) communicate with proxy voting advice businesses and non-proponent shareholders (*e.g.,* proxy solicitation costs) and engage with non-proponent shareholders; (v) if the company intends to exclude the proposal, file a notice with the Commission; and (vi) prepare a statement of opposition to the submission.

Some commenters added that the costs that companies incur to consider a shareholder proposal depend on, among others: (i) Whether the proposal is an initial submission or resubmission; [288] (ii) whether or not the company seeks no-action relief from Commission staff; [289] (iii) the nature of the proposal, including whether the topic of the proposal is one with which the company is familiar; [290] (iv) whether the company engages with the proponent, whether the proponent engages with the company, and, if there is engagement, the manner of the engagement (*e.g.,* face-to-face meetings versus phone calls); [291] (v) the corporate governance of the company, and any changes thereto, over the course of the years of submission; [292] (vi) the importance of the issue raised in the proposal to the company and the proponent and the resources each utilizes; [293] and (vii) the need to seek outside legal advice, proxy solicitation services, consulting services, or other advisory services to respond to the proposal.[294] Hence, there is variation in the costs that companies incur to process shareholder proposals.[295]

The benefits of shareholder proposals to companies (and indirectly their shareholders) generally are the facilitation of shareholder engagement with the company and other shareholders and, in the case of a shareholder proposal that is adopted, the potential benefit of that proposal to the company (and indirectly its shareholders). These benefits are difficult to isolate from other forms of engagement and corporate activities, and cannot be reasonably quantified.[296] In any event, as discussed below we do not expect the amendments to

(*e.g.,* Broadridge & PwC, ProxyPulse: 2019 Proxy Season Review, *available at https://www.broadridge.com/_assets/pdf/broadridge-proxypulse-2019-review.pdf;* Sullivan & Cromwell Report, *supra* note 60). Further, our review of comment letters suggests that the results of our analysis of the effects of the amendments to the resubmission thresholds using 2011–2018 data likely would be qualitatively similar if we expanded our sample to include 2019 data. *See* letter from Council of Institutional Investors dated May 19, 2020.

A commenter criticized the use of one year of data for some of this analysis arguing that a single year of data may not be representative of current practices. *See* letter from Boston Trust Walden et al. dated January 27, 2020. We believe the 2018 data are representative.

For most of our analysis both in this release and in the Proposing Release we use data from 2018 because we believe that using more recent data would not materially alter our conclusions. Nevertheless, we acknowledge that certain market developments, such as the Covid-19 pandemic, may affect certain aspects of our statistics, such as the adjustment of the $2,000 threshold for the growth in Russell 3000. Whenever relevant, we have updated certain relevant statistics throughout the release using more recent data.

[285] The amendments may also have second-order effects on providers of administrative and advisory services related to proxy solicitation and shareholder voting. Nevertheless, we believe that any such effects likely will be small because shareholder proposals are a small fraction of management proposals and so any potential change in the number of excludable shareholder proposals as a result of the rule amendments likely will have a limited effect on the business of providers of administrative and advisory services related to proxy solicitation and shareholder votes.

Some commenters argued that the economic analysis in the Proposing Release did not consider the impact of the rule amendments on groups other than shareholders, such as the company's employees and society in general. *See, e.g.,* letters from Better Markets dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Local Authority Pension Fund Forum dated February 3, 2020; Pulte Institute for Global Development dated January 31, 2020. We acknowledge that the rule amendments may affect groups other than a company's shareholders, but we lack information that would allow us to reliably estimate the number of those entities and the effects of the rule amendments on those entities.

[286] As we discuss in detail in Sections V.B.2 and V.D.2 below, the company's costs and benefits are indirectly borne by its shareholders.

[287] *See* Rule 14a–8(j). While Rule 14a–8(j) requires a company to ''file its reasons'' for exclusion with the Commission, most companies provide such information in the form of a no-action request.

[288] For example, some commenters stated that in the case of statements in opposition of resubmitted proposals, companies often repeat the arguments made in a prior year, which should result in a lower cost of responding to resubmissions relative to first-time submissions. *See, e.g.,* letters from AFL–CIO dated February 3, 2020; CalPERS dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Brotherhood of Teamsters dated February 3, 2020; Principles for Responsible Investment dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020. *See also* letter in response to the Proxy Process Roundtable from Shareholder Rights Group dated December 4, 2018. In certain instances, however, resubmissions could be costlier than initial submissions. For example, companies might decide to challenge a resubmission or to make a concession to the proponent in exchange for the proposal being dropped and incur the associated costs following low support for the initial submission.

[289] *See, e.g.,* letters from CalPERS dated February 3, 2020; John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020; International Brotherhood of Teamsters dated February 3, 2020; Richard A. Liroff dated January 28, 2020.

[290] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Richard A. Liroff dated January 28, 2020.

[291] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; International Brotherhood of Teamsters dated February 3, 2020; Richard A. Liroff dated January 28, 2020.

[292] *See, e.g.,* letter from Richard A. Liroff dated January 28, 2020.

[293] *See, e.g.,* letter from Council of Institutional Investors dated January 30, 2020.

[294] *See, e.g.,* letters from John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020; Richard A. Liroff dated January 28, 2020.

[295] We requested from commenters, but did not receive, data that would allow us to estimate the opportunity costs associated with shareholder proposals. One commenter noted that there is no reliable evidence that companies have to forgo economically beneficial activities because of the need to respond to shareholder proposals. *See* letter from Council of Institutional Investors dated January 30, 2020. Other commenters, however, agreed that shareholder proposals impose opportunity costs on companies and their shareholders. *See, e.g.,* letters from American Securities Association dated February 3, 2020; Business Roundtable dated February 3, 2020; Nareit dated February 3, 2020; National Association of Manufacturers dated February 3, 2020; Society for Corporate Governance dated February 3, 2020.

[296] *See infra* Section V.E.2 for additional details.

significantly reduce shareholder engagement.[297]

We estimate that 18,594 companies are subject to the federal proxy rules and thus could potentially be affected by the final rule amendments; out of the 18,594 companies, 5,637 actually filed proxy materials with the Commission during calendar year 2018.[298] Among all Russell 3000 companies that held annual meetings in calendar year 2018, 439 (15 percent) received at least one shareholder proposal.[299] Among S&P 500 companies, 266 (53 percent) received at least one shareholder proposal in 2018.

2. Non-Proponent Shareholders

The final amendments may also affect non-proponent shareholders of companies receiving shareholder proposals. These shareholders, particularly when considered in the aggregate, may incur significant costs to consider and vote on these proposals. Several commenters to the Commission's proposed amendments to the exemptions from the proxy rules for proxy voting advice, particularly institutional investors who typically vote a large number of proposals (which may include company and shareholder proposals) each proxy season, expressed that they face significant resource challenges in determining how to vote on those proposals.[300] In addition, all shareholders may incur passed-through costs associated with companies' consideration and processing of shareholder proposals and experience the economic impact of shareholder proposals that are implemented. According to a recent study based on the 2016 Survey of Consumer Finances, approximately 65 million households owned stocks directly or indirectly (through other investment instruments).[301] Our analysis of Form N–CEN data shows that there were 14,605 registered investment companies as of May 2020.[302] Non-proponent shareholders may benefit from shareholder proposals as a component of overall engagement as discussed above and, in certain cases, certain shareholders may benefit if they otherwise would have incurred the costs to submit a substantially similar proposal.

3. Proponents of Shareholder Proposals

Proponents of shareholder proposals can be motivated by expectations of pecuniary and non-pecuniary benefits and may be affected by the final amendments, which may limit their ability to submit shareholder proposals. We estimate that there were 170 proponents—38 individual proponents and 132 institutional proponents—that served as lead proponent or co-proponent during calendar year 2018 and submitted a shareholder proposal that was included in a proxy statement.[303] As broad context, we note that the ratio of the number of estimated proponents whose proposals appeared in proxy statements during 2018 (*i.e.,* 170) to the number of direct and indirect investors in companies subject to the proxy rules (*i.e.,* 65 million) is extremely small (*i.e.,* 0.0000026 to one). The ratio is less than three shareholder-proponents per million investors. In other words, for both institutional and retail shareholders, the pool of shareholders that has demonstrated an interest in submitting shareholder proposals generally is separate and distinct from the overall general pool of shareholders. As a result, extrapolating from the general pool of shareholders to the pool of shareholders with an interest in submitting a proposal (and vice versa) is unlikely to provide a meaningful basis for analysis and insight.

C. Estimated Reduction in the Number of Shareholder Proposals

We expect the primary economic effects of the final amendments, in the aggregate, to derive from the reduction in shareholder proposals included in companies' proxy statements. Because of the potential ways in which

[297] *See infra* Section V.C.

[298] The affected companies (*i.e.,* 18,594) comprise 5,758 companies with a class of securities registered under Section 12 of the Exchange Act, 20 companies without a class of securities registered under Section 12 of the Exchange Act that filed proxy materials, and 12,718 registered management investment companies, and 98 Business Development Companies. Of 5,690 entities that filed proxy materials with the Commission, we identified 53 that were not companies, and have excluded these from our estimate of companies that filed proxy materials during calendar year 2018.

We estimate the number of registrants with a class of securities registered under Section 12 of the Exchange Act by reviewing all Forms 10–K filed during calendar year 2018 with the Commission and counting the number of unique registrants that identify themselves as having a class of securities registered under Section 12(b) or Section 12(g) of the Exchange Act. Foreign private registrants that filed Forms 20–F and 40–F and asset-backed registrants that filed Forms 10–D and 10–D/A during calendar year 2018 with the Commission are excluded from this estimate. This estimate excludes BDCs that filed Form 10–K in 2018.

We identify the issuers without a class of securities registered under Section 12 of the Exchange Act that filed proxy materials as those (1) subject to the reporting obligations of Exchange Act Section 15(d) but that do not have a class of equity securities registered under Exchange Act Section 12(b) or 12(g) and (2) that filed any proxy materials during calendar year 2018 with the Commission. The proxy materials we consider in our analysis are DEF14A; DEF14C; DEFA14A; DEFC14A; DEFM14A; DEFM14C; DEFR14A; DEFR14C; DFAN14A; N–14; PRE 14A; PRE 14C; PREC14A; PREM14A; PREM14C; PRER14A; PRER14C. Form N–14 can be a registration statement and/or proxy statement. We manually review all Forms N–14 filed during calendar year 2018 with the Commission and we exclude from our estimates Forms N–14 that are exclusively registration statements. To identify registrants reporting pursuant to Section 15(d) but not registered under Section 12(b) or Section 12(g), we review all Forms 10–K filed in calendar year 2018 with the Commission and count the number of unique registrants that identify themselves as subject to Section 15(d) reporting obligations but with no class of equity securities registered under Section 12(b) or Section 12(g).

We estimate the number of unique registered management investment companies based on Forms N–CEN filed between June 2018 and August 2019 with the Commission. Open-end funds are registered on Form N–1A. Closed-end funds are registered on Form N–2. Variable annuity separate accounts registered as management investment companies are trusts registered on Form N–3.

BDCs are entities that have been issued an 814-reporting number. Our estimate includes 88 BDCs that filed Form 10–K in 2018 as well as BDCs that may be delinquent or have filed extensions for their filings. Our estimate excludes six wholly-owned subsidiaries of other BDCs.

The entities that filed proxy materials with the Commission (*i.e.,* 5,690) are subset of affected entities (*i.e.,* 18,594) that filed any of the following proxy materials during calendar year 2018 with the Commission: DEF14A; DEF14C; DEFA14A; DEFC14A; DEFM14A; DEFM14C; DEFR14A; DEFR14C; DFAN14A; N–14; PRE 14A; PRE 14C; PREC14A; PREM14A; PREM14C; PRER14A; PRER14C.

[299] Several companies received multiple shareholder proposals during calendar year 2018. In addition, a few proposals were submitted to companies outside of the Russell 3000 index. Using FactSet's corporate governance database, SharkRepellent (*available at https://sharkrepellent.net*), we estimate that in 2018, there were 19 voted shareholder proposals at 11 companies outside of the Russell 3000 index. Our analysis focuses on proposals submitted to companies within the Russell 3000 index because this sample represents the vast majority of submitted shareholder proposals.

[300] *See, e.g.,* letters from Investment Company Institute dated February 3, 2020; New York State Comptroller dated February 3, 2020; Ohio Public Employees Retirement System dated February 3, 2020. We received mixed comments from some of these commenters on the proposed amendments to Rule 14a–8.

[301] *See* Jesse Bricker et al., *Changes in U.S. Family Finances from 2013 to 2016: Evidence from the Survey of Consumer Finances,* 103 Fed. Res. Bull. at 20, 39 (Sept. 2017), *available at https://www.federalreserve.gov/publications/files/scf17.pdf* (''Bricker et al. (2017)'') (51.9% of the 126.0 million families represented owned stocks). This is a triennial survey, and the latest data available as of this time is from the 2016 survey.

[302] Data is retrieved from Form N–CEN filings with the Commission as of May 2020. Form N–CEN only covers institutional investors that are registered investment companies.

[303] Data is retrieved from proxy statements (*see* Proposing Release at 66487 for a discussion of this data and its limitations). This data includes only shareholder proposals that appeared on the companies' proxy statements in 2018. In a broader set of submitted shareholder proposals, which includes voted, omitted, and withdrawn proposals, we estimate that 278 unique proponents submitted a proposal as lead proponent or co-proponent during calendar year 2018. Data is retrieved from ISS Analytics.

proponents may satisfy, or alter their behavior to satisfy, the amended ownership thresholds for initial submissions, we believe it is more likely that the reduction in shareholder proposals will result from the amendments to the resubmission thresholds. The magnitude of the overall reduction will determine the magnitude of the benefits and costs discussed in Section V.D below.[304]

We received two comments on the Preliminary Staff Analysis and the August 14, 2020 memorandum.[305] One of these commenters asserted that the Commission should have provided the public notice of and an opportunity to comment on the Preliminary Staff Analysis in the Proposing Release.[306] As discussed above and in the August 14, 2020 memorandum, when Commission staff receives a data set in the context of a rulemaking, it often will attempt to conduct preliminary analyses with the data in an effort to determine whether analysis of the data could reliably inform the Commission's decision-making, including assessing limitations in the data and assumptions regarding the data that would be necessary or appropriate as well as its analytical value to the proposed rulemaking in light of those limitations and assumptions. Consistent with that approach, staff analyzed the data set provided by Broadridge in connection with the Commission's consideration of the proposed amendments to Rule 14a-8. However, as described in the August 14, 2020 memorandum from the Commission's Chief Economist accompanying the Preliminary Staff Analysis, due to the significant limitations in the data and the extent and nature of the related assumptions that would be necessary to make use of it, neither the data set nor the associated Preliminary Staff Analysis could be used to reliably assess the potential impact of our rule amendments on retail shareholders and accordingly, neither the data nor the related analysis were included in the Proposing Release. This is not an unprecedented occurrence in the context of a proposed rulemaking, and we note that in the Proposing Release the Commission requested that commenters submit data that would allow the Commission to reliably assess the impact of the proposal.[307]

The Commission satisfied its obligation under the Administrative Procedure Act (''APA'') to include in the Proposing Release ''either the terms or substance of the proposed rule or a description of the subjects and issues involved,'' [308] and to ''give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.'' [309] These requirements also entail a duty ''to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules.'' [310] As the Commission's Chief Economist explained in his August 14, 2020 memorandum accompanying the Preliminary Staff Analysis, the staff did not rely on the Broadridge data set or the Preliminary Staff Analysis in formulating its recommendations for the Commission, having concluded that the data set had limitations that significantly narrowed its potential value in analyzing the impact of the proposed amendments. Consequently, the Commission did not rely on this data or analysis in determining to propose the amendments.

Although the Commission was not obligated to do so, it referenced the Broadridge data set and its limitations in the Proposing Release and invited commenters to submit data that would allow us to reliably estimate the potential effects of the rule.[311] Moreover, we have provided an opportunity for public comment on the Preliminary Staff Analysis as well as a memorandum from the Chief Economist discussing the limitations of that analysis, which were placed in the public comment file on August 14, 2020.[312] In formulating the final amendments, we have considered the comments received since that time, as discussed further below.[313]

Two commenters asserted that the Proposing Release should have addressed the figures in the Preliminary Staff Analysis, including the attempts to estimate the percentage of all companies for which less than 25% or 5% of accounts in the Broadridge data set would be eligible to have their shareholder proposal included in the company's proxy statement under the baseline and under the proposed amendments.[314]

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[304] Some commenters stated that the economic analysis should consider the interaction of the effects of the amendments to Rule 14a–8 with the effects of the amendments to Rule 14a–2(b). *See, e.g.,* letter from Senator Sherrod Brown dated August 21, 2020. In particular, commenters argued that the amendments to Rule 14a–2(b) will make it harder for shareholder proposals to meet the amended resubmission thresholds because the amendments to Rule 14a–2(b) will allow management to influence proxy voting advice businesses' recommendations related to proposals that management considers unfavorable to them. *See, e.g.,* letters from Ceres et al. dated February 3, 2020; Shareholder Rights Group dated January 6, 2020; Trillium Asset Management dated February 3, 2020. A commenter also stated that the amendments to Rule 14a–2(b) will increase shareholders' costs of processing shareholder proposals because the cost of proxy voting advice businesses will increase and proxy voting advice will be issued with a delay. *See, e.g.,* letter from Council of Institutional Investors dated January 30, 2020. To the extent that there is an increase in shareholders' costs of processing shareholder proposals from the amendments to Rule 14a–2(b), any cost savings associated with the increase in excludable proposals as a result of the amendments to Rule 14a–8 may be higher. Nevertheless, we believe that any such effects that result from the interaction between the amendments to Rule 14a–8 and Rule 14a–2(b) likely will be small because the final amendments to Rule 14a–2(b) include certain revisions intended to mitigate the unintended consequences identified by commenters (*i.e.,* undue influence and increased costs).

[305] *See* letters from Council of Institutional Investors et al. dated September 4, 2020; Sherrod Brown dated August 21, 2020.

[306] *See* letter from Council of Institutional Investors et al. dated September 4, 2020.

[307] *See* Proposing Release at 66508–66509.

[308] 5 U.S.C. 553(b)(3).

[309] *Id.* 553(c).

[310] *Owner-Operator Indep. Drivers Ass'n, Inc.* v. *Fed. Motor Carrier Safety Admin.,* 494 F.3d 188, 201–03 (D.C. Cir. 2007) (quotation omitted).

[311] Broadridge was not identified in the Proposing Release. Until recently, Broadridge had asked not to be identified as the source of the data set. Additionally, Broadridge did not submit the data set to the public comment file in response to the request for comment. After receiving confirmation that the staff could attribute the Broadridge data set by name, the staff added the Preliminary Staff Analysis to the comment file.

[312] One commenter noted that the Preliminary Staff Analysis was added to the comment file after the comment period closed in February 2020. *See* letter from Council of Institutional Investors et al. dated September 4, 2020. The Proposing Release made clear, however, that we or the staff ''may add studies, memoranda, or other substantive items to the comment file during this rulemaking.'' *See* Proposing Release at 66458. Moreover, the Commission and staff have historically considered comments submitted after a comment period closes but before adoption of a final rule, consistent with the Commission's Informal and Other Procedures (17 CFR 202.6). Consistent with that practice, we have done so here.

[313] We disagree with a commenter who argued that the inclusion of the Preliminary Staff Analysis in the comment file *after* the Proposing Release was inconsistent with the staff's Current Guidance on Economic Analysis in SEC Rulemakings. *See* letter from Council of Institutional Investors et al. dated September 4, 2020 (citing Current Guidance on Economic Analysis in SEC Rulemakings, *available at https://www.sec.gov/divisions/riskfin/rsfi_guidance_econ_analy_secrulemaking.pdf* (''Staff Guidance'')). As noted above, the Proposing Release specifically indicated that ''studies, memoranda, or other substantive items'' might be added to the comment file during the rulemaking. Nor does the Staff Guidance require that the Commission engage in economic analysis based on data that it reasonably believes cannot reliably inform an assessment of the benefits and costs of a rule. *See* Staff Guidance at 14. Rather, the Staff Guidance is designed to allow for flexibility in the context of any particular rulemaking (*id.* at 2) and the approach taken here was appropriate in the circumstances. In any event, the Staff Guidance is derived from the Commission's statutory obligations under the APA and the Exchange Act, among others, and does not itself impose enforceable obligations independent of those requirements.

[314] *See* letters from Council of Institutional Investors et al. dated September 4, 2020; Sherrod Brown dated August 21, 2020.

As described in the August 14, 2020 memorandum, the Broadridge data set suffered from significant limitations. As only one example, in analyzing the potential impact of possible changes to shareholder proposal eligibility, the staff was unable to determine with reasonable accuracy from the data set whether the snapshot of account holdings provided by Broadridge could be used to determine whether individual investors in fact met ownership and duration thresholds under the current or revised eligibility requirements (and therefore was unable to determine with reasonable accuracy the potential impact), because the data set does not identify account holdings as of the deadline to submit a shareholder proposal or as of the annual meeting date. Rather, it only includes data points as of the record date, which do not extend sufficiently in time to capture the minimum holding requirements. Additionally, neither Broadridge nor the staff were able to confirm that the anonymized accounts in the Broadridge data set represented retail shareholders, and the data was provided on an account-level basis, not an investor-level basis, while investors may hold securities in the same company through more than one account. For these and other reasons, including those set forth in the August 14, 2020 memorandum, we believe the Broadridge data, including through the Preliminary Staff Analysis, cannot be used to reliably determine the number of retail investors who would be affected by the proposed amendments.

In addition, and apart from the specific issues associated with the limitations of the Broadridge data and the reliability of the Preliminary Staff Analysis, we do not believe an analysis of which companies have, for example, 5%, 10%, or 25% of their accounts eligible to submit proposals under the current or revised submission thresholds provides a meaningful basis on which to analyze the impact of the proposals. We note, for example, that we approximate that only roughly 0.0003% of investors actually submitted shareholder proposals that appeared in 2018 proxy statements, and that such a general analysis would not allow us to estimate reliably the impact of the proposals on that small subset of shareholders that are likely to submit proposals.[315]

Separate from the limitations inherent in extrapolating from a large pool of shareholders with diversified preferences to a very small subset of that group that expresses a specific preference, such a general analysis is static and, therefore, would not reflect the expectation that shareholders with a specific preference for submitting a proposal would adjust their holdings to meet the revised submission thresholds, including by holding shares for an additional period of time or otherwise adjusting their portfolios. For example, many investors also invest through investment funds, which would not be captured by company-specific account-level data. However, these shareholders could reallocate their fund holdings to increase their positions in individual companies if they desired to submit a shareholder proposal and did not want to wait to meet the revised eligibility requirements. Shareholders also could make various other adjustments to their holdings to address their individual eligibility preferences. Because, as discussed below, we do not expect the marginal cost of these adjustments to be significant, the inability to account for this behavior significantly narrowed the potential value of the analysis in analyzing the impact of possible changes to the eligibility thresholds.

One commenter expressed the view that it was inappropriate to distinguish between retail investors who have filed proposals in the past and those who have not in considering the likely impact of the proposed amendments on retail shareholders.[316] This commenter argued that investors who have not exercised their rights to have a shareholder proposal included in the company's proxy statement would nonetheless bear a cost if those rights were taken away, because a right can have value even if it is not exercised.

The Commission notes that every retail shareholder cited by the commenter whose current eligibility to submit a proposal is based on having held at least $2,000 worth of company stock for at least one year will continue to be eligible to submit a proposal during the transition period. In addition, while these shareholders' eligibility may be affected in the future, they can maintain their eligibility at that time by simply continuing to maintain at least $2,000 of company stock. More generally, the Commission has considered the potential costs and benefits of the rule amendments, including those associated with retail shareholders who, in the future, would meet the current eligibility thresholds but who may not meet the revised thresholds because, for example, they choose not to continue to hold at least their $2,000 worth of company securities for any additional required time. We continue to believe that, to the extent that any shareholder who has held at least $2,000 worth of company securities for one year chooses not to meet the revised eligibility thresholds, including by simply holding that same dollar amount of stock for a maximum of two additional years, that shareholder has not demonstrated a sufficient investment interest in a company to be able to draw on company and shareholder resources for the purpose of including a proposal in the company's proxy statement, including requiring fellow shareholders to potentially review, consider, and vote on that proponent's proposal.

Moreover, as discussed in more detail below, the costs to the shareholder-proponent to submit a proposal are low, including when compared to the costs incurred by companies and non-proponent shareholders, such as, among others, the costs to the shareholder to review, consider, and vote on the proposal. To the extent that the potential shareholder-proponents cited by the commenter incur additional costs to maintain eligibility under the new thresholds—including, for example, costs associated with maintaining at least $2,000 worth of stockholdings for a maximum of two additional years (which could be offset to some extent by benefits of holding the shares)—we believe those costs would be appropriate in light of the related benefits of the rule amendments, including those associated with an increased alignment of interest between the proponent and the non-proponent shareholders who would incur costs associated with reviewing, considering, and voting on the proponent's proposal.[317]

[315] 0.0003% = 170 unique proponents that submitted proposals that were included in a company's proxy statement as lead proponent or co-proponent during calendar year 2018/65 million U.S. investors. *See supra* note 72.

Even looking at a broader set of submitted shareholder proposals, which includes voted, omitted, and withdrawn proposals, the estimated 278 unique proponents who submitted a proposal as lead proponent or co-proponent during calendar year 2018 represent only approximately 0.0004% of all shareholders. *See* Memorandum.

[316] *See* letter from Council of Institutional Investors et al. dated September 4, 2020.

[317] For the same reason, we disagree with one commenter's assertion that ''the impact of the proposed amendments would be much broader than the Commission's release asserted, effectively depriving most retail shareholders of the rights and ability to use the shareholder proposal process to protect and advance their interests as investors.'' *See* letter from Council of Institutional Investors et al. dated September 4, 2020. As noted above, every retail shareholder cited by the commenter who currently is eligible to submit a proposal by having held $2,000 worth of company stock for at least one year will continue to be eligible to submit a proposal by simply continuing to maintain $2,000

Continued

We also believe that the cost, if any, to shorter-term shareholders that have not previously demonstrated a desire to submit a shareholder proposal of the potentially applicable longer holding periods under the amended thresholds is likely to be small for a number of reasons. For example, and more specifically, (1) given that such a small number of total shareholders have submitted proposals over time, it would not be expected that a significant number of smaller, shorter-term shareholders that have not previously demonstrated a desire to submit a shareholder proposal would change their preferences and desire to submit a proposal, and (2) even if a particular shareholder changed his or her preferences, he or she could choose to remain eligible by incurring the marginal cost of holding at least $2,000 of his or her current shareholding for a total of three years. Accordingly, we estimate the potential loss in value cited by the commentator, if any, to be low.

In the Proposing Release, we estimated the reduction in the number of shareholder proposals assuming no change in shareholder-proponent behavior as a result of the rule amendments.[318] This analysis provides an upper bound estimate of the reduction in shareholder proposals that is unlikely to be observed in practice because shareholder-proponents are expected to respond to the final amendments by taking actions to mitigate the effects of rule amendments on their ability to submit proposals. Such actions may reduce the magnitude of the final amendments' effects on the number of shareholder proposals, thereby reducing the benefit of the amendments but also reducing the costs. However, as noted above, extrapolating from the general pool of shareholders has significant limitations, and it is difficult to anticipate the shareholder-proponents' responses. Accordingly, it should be recognized that our efforts to provide a quantitative analysis are inherently limited. In this section, we first summarize the analysis included in the Proposing Release from which we estimate the upper bound of the reduction and then describe how changes in shareholder-proponent behavior could affect the magnitude of the reduction in shareholder proposals.

Table 1 below provides an estimated range of the upper bound of the percentage of current shareholder proposals that we anticipate could be excludable as a result of the rule amendments assuming no change in shareholder-proponents' behavior and not taking into account the temporary effect of the transition period that the final rules provide.[319] As discussed in more detail below, we do not believe this assumption will prove to be correct in practice. We can only estimate the range, and not a precise number, of the reduction in shareholder proposals associated with changes to the ownership thresholds because we do not have data on duration of holdings for shareholder-proponents.[320] We do not expect the final amendments relating to the one-percent ownership threshold and shareholder engagement or the final amendment requiring certain documentation when using a representative to meaningfully impact the number of shareholder proposals included in companies' proxy statements, because the one-percent

of company stock for a maximum of two additional years.

[318] *See* Proposing Release at 66496–66498.

[319] *See* Proposing Release at 66496 for details on the methodology and its limitations. Table 1 does not account for possible overlap of excludable proposals across final amendments. In particular, if final amendments result in a particular proposal being excludable under both amended Rule 14a–8(b) and amended Rule 14a–8(i)(12), we include this proposal in the estimation of the effects for both of the final amendments.

[320] Several commenters provided staff with statistics related to equity holdings of U.S. investors. In particular, several commenters provided ownership data regarding themselves or their clients. *See, e.g.,* letters from CalPERS dated February 3, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; James McRitchie dated November 5, 2019; James McRitchie dated July 21, 2020. One commenter cited a Department of Labor study observing that the median brokerage account balance of U.S. investors was $6,200 in 2013. *See* letter from Better Markets dated February 3, 2020 (citing Advanced Analytical Consulting Group & Deloitte, Brokerage Accounts in the United States (Nov. 30, 2015), *available at https://www.dol.gov/sites/dolgov/files/EBSA/researchers/analysis/retirement/brokerage-accounts-in-the-us.pdf* (''Department of Labor Study'')). Another commenter cited the same Department of Labor study noting that households with a brokerage account owned $248,000 in stocks on average in 2013. *See* letter from Jane Bulnes-Fowles dated February 3, 2020 (citing the Department of Labor Study). A third commenter cited a Census Bureau study observing that among U.S. households, the median holdings of stocks and mutual funds was $47,000 in 2016. *See* letter from Paul Rissman dated January 15, 2020 (citing Jonathan Eggleston & Robert Munk, Net Worth of Households: 2016, U.S. Census Bureau (Oct. 2019), *available at https://www.census.gov/content/dam/Census/library/publications/2019/demo/p70br-166.pdf*). A fourth commenter cited a study from the National Institute on Retirement Security, which analyzed data from the U.S. Census Bureau and showed that the median U.S. retirement account balance is zero, and from those accounts with a non-zero balance, the median account balance is approximately $40,000. *See, e.g.,* letter from AFL–CIO dated February 3, 2020 (citing Jennifer Erin Brown et al., Retirement in America: Out of Reach for Working Americans?, National Institute on Retirement Security, at 1 (Sept. 2017), *available at https://www.nirsonline.org/wp-content/uploads/2018/09/SavingsCrisis_Final.pdf*) (''*Brown (2017)*''). A fifth commenter cited a report documenting an average 401(k) balance in the third quarter of 2019 of $105,200. *See* letters from Shareholder Commons dated January 31, 2020 (citing Fidelity Investments, Building Financial Futures, *available at https://sponsor.fidclity.com/binpublic/06PSWwebsite/documents/BuildingFinancialFutures.pdf*). Some commenters cited a median value of retail investors' stock portfolios equal to $27,699. *See, e.g.,* letter from Better Markets dated February 3, 2020. A final commenter cited a Federal Reserve bulletin according to which the median retirement portfolio in the United States was $60,000 in 2016. *See, e.g.,* letter from Ceres et al. dated February 3, 2020 (citing Bricker et al. (2017), *supra* note 301). *See also* letter from James McRitchie dated July 21, 2020 (providing statistics on share ownership similar to the statistics provided by other commenters). Relatedly, some commenters noted that in practice, shareholder-proponents must hold a share value significantly higher than the required ownership threshold because stock prices are volatile and share ownership thresholds must be maintained for a certain period of time. *See, e.g.,* letter from First Affirmative Financial Network, LLC dated January 24, 2020. The above-mentioned statistics provide information that is additional to the ownership data from proxy statements and no-action letters because they provide ownership information of potential rather than current proponents. Nevertheless, these statistics do not allow us to distinguish between the holdings of all shareholders and the holdings of the shareholders that are likely to submit a proposal, so we have not used them in our analysis.

Other commenters provided us with statistics on shareholders' ownership duration (*see also* Proposing Release at 66490 for additional statistics on shareholders' ownership duration). In particular, one commenter cited a white paper that estimated the average duration of holdings across all shareholders of nine months as of December 2018 using data of share turnover for NYSE listed securities. *See* letter in response to the Proxy Process Roundtable from Shareholder Rights Group dated December 4, 2018. Another commenter cited an academic study, which estimated that the average holding period for individual accounts at a U.S. discount brokerage was 16 months between 1991 and 1996. *See* letter from AFL–CIO dated February 3, 2020 (citing Brad Barber & Terrance Odean, *Trading Is Hazardous to Your Wealth: The Common Stock Investment Performance of Individual Investors,* 55 J. FIN. 773, 775 (2000) (''Barber & Odean (2000)'')). Using the same data as in Barber & Odean 2000, another paper found that the median holding period of individual investors is 207 trading days. *See* Deniz Anginer, Snow Xue Han & Celim Yildizhan, *Do Individual Investors Ignore Transaction Costs?* (Working Paper, 2018), *available at https://ssrn.com/abstract=2972845.* A third commenter cited a study, which estimated that the average holding period of mutual funds between 2005 and 2015 was 15 to 17 months. *See* letter from AFL–CIO dated February 3, 2020 (citing Anne M. Tucker, *The Long and The Short: Portfolio Turnover Ratios & Mutual Fund Investment Time Horizons,* 43 J. Corp. L. 581 (2018)). Finally, another commenter cited an academic study that showed that the median duration of holdings for institutional investors in 2015 was two years. *See* letter from Institute for Policy Integrity dated February 3, 2020 (citing K.J. Martijn Cremers & Simone M. Sepe, *Institutional Investors, Corporate Governance, and Firm Value*, 41 Seattle U. L. Rev. 387, 403 (2018)). Nevertheless, it is difficult to infer duration of holdings of shareholder-proponents from these studies because they do not separately consider holdings of shareholders that already submitted or are likely to submit shareholder proposals. Drawing conclusions about duration of holdings based on the data provided by commenters would be inherently speculative because shareholder-proponents constitute a very small (*i.e.,* three shareholder-proponents per million investors) and non-random set of shareholders.

ownership threshold currently is rarely utilized in light of the $2,000/one-year threshold and the majority of shareholders that submit a proposal through a representative already provide much of the documentation that is mandated by the final amendments, consistent with existing staff guidance.[321]

TABLE 1—UPPER BOUND ESTIMATE OF THE PERCENTAGE OF EXCLUDABLE PROPOSALS BY RULE AMENDMENT ASSUMING NO CHANGE IN SHAREHOLDER-PROPONENTS' BEHAVIOR

Amendment:	Percent
Rule 14a–8(b)—ownership thresholds and prohibition on aggregation[322]	0–56
Rule 14a–8(c)—one proposal per person[323]	2
Rule 14a–8(i)(12)—resubmission thresholds[324]	5

These estimates are subject to several significant limitations and should be interpreted with caution. First, as noted earlier, when estimating the number of potentially excludable shareholder proposals in the analysis above, we assume that proponent behavior with respect to shareholder proposal submissions will remain unchanged. In reality, we believe this is highly unlikely. As noted, of the 65 million U.S. investors, only 170 submitted shareholder proposals that appeared in proxy statements in 2018 and were subsequently voted, and of those, only 38 were individuals (the rest were institutional investors). To meet the new initial submission thresholds, these investors—who typically already have owned at least $2,000 of company stock for at least one year or perhaps longer—would already be eligible to submit a proposal due to their holding period or the size of their holding, or would need to hold the same amount of stock for at most two more years.[325]

Accordingly, we believe it is likely that, in response to the amendments, proponents that desire to submit a proposal but could be precluded from submitting shareholder proposals due to the new requirements would decide to hold shares for a longer period or increase their holdings of certain stocks to meet the amended eligibility requirements.[326] If shareholders respond by changing their investment behavior, or if many currently eligible holders are already long-term holders, the actual number of newly excludable shareholder proposals as a result of changes to Rule 14a–8(b) and Rule 14a–8(c) will likely be significantly lower than the upper bound of excludable proposals estimated above.

Second, another significant limitation in our data, and accordingly in the estimates presented in Table 1, is that it relies on proof of ownership letters provided by shareholder-proponents in connection with their shareholder proposals. Those letters typically are written by a broker-dealer or custodian of the shares and are written solely for the purpose of proving that the proponent meets the minimum size and length of ownership threshold requirements. For a number of reasons, which may include privacy concerns because in many cases these letters are made public, proponents may choose to keep some of their holdings in accounts that are separate from the account they use to prove compliance with the ownership thresholds. Thus, this analysis could underestimate proponents' actual holdings and, accordingly, overestimate the number of newly excludable proposals.

Third, an issue that is sufficiently important to the broader shareholder base can be brought to the company's attention by other shareholders, including those that continue to be eligible to submit a shareholder proposal. Therefore, to the extent that shareholders with holdings that satisfy the amended ownership thresholds choose to take up proposals of shareholder-proponents precluded from submitting certain proposals under the final rule amendments, these proposals may continue to be included in companies' proxy statements.[327]

[321] *See* Proposing Release 66499.

[322] *See* Proposing Release at 66497. Table 1 uses data from proxy statements to estimate the number of excludable proposals as a result of the final amendments to Rule 14a–8(b) and Rule 14a–8(c). Our analysis using data from no-action letters yields qualitatively similar results. The low end of the range (*i.e.,* 0%) assumes that all of the 170 proponents held the stock for three years. The high end of the range (*i.e.,* 56%) assumes that none of the 170 proponents, all of whom held the stock for one year, held the stock for three years, and assumes that proponents do not hold any more company stock outside of the single account that they cite for their public proof of ownership. We believe these assumptions are overinclusive.

Table 1 estimates the joint impact of the amendments to the ownership thresholds and the prohibition on aggregation of shareholdings on the number of shareholder proposals included in companies' proxy materials. On the one hand, we estimate that changing the ownership thresholds while maintaining shareholders' ability to aggregate holdings across shareholder-proponents would have resulted in a reduction in the number of shareholder proposals included in companies' proxy statements in 2018 between zero and 54 percent. On the other hand, we estimate that prohibiting aggregation of holdings across shareholder-proponents without raising ownership thresholds would not have resulted in a change in the number of shareholder proposals included in companies' proxy statements in 2018.

[323] *See* Proposing Release at 66497.

[324] In the Proposing Release, we estimated that the amendments to Rule 14a–8(i)(12) could have resulted in 30 additional excludable proposals in 2018. *See* Proposing Release at 66500 n.259. Because we are not adopting the proposed Momentum Requirement, our estimated reduction in the number of shareholder proposals is lower than the estimate in the Proposing Release. In particular, we estimate that the amendments to the resubmission thresholds could result in 23 additional excludable proposals in 2018, which is approximately 5% of the 423 shareholder proposals that appear as first-time submissions or resubmissions during 2018 in a report prepared by the Council of Institutional Investors (*see* Proposing Release at 66469 n.92). *See* Proposing Release at 66490 n.197.

One commenter estimated the number of excludable proposals as a result of the amendments to the resubmission thresholds to be around 21%. *See* letter from Sustainable Investments Institute dated February 3, 2020. The commenter's analysis only examines the effects of the rule amendments on environmental and social proposals; it does not include governance and other proposals in the analysis. In addition, based on our understanding of the methodology used, we believe that the commenter's estimate of the effect of the rule amendments is overstated because the commenter counts as excludable all proposals that do not meet the resubmission thresholds regardless of whether those proposals were ultimately resubmitted or not. We are unable to confirm whether the commenter's classification of proposals as resubmissions is accurate. The same limitations apply to the updated analysis using data from the 2020 proxy season conducted by Sustainable Investments Institute and included as an attachment to the letter from Council of Institutional Investors et al. dated July 29, 2020.

[325] If they held more than $2,000 but less than $15,000 or $25,000 in stock and had not yet met the three-year holding period.

[326] We note that portfolio reallocation is not costless or frictionless. We discuss costs associated with this type of reallocation in detail below in Section V.D.

[327] As discussed below, institutional investors are less likely to be affected by the amendments to the ownership thresholds than retail investors (*see infra* note 392 and accompanying text). Several commenters discussed the likelihood of shareholders with larger stakes taking up shareholder proposals of proponents who would no longer meet amended eligibility requirements. In particular, one commenter argued that some asset managers have conflicts that may make them less likely to take up proposals that would have been submitted by the newly excludable proponents. The commenter asserted that some asset managers are reluctant to submit proposals against a company's management because they rely on a company's

Continued

Fourth, the aggregate reduction in shareholder proposals may be lower than the one estimated above if shareholder-proponents decide to rotate proposals on similar topics among different companies or to submit proposals to the same company but on a different topic in response to changes to the resubmission thresholds. Lastly, shareholder-proponents may use alternative avenues of communication with management, which will not impact the number of excludable proposals but may impact the aggregate economic effects of the rule amendments. While we expect changes in behavior described above to moderate the reduction in submitted shareholder proposals and impact the economic effects of the rule amendments, we cannot quantify the magnitude of this impact because we cannot reliably predict the extent to which shareholder-proponents would change their behavior in response to final amendments.

In addition, our estimation of newly excludable proposals does not reflect the final amendments' transition provision, which will temporarily decrease the number of excludable proposals as a result of the amendments to the ownership thresholds.[328] Finally, we note that while the final amendments may result in a reduction in the number of shareholder proposals, companies may always elect to include in their proxy materials, or implement proposals, that will otherwise be excludable if they believe that those proposals will benefit shareholders.[329]

D. Analysis of Costs and Benefits and Effects on Efficiency, Competition, and Capital Formation of the Final Rule Amendments

1. Companies

As a result of the final amendments, companies will likely experience cost savings because they will be able to exclude more proposals. Here, we note again that shareholders may take steps to significantly offset the effects resulting from the change to the initial submission thresholds at relatively low cost (*e.g.,* a shareholder who currently meets the current threshold of holding at least $2,000 of company stock for one year can, to the extent that it has not already held the stock for three years, meet the revised threshold by holding the stock for at most two more years or can rely on the transition provision for a temporary period of time).[330] Thus, we are more confident that the changes in the resubmission thresholds will reduce the number of shareholder proposals. Companies incur direct costs associated with the consideration and processing of submitted proposals. Moreover, companies may experience cost savings if shareholders are discouraged from submitting proposals that would be excludable based on the final amendments. This is because companies incur certain direct costs even in connection with excludable proposals (*e.g.,* companies will need to file a notice with the Commission that they intend to exclude the proposal).[331]

i. Cost Savings Due to Fewer Shareholder Proposals

To quantify the cost savings companies will likely experience as a result of the final amendments, we use the estimated upper bound reduction in the number of shareholder proposals from Section V.C above and estimates provided by commenters on the average costs that companies incur to process shareholder proposals.[332]

management for the assignment of the administration of the company's defined contribution plan and the inclusion of the asset manager's products in the menu of investment options available to plan participants. *See* letter from Lucian A. Bebchuk dated February 3, 2020 (citing Lucian A. Bebchuk & Scott Hirst, *Index Funds and the Future of Corporate Governance: Theory, Evidence, and Policy,* 119 Colum. L. Rev. 2029 (2019)). In addition, commenters indicated that some larger shareholders may become more active in submitting shareholder proposals but this response will be muted by regulatory disincentives, the fact that large investors are less nimble than smaller investors that have more flexibility to submit proposals on emerging matters, and the fact that large institutions have direct access to management and thus are less likely to submit a shareholder proposal. *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; James McRitchie dated February 2, 2020.

[328] The transition provision will temporarily exempt from the new ownership thresholds certain shareholder-proponents that met the former eligibility requirements and maintain continuous ownership of their shares, allowing these shareholders to continue to submit shareholder proposals for inclusion in companies' proxies for a period of time using the $2,000 threshold.

[329] Among shareholder proposals resubmitted to Russell 3000 companies during 2011 to 2018, ten proposals appeared in company proxies and were voted on despite receiving low voting support in prior submissions and being eligible for exclusion under the current resubmission thresholds.

[330] Commenters have also argued that certain proponents use the threat of submitting a shareholder proposal as a means to force the company to implement unrelated changes. *See, e.g.,* letter from Center for Capital Markets Competitiveness dated January 31, 2020. We are unable to confirm whether and how frequently these events occur but we believe that the rule amendments may reduce the occurrence of any such events because proponents would need to either invest more money in the company or hold the company's shares for a longer period of time to make the threat credible.

[331] It is also possible that, as a result of the revised resubmission thresholds, proponents of proposals that are unlikely to meet the resubmission thresholds may be less likely to submit those proposals initially because they expect that their proposals will be excluded on a subsequent resubmission.

[332] A number of commenters responded to our request for data on the cost of shareholder proposals. One commenter indicated that, based on the experience of one of its staffers who had represented registrants, no-action correspondence represents the most substantial cost related to shareholder proposals, with a marginal cost to the company of less than $20,000. *See, e.g.,* letter from CalPERS dated February 3, 2020. Two commenters cited the $18,982 cost estimate to print and mail a single shareholder proposal included in the Paperwork Reduction Act (''PRA'') section of the Proposing Release and derived from a July 2009 survey by Business Roundtable. *See* letters from John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020 (citing the cost estimates from the letter in response to Facilitating Shareholder Director Nominations, Release No. 34–60089 (June 10, 2009) [74 FR 29024 (June 18, 2009)] from Business Roundtable dated August 17, 2009, *available at https://www.sec.gov/comments/s7-10-09/s71009-267.pdf*) (''2009 BRT Letter''). Yet another commenter indicated that the cost of shareholder proposals ranges from $50,000 to $100,000 or more per proposal. *See* letter from Business Roundtable dated February 3, 2020 (noting that ''[a]lthough many member companies reported that it was difficult to quantify the costs of shareholder proposals, several reported costs ranging from $50,000 to $100,000 or more per proposal. In addition, a number of companies noted that their costs for first-time proposals are generally higher than those incurred for resubmitted proposals''). Finally, according to a commenter, the $87,000 to $150,000 per proposal is a fair range of cost estimates for typical proposals, even though the cost of certain proposals may exceed the high end of the range. *See* letter from Center for Capital Markets dated January 31, 2020.

One commenter conducted a survey of its members regarding the costs associated with shareholder proposals. *See* letter from Society for Corporate Governance dated February 3, 2020. According to the survey, 24% of the respondents stated that they spend no money or a negligible dollar amount on average annually to manage/respond to shareholder proposals, 12% stated that they spend more than a negligible amount but less than $5,000, eight percent mentioned that they spend between $5,000 and $10,000, and 29% stated that they spend between $10,000 and $20,000. In addition, a number of survey respondents indicated that they spend more than $20,000. For example, one respondent reported costs ''[i]n excess of $50,000''; one respondent reported costs of ''well over'' $125,000; and a third respondent reported incurred expenses of $109,792 in 2018, which included the cost of seeking no-action relief, for one proposal and $133,587 in 2019 for a proposal that was ultimately included in the proxy statement. Two other respondents reported costs of up to $100,000; and another respondent reported costs of ''more than $200,000'' in ''outside counsel expenses alone'' to process the shareholder proposals it receives. Although informative, we are unable to use these survey responses to precisely estimate cost savings associated with the rule amendments because they refer to the annual cost of shareholder proposals for each respondent rather than the cost of a single proposal. While we have information of the number of proposals submitted at each company in the Russell 3000 index, we lack information on the identity of respondents in the survey. Thus, we are unable to estimate the average cost of a single proposal from this data. For example, although 24% of respondents stated that they spend no money or a negligible dollar amount on average annually to manage/respond to shareholder proposals, we are unable to determine whether this is because they do not spend money to respond or because they have not received

Some commenters criticized the estimates of costs that companies incur to process shareholder proposals used in the estimation of the cost savings to companies in the Proposing Release. A number of commenters argued that the cost estimates discussed in the economic analysis of the Proposing Release were unreliable.[333] In particular, commenters argued that the $150,000 cost estimate provided by a commenter in response to the Proxy Process Roundtable [334] and used as an upper bound of our cost estimates in the Proposing Release is unreliable because: (i) It is not based on any hard data; (ii) it is based on costs incurred by financial services firms rather than corporations; and (iii) it is likely at the high end of a range of costs.[335] Commenters also argued that the $50,000 per proposal cost estimate provided by one observer [336] and used as a lower bound of our cost estimates in the Proposing Release likely is unreliable because it is based on anecdotal reports.[337] Finally, a number of commenters, without providing cost estimates of their own, argued that the actual costs of processing shareholder proposals are lower than existing cost estimates because these estimates are exaggerated by certain commenters.[338]

Some other commenters stated that the economic analysis should distinguish between the costs that are discretionary (*e.g.,* cost of submitting a no-action request to Commission staff, the decision to use an outside law firm instead of in-house personnel, or the expenses related to soliciting investors) and mandatory (*e.g.,* the cost of printing and mailing the shareholder proposal materials).[339] Relatedly, for those costs that are discretionary, some commenters argued that companies' decisions to incur those costs may be suboptimal and to the detriment of investors.[340] In particular, several commenters argued that the volume of unsuccessful no-action requests is suggestive of an unproductive use of company resources, and thus the actual, non-discretionary costs of processing shareholder proposals (and consequently the actual cost savings of the rule amendments) are low.[341] As a response to commenters that were concerned with distinguishing between discretionary and non-discretionary costs, we use an estimate of non-discretionary costs (*i.e.,* the cost of printing and mailing shareholder proposals) as the lower bound for our direct cost savings estimates in the economic analysis.[342]

proposals. Several of the respondents noted in their comments that they had not received a shareholder proposal in recent years. Further, the Council of Institutional Investors estimates that S&P 500 companies received 77% of the proposals received by Russell 3000 companies as of the end of the third quarter 2017 (*see* Jonas Kron & Brandon Rees, *Frequently Asked Questions about Shareholder Proposals,* Council of Institutional Advisors, at 1 (last visited Aug. 21, 2020), *available at https://www.cii.org/files/10_10_Shareholder_Proposal_FAQ(2).pdf* (''CII FAQ'')), but 47% of the Society for Corporate Governance survey respondents were not in the S&P 500. Further, the types of costs included in the survey responses differ across respondents and so we cannot use the survey responses to estimate the total cost of a typical shareholder proposal.

[333] *See* letters from AFL–CIO dated February 3, 2020; As You Sow dated February 3, 2020; Better Markets dated February 3, 2020; CalPERS dated February 3, 2020; John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020; CtW Investment Group dated February 3, 2020; Impax Asset Management dated January 20, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Brotherhood of Teamsters dated February 3, 2020; Richard A. Liroff dated January 28, 2020; Paul M. Neuhauser dated February 3, 2020; Segal Marco Advisors dated February 3, 2020; Tom Shaffner dated December 17, 2019; UAW Retiree Medical Benefits Trust dated January 30, 2020. Some of the points raised by commenters were also discussed in the Proposing Release. *See* Proposing Release at 66496.

[334] *See* letter in response to the Proxy Process Roundtable from American Securities Association dated June 7, 2019.

[335] *See, e.g.,* letters from Better Markets dated February 3, 2020; John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Segal Marco Advisors dated February 3, 2020; Tom Shaffner dated December 17, 2019; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[336] *See* Statement of Darla C. Stuckey, President and CEO, Society for Corporate Governance, before the H. Comm. on Financial Services, Subcomm. on Capital Markets and Government Sponsored Enterprises, Sept. 21, 2016 (noting ''a lower legal cost estimate based on anecdotal discussions with [the Society for Corporate Governance] members of $50,000 per proposal'').

A number of commenters criticized cost estimates that other commenters provided and were cited in the Proposing Release but which we did not use in the estimation of cost savings because they fell within the lower and upper bounds of the cost estimates we used. *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; RK Invest Law dated February 3, 2020; Segal Marco Advisors dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[337] *See, e.g.,* letters from John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020.

[338] *See, e.g.,* letters from AFL–CIO dated November 1, 2017 (enclosed in November 27, 2019 letter); Athena Impact dated January 17, 2020; Dominican Sisters of Springfield Illinois dated January 23, 2020; Impax Asset Management dated January 20, 2020; Stephen Lewis dated January 29, 2020; Neuberger Berman dated January 27, 2020; US SIF dated January 31, 2020. As discussed in more detail below, the cost estimates used in the economic analysis are informed by the Commission's decades-long experience with Rule 14a–8 and the various forms of outreach on the proxy process that the Commission has conducted over the years. *See infra* note 346.

[339] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; CtW Investment Group dated February 3, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Impax Asset Management dated January 20, 2020; International Brotherhood of Teamsters dated February 3, 2020; Richard A. Liroff dated January 28, 2020; James McRitchie dated February 2, 2020; US SIF dated January 31, 2020.

A commenter also argued that the largest cost associated with shareholder proposals is the cost of submitting a no-action request to Commission staff, and ''the only proposals excludable under the new rules would be those that otherwise could meet the requirements of Rule 14a–8, and would not fall within the subset of proposals likely to generate the highest costs.'' *See* letter from John Coates and Barbara Roper dated January 30, 2020. We understand this comment to mean that the proposals excludable under the rule amendments would be those that otherwise meet the requirements of Rule 14a–8 and thus companies would not be required to incur costs associated with a no-action request to exclude those proposals. We disagree with the commenter's assessment, including as a factual matter. For example, a proposal that may be excludable under the new rules because the proponent did not have a sufficiently long-term interest in the company also may have been excludable by the company for one of the other reasons enumerated in paragraph (i) of Rule 14a–8. To the extent that the rule amendments will deter proponents from submitting some shareholder proposals that are excludable under the rule amendments and other Rule 14a–8 requirements, companies and their shareholders could realize cost savings by avoiding having to seek no-action relief for those shareholder proposals.

Some commenters implied that because many proposals are withdrawn, the cost of shareholder proposals is small. *See, e.g.,* letter from Impax Asset Management dated January 20, 2020. We disagree with this assertion because companies may incur significant direct and opportunity costs to engage with shareholders and achieve the withdrawal of a proposal.

Some commenters also suggested that if companies wish to avoid the expenses associated with shareholder proposals, they could simply include those proposals in their proxy materials. *See, e.g.,* letter from Impax Asset Management dated January 20, 2020. Companies and their shareholders incur costs associated with the inclusion of proposals in the proxy materials. In addition, we believe that companies likely will expend time and effort to analyze and assess a shareholder proposal, either because it is not obvious whether the proposal will be beneficial for shareholders or because further communication with the proponent may be beneficial.

[340] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Richard A. Liroff dated January 28, 2020; James McRitchie dated February 2, 2020; US SIF dated January 31, 2020. *See also* Brown (2017), *supra* note 320, at 21; Adam M. Kanzer, *The Dangerous ''Promise of Market Reform'': No Shareholder Proposals,* Harvard Law School Forum on Corporate Governance and Financial Regulation (Jun. 15, 2017), *available at https://corpgov.law.harvard.edu/2017/06/15/the-dangerouspromise-of-market-reform-no-shareholder-proposals/,* at 2; James McRitchie, *SRI Funds & Advisors Send Open Letters on Lawsuits Against Shareholders, CorpGov.net* (Mar. 24, 2014), *available at https://www.corpgov.net/2014/03/sri-funds-advisors-send-open-letters-on-lawsuits-against-shareholders/;* letter in response to the Proxy Process Roundtable from Investor Voice, SPC dated November 14, 2018.

[341] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020.

[342] *See infra* note 344.

Several commenters also argued that the economic analysis should consider the marginal rather than the average cost of shareholder proposals, and suggested the marginal costs would be significantly lower than the average costs because all fixed costs of handling proposals will remain.[343] While we agree with the commenters that the economic analysis should consider the marginal cost of shareholder proposals, we do not believe that the marginal costs would be significantly lower than the average costs because many of the costs associated with processing shareholder proposals are variable costs, such as reviewing the proposal and addressing issues raised in the proposal, engaging in discussions with the proponent, and printing and mailing materials associated with the particular proposal.

We recognize that there is variation in the costs to companies of responding to shareholder proposals, and we have considered all of the comments received in estimating cost savings to companies. In response to these comments, we have adjusted our estimate of the lower end of the costs. We use the estimate of $18,982 to print and mail a single shareholder proposal, rounded up to $20,000, as the lower bound for our direct cost estimates in the economic analysis.[344] We continue to use $150,000 as the upper bound for our direct cost estimates in the economic analysis, which we believe represents a reasonable upper end of potential costs of processing a shareholder proposal, including legal and management time to consider a shareholder proposal and the cost of submitting a no-action request to Commission staff.[345] Nevertheless, we acknowledge that the cost of processing certain proposals may be outside of this $20,000 to $150,000 range due to the large variation in the types of proposals.[346]

Hence, we estimate that, as a result of the final amendments to Rule 14a–8(b) and Rule 14a–8(c), all Russell 3000 companies together may experience an upper bound annual cost savings associated with a decrease in the number of submitted proposals ranging from $332,400 to $72.30 million per year.[347] In addition, we estimate that as a result of the final amendments to the resubmission thresholds, all Russell 3000 companies together may experience an upper bound annual cost savings associated with a decrease in the number of submitted proposals ranging from $831,000 to $6.23 million per year.[348] In total, we estimate that all Russell 3000 companies may experience an upper bound of annual cost savings ranging from $1.16 million to $78.53 million per year, assuming no change in proponents' behavior as a result of the final amendments.

Commenters argued that the cost savings estimated in the Proposing Release and arising from the rule amendments are not substantial because: (i) Shareholder proposals are a small fraction of management proposals and so the cost savings of the rule amendments will be small; [349] and (ii) the cost savings arising from the rule amendments are small relative to companies' market capitalization and relative to the costs arising from the rule amendments.[350] Commenters also

[343] *See, e.g.,* letters from John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020.

[344] The $18,982 estimate was derived in 2009 and is equal to $22,600, when adjusted for inflation (*see supra* note 58 for the source of inflation adjustment data). To be conservative in our cost savings estimates and for ease of discussion and calculations, we use $20,000 as the rounded up estimate of $18,982. *See* letters from John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020.

See Proposing Release at 66510 (citing 2009 BRT Letter, *supra* note 332). We use this cost estimate as the lowest range because the cost of printing and mailing a shareholder proposal is the only non-discretionary cost that all companies must incur when they are required to include a shareholder proposal in their proxy statement. The cost of printing and mailing shareholder proposals, however, only captures a subset of the direct costs that the company may incur. It is unclear whether this cost estimate captures the cost of tallying votes for an additional shareholder proposal. In addition, this cost estimate is the average cost of printing and mailing a shareholder proposal rather than the marginal cost of printing and mailing an additional shareholder proposal.

[345] *See* Proposing Release at 66461. *See* letter from Center for Capital Markets, dated January 31, 2020.

[346] Some commenters suggested that the Commission should have conducted independent research on the cost of shareholder proposals. *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020. We note that the Commission has conducted various forms of outreach over the years on the proxy process, including hosting the Proxy Process Roundtable and soliciting public input on the Rule 14a–8 ownership thresholds and the costs of submitting shareholder proposals. That input informed our cost estimates in the Proposing Release, and we specifically requested comment on the estimates and data to help us refine our analysis. We considered all of this information thoroughly, leveraging our decades of experience with Rule 14a–8, when evaluating whether the available information is reliable and sufficient. We have no reason to believe that additional study of the costs of shareholder proposals would yield materially different information, nor are we aware of additional sources of information that would further inform these cost estimates.

One commenter also argued that the cost estimate of shareholder proposals used in the economic analysis of the Proposing Release is inconsistent with the cost estimate of shareholder proposals used in the PRA of the release. *See* letter from John Coates and Barbara Roper dated January 30, 2020. Our revised economic analysis takes into account the lowest cost estimate discussed in the PRA of the Proposing Release. The cost estimates in the PRA section of this release may be different than the cost estimates in the economic analysis because the economic analysis applies a range of cost estimates to all proposals (*i.e.,* those that are included in the proxy statement without seeking no-action relief, those that are included in the proxy statement after seeking no-action relief, those that are omitted from the proxy statement after seeking no-action relief, and those that are withdrawn) while the PRA uses an average cost estimate per proposal category. In addition, the PRA makes certain assumptions regarding hourly costs to arrive at a cost estimate per proposal category while the economic analysis uses per-proposal cost estimates provided by commenters or surveys.

[347] $332,400 = $20,000 (*see supra* note 344) × 2% (*i.e.,* minimum upper bound percentage of excludable proposals as a result of the amendments to Rules 14a–8(b) and 14a–8(c) from Table 1 above) × 831 (*i.e.,* all proposals submitted to be considered at 2018 shareholders' meetings).

$72.30 million = $150,000 (*see supra* note 344) × 58% (*i.e.,* maximum upper bound percentage of excludable proposals as a result of the amendments to Rules 14a–8(b) and 14a–8(c) from Table 1 above) × 831 (*i.e.,* all proposals submitted to be considered at 2018 shareholders' meetings).

Our analysis assumes that the distribution of ownership for proponents with exact ownership information in the proxy statements is the same as the distribution of ownership for proponents with minimum or no ownership information in the proxy statements and the distribution of ownership for proponents that submitted proposals that were ultimately withdrawn or omitted. Our analysis also applies the same per-proposal cost estimate to voted, omitted, and withdrawn proposals, and it applies the same per-proposal cost estimate to operating companies and management companies. Further, our analysis does not account for overlap in the excludable proposals under the various aspects of the rule amendments. Lastly, our analysis assumes that companies will not reallocate the time and resources that will be freed up as a result of the reduction in proposals to process the remaining proposals, if any.

[348] $831,000 = $20,000 (*see supra* note 344) × 5% (*i.e.,* upper bound percentage of excludable proposals as a result of the amendments to Rule 14a–8(i)(12) from Table 1 above) × 831 (*i.e.,* all proposals submitted to be considered at 2018 shareholders' meetings).

$6.23 million = $150,000 (*see supra* note 344) × 5% (*i.e.,* upper bound percentage of excludable proposals as a result of the amendments to Rule 14a–8(i)(12) from Table 1 above) × 831 (*i.e.,* all proposals submitted to be considered at 2018 shareholders' meetings).

Our analysis applies the same per-proposal cost estimate to voted, omitted, and withdrawn proposals and to operating companies and management companies. In addition, our analysis assumes that the amendments to Rule 14a–8(i)(12) will have the same effect on proposal eligibility of voted, withdrawn, and omitted proposals. Lastly, our analysis assumes that companies will not reallocate the time and resources that will be freed up as a result of the reduction in proposals to process the remaining proposals, if any.

[349] *See, e.g.,* letter from AFL–CIO dated February 3, 2020; Council of Institutional Investors dated January 30, 2020.

[350] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; CtW Investment Group dated February 3, 2020; Impax Asset Management dated January 20, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Brotherhood of Teamsters dated February 3, 2020; Segal Marco Advisors dated

suggested that the cost of shareholder proposals is small for smaller companies because smaller companies do not receive proposals frequently, and so any benefits to those companies due to the rule amendments is limited.[351] We acknowledge that the costs of shareholder proposals may be a small percentage of companies' market capitalization but we continue to believe that these costs are nonetheless significant in terms of the time and attention from company management. Further, we continue to believe that the rule amendments better ensure that the attendant burdens for other shareholders and companies associated with the processing of shareholder proposals and the inclusion of such proposals in the company's proxy statement are incurred in connection with those proposals that are (1) submitted by shareholders with a sufficient demonstrated interest in the company and (2) with respect to resubmissions, more likely to receive support from fellow shareholders.[352] Lastly, the cost savings estimates cited by commenters only reflect a subset of the benefits of the rule amendments (*i.e.,* the benefits that we were able to quantify in our economic analysis) and does not include a quantification of other qualitative benefits of the rule amendments, which are discussed below.

ii. Other Economic Benefits to Companies

In addition to the direct cost savings to companies discussed above, by requiring a statement from the proponent that he or she is willing to meet with the company after submission of the shareholder proposal, the final amendments may encourage more direct communication between the proponent and the company. This may foster potential beneficial shareholder engagement more generally; it may promote more frequent resolution of proposals outside the voting process. Although companies would incur costs (*e.g.,* management and legal time) to engage with shareholder-proponents, companies may choose to do so if they expect a benefit, including if they expect the cost of the resolution outside of the proxy process to be lower than the cost that they and their shareholders would incur to process a shareholder proposal.[353] We believe that this requirement may increase engagement between management and shareholder-proponents because it will require proponents to set aside time to communicate with management and provide specific contact information to facilitate that discussion. This amendment will enable companies to know whom to contact and when to do so if they wish to engage with the proponent about the proposal. Further, although the revised rule will not require companies to engage with shareholder-proponents, companies may be more likely to engage if they are provided with the shareholder-proponent's contact information and availability at the time the proposal is submitted.

Also, to the extent that the practices of certain proponents are not already consistent with the final amendments related to proposals submitted through a representative, the final amendments will likely benefit companies by clearly communicating to companies that proponents authorize representatives to act on their behalf. The requirements under the final amendments would provide a meaningful degree of assurance as to the shareholder-proponent's identity, role, and interest in a proposal that is submitted for inclusion in a company's proxy statement.[354] Further, the final amendments will likely result in cost savings to companies that currently expend resources to obtain information that is not provided by proponents but will be required under the final amendments.[355] We expect that any cost savings associated with the final amendments related to proposals submitted through a representative will likely be small because most proponents and representatives already provide much of the documentation and information required by the rule amendments.

To the extent that the final amendments will reduce the costs to companies of processing shareholder proposals, the final amendments may result in efficiency improvements. In addition, to the extent that the final amendments will reduce costs to companies associated with the shareholder-proposal process, the final amendments may be a positive factor in the decision of businesses to become public reporting companies, which could positively affect capital formation on the margin.[356] Nevertheless, we believe that any such effects likely will be minimal because most firms receive few proposals each year and the costs of responding to proposals likely are a small percentage of the costs associated with being a public company.[357] In addition, companies that have recently had an initial public offering infrequently receive shareholder proposals.[358]

Several commenters argued that the rule amendments will increase companies' cost of capital by reducing the effectiveness of shareholder oversight, the efficiency of corporate

February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[351] *See* letter from Paul M. Neuhauser dated February 3, 2020. Another commenter argued that the proposed amendments will disproportionately benefit a small subset of large companies. *See* letter from Sustainable Investments Institute dated February 3, 2020.

[352] Analysis in the Proposing Release showed that of resubmitted proposals that ultimately obtain majority support, the overwhelming majority have garnered more than 15% on their second submission and more than 25% on their third submission. Based on our review of shareholder proposals that received a majority of the votes cast on a second or subsequent submission between 2011 and 2018, 95% received support greater than 15% on the second submission, and 100% received support greater than 25% on the third or subsequent submission. In addition, of the 22 proposals that obtained majority support on their third or subsequent submissions, approximately 95% received support of over 15% on their second submission, and 100% received support of over 25% on their third or subsequent submission. *See* Proposing Release at Section IV.B.3.iv.

[353] Some commenters supported the idea that requiring a statement from the proponent that he or she is willing to meet with the company will improve communication between proponents and companies. *See, e.g.,* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Church Investment Group dated January 29, 2020; National Association of Manufacturers dated February 3, 2020. Other commenters, however, argued that certain companies are unwilling to engage with proponents and there is no evidence that this rule amendment will actually increase engagement between management and shareholder-proponents. *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; CalPERS dated February 3, 2020; Ceres et al. dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; International Brotherhood of Teamsters dated February 3, 2020; Local Authority Pension Fund Forum dated February 3, 2020; Paul M. Neuhauser dated February 3, 2020; Segal Marco Advisors dated February 3, 2020; Trillium Asset Management dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[354] *See, e.g.,* letters from Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; National Association of Manufacturers dated February 3, 2020.

[355] *See, e.g.,* Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Nasdaq, Inc. dated February 3, 2020.

[356] *See, e.g.,* letters from American Securities Association dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; *see also* letter in response to the Proxy Process Roundtable from Center for Capital Markets Competitiveness dated December 20, 2018.

[357] Between 1997 and 2018 for Russell 3000 companies that received a proposal, the median number of proposals was one per year. *See* Roundtable Transcript, *supra* note 141, comments of Brandon Rees, Deputy Director of Corporations and Capital Markets, AFL–CIO; *see also* letters in response to the Proxy Process Roundtable from Ceres dated November 13, 2019; Mercy Investment Services, Inc. dated December 3, 2018; Presbyterian Church U.S.A. dated November 13, 2018.

[358] *See infra* note 395.

governance arrangements, the extent to which governance arrangements conform with best governance practice, and companies' overall environmental, social, and governance (''ESG'') performance.[359] Relatedly, one of these commenters argued that the rule amendments will harm capital formation because investors might shy away from capital markets if they believe that their ability to make changes to companies that would benefit the companies and their shareholders is compromised.[360] We agree with commenters that the proxy system is important to the cost of capital and capital formation, and some changes prompted by shareholder proposals may be considered beneficial by other shareholders. Nevertheless, there are a number of avenues through which shareholders can encourage change at public companies. Under the final amendments, shareholders can and, we expect, will continue to pursue these other avenues of engagement, which may help mitigate any potential increase in the number of excludable proposals. In addition, we note again that many proposals that would be newly excludable under these rule amendments would be (1) those in which the proponent has not demonstrated a meaningful interest in the company (*e.g.,* by holding $2,000 of stock for three years, or higher amounts for shorter periods of time) or (2) resubmissions of proposals which shareholders have already expressed substantial disapproval (*e.g.,* at least 75 percent, 85 percent or 95 percent disapproval) in prior years. We believe these changes will improve capital formation because companies and fellow shareholders will no longer expect to bear the costs of responding to, reviewing, and voting on these types of proposals, which we believe do not warrant use of the company's proxy statement.

iii. Costs of Updating Policies and Procedures

We acknowledge here, as we did in the Proposing Release, that companies may incur one-time costs to amend their policies and procedures in light of the final amendments. The one-time costs that companies may incur include (i) reviewing the requirements of the final amendments; (ii) modifying the existing policies and procedures to align with the requirements of the final amendments; and (iii) preparing new training materials and administering training sessions for staff in affected areas. According to commenters, the change to a three-tiered approach to submission thresholds will also increase compliance complexity because companies will be required to consider multiple thresholds for the purpose of evaluating whether a proposal is eligible for exclusion.[361] Nevertheless, we expect the one-time costs and the costs associated with increased complexity to be minimal because companies already have in place policies and procedures to implement Rule 14a–8's requirements and will only need to modify those policies and procedures to comply with the final amendments rather than create new policies and procedures.[362]

iv. Effects on Competition

To the extent that the final amendments will result in cost savings for U.S. firms, the final amendments may improve U.S. firms' competitive position relative to foreign firms, because foreign firms are not subject to the federal proxy rules.[363] Further, to the extent that the final amendments to the ownership (resubmission) thresholds will have disproportionate effects on smaller (larger) companies, the final amendments may alter competition between firms of different sizes.[364] The amendments to the ownership thresholds could have a disproportionate effect on companies with smaller market capitalization because shareholder-proponents' holdings are more likely to be below the amended ownership thresholds in smaller companies, to the extent that investors hold stocks proportionately to the companies' market capitalization (*e.g.,* investors hold the market portfolio).[365] In addition, the final amendments to the resubmission thresholds will likely have a greater effect on larger companies because larger companies are more likely to receive shareholder proposals.[366] Nevertheless, we expect that any such effects likely will be minimal because the cost of processing shareholder proposals likely is a small percentage of companies' total cost of operations.

2. Non-Proponent Shareholders

Non-proponent shareholders may benefit from the decrease in the number of proposals because they may commit fewer resources to reviewing and voting on shareholder proposals.[367] We are unable to quantify the costs to non-proponent shareholders of reviewing and voting on shareholder proposals, but we believe the cost savings from a decrease in the number of proposals will be significant. The reason is that the number of non-proponent shareholders at each registrant is very large in absolute terms and relative to the number of shareholder-proponents. Consequently, we expect the aggregate cost savings associated with the elimination of a shareholder proposal (*e.g.,* the aggregate cost to shareholders to review and vote on the proposal) will be significant in absolute terms and much larger when compared to the potential costs to shareholder-proponents, such as the costs to craft and submit the proposal or, in the case of a potential proponent, the costs to acquire and hold shares for a sufficient period of time to meet the eligibility requirements.

While these cost savings are difficult to estimate across the wide array of shareholder types, we believe that the cost savings are significant. For example, we note that many investment

[359] *See, e.g.,* letters from Lucian A. Bebchuk dated February 3, 2020; Ceres et al. dated February 3, 2020; Illinois Treasurer dated January 16, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; International Brotherhood of Teamsters dated February 3, 2020; James McRitchie dated February 2, 2020; Oxfam dated February 3, 2020; Segal Marco Advisors dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[360] *See* letter from Lucian A. Bebchuk dated February 3, 2020.

[361] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Local Authority Pension Fund Forum dated February 3, 2020.

[362] No company or company representatives argued that the final rule amendments will increase administrative costs.

[363] *See* Proposing Release at 66459 n.3.

[364] *See infra* Section V.E.1 for detailed discussion of the potentially disproportionate effects of the rule amendments.

[365] *See, e.g.,* John Y. Campbell, *Household Finance,* 61 J. Fin. 1553 (2006) (discussing households' stock holdings).

See also, e.g., letters from CalPERS dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Paul Rissman dated January 15, 2020; Trillium Asset Management dated February 3, 2020 (arguing that the amended thresholds will have a larger effect on smaller companies).

[366] Our analysis shows that 20% of resubmitted shareholder proposals at S&P 500 companies would be excludable under the proposed resubmission thresholds, as compared to 12% of proposals resubmitted to non-S&P 500 firms. *See* Proposing Release at 66502.

[367] One commenter argued that the costs shareholders incur to review and consider shareholder proposals are discretionary because ''[a]ny shareholder that thinks analyzing the proposal is a waste of time and resources can simply decide not to review them. Instead, the shareholder could either follow the advice of a hired proxy advisor, or vote by default with management, thereby supporting the status-quo world without the proposal.'' *See* letter from Institute for Policy Integrity dated February 3, 2020. Nevertheless, we note that institutional shareholders commit significant resources to reviewing and voting on shareholder proposals. *See infra* note 372. *See also* Commission Guidance Regarding Proxy Voting Responsibilities of Investment Advisers, Guidance, Release Nos. IA–5325 IC–33605 (Jul. 22, 2020) [84 FR 47420 (Sept. 10, 2019)].

advisers (among others) retain proxy voting advice businesses to perform a variety of services to reduce the burdens associated with proxy voting determinations, including determinations on shareholder proposals.[368] One major proxy voting advice business, Institutional Shareholder Services (''ISS''), reports a fee ranging from $5,000 to above $1,000,000 for these services [369] and 2,000 institutional clients,[370] which suggests an aggregate lower bound cost of $10 million and an upper bound cost of $2 billion for these clients of outsourcing certain voting related matters, not including the internal costs associated with voting, including the monitoring of the proxy voting advice businesses. We recognize that these fees cover a broad range of services provided by ISS (*e.g.,* voting services, governance research, ratings provision, etc.) in addition to reviewing and providing voting advice and services with respect to shareholder proposals.[371] They also reflect an aggregate cost and not the incremental cost of considering an additional shareholder proposal. However, these figures are nonetheless an indication that institutional shareholders commit significant resources to reviewing and voting on shareholder proposals.[372] Similarly, with respect to retail shareholders, we note that, if we assume a company has 100,000 shareholders and 50% of them (in number) are individual investors who spend 0–60 minutes reading a proposal at a cost of $25 per hour, then the consideration of one proposal could impose a cost of $0–$1,250,000 for the individual shareholders of such a hypothetical company.

While these figures do not provide a reliable basis for quantifying the cost savings of the amendments to non-proponent shareholders of a reduction in the number of shareholder proposals, they provide general support for our belief that the costs to non-proponent shareholders of analyzing and voting on shareholder proposals are significant, particularly in comparison to the costs to proponents to (i) meet the eligibility criteria and (ii) craft and submit a proposal. At a minimum, this supports the Commission's longstanding view that there should be a demonstrated alignment of ownership and investment interest between shareholder-proponents and shareholders generally. In addition, if the final amendments are effective in excluding proposals that are not submitted by proponents with a long-term or significant interest in the company or that are unlikely to receive support from other shareholders or to be implemented by management, then the decrease in the number of proposals may allow shareholders to focus their limited resources on the assessment and processing of proposals that are more likely to be aligned with their interests or have the potential to garner majority support and be implemented. Shareholders also will benefit indirectly from any decrease in the costs borne by companies.[373]

We discuss potential costs to companies and non-proponent shareholders from the potential decrease in the number of proposals as a result of the rule amendments in Section V.E.2 below.

3. Proponents of Shareholder Proposals

The final amendments may impose costs on proponents of shareholder proposals. These costs may arise as a result of a currently eligible proponent either having to invest additional funds to immediately submit a proposal or having to wait to submit a shareholder proposal and thus forgo the potential benefits associated with the immediate inclusion of the proposal in a company's proxy statement at the expense of other shareholders and the company. In each instance, we expect the shareholder-proponent who has not met the eligibility thresholds to choose the option that yields the greatest net benefit for himself or herself. For example, in instances where the benefit to the proponent associated with a more immediate proposal submission is large enough, we expect that the proponent will elect to incur the costs of investing additional funds to satisfy the amended ownership thresholds. The amended ownership thresholds, however, may deter proponents from submitting proposals for which the aggregate benefit to all shareholders exceeds the cost to the proponent of submitting a proposal. This may occur because the cost of meeting the new ownership thresholds is incurred by the proponent while any benefits associated with the proposal are widely dispersed among all shareholders. Nevertheless, since we believe these behavioral responses of proponents involve relatively modest costs, we expect that in many instances, the final amendments will not represent a significant hurdle for shareholder-proponents.

Commenters stated their belief that because of the final amendments to the ownership thresholds, shareholder-proponents may incur higher administrative costs to track their holdings for more than one year and prove their eligibility to submit a proposal.[374] Further, the change to a three-tiered approach could increase compliance complexity because shareholder-proponents will be required to consider multiple thresholds for the purpose of evaluating whether a proposal is eligible for exclusion, although we would expect those costs to be minimal for current proponents because those proponents already have in place processes to comply with Rule 14a–8's requirements and will only need to modify these processes to comply with the final rule rather than creating new ones.[375]

In addition, following the transition period, the final amendments to the ownership thresholds and the limitation on the ability to aggregate holdings across proponents may impose costs on

[368] We have limited data on fees charged by proxy voting advisory services. ISS reports a fee ranging from $5,000 to above $1,000,000 on Form ADV, and this covers a broad range of services provided by ISS (*e.g.,* voting services, governance research, ratings provision, etc.).

[369] *See* ISS Form ADV dated Mar. 27, 2020 *available at https://www.issgovernance.com/file/duediligence/iss-adv-part-2a-march-2020.pdf,* at 5.

[370] *See* ISS Form ADV dated Apr. 23, 2020 *available at https://reports.adviserinfo.sec.gov/reports/ADV/111940/PDF/111940.pdf,* at 14.

[371] *See id.*

[372] Indeed, a number of commenters to the Commission's proposed amendments to the exemptions from the proxy rules for proxy voting advice, particularly institutional investors who typically vote a large number of proposals each proxy season, expressed that they face significant resource challenges in determining how to vote on shareholder proposals. *See, e.g.,* letters in response to Amendments to Exemptions from the Proxy Rules for Proxy Voting Advice, Release No. 34–87457 (Nov. 5, 2019) [84 FR 66518 (Dec. 4, 2019)] from Ohio Public Employees Retirement System dated February 3, 2020; Council of Institutional Investors dated February 13, 2020; Investment Company Institute dated February 3, 2020; MFS Investment Management dated February 3, 2020; Institutional Adviser Association dated February 3, 2020.

[373] *See, e.g.,* letter from Business Roundtable dated February 3, 2020. *See also* letter in response to the Proxy Process Roundtable from Business Roundtable dated June 3, 2019 (noting ''shareholders can lose sight of matters of true economic significance to the company if they are spending time considering one, or even numerous, immaterial proposals. The resources and attention expended in addressing shareholder proposals cost the company and its shareholders in absolute dollars and management time and, perhaps worse, divert capital resources to removal of an immediate distraction and away from investment in value-adding allocations, such as research and development and corporate strategy'').

[374] The commenter stated that costs that proponents would bear as a result of longer holding periods include administrative costs to track their holdings for more than one year and prove their eligibility to submit a proposal. This commenter also stated that this administrative cost will also be higher whenever the proponent changes brokers or banks. *See, e.g.,* letter from AFL–CIO dated February 3, 2020.

[375] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Local Authority Pension Fund Forum dated February 3, 2020.

proponents that currently satisfy the ownership thresholds but do not currently satisfy the new thresholds, who may take actions to preserve their ability to submit shareholder proposals under the new thresholds.[376] These costs may arise from some combination of: (i) Shareholder-proponents' efforts to reallocate shareholdings in their portfolio to satisfy the dollar ownership thresholds; (ii) decreased diversification of shareholder-proponents' portfolio because a larger portion of their wealth may be invested in a particular company; [377] and (iii) shareholder-proponents holding the shares for longer periods of time to satisfy the duration thresholds.

A shareholder-proponent that chooses to reallocate assets to meet the new ownership thresholds may incur transaction costs to buy shares and, depending on the shareholder-proponent's liquidity, may incur transaction costs to sell other assets to raise cash to buy shares or incur borrowing costs to raise cash to buy shares. However, we expect a negligible number of shareholders to incur these costs because, as discussed elsewhere in this release, most investors do not submit proposals. Furthermore, in theory, reallocation of portfolio assets might mean that a shareholder-proponent deviates from what would be an efficient portfolio in the absence of the final amendments. For example, a shareholder who held the minimum amount of shares for the purpose of submitting a shareholder proposal for the minimum amount of time could, instead of holding $2,000 of shares for an additional two years, choose to increase her holdings in a company from $2,000 to $25,000 to retain the ability to submit a shareholder proposal in one year. In theory, such a deviation could result in a portfolio that no longer supplies the shareholder-proponent with the desired levels of risk and return. However, if the shareholder made the minimum investment for purposes of submitting the proposal, such a portfolio-oriented investment strategy would be of secondary consideration. More generally, we do not believe that the additional investment in the company needed to hold the same $2,000 of stock for three years instead of one, or to meet the revised threshold for a one-year holding period (*i.e.,* $25,000 − $2,000 = $23,000), on its own constitutes a cost to shareholder-proponents, as this amount represents the holding or purchase of assets that will earn an expected rate of return in the form of capital gains and/or dividends. The impact of reduced diversification on portfolio risk and return that may result from increasing holdings in a particular company would depend on the size of a shareholder-proponent's asset holdings, and would be larger for shareholder-proponents with smaller portfolios. However, shareholder-proponents may be able to mitigate the costs of reduced diversification by reducing exposures to assets with similar risk characteristics.[378] Also, in theory, a shareholder-proponent might incur costs by choosing to hold shares for longer than would otherwise be efficient resulting, for example, in the borrowing of funds to meet liquidity needs or a delay in purchases of alternative assets.[379] We lack sufficient data to quantify their effects because we lack data on proponents' portfolio holdings, investment preferences and resources.

The final amendments to the 14a–8(b) shareholder engagement component may impose the following costs on shareholder-proponents: (i) Direct costs associated with disclosing the times the proponents will be available to communicate with management as well as preparing to and communicating with management and (ii) the opportunity costs associated with setting aside and spending time to communicate with management instead of engaging in other activities.[380] Certain commenters also argued that this aspect of the rule amendments could discourage shareholders from submitting proposals because some shareholder-proponents may be reluctant to engage directly with the company.[381] We expect the direct costs associated with this aspect of the rule amendments to be minimal because the information required to be disclosed is readily available, the rule does not prescribe any particular form or degree of engagement with the company, and proponents can use inexpensive means of communication with the company, such as teleconference calls. We also note that the rule does not prohibit representatives from participating in any meetings that take place or advising the shareholder-proponent with respect to all aspects of the engagement process.

The final rule amendment requiring certain documentation when a proponent submits a proposal through a representative may result in shareholders that submit a proposal through a representative incurring minimal costs to ensure that their practices are consistent with the final amendments.[382] To the extent that the practices of certain proponents are not

[376] Any such effects will be mitigated temporarily by the transition period of the final amendments. *See* Section III.

[377] The costs of diversification arise from lower risk-adjusted expected return of an undiversified portfolio compared to a diversified one. *See, e.g.,* letters from First Affirmative Financial Network, LLC dated January 24, 2020; Jantz Management LLC dated January 21, 2020; Shareholder Commons dated January 31, 2020; Wright-Ingraham Institute dated February 3, 2020.

[378] For example, a shareholder-proponent might reduce the impact of acquiring additional shares of Company A on portfolio diversification by liquidating shares of other companies in the same industry.

[379] In such a case, we can express the opportunity cost of holding shares in one company while delaying the purchase of shares in another company as the difference in risk-adjusted expected returns between the shares held and the shares to be purchased.

[380] *See, e.g.,* letters from Boston Trust Walden et al. dated January 27, 2020; Ceres et al. dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Paul Rissman dated January 15, 2020; Segal Marco Advisors dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

Some commenters argued that the requirement that a proponent should state its availability to meet with management will impose costs on companies because ''companies will be hard-pressed to assemble personnel with appropriate expertise to engage substantively on the proposal, given the short notice, and schedules of both investors and companies are crowded not only with proposal-related business but also with holiday obligation.'' *See, e.g.,* letters from Ceres et al. dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020. While we acknowledge that this rule amendment may also impose costs on companies, we believe that companies will choose to engage with proponents only if they believe the benefits of the engagement outweigh the costs.

[381] *See, e.g.,* letters from Interfaith Center on Corporate Responsibility dated January 27, 2020; Paul Rissman dated January 15, 2020.

One commenter argued that the Commission should not get involved in issues of shareholder-management engagement, and if the Commission does, it should conduct a survey of both investors' and companies' current practices. *See* letter from Investor Environmental Health Network dated January 31, 2020. *See supra* note 346 for our response to related commenter suggestions that the Commission should conduct additional analysis.

Some commenters also argued that the Commission has not identified a market failure that this aspect of the rule amendments seeks to address, especially given the increase in the number of withdrawn proposals over time, which suggests increased engagement between proponents and companies. *See, e.g.,* letter from AFL–CIO dated February 3, 2020. We understand that proactive company engagement with shareholders has increased in recent years, and shareholders frequently withdraw their proposals as a result of company-shareholder engagement. Nevertheless, we believe that further facilitating engagement would be beneficial both to companies and to shareholders.

[382] Some commenters argued that the rule amendment requiring certain documentation when a proponent submits a proposal through a representative will create ambiguity that can be exploited by management to exclude beneficial proposals. *See, e.g.,* letter from As You Sow dated February 3, 2020. We disagree with the commenter that management will be able to exploit any ambiguity to exclude beneficial proposals because management must provide its reasons for excluding a proposal to the Commission and the shareholder-proponent prior to excluding a shareholder proposal and proponents can contest exclusions of proposals that they deem to be inappropriate.

consistent with the final amendments, the final amendments will also impose minimal costs on proponents to provide this additional documentation. Some commenters argued that this aspect of the rule amendments would be more burdensome for institutional investors, who always act through agents, and that it would interfere with contractual relations, such as attorney-client relations.[383] As discussed in Section II.B.3, where a shareholder-proponent is an entity and thus can act only through an agent, compliance with the amended rule will not be necessary if the agent's authority to act is apparent and self-evident such that a reasonable person would understand that the agent has authority to act. In addition, although shareholder-proponents who elect to submit a proposal through a representative will be required to provide additional information about their submissions, the rule will not prevent them from using representatives in accordance with state law. We requested, but did not receive, data on or estimates of the specific costs that representatives and proponents will incur to comply with this aspect of the rule amendments. Nevertheless, we believe that any costs associated with this aspect of the rule amendments will be small because the vast majority of the proponents and representatives that will be required to provide documentation under the final amendments already provide much of this documentation.

The amendments to the resubmission thresholds will impose costs on proponents to the extent they may spend more resources in preparing a proposal to seek to garner sufficient levels of support to satisfy the final amendments.[384] Any effect of the amendments to resubmission thresholds may be mitigated by the fact that companies' ability to exclude certain resubmissions will be limited to a three-year cooling-off period regardless of the level of support the proposal last received.

E. Other Potential Effects of the Amendments

Rule 14a–8 sets thresholds at which it is appropriate for a shareholder proposal to be considered for inclusion in the company's proxy materials initially, or on resubmission. For example, the thresholds for initial proposals are designed to help ensure that the interests of those who submit them are appropriately aligned with fellow shareholders, by indicating a sufficient economic stake or investment interest in the company. The thresholds for resubmissions are designed to provide a modest cooling-off period for those proposals that previously were disapproved by fellow shareholders by a large margin (*i.e.,* 75 percent, 85 percent, or 95 percent disapproval). In neither case are the thresholds designed to or meant to judge the merits of any particular proposal. Nevertheless, commenters asserted that the amendments may have certain unintended effects. In the Proposing Release, we provided descriptive statistics on shareholder proposals by type of proposals, proponents, and companies.[385] In this section, we address the comments we received on potential effects of the rule amendments on excludable proposals by type of proposal, proponent, and company.[386] We also consider comments about economic effects of the final rule amendments on the quality of submitted proposals,[387] as well as issues raised by commenters with our use of voting support in the economic analysis included in the Proposing Release.[388]

We believe that many of the potential negative effects suggested by commenters that would result from our adoption of the proposal and discussed in this section would be mitigated if shareholder-proponents adjust their behavior in light of the amendments. For example, any negative effects related to the changes in initial submission thresholds could be mitigated to the extent that shareholder-proponents (who, again, are an extremely small percentage of total shareholders) adjust their behavior to hold at least $2,000 of shares for at most two additional years or hold higher amounts. Of course, to the extent that shareholders adjust their behavior in this way, the cost savings associated with the amendments would also be reduced. Negative effects to shareholder-proponents related to the exclusion of proposals that may provide benefits to companies and their shareholders may be substantially mitigated to the extent that the final amendments are more likely to exclude shareholder proposals with an observable measure of low shareholder interest (*i.e.,* low voting support among shareholders).[389] As explained above, the number of non-proponent shareholders—who must review, consider, and vote on shareholder proposals—is very large relative to shareholder-proponents; accordingly, we believe that any costs set forth below are appropriate in light of the benefits to other shareholders. In addition, the negative effects of the final rule amendments could be mitigated to the extent that companies elect to include in their proxy materials or implement otherwise excludable proposals that they believe will benefit shareholders; that eligible shareholders take up proposals that may benefit other shareholders from the proponents precluded from submitting certain proposals under the final rule amendments; or that shareholder-proponents are able to influence management and other shareholders through means other than the submission of shareholder proposals.

1. Effects of the Rule Amendments on Excludable Proposals by Type of Proposal, Proponent, and Company

As discussed above, the amendments set thresholds at which it is appropriate for a shareholder proposal to be

[383] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Paul M. Neuhauser dated February 3, 2020.

[384] *See, e.g.,* letters from Center for Capital Markets Competitiveness dated January 31, 2020; National Association of Manufacturers dated February 3, 2020.

One commenter disagreed with the assertion that that the resubmission thresholds will improve proposal quality because proponents already request feedback on their proposals prior to submitting them to the company. *See* letter from Interfaith Center on Corporate Responsibility dated January 27, 2020.

A commenter also suggested that an increase in the resubmission thresholds will provide stronger incentives to some proponents to submit proposals on certain topics with the intent of obtaining low levels of support for certain subject matters, thus rendering proposals on the same subject matter excludable for three years. *See* letter from Council of Institutional Investors dated January 30, 2020; *see also* letter in response to the Proxy Process Roundtable from the City of New York Office of the Comptroller dated January 2, 2019; Sustainable Investments Institute dated November 12, 2018. We do not agree with the commenter's concern. As the Commission has previously stated, considerations regarding the rule's application are based upon the ''substantive concerns raised by a proposal rather than the specific language or actions proposed to deal with those concerns,'' such that ''an improperly broad interpretation of the . . . rule will be avoided.'' *See* 1983 Adopting Release, *supra* note 2.

[385] *See* Proposing Release at 66478–66487.

[386] *See infra* Section V.E.1.

[387] *See infra* Section V.E.2.

[388] *See infra* Section V.E.3.

[389] Using data from proxy statements, we estimate that the average voting support for proposals that may have been excludable as a result of changes to the ownership threshold is approximately 31%, which is not statistically different from the voting support for the remaining proposals in the sample used for this analysis. *See* Proposing Release at 66497 for a detailed description of this analysis. Further, we estimate that approximately 5.3% of shareholder proposals used for this analysis received majority support and may have been excludable under final amendments to the ownership thresholds.

Using data on shareholder proposal resubmissions, we estimate that in 2018, none of the proposals that would have been excludable as a result of final rule amendments to the resubmission thresholds would have generated majority support. *See* Proposing Release at 66499 for a detailed description of this analysis.

considered for inclusion in the company's proxy materials based on content-neutral criteria designed to provide access to the company proxy to shareholder-proponents that have sufficient indicia of alignment with the interests of other shareholders who bear the costs associated with the inclusion of such proposals in the company's proxy statement. The amendments are not designed to include or exclude certain types of proposals or proponents.[390] However, as discussed in the Proposing Release (and raised by commenters), the rule amendments may have different effects on certain proposal types, proponents, and companies.[391]

As a first example, the final amendments to the ownership thresholds could have a greater effect on retail shareholder-proponents compared to institutional shareholder-proponents because the average holdings of retail investors are typically lower than the average holdings of institutional investors and so the final ownership thresholds are more likely to affect retail investors.[392] Again, however, shareholders holding the current threshold of $2,000 worth of company stock could still meet the new ownership thresholds by, for example, holding that stock for three years. Generally, to the extent that such a shareholder would instead have sold that stock after one year or two years, we would not view that shareholder as having the alignment of interest with other long-term shareholders that warrants the use of the company's proxy statement.

Second, to the extent that retail investors with smaller holdings and shorter holding periods are more likely to submit certain types of proposals than institutional investors, absent a change in behavior (*e.g.,* holding for a longer period if necessary to make a proposal) the final rule amendments to the ownership thresholds could decrease the number of those types of proposals more than other types of proposals.[393] Third, the final rule amendments to the ownership thresholds could affect companies and their shareholders with smaller market capitalization more than those with larger market capitalization and those with more volatile stock prices more than those with less volatile stock prices. For firms with smaller market capitalization, shareholder-proponents' holdings are more likely to be below the amended ownership thresholds, to the extent that investors that would be expected to make proposals hold stocks proportionately to the companies' market capitalization (*e.g.,* investors hold the market portfolio).[394] However, such a broad portfolio-based approach with low holdings in individual stocks may be inconsistent with the company-specific analysis that would be expected from a shareholder-proponent. The ownership holding of the proponent is more likely to fall below the ownership thresholds under Rule 14a–8 during any given period of time for volatile stocks than it is for less volatile stocks. Fourth, the final amendments to the ownership thresholds could decrease the number of proposals received by companies that have been public for fewer than three years more than the number of proposals received by seasoned companies because the average duration of investors' holdings will be, by their nature, shorter for those firms. However, shareholder proposals appear to be less likely in the case of newer public companies.[395] Fifth, to the extent the final amendments to Rule 14a–8(i)(12) result in a reduction in shareholder proposals, larger companies and their shareholders in general may be more affected than smaller companies and their shareholders because larger companies are more likely to receive shareholder proposals. Sixth, the final amendments to Rule 14a–8(i)(12) will likely have a greater effect on companies with dual-class voting shares for which insiders hold the majority of the voting shares.[396] Seventh, as suggested by

[390] *Cf.* letter from Council of Institutional Investors et al. dated July 29, 2020 (expressing concern that ''the true regulatory goal of the amendments is to curtail shareholder proposals related to environmental or social topics'').

[391] *See* Proposing Release at 66499–66502 for detailed discussion of the potentially disproportionate effects of the rule amendments.

[392] *See, e.g.,* letters from As You Sow dated February 3, 2020; Better Markets dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; CalPERS dated February 3, 2020; Center Political Accountability dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Council of Institutional Investors et al. dated July 29, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Patricia Hathaway dated January 31, 2020; International Brotherhood of Teamsters dated February 3, 2020; Local Authority Pension Fund Forum dated February 3, 2020; James McRitchie dated July 21, 2020; Newground Social Investment dated February 3, 2020; Maria M. Patterson, NYU Stern School of Business dated January 30, 2020; Segal Marco Advisors dated February 3, 2020; Tom Shaffner dated December 17, 2019; Robert K. Silverman dated February 3, 2020; Sisters of St. Dominic dated January 31, 2020; Trustee of Donations to the Protestant Episcopal Church dated January 31, 2020; US SIF dated January 31, 2020. *See also* Recommendation of the IAC, *supra* note 18.

Some commenters argued that the amendment related to proponents' ability to aggregate their holdings disadvantages retail investors relative to institutional investors because institutional investors can aggregate the investments of various individuals to submit a proposal, but retail investors no longer will be able to aggregate their holdings with other proponents to become eligible to submit a proposal. *See, e.g.,* letters from AFL–CIO dated February 3, 2020; First Affirmative Financial Network, LLC dated January 24, 2020. Although institutional portfolios represent the aggregate holdings of multiple individuals, institutional investors' submission of shareholder proposals may reflect predetermined investment policies rather than the preferences of each individual investor or any subset of individual investors.

Relatedly, several commenters argued, but did not provide any data, that the rule may have a disproportionate effect on women and people of color to the extent that shareholder wealth varies with gender and ethnicity, and the effect of the rule amendments will vary with the wealth of shareholders. *See, e.g.,* letters from Jantz Management LLC dated January 21, 2020; Shareholder Commons dated January 31, 2020. We note that the mitigating factors discussed elsewhere in the release, such as the availability of other forms of shareholder communication with management and the possibility that other eligible investors may take up the topics of excludable proposals, may reduce the impact of the exclusion of proposals by all proponents, including women and people of color.

[393] *See* Proposing Release at 66499. Untabulated analysis shows that 86% of the proposals submitted by individual investors are governance proposals, whereas 47% of the proposals submitted by institutional investors are governance proposals. Data is retrieved from ISS Analytics for Russell 3000 companies between 2004 and 2018 and classifications are based on ISS Analytics determinations.

[394] *See supra* note 365.

See also, e.g., letters from CalPERS dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Paul Rissman dated January 15, 2020; Trillium Asset Management dated February 3, 2020 (arguing that the amended thresholds will have a larger effect on smaller companies).

[395] We note that newly listed companies currently receive proposals less frequently than seasoned companies, and thus the overall impact of the increase in the ownership thresholds might be less pronounced for newly listed companies. *See* CII FAQ, *supra* note 332. *See also* Roundtable Transcript, *supra* note 141, comments of Jonas Kron, Senior Vice President and Director of Shareholder Advocacy, Trillium Asset Management (''Less than nine percent of Russell 3000 companies that have had an IPO since 2004 have received a shareholder proposal.''); Ning Chiu, Counsel, Capital Markets Group, Davis Polk & Wardwell LLP (acknowledging that ''IPO companies don't always get a lot of proposals'').

See also, e.g., letters from Council of Institutional Investors dated January 30, 2020; International Brotherhood of Teamsters dated February 3, 2020; US SIF dated January 31, 2020.

[396] A number of commenters expressed the view that the proposed amendment would have a more pronounced effect at companies with dual-class voting structures. *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Boston Trust Walden et al. dated January 31, 2020; CFA Institute dated February 3, 2020; Connecticut State Treasurer dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Council of Institutional Investors et al. dated July 29, 2020; Representative Bill Foster et al. dated January 31, 2020; Friends Fiduciary Corporation dated February 2, 2020; Illinois State Treasurer dated January 16, 2020; International Brotherhood of Teamsters dated February 3, 2020; International Corporate Governance Network dated December 4, 2019; Loring, Wolcott & Coolidge dated January 31, 2020; New York State Comptroller dated February 3,

commenters, the effects of the final amendments to the ownership threshold will depend on differences in share turnover across companies and over time.

The final amendments could in theory have larger effects on companies entering or exiting an index and newly-merged firms because these companies experience a significant shift in their shareholder base and, if longer term shareholders are replaced by newer shareholders, upon initial entry into the index fewer shareholders will be eligible to submit a shareholder proposal to those companies due to shorter holding periods.[397] However, to the extent current longer-term shareholders continue to hold a sufficient investment following a company's entry into the index, this potential change in eligibility would be lower. Further, a shift into an index could increase the number of shareholders eligible to submit a proposal over time because shareholders that follow an index-based strategy hold shares in the index longer.

In addition, as share turnover increases and thus investors hold shares for a shorter period of time, the number of investors who will meet the ownership duration thresholds would be expected to decrease to the extent share turnover reflects entry and exit from a particular investment as opposed to increasing or decreasing the extent of that particular investment.[398] For example, market-weighted index strategies require regular rebalancing of positions, which, in turn, may lead others to alter positions in anticipation or as a result of such rebalancing. Literature has documented a general upward trend in share turnover.[399] This general trend in turnover likely reflects other factors that also are unrelated to the ability or desire to submit shareholder proposals.

We are not arbiters of the type or substance of a proposal. That said, the final amendments also may have effects that vary for different types of proposals. Based on historical data, the final amendments to Rule 14a–8(i)(12) may have a greater impact on the resubmission of shareholder proposals relating to environmental and social issues compared to shareholder proposals on governance issues because: (i) Shareholder proposals on environmental and social issues historically have tended to receive lower shareholder support than those on governance issues, on average; (ii) proposals on environmental and social issues are more likely to be resubmitted compared to proposals on governance issues with similar levels of shareholder support, and thus will be more likely to be affected by the changes in the resubmission thresholds; and (iii) shareholder proposals on social and environmental issues historically have tended to take longer to gain support than proposals on governance issues. Again, however, to the extent that these proposals are excludable because they have received low levels of shareholder support in the past, companies and their non-proponent shareholders may benefit from their exclusion subject to a right to resubmit after a cooling-off period. Second and relatedly, the final amendments to the resubmission thresholds may have a greater effect on shareholder proposals submitted by non-individual proponents because these proponents have tended to submit environmental and social proposals at a higher frequency than individual investors do.

Several commenters argued that voting support may fluctuate across years for many reasons and this volatility may not be associated with the value of the shareholder proposals. In particular, voting support may fluctuate due to changes in the company performance, changes in the phrasing of the proposal, changes in shareholder base, changes in the proponent, exercise of stock options and equity awards, or changes in market circumstances.[400] To the extent that the voting support for certain types of proposals may be more volatile, companies may be more or less likely to exclude these proposals from their proxy statements as a result of the rule amendments.[401] We find that the dispersion in the change in voting support from a prior submission to a resubmission is higher for governance proposals than for environmental or social proposals.[402] In addition, we find that the dispersion in the change in voting support is higher among proposals submitted to non-S&P 500 companies than those submitted to S&P 500 companies.[403] As a result, changes to the resubmission thresholds may have a different effect on proposals of different types and submitted to companies of different sizes.

2. Economic Effects of Final Rule Amendments on the Quality of Shareholder Proposals

The rule amendments are likely to result in the exclusion of certain proposals that would have otherwise been included in the proxy statement and submitted for a vote.[404] Certain commenters have noted that, if by increasing companies' ability to exclude certain proposals the final amendments decrease shareholders' willingness to submit certain proposals,[405] the final

2020; Shareholder Association for Research & Education dated January 30, 2020; Trillium Asset Management dated February 3, 2020.

[397] *See, e.g.,* letter from International Brotherhood of Teamsters dated February 3, 2020.

[398] Proponents may have some discretion in how frequently they trade shares, and thus they may decide to hold shares for a longer period of time to satisfy the amended ownership duration thresholds. However, several commenters argued that the duration of stockholdings is not discretionary, although they did not provide data to support this statement. *See, e.g.,* letters from Interfaith Center on Corporate Responsibility dated January 27, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[399] *See, e.g.,* Tarun Chordia, Richard Roll & Avanidhar Subrahmanyam, *Recent Trends in Trading Activity and Market Quality,* 101 J. Fin Econ. 243 (2011). Some commenters noted that considering market trends of greater diversification and lower average holding times is important for describing how the rule amendments may effect investors. *See, e.g.,* letter from As You Sow dated February 3, 2020.

[400] *See, e.g.,* letters from Center for Political Accountability dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; International Brotherhood of Teamsters dated February 3, 2020; James McRitchie dated February 2, 2020; Morningstar, Inc. dated February 3, 2020; Principles for Responsible Investment dated February 3, 2020; Segal Marco Advisors dated February 3, 2020; Teachers Insurance and Annuity Association of America (TIAA) dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020; US SIF dated January 31, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[401] *See* letters from As You Sow dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[402] To measure how voting support fluctuates across multiple submissions of a proposal to the same company, we compute the standard deviation of the change in voting support from a prior submission to a subsequent submission. We find that the standard deviation is 10.7% for governance proposals as compared to 9.0% for environmental proposals and 7.6% for social proposals. Differences between these standard deviation estimates are statistically significant.

[403] We find that the standard deviation is 9.3% for proposals submitted to S&P 500 companies and 11.5% for proposals submitted to non-S&P 500 companies. Differences between these standard deviation estimates are statistically significant.

[404] In addition to the exclusion of proposals that would have otherwise been included in the proxy statements, certain commenters have asserted that there may be a reduction in negotiated resolutions between management and proponents. *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Institute for Policy Integrity dated February 3, 2020; Lucian A. Bebchuk dated February 3, 2020. Because the rule amendments do not prevent proponents from communicating their views to management by means other than through the company's proxy materials, we believe that the rule amendments are unlikely to result in a reduction in negotiated resolutions.

[405] Companies occasionally allow proposals that do not meet the current eligibility thresholds to be voted on. At the same time, companies may expend additional time and resources to exclude proposals that are submitted despite not being eligible for

Continued

amendments may limit information available to management about shareholder views on issues raised in shareholder proposals and inhibit communication among shareholders.[406] In a similar vein, commenters have asserted that a potential decrease in the number of proposals may limit or slow the consideration of changes that may benefit companies and their shareholders.[407] Commenters have also noted that by potentially increasing the number of proposals companies can exclude from being put to a vote on an initial submission or a resubmission, the final amendments may prompt proponents to utilize (or utilize to a greater extent) alternative avenues of influence, such as public campaigns, litigation over the accuracy of proxy materials, ''vote no'' campaigns on corporate directors, or demands to inspect company documents. These and other means of engagement may be effective, but also have their own associated costs. Because of the varied number of ways shareholders can engage with management in lieu of submitting a proposal, companies may confront lesser or greater uncertainty in their interaction with shareholders, proponents in certain instances may incur lower or higher costs to engage with management, and the efficiency of management's engagement with shareholders may increase or decrease.[408] While we lack data to determine whether these other forms of engagement, in the aggregate, will be more costly and disruptive, we nonetheless believe that it is appropriate to alter the ownership thresholds to ensure greater alignment of interests in the context of shareholder proposals. To the extent companies perceive that their exclusion of shareholder proposals increases the overall costs associated with shareholder engagement, they may partially mitigate these costs by including proposals that would otherwise be excludable under the final amendments.[409]

To the extent that some excludable shareholder proposals may, if they had been submitted, have benefited companies and their shareholders, the exclusion of those proposals could impose costs on companies and their shareholders and decrease the efficiency of the shareholder-proposal process.[410] Some commenters disagreed that the final amendments will result in the

submission. Hence, to the extent that the rule amendments will discourage proponents from submitting certain proposals, the rule amendments will have an effect that may be different than and incremental to the effect of companies' ability to exclude certain proposals.

[406] *See supra* Section V.C for discussion of factors that may mitigate any such effects.

Commenters argued that shareholder proposals are a valuable form of communication between management and shareholders as well as among shareholders because they can challenge management's group thinking, allow the introduction of outside points of view on emerging issues, raise issues that cut across various departments in a company, and provide information to management that management would otherwise pay to obtain (*e.g.,* through the hiring of consulting firms). *See, e.g.,* letters from As You Sow dated February 3, 2020; Lucian A. Bebchuk dated February 3, 2020; CalPERS dated February 3, 2020. *See also* Recommendation of the IAC, *supra* note 18. Commenters also noted that, through the engagement process motivated by the submission of shareholder proposals, management may provide information that is relevant to shareholders. *See, e.g.,* letters from Center for Political Accountability dated January 31, 2020; Shareholder Rights Group dated January 6, 2020. Relatedly, commenters stated that even proposals that receive low voting support may be beneficial because the voting outcome of shareholder proposals may provide accurate aggregated information regarding shareholders' preferences on various topics, and this information becomes even more valuable as it is aggregated across various companies. *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Tom Shaffner dated December 17, 2019. Commenters also stated that shareholder proposals are a unique form of communication with management because—in contrast to other forms of communication such as social media—shareholder proposals can motivate management to engage with shareholders and the prospect of receiving shareholder proposals can incentivize management to proactively adopt certain resolutions. *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Impax Asset Management dated January 20, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020. Some commenters argued that shareholder proposals are beneficial not only because they encourage communication between management and shareholders but also because they encourage both proponent and non-proponent shareholders to communicate with each other through the submission of proposals, deliberation on existing proposals, and the voting process. *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Tom Shaffner dated December 17, 2019; Shareholder Rights Group dated January 6, 2020. In addition, other commenters noted that shareholder proposals may have market-wide benefits that extend beyond the companies receiving them. *See, e.g.,* letters from Interfaith Center on Corporate Responsibility dated January 27, 2020; Pulte Institute for Global Development dated January 31, 2020; Shareholder Rights Group dated January 6, 2020. Some commenters argued that shareholder proposals may provide a valve to release tensions and avoid more costly and disruptive forms of engagement such as proxy contests, litigation, efforts related to regulatory change, books and records requests, etc. *See, e.g.,* letters from Center for Political Accountability dated January 31, 2020; Council of Institutional Investors dated January 30, 2020; Pulte Institute for Global Development dated January 31, 2020.

[407] *See, e.g.,* letters from Lucian A. Bebchuk dated February 3, 2020; Center for Political Accountability dated January 31, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Shareholder Rights Group dated January 6, 2020; US SIF dated January 31, 2020; Council of Institutional Investors et al. dated July 29, 2020 (arguing that the amendments might result in the exclusion of valuable proposals).

Commenters stated that the implementation of shareholder proposals has helped companies manage risk, enhance disclosures, limit insiders' entrenchment, and implement long-term value-enhancing changes. *See, e.g.,* letters from Lucian A. Bebchuk dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Richard A. Liroff dated January 28, 2020; Pulte Institute for Global Development dated January 31, 2020; Shareholder Rights Group dated January 6, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[408] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; CtW Investment Group dated February 3, 2020; Oxfam dated February 3, 2020; Pulte Institute for Global Development dated January 31, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020. *See also* Brown (2017), *supra* note 320, at 24–25; letter to Jeb Hensarling, Chairman, and Maxine Waters, Ranking Member, House Financial Services Committee, from Jeffrey P. Mahoney, General Counsel, Council of Institutional Investors dated April 24, 2017, *available at https://democrats-financialservices.house.gov/uploadedfiles/letter_-_cii_04.27.2017.pdf;* Ceres et al., *The Business Case for the Current SEC Shareholder Proposal Process,* (2017), at 11–12, *available at https://www.ussif.org/files/Public_Policy/Comment_Letters/Business%20Case%20for%2014a-8.pdf* (''Ceres Business Case''), at 11; letters in response to the Proxy Process Roundtable from Council of Institutional Investors dated January 31, 2019; Los Angeles County Employees Retirement Association dated October 30, 2018; MFS Investment Management dated November 14, 2018; US SIF dated November 9, 2018.

Some commenters, however, argued that alternative methods of communication, such as social media, are not a substitute for shareholder proposals because they do not ''allow aggregation of shareholder preferences or accommodate discussions about complex subjects of the type raised in shareholder proposals.'' *See, e.g.,* letter from Interfaith Center on Corporate Responsibility dated January 27, 2020. Relatedly, one commenter criticized the economic analysis because it did not empirically examine the effects of technological advances on the shareholder proposal process. *See* letter from Council of Institutional Investors et al. dated July 29, 2020. Based on the Commission's decades-long experience with Rule 14a-8 and the various forms of outreach on the proxy process that the Commission has conducted over the years, we continue to believe that technological advances over recent years have facilitated shareholder engagement.

[409] For example, our analysis shows that, in our sample, 10 shareholder proposals submitted to nine companies were resubmitted and voted on despite being eligible for exclusion under the current resubmission thresholds. Five of these proposals were resubmitted in the year following a previous vote during 2011 to 2017. *See* Proposing Release, at n.200.

Companies could also reach an agreement with the shareholder-proponent.

[410] *See* Proposing Release at 66494–66495 for a detailed discussion of potential benefits to companies and shareholders associated with the submission and consideration of shareholder proposals.

The potential decrease in the number of shareholder proposals also may be costly to the various providers of administrative and advisory services related to shareholder voting because the demand for the services of these providers may decrease. Examples of these service providers include proxy voting advice businesses, tabulators of voting, and proxy solicitors, and others who seek to profit from shareholder proposals (such as investment advisers who market their services as shareholder-proponent for their clients).

exclusion of beneficial proposals, stating instead that these amendments will be beneficial to companies and their shareholders because they will result in the exclusion of proposals that are not related to long-term shareholder value.[411] In particular, the benefits of shareholder proposals as a result of the rule amendments may increase because the average stockholdings of shareholder-proponents will likely increase as a result of the amendments to the ownership thresholds. A shareholder with a larger ownership stake in a company will bear a larger percentage of the passed-through costs associated with processing a shareholder proposal relative to a proponent with a lower ownership stake. This differential may, in theory, cause larger shareholders to be less likely to submit proposals that are unlikely to garner majority support and/or be implemented by management.[412]

Relatedly, by eliminating shareholders' ability to aggregate their holdings with those of other shareholders, the final amendments will require each proponent to have a higher economic stake or investment interest in the company. As a result, we expect that shareholder-proponents that would have otherwise aggregated their shares with other shareholders in order to meet the eligibility thresholds would need to increase their holding amount or duration to submit a proposal under the final amendments. Such shareholder-proponents would bear a larger percentage of the costs of processing a shareholder proposal and therefore, also in theory, may be marginally less likely to submit proposals that are unlikely to garner majority support and/or be implemented by management.

Nevertheless, to the extent that the amendments to the ownership thresholds and the ability to aggregate will exclude proposals that may benefit companies and investors, the rule amendments will impose costs on companies and their investors. Several commenters asserted that there is no relation between proponents' level and duration of ownership and the value of submitted shareholder proposals, so the amendments to Rule 14a–8(b) would not effectively distinguish shareholder proposals on the basis of their potential benefits.[413] The rules, however, do not attempt to distinguish proposals on the basis of their potential benefits. As already discussed, an attempt to determine in advance which proposals will be beneficial would be inherently speculative and our proxy rules are not designed to do so. Rather, the proxy rules have long relied on ownership thresholds as indicia of an economic stake or investment interest in the company to infer a reasonably sufficient alignment of interest with non-proponent shareholders such that it is appropriate to include a proposal in the company's proxy materials at the expense of other shareholders.[414] Consistent with this purpose, the amendments update those thresholds.

Relatedly, some commenters stated that certain companies may be in urgent need of reform and the increase in the holding period at the $2,000 ownership threshold may in theory delay the implementation of such reforms.[415] To the extent a company is in urgent need of reform, it may be more likely that a proposal, or a similar one, that addresses the issue will be submitted by another shareholder who meets the eligibility thresholds and, more generally, that the issues in need of urgent attention will be the subject of other forms of engagement.

The benefits of submitted proposals may also marginally increase as a result of the one-proposal-per-person requirement because proponents may prioritize the submission of proposals with higher expected benefits ahead of those with lower expected benefits for a given company.[416] On the other hand, some commenters argued that the one-proposal-per-person requirement may increase costs to companies and their shareholders because the one-proposal-per-person amendment could discourage proponents from using a representative to help craft proposals and supporting statements.[417] Further, commenters described additional costs the one-proposal final amendment may impose, assuming that shareholders' reliance on representatives will change.[418] Commenters noted that these costs may arise from (i) companies having to deal with multiple proponents instead of dealing with few representatives, which will make engagement less efficient; (ii) companies having to submit and Commission staff having to review more no-action requests because the proposals submitted by inexperienced proponents may be less well-drafted than those submitted by experienced representatives and thus may be more likely to be sought to be excluded;[419] and (iii) less frequent and meaningful dialogue between proponents and companies because proponents may have less experience and expertise than representatives at effectively communicating with management.[420] Relatedly, several commenters argued that the one-proposal final amendment will interfere with proponents' fiduciary relationships with their investment advisers, who might act as their representatives, or other entities with whom proponents have contractual relationships.[421] As a result, the commenters asserted that the proposed amendments may impose costs on investment advisers and their clients.[422]

[411] *See* letters from American Securities Association dated February 3, 2020; Business Roundtable dated February 3, 2020; Center for Capital Markets Competitiveness dated January 31, 2020; Compass Lexecon dated December 23, 2019; National Association of Manufacturers dated February 3, 2020.

[412] *See, e.g.,* letter from Center for Capital Markets Competitiveness dated January 31, 2020 (arguing that shareholders who submit proposals under the rule amendments ''will have to have a little bit more skin in the game'').

[413] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; As You Sow dated February 3, 2020; Better Markets dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Lila Holzman dated January 25, 2020; International Corporate Governance Network dated December 4, 2019; Institute for Policy Integrity dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Maryknoll Sisters of St. Dominic, Inc. dated January 17, 2020; Newground Social Investment dated February 3, 2020; Segal Marco Advisors dated February 3, 2020; Shareholder Commons dated January 31, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[414] *See* 1982 Proposing Release, *supra* note 2; 1983 Adopting Release, *supra* note 2.

[415] *See, e.g.,* letters from Segal Marco Advisors dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[416] *See* letter from Robeco dated January 16, 2020.

[417] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; James McRitchie dated February 2, 2020.

In addition, some commenters argued that the one-proposal amendment may impose costs on proponents associated with proponents incurring higher recordkeeping costs to comply with the requirement. We generally expect any such costs will be minimal. *See, e.g.,* letter from AFL–CIO dated February 3, 2020.

[418] *See, e.g.,* letter from James McRitchie dated February 2, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[419] *See, e.g.,* letters from CalPERS dated February 3, 2020; Paul Rissman dated January 15, 2020.

[420] *See, e.g.,* letters from As You Sow dated February 3, 2020; Boston Trust Walden et al. dated January 27, 2020; CalPERS dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; James McRitchie dated February 2, 2020; Paul Rissman dated January 15, 2020; Tom Shaffner dated December 17, 2019; Trillium Asset Management dated February 3, 2020; US SIF dated January 31, 2020.

[421] *See, e.g.,* letters from As You Sow dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; James McRitchie dated February 2, 2020; Trillium Asset Management dated February 3, 2020; US SIF dated January 31, 2020.

[422] Some commenters argued that this aspect of the amendments is unworkable for institutional investors who always rely on representatives to submit a proposal because they are not natural persons. In particular, for institutional investors that share an investment adviser or pension plan

Continued

We expect that any costs related to the one-proposal amendment will be small, including because we estimate that the amendment to Rule 14a–8(c) will only affect a small number of proposals and proponents.[423] In addition, the amendment will restrict the representative's ability to submit a proposal on the proponent's behalf but otherwise will not limit or interfere with the representative's ability to assist the proponent with drafting a proposal, navigating the submission process, or presenting the proposal at the annual meeting, and thus any potential effects of the rule amendment will be limited.

Lastly, the final amendments to the resubmission thresholds may benefit companies and their shareholders to the extent that they change proponents' behavior in ways that result in proposals that obtain higher levels of support. In particular, due to the higher thresholds, proponents may formulate proposals that are more likely to garner sufficient levels of shareholder support to avoid future exclusion.[424] In addition, proponents may market and communicate their proposal to other shareholders to increase support for their proposal. As a result, companies and their shareholders could benefit from the submission of shareholder proposals that are more likely to receive higher levels of support and/or be implemented by management. Similarly, the amended resubmission thresholds may discourage the submission of proposals that are less likely to garner majority voting support and/or be implemented by management.[425]

Some commenters stated that the Proposing Release's economic analysis was incomplete because it did not provide a dollar estimate of the cost of excluding certain proposals as a result of the rule amendments.[426] Although some commenters suggested we should attempt to estimate the hypothetical value of excluded proposals, our analysis does not attempt to quantify whether excluded proposals would have (in the event they would have been adopted or would have been adopted sooner) resulted in benefits (or harm) to companies or their shareholders. Any such focus would both require us to opine on the merits of specific proposals and be inherently speculative. Such an exercise also would not be consistent with the intent of Rule 14a–8, which is to set thresholds at which it is appropriate for a shareholder proposal to be considered for inclusion in the company's proxy materials initially, or on resubmission, without opining on the merits of specific proposals. The thresholds for initial proposals are intended to ensure that the interests of those who submit them are appropriately aligned with fellow shareholders. The thresholds for resubmissions are designed to exclude temporarily (through a modest cooling-off period) those proposals that previously were disapproved by fellow shareholders by a large margin. In neither case are the thresholds designed to favor or disadvantage particular types of proposal topics. In addition, we describe additional significant methodological and empirical challenges of doing this type of analysis below.

Specifically, some commenters suggested that to estimate the costs of the rule amendments, the economic analysis should consider studies documenting a correlation between companies' ESG policies and financial performance.[427] In particular, one commenter employed this methodology to estimate the cost of the rule amendments as ranging from $223.9 million to $129.7 billion.[428] We believe that the commenter's cost estimate of the rule amendments is not instructive for the following reasons. First, we do not believe that this type of study accurately predicts the economic effects of the amendments because ESG policies could be implemented for reasons other than the submission of shareholder proposals, including shareholder engagement that does not involve the submission of shareholder proposals. In addition, the studies cited by the commenter do not provide evidence of a causal relation between governance, environmental, and social provisions and firm value. Lastly, the commenter used an estimate of 530 excludable proposals annually; however, as discussed in more detail above, we continue to expect that the upper bound estimate of the number of excludable proposals under the rule amendments will range from 58 to 524 annually and that changes in behavior by shareholder-proponents may mitigate this effect.[429]

Other commenters suggested that the economic analysis should use estimates of changes in market capitalization around events related to shareholder proposals that are provided in academic literature to estimate the cost of exclusion of certain proposals as a result

administrator, the amendment will impose unintended ''first to file'' constraints. *See, e.g.,* letter from AFL–CIO dated February 3, 2020. Other commenters, however, argued that that this aspect of the amendments will create a bias towards institutional investing because anyone whose investments are made through institutions is automatically and necessarily represented in the course of filing a shareholder proposal, but individual investors will be more limited in their ability to use a representative. *See, e.g.,* letter from Shareholders Rights Group dated March 18, 2020.

[423] *See supra* tbl.1.

[424] *See, e.g.,* letters from Center for Capital Markets Competitiveness dated January 31, 2020; National Association of Manufacturers dated February 3, 2020.

One commenter disagreed with the assertion that that the resubmission thresholds will improve proposal quality because proponents already request feedback on their proposals prior to submitting them to the company. *See* letter from Interfaith Center on Corporate Responsibility dated January 27, 2020.

[425] Proponents incur costs to submit proposals, which may already deter some proponents from resubmitting proposals that have a low likelihood of receiving sufficient levels of shareholder support.

[426] *See* letters from Lucian A. Bebchuk dated February 3, 2020; CalPERS dated February 3, 2020; John Coates and Barbara Roper dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Richard A. Liroff dated January 28, 2020; James McRitchie dated February 2, 2020; Tom Shaffner dated December 17, 2019; Shareholder Rights Group dated January 6, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[427] *See, e.g.,* letters from Athena Capital Advisors dated January 17, 2020; Lucian A. Bebchuk dated February 3, 2020; Betty Cawley dated January 8, 2020; Ceres et al. dated February 3, 2020; Council of Institutional Investors dated January 30, 2020; Muriel Finegold dated January 29, 2020; Impax Asset Management dated January 20, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Richard A. Liroff dated January 28, 2020; Newground Social Investment dated February 3, 2020; Principles for Responsible Investment dated February 3, 2020; Segal Marco Advisors dated February 3, 2020; Seventh Generation Interfaith Coalition for Responsible Investment dated January 28, 2020; Stardust dated January 29, 2020; Tides dated January 15, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[428] *See* letter from Tom Shaffner dated December 17, 2019.

Another commenter estimated the value of shareholder engagement to be equal to $19.6 billion per year. *See* letter from Newground Social Investment dated February 3, 2020. We do not rely on this estimate for purposes of estimating the economic effects of the final amendments because the commenter did not estimate the cost of the rule amendments but rather the benefit of shareholder proposals in general. Further, the commenter applied an estimate of value from a proposal submitted to a single company to all companies in Russell 3000, regardless of whether those companies received a proposal. Applying the same value estimate to all Russell 3000 companies also ignores variation in the value of proposals.

[429] 58 = (0% minimum upper bound percentage of excludable proposals as a result of the amendments to 14a–8(b) + 2% upper bound percentage of excludable proposals as a result of the amendments to 14a–8(c) + 5% upper bound percentage of excludable proposals as a result of the amendments to 14a–8(i)(12)) × 831 (all proposals submitted to be considered at 2018 shareholders' meetings). 524 = (56% maximum upper bound percentage of excludable proposals as a result of the amendments to 14a–8(b) + 2% upper bound percentage of excludable proposals as a result of the amendments to 14a–8(c) + 5% upper bound percentage of excludable proposals as a result of the amendments to 14a–8(i)(12)) × 831 (all proposals submitted to be considered at 2018 shareholders' meetings). *See supra* tbl.1.

of the rule amendments.[430] Using an average short-run stock price reaction of 0.06 percent around events related to shareholder proposals cited in Denes et al. (2017), one commenter estimated that rule amendments would result in a $4.3 billion reduction in annual stock market valuations.[431]

In the Proposing Release, we summarized the findings of empirical literature that examines whether proposals are economically beneficial by studying short-run abnormal stock returns[432] around key events related to shareholder proposals.[433] Several commenters criticized our discussion of short-term stock price reactions studies, arguing that the economic analysis instead should look at the long-run effects of shareholder proposals.[434] We agree with commenters that there are significant limitations to using short-term market reactions to measure the benefits of shareholder proposals because these estimates: (i) May confound the benefits of shareholder proposals with the benefits of other concurrent information releases (*e.g.,* submission of management proposals); (ii) may not capture anticipatory effects of shareholder proposals as information about the submission of a shareholder proposal may leak prior to the event date considered by the academic study; (iii) may reflect the benefits of the average shareholder proposal rather than the benefits of the excludable shareholder proposals as a result of the rule amendments; and (iv) may capture various effects such as signaling effects (*e.g.,* the submission of a proposal may signal that the targeted company is underperforming or that the initial negotiations between proponent and company failed), market expectations regarding the voting outcome, market expectations regarding the probability of implementation of a proposal, etc.[435] We also believe that the limitations observed in short-run studies are even more pronounced in long-run studies.[436] For these reasons, we do not rely on either short-run return studies or long-run return studies to measure the benefits of excludable shareholder proposals in our economic analysis.

3. Comments Regarding Voting Support and Economic Effects of the Rule Amendments

In the Proposing Release, we provide descriptive statistics on the voting support and the probability of obtaining majority support for all proposals, by proposal topic, and by proponent type.[437] This analysis allowed us to provide some evidence on the effects of the proposed amendments on proposals that may garner high and/or majority shareholder support, and to examine whether the proposed amendments to the resubmission thresholds may have larger effects for some types of proposals and proponents than for others.

Several commenters suggested that shareholder voting support may not be the best or only metric to assess the economic effects of the rule amendments because it does not account for:

- The effects of withdrawn proposals that resulted in a company's implementation of beneficial measures;[438]
- the effects of changes implemented without the passage of a shareholder proposal but following the passage of similar proposals at many other companies;[439]
- the effects of proposals that received low levels of support but resulted in a company's implementation of beneficial measures;[440] and
- the effects of company-shareholder engagement without the submission of a formal shareholder proposal but against the background of the company's expectation that a proposal might be

[430] *See, e.g.,* Lucian A. Bebchuk dated February 3, 2020.

[431] *See* letter from AFL–CIO dated February 3, 2020. *See also,* Matthew R. Denes, Jonathan M. Karpoff & Victoria B. McWilliams, *Thirty Years of Shareholder Activism: A Survey of Empirical Research,* 44 J. Corp. Fin. 405 (2017) (''Denes et al. (2017)'').

[432] We refer to abnormal stock returns because they are adjusted for changes in prices that are attributable to events that have market-wide implications (*e.g.,* changes in interest rates, natural disasters, etc.) and thus only capture the effect of firm-specific information releases.

[433] *See* Proposing Release at 66495. The main events related to shareholder proposals studies in academic literature comprise the initial press announcement of submission of a shareholder proposal, the proxy mailing date, and the date of the shareholder meeting. *See* Denes et al. (2017), *supra* note 431.

[434] *See, e.g.,* letters from Impax Asset Management dated January 20, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Segal Marco Advisors dated February 3, 2020; Tom Shaffner dated December 17, 2019; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[435] *See, e.g.,* Stuart L. Gillan & Laura T. Starks, *Corporate Governance Proposals and Shareholder Activism: The Role of Institutional Investors,* 57 J. Fin. Econ. 275 (2000) (''Gillan & Starks (2000)''); Diane Del Guercio & Jennifer Hawkins, *The Motivation and Impact of Pension Fund Activism,* 52 J. Fin. Econ. 293 (1999).

Commenters provided additional reasons for why short-term stock market reaction may be inappropriate to assess the benefits of shareholder proposals. One commenter argued that stock price reactions around shareholder meetings may not capture the benefits of shareholder proposals because companies do not have to disclose the voting outcome until several days after the shareholder meeting. *See* letter from Interfaith Center on Corporate Responsibility dated January 27, 2020. Another commenter argued that stock returns may not fully capture the utility shareholders derive from proposals because investors may seek not only financial returns but also changes such as the ''integration of environmental and social concerns in business decisions.'' *See* letter from Institute for Policy Integrity dated February 3, 2020. Other commenters argued that short-term stock market reactions do not capture the long-term impact of shareholder proposals on firm value. *See, e.g.,* letters from Tom Shaffner dated December 17, 2019; UAW Retiree Medical Benefits Trust dated January 30, 2020. Finally, a commenter argued that event studies capture shareholders' expectations about the future impact of a proposal but these expectations may turn out not to be correct. *See* letter from UAW Retiree Medical Benefits Trust dated January 30, 2020.

Academic literature employs various methods to address the issues with short-window event studies discussed above. For example, some academic literature uses the date of the initial press announcement of the shareholder engagement rather than the proxy mailing date as the event date to isolate the effect of the shareholder proposals from the effect of other items on the proxy statements. *See, e.g.,* Jonathan M. Karpoff, Paul H. Malatesta & Ralph A. Walkling, *Corporate Governance and Shareholder Initiatives: Empirical Evidence,* 42 J. Fin. Econ. 365 (1996). Other academic literature uses techniques such as regression discontinuity to isolate the anticipatory effects of voting outcomes from the benefits of implementation of certain shareholder proposals. *See* Vicente Cuñat, Mireia Gine & Maria Guadalupe, *The Vote Is Cast: The Effect of Corporate Governance on Shareholder Value,* 67 J. Fin. 1943 (2012). Finally, assuming semi-strong form of market efficiency, companies' short-term stock price reaction should capture investors' expectations of both the short- and long-term benefits and costs of shareholder proposals. According to the semi-strong form of market efficiency, stock prices fully reflect all publicly available information, not just information related to short-term changes. *See, e.g.,* Eugene F. Fama, *Efficient Capital Markets: A Review of Theory and Empirical Work,* 25 J. Fin. 383 (1970) (discussing the concept of market efficiency); James M. Patell & Mark A. Wolfson, *The Intraday Speed of Adjustment of Stock Prices to Earnings and Dividend Announcements,* 13 J. Fin. Econ. 223 (1984) (testing the efficient market hypothesis).

[436] *See, e.g.,* Gillan & Starks (2000), *supra* note 435.

[437] *See* Proposing Release at 66483–66487.

[438] *See, e.g.,* letters from Lucian A. Bebchuk dated February 3, 2020; CalPERS dated February 3, 2020; Center for Political Accountability dated January 31, 2020; Institute for Policy Integrity dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[439] *See, e.g.,* letter from Lucian A. Bebchuk dated February 3, 2020.

[440] *See, e.g.,* letters from Lucian A. Bebchuk dated February 3, 2020; CalPERS dated February 3, 2020; John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020; Institute for Policy Integrity dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; James McRitchie dated February 2, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020; US SIF dated January 31, 2020.

Relatedly, commenters have argued that voting support is not a relevant metric for assessing the amendments' economic effects because proposals are almost never binding and just learning about the voting outcome may be valuable information to a company. *See, e.g.,* letter from Council of Institutional Investors dated January 30, 2020.

submitted if the company does not agree to make satisfactory changes.[441]

Commenters also suggested that voting support is becoming a less informative metric with the increase in uninformed voting by passive investors that frequently side with management.[442] A few commenters argued that voting support may be an unreliable measure of actual shareholder support for a proposal because of proxy voting advice businesses' influence of voting outcomes.[443] In addition, two commenters stated that voting outcomes are unreliable because of issues with the counting of votes.[444] While we acknowledge the views of commenters, we continue to believe that voting support is a useful and relevant metric for purposes of our economic analysis because that is the established metric for shareholder voting generally and most likely to result in implementation of a shareholder proposal. Further, substituting other subjective views or metrics could have the effect of raising the views of others over the views of shareholders. Our economic analysis acknowledges and seeks to account for the fact that the rule amendments may affect not only voted proposals but also omitted and withdrawn proposals by applying the percentage of excludable proposals estimated over the sample of voted proposals to all submitted proposals.[445] Relatedly, some commenters argued that the economic analysis should examine the effect of resubmission thresholds on implemented proposals rather than proposals that received majority support. According to these commenters, certain resubmitted proposals are withdrawn because management expects that these proposals are likely to garner majority support, which results in proposal implementation without going to a vote, and ignoring those withdrawn proposals in the economic analysis misestimates the effects of the rule amendments on the likelihood of receiving broad or majority support upon a resubmission.[446] More generally, commenters argued that companies implement proposals even when those proposals do not receive majority support.[447] While we agree with commenters that companies may implement proposals (in whole or in part, or in an alternative form) even when they do not receive majority support, we lack data to reliably identify resubmitted proposals that were implemented by management. Finally, the probability that a shareholder proposal will be implemented is higher for proposals that receive majority support, and thus we believe that our statistics on proposals that receive majority support are a good approximation of statistics for implemented proposals.[448]

Some commenters also argued that using a majority-support threshold in the economic analysis is not appropriate because majority approval has no legal significance and there is a positive relation between voting support and the probability of implementation of shareholder proposals in general, even when voting support falls short of the majority of shares.[449] In addition, several commenters cited academic research that suggests that the passing rate of shareholder proposals may in some cases be impacted by management expending resources to influence results for proposals that are close to a majority threshold.[450] In the Proposing Release, we examined the percentage of proposals that received majority support as opposed to some other voting threshold because studies show that the probability of implementation of a shareholder proposal increases significantly once the proposal receives majority support.[451]

F. Reasonable Alternatives

We have considered the relative costs and benefits of reasonable alternatives to the final amendments. The discussion below is limited to reasonable alternatives within the scope of Rule 14a–8.

1. Alternative Amendments to Rule 14a–8(b) and Rule 14a–8(c)

i. Alternative Ownership Thresholds

We considered a number of alternative approaches to the ownership thresholds. First, we considered whether to increase the $2,000/one-year threshold in the current requirement to a $25,000/one-year threshold without providing additional eligibility options. Using proponents' exact ownership information from the proxy statements and assuming no change in proponents' ability to aggregate their holdings to submit a joint proposal, such an increase would have resulted in the excludability of an upper bound estimate of 56 percent of the proposals with exact proponents' account ownership information to be considered at 2018 shareholder meetings.[452] The

[441] *See, e.g.,* letters from Lucian A. Bebchuk dated February 3, 2020; Center for Political Accountability dated January 31, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020.

[442] *See, e.g.,* letter from Tom Shaffner dated December 17, 2020.

[443] *See, e.g.,* letters from Business Roundtable dated February 3, 2020; Exxon Mobil Corporation dated February 3, 2020; Society for Corporate Governance dated February 3, 2020.

[444] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Council of Institutional Investors dated January 30, 2020. *See also* Recommendation of the IAC, *supra* note 18.

[445] *See, e.g., supra* notes 347 and 348.

[446] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; Institute for Policy Integrity dated February 3, 2020.

[447] *See, e.g.,* letter from Institute for Policy Integrity dated February 3, 2020.

[448] *See infra* note 451.

[449] *See, e.g.,* letters from AFL–CIO dated February 3, 2020; John Coates and Barbara Roper dated January 30, 2020; Council of Institutional Investors dated January 30, 2020; Impax Asset Management dated January 20, 2020; Institute for Policy Integrity dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Tom Shaffner dated December 17, 2019. *See also* Recommendation of the IAC, *supra* note18.

[450] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; Impax Asset Management dated January 20, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; New York City Comptroller dated February 3, 2020 (citing Laurent Bach & Daniel Metzger, *How Close Are Close Shareholder Votes?,* 32 Rev. Fin. Stud. 3183 (2019) (''Bach & Metzger (2019)'')); Tom Shaffner dated December 17, 2019. Bach & Metzger (2019) provide evidence consistent with the idea that management attempts to influence voting outcomes by encouraging the participation of retail shareholders, who are more likely to vote with management, and exercising option packages to obtain additional votes.

[451] *See* Proposing Release at 66485. For example, a 2010 study by Ertimur et al. shows that ''proposals that won at least one majority vote in the past are more likely to be implemented (34.2% versus 22.9%).'' *See* Yonca Ertimur, Fabrizio Ferri & Stephen R. Stubben, *Board of Directors' Responsiveness to Shareholders: Evidence from Shareholder Proposals,* 16 J. Corp. Fin. 53 (2010) (''Ertimur et al. (2010)''). Similarly, a 2017 study by Bach and Metzger showed that ''when the 50%-threshold is passed, there is a very sizeable jump of about 20% of the implementation likelihood.'' *See* Laurent Bach & Daniel Metzger, *How Do Shareholder Proposals Create Value?* (Working Paper, Mar. 2017) (''Bach & Metzger (2017)''). However, only crossing the management-defined majority threshold (as opposed to the simple majority threshold defined as the ratio of ''for'' votes divided by the sum of ''for'' and ''against'' votes) has a positive effect on the probability that the proposal is implemented. *Id.* The management-defined majority threshold may differ from a simple majority threshold. *Id.* In 43% of their sample, the management threshold is the same as the simple majority threshold. *See id.* In our analysis, we define majority support as the simple majority threshold because we lack data on the management-defined majority threshold.

[452] Companies have discretion in the type of information they must include in the proxy statements regarding proponents' ownership (*see* Rule 14a–8(l)). In particular, the company's proxy statement must include either proponents' share ownership or a statement that this information will be provided to shareholders upon request. Whenever the company discloses proponents' ownership information, the company may disclose the actual dollar value, the actual number of shares, a minimum dollar value, or a minimum number of shares held by the proponent. In addition, whenever the company discloses proponents' ownership information, the company may disclose ownership information for a subset of the proponents submitting a proposal, and the company

advantage of increasing only the dollar amount in the current threshold is that the rule would be less costly for shareholder-proponents and companies to implement and monitor. The disadvantage of such an approach would be that shareholders would not have the flexibility to become eligible to submit shareholder proposals by either increasing their holdings or holding the shares of a company for a longer period of time as under the adopted approach.

Alternatively, we considered using a tiered approach, but with different combinations of minimum dollar amounts and holding periods. For example, we considered (i) $2,000 for five years, $15,000 for three years, and $25,000 for one year or (ii) $2,000 for three years, $10,000 for two years, and $50,000 for one year. We are unable to estimate the incremental effects of the first alternative relative to the effects of the final amendments discussed in Section V.D above because we lack data on proponents' ownership duration. Regarding the effects of the second alternative, assuming all proponents held the shares for only one year, the increase in the dollar ownership thresholds from $2,000 to $50,000 (*i.e.,* third tier of the alternative ownership threshold) could result in the exclusion of 65 percent of the proposals based on the ownership information of proponents at 2018 shareholder meetings.[453] On the other hand, assuming all proponents held the shares for at least three years, the ownership thresholds of the second alternative would not result in a change in the number of excludable proposals relative to the current thresholds.

We also considered whether to index the adopted ownership thresholds for inflation or to maintain a single ownership threshold but index it to inflation, as recommended by several commenters.[454] The benefit of such an approach would be that the thresholds would adjust over time without the need for additional rulemaking. The disadvantage of such an approach would be that compliance with the rule could be more cumbersome as companies and shareholder-proponents would have to monitor periodically adjusted ownership thresholds.

Different thresholds could result in the exclusion of more or fewer proposals, depending on the particular thresholds. Any set of ownership thresholds has various tradeoffs associated with any given choice along the range of potential alternatives, the magnitude of which can vary based on a shareholder's actual holdings. The final rules attempt to address the interests of shareholders who seek to use the company's proxy statement to advance their own proposals at little or no cost to themselves, while recognizing that other shareholders and companies bear the burdens associated with the inclusion of such proposals and thus have an interest in ensuring that the interests of proponents are sufficiently aligned with those of other shareholders.

ii. Percent-of-Ownership Threshold

We considered whether to instead adopt an ownership requirement based solely on the percentage of shares owned. For example, we considered eliminating the dollar ownership threshold and retaining the one-percent ownership threshold. Using proponents' exact ownership information from the proxy statements and assuming no change in proponents' ability to aggregate their holdings to submit a joint proposal, we estimate that using a one-percent ownership threshold and removing the $2,000/one-year threshold would have resulted in an upper bound estimate of 149 proposals, or 99 percent of the proposals to be considered in 2018 shareholder meetings that provide exact proponents' ownership information, being excludable under the final amendments, again assuming no change in proponent behavior.[455]

The advantage of a percentage-of-ownership threshold is that it would permit shareholders owning the same proportion of a larger company as of a smaller company to submit a proposal, and so the rule would have similar effects on smaller and larger companies.[456] The percentage-of-ownership threshold, however, may be somewhat harder to implement because of changes in companies' capital structure over time. We also believe that a percentage-of-ownership threshold of one percent would prevent the vast majority of shareholders from submitting proposals,[457] which, in turn, could have a chilling effect on shareholder engagement. In addition, the types of investors that hold more than one percent of a company's shares are generally large institutional investors and commenters noted that these types of investors are more likely to be able to communicate directly with management, and thus do not typically use shareholder proposals.[458]

may disclose actual holdings information for some of the proponents and minimum holdings information for the rest of the proponents submitting the same proposal. The type of ownership information the company discloses (*i.e.,* actual holdings versus minimum holdings and dollar value versus number of shares) frequently depends on the type of information provided in the proof-of-ownership letter furnished by the proponent. In particular, proponents also have discretion in the type of information they must provide in the proof-of-ownership letters (*see* Rule 14a–8(b)(2)). Proponents may disclose the exact duration and level of their holdings or they may confirm that they meet the minimum ownership thresholds. Hence, there is available data in the proxy statements regarding proponents' exact ownership for only a subset of the proponents, and data regarding proponents' minimum ownership for the remaining proponents. More specifically, there were 447 unique voted proposals for shareholder meetings held in 2018. Out of the 447 proposals, 287, or 64 percent, contained information on proponents' actual and/or minimum holdings, whereas the remaining 160, or 36 percent, did not contain information on proponents' ownership. Further, in our sample of proxy statements, there were 198 proponents that submitted 150 unique proposals for which the proxy statements mentioned the proponents' actual holdings, and 159 proponents that submitted 139 unique proposals for which the proxy statements mentioned the proponents' minimum holdings.

[453] 65% = 97 (excludable proposals under a $50,000/one-year threshold)/150 (proposals with exact proponents' ownership information in proxy statements, *see supra* note 452). This estimate assumes that proponents do not own any shares of company stock outside of the account used to prove ownership. In the case of institutional shareholders, in particular, this assumption is overinclusive and our estimate should be viewed as an upper bound. This estimate assumes that proponents will not be permitted to aggregate their holdings to meet the ownership threshold. *See* Proposing Release at 66506.

[454] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; First Affirmative Financial Network, LLC dated January 24, 2020; Society for Corporate Governance dated February 3, 2020.

As of February 2020, the $2,000 threshold as adopted in May 1998 would be equal to $3,178 after adjusting for inflation (*see supra* note 58) and it would be equal to $7,470 after adjusting for the growth in Russell 3000 index (*see supra* note 59).

One commenter argued that adjusting the $2,000 threshold for inflation would result in excessive ownership thresholds because ''the original increase from $1,000 to $2,000 already included a future inflationary adjustment.'' The same commenter argued that adjusting the ownership thresholds using the growth in the Russell 3000 ''only makes sense for investors who have been in the market during this entire time; new entrants to the market would not have benefitted from market growth and as such the Russell Index comparison simply doesn't make sense.'' *See* letter from Tom Shaffner dated December 17, 2019.

[455] 99% = 149 (number of excludable proposals under a 1% threshold)/150 (proposals with exact proponents' ownership information in proxy statements). For proposals that are submitted by more than one proponent, these estimates assume that the proposals will still be submitted if the aggregate ownership of the co-proponents met the alternative percent-of-ownership threshold. For proposals that are submitted by multiple proponents, some of which provide exact and others provide minimum holdings information, we assume that the ownership of the proponents with minimum holdings information is equal to the lowest end of the ownership range. *See* Proposing Release at 66507.

[456] *See supra* note 394 and accompanying text.

[457] *See supra* note 9.

[458] *See, e.g.,* letters from James McRitchie dated February 2, 2020; Tom Shaffner dated December 17, 2019; Shareholder Rights Group dated January 6, 2020; Trillium Asset Management dated February 3,

Continued

iii. Eligibility Thresholds Based on the Size of a Shareholder's Total Investment Portfolio

Some commenters argued that the eligibility thresholds should be a function of investors' wealth, not an absolute dollar amount.[459] Setting the eligibility thresholds to be a function of investors' wealth would ensure that all shareholders, regardless of their wealth, are able to submit proposals. Nevertheless, imposing such requirements would increase complexity because measuring and proving one's own wealth would be complex and time consuming, potentially adding significant costs to the shareholder-proposal process.

2. Alternative Amendments to Rule 14a–8(i)(12)

i. Alternative Resubmission Thresholds

We estimate that the new resubmission thresholds contained in the final amendments of 5/15/25 percent would result in an additional five percent of proposals being excludable relative to current thresholds. We considered proposing different resubmission thresholds, including raising the thresholds to 5/10/15 percent, 6/15/30 percent, or 10/25/50 percent. All three alternative threshold levels would increase the number of proposals eligible for exclusion relative to the baseline, with the first expected to have smaller effects relative to the final amendments and the second and third expected to have larger effects relative to the final amendments. Under these three alternative thresholds, we estimate that two percent, eight percent, and 20 percent of proposals, respectively, would be excludable relative to the baseline 3/6/10 percent thresholds.[460]

In addition, we considered whether the rule should remove resubmission thresholds for the first two submissions and, instead, allow for exclusion if a matter fails to receive majority support by the third submission. Under this alternative, no proposal would be eligible for exclusion on its first two submissions, allowing shareholder proposals at least two years to gain traction. We estimate that 15 percent of proposals would be excludable relative to the baseline.[461] We decided against adopting these alternative resubmission thresholds because we believe that the final amended resubmission thresholds appropriately reduce the costs to companies and their shareholders of responding to proposals that do not garner significant shareholder support and may be unlikely to do so in the near future, while at the same time preserving shareholders' ability to engage with a company and other shareholders through the shareholder-proposal process and, through the modest cooling-off period, providing for resubmission in the future based on the initial submission criteria.

ii. Different Vote-Counting Methodologies

We considered whether to change how votes are counted for purposes of applying the resubmission thresholds. For example, we considered whether votes by insiders should be excluded from the calculation of the percentage of votes that a proposal received. We also considered whether to apply a different vote-counting methodology for companies with dual-class voting structures. Several commenters highlighted how the presence of a subset of shareholders with special voting rights could make the voting threshold requirement difficult to satisfy.[462] Applying different vote-counting methodologies for votes by insiders and for companies with dual-class shares would make it easier for shareholder proposals to meet the resubmission thresholds and thus potentially could allow for the submission of a greater number of proposals that would benefit companies and their shareholders.[463] However, because this approach may still require companies and their shareholders to continue to incur costs associated with processing proposals that are less likely to garner majority support based on all votes cast and that are less likely to be implemented by management, we believe that the adopted approach is more appropriate. In addition, applying different vote-counting methodologies for votes by insiders and for companies with dual-class shares could increase the rule's complexity and thus could increase the costs of rule implementation to the detriment of shareholders.

iii. Exception to the Rule if Circumstances Change

Several commenters pointed out the possibility of an initially unpopular proposal gaining popularity in subsequent years following changes in company circumstances or other market developments.[464] We acknowledge that changes in circumstances could change a proposal's voting support across years. For this reason, we considered whether to provide an exception to the final rule amendments that would allow an otherwise excludable proposal to be resubmitted if there were material developments that suggest a resubmitted proposal may garner significantly more votes than when it was previously voted on. We expect that such an exception would lower the number of proposals eligible for exclusion under the final amendments, but the magnitude of the decrease would depend on what types of developments qualify for the exception and how many companies experience these particular types of developments. Shareholders could benefit from the lower number of proposals eligible for exclusion to the extent that the submitted proposals would result in changes that would benefit companies and their shareholders. However, such an exception may impose significant costs on companies associated with determining whether changes in circumstances qualify for the exception. In addition, as noted above, there are various alternative means for shareholder engagement, including with regard to recent developments, and the amendments provide shareholder-proponents with the ability to resubmit initially unpopular proposals after a modest cooling-off period. Hence, we

2020; *see also* letters in response to the Proxy Process Roundtable from MFS Investment Management dated November 14, 2018; Pax World Funds dated November 9, 2018; Shareholders Right Group dated December 4, 2018; *see also* Ceres Business Case, *supra* note 408, at 9; Eugene Soltes, Suraj Srinivasan, & Rajesh Vijayaraghavan, *What Else do Shareholders Want? Shareholder Proposals Contested by Firm Management* (Harvard Bus. Sch. Accounting & Mgmt. Unit, Working Paper, 2017) (''Soltes et al. (2017)'').

On the other hand, one commenter argued against the assertion that large institutional investors have certain privileges when attempting to engage with companies and noted difficulties that large investors also experience. *See* letter from CalPERS dated February 3, 2020.

[459] *See, e.g.,* letters from First Affirmative Financial Network, LLC dated January 24, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020.

[460] *See* Proposing Release at 66490 for a detailed description of the data on resubmitted proposals.

[461] This estimate is an upper bound of the number of excludable proposals under this alternative because it will allow all proposals following first and second submissions to be resubmitted. We cannot identify all proposals that would have been resubmitted but were not because they were eligible for exclusion under the current resubmission thresholds for first and second submissions.

[462] *See supra* note 203. *See also* letter in response to the Proxy Process Roundtable from City of New York Office of the Comptroller dated January 2, 2019.

[463] *See* Section V.C.3.ii.d for detailed discussion on this topic.

[464] *See supra* notes 203 and 400. *See also* letters in response to the Proxy Process Roundtable from the City of New York Office of the Comptroller dated January 2, 2019; Shareholder Rights Group dated December 4, 2018; Teachers Insurance and Annuity Association of America (TIAA) dated June 10, 2019.

decided against adopting this alternative.

iv. Momentum Requirement

In the Proposing Release we considered a Momentum Requirement that would allow companies to exclude proposals previously voted on by shareholders three or more times in the preceding five calendar years if: (i) The most recent vote occurred within the preceding three calendar years; (ii) at the time of the most recent shareholder vote, the proposal did not receive a majority of the votes cast; and (iii) support declined by 10 percent or more compared to the immediately preceding shareholder vote on the same subject matter.

We indicated, and a number of commenters agreed, that the main benefit of the proposed Momentum Requirement would be that it would decrease the number of proposals that companies and their shareholders would consider, and thus companies and their shareholders could experience cost savings.[465] Relatedly, the proposed Momentum Requirement would exclude proposals that have historically garnered low levels of support and thus would allow shareholders to focus on the processing of proposals that may garner higher levels of voting support and may be more likely to be implemented by management. In the Proposing Release, we estimated that the Momentum Requirement would have resulted in an additional 57 (4 percent) excludable resubmitted proposals over the 2011–2018 sample period.[466] We considered the costs of the proposed Momentum Requirement in the Proposing Release and recognized costs the proposed Momentum Requirement would have likely imposed on shareholder-proponents and companies. We considered how the Momentum Requirement would have imposed costs on shareholder-proponents and companies because it would have made the determination of shareholder proposal eligibility more complex. We also acknowledged that the requirement's potential effects, including the costs associated with the exclusion of beneficial proposals, could vary across different types of companies, proposals, and share-class structures. Several commenters argued that a 10 percent decrease in voting support does not necessarily imply a persistent waning of voting support, and so the proposed Momentum Requirement could result in the exclusion of proposals that would meet resubmission thresholds.[467] As a response to those commenters, we examined the subset of resubmitted proposals that had not garnered majority support in prior rounds of voting and experienced a 10 percent or greater decline in voting support relative to the immediately prior submission, but were still eligible to be resubmitted in the subsequent year under the current resubmissions thresholds. We found 264 such resubmissions, 139 (53 percent) of which were actually subsequently resubmitted. Among these 139 proposal resubmissions, 56 proposals (40 percent) experienced a further decline in support, while 33 (24 percent) saw an increase in support lower than ten percent and 50 (36 percent) saw an increase in support greater than ten percent.[468]

Relatedly, some commenters argued that there are various factors that might create volatility in voting support across years (*e.g.,* changes in company performance, changes in the phrasing of the proposal, changes in shareholder base, changes in the proponent, market developments, etc.), and so relying on year-over-year changes in voting support to decide whether a proposal may be resubmitted likely is inappropriate.[469] Some commenters also argued that the Momentum Requirement is problematic because it would allow proposals with lower levels of support that have not lost momentum to be resubmitted while excluding proposals with higher levels of support.[470] Other commenters argued that the proposed Momentum Requirement is unclear[471] and that it would increase the complexity of the shareholder proposal eligibility requirements.[472] In addition, some commenters argued that the Momentum Requirement relies on voting outcomes and those numbers are unreliable because of issues with the counting of votes.[473] Finally, some commenters argued that the Momentum Requirement would impose costs because it would require more detailed vote counts.[474]

Based on our additional analysis and the comments received, we are not adopting the proposed Momentum Requirement.

VI. Paperwork Reduction Act

A. Background

Certain provisions of our rules and schedules that would be affected by the amendments contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[475] We published a notice requesting comment on changes to these collection of information requirements in the Proposing Release and have submitted these requirements to the Office of Management and Budget (''OMB'') for review in accordance with the PRA.[476] The hours and costs associated with preparing, filing, and sending the schedules, including preparing documentation required by the shareholder-proposal process, constitute paperwork burdens imposed by the collection of information. An agency may not conduct or sponsor, and a person is not required to comply with, a collection of information unless it displays a currently valid OMB control number. Compliance with the information collection is mandatory. Responses to the information collections are not kept confidential and there is no mandatory retention period for the information disclosed. The title for the affected collection of information is:

''Regulation 14A (Commission Rules 14a–1 through 14a–21 and Schedule 14A)'' (OMB Control No. 3235–0059).

We adopted the existing regulations and schedule pursuant to the Exchange Act. The regulations and schedules set forth the disclosure and other requirements for proxy statements filed by issuers and other soliciting parties.

[465] *See, e.g.,* National Association of Manufacturers, dated February 3, 2020.

[466] *See* Proposing Release at 66500. We estimate that the Momentum Requirement would have resulted in an additional 7 excludable resubmitted proposals in 2018 alone.

[467] *See, e.g.,* letters from Interfaith Center on Corporate Responsibility dated January 27, 2020; Principles for Responsible Investment dated February 3, 2020.

[468] We find that 2 (1%) shareholder proposals received majority support in a resubmission, which followed a 10% drop in support. Among the 56 proposals that experienced a further decline in support, the average decline was 16%. Among the 83 proposals that experienced an increase in support, the average increase was 35%.

[469] *See supra* note 400.

Some commenters also suggested that the economic analysis should analyze which proposals have higher volatility in voting support and thus would be more likely to be affected by the momentum requirement. *See, e.g.,* letters from As You Sow dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Segal Marco Advisors dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020. *See supra* Section V.C.2.iii for this analysis.

[470] *See, e.g.,* letter from AFL–CIO dated February 3, 2020.

[471] *See, e.g.,* letters from Council of Institutional Investors dated January 30, 2020; James McRitchie dated February 2, 2020.

[472] *See also* letter from CalPERS dated February 3, 2020.

[473] *See supra* note 444.

[474] *See* letter from CalPERS dated February 3, 2020.

[475] 44 U.S.C. 3501 *et seq.*

[476] 44 U.S.C. 3507(d); 5 CFR 1320.11.

B. Summary of Comment Letters and Revisions to PRA Estimates

In the Proposing Release, we requested comment on the PRA burden hour and cost estimates and the analysis used to derive such estimates. We received four comment letters that directly addressed the PRA analysis of the proposed amendments.[477] Three of those comment letters addressed one of the cost estimates used in informing our PRA estimates, and one comment letter addressed several other aspects of the PRA analysis. None of those commenters provided additional data for consideration. We also received comment letters that, while not specifically referencing the PRA analysis, did address the cost estimates per proposal cited in both the PRA and the Economic Analysis sections of the Proposing Release. We address both types of comments below, starting with comments about the numeric estimates.

The Proposing Release used a range of available cost estimates for purposes of developing the PRA burden hours and cost estimates, including estimates associated with a company's receipt of a shareholder proposal of approximately $50,000, $87,000, more than $100,000, and approximately $150,000.[478] As discussed in Section V above, while not in direct response to the PRA analysis, a number of commenters provided estimates associated with a company's receipt of a shareholder proposal.[479] Many of these estimates were within the range of estimates that were used in developing our PRA estimates, and we received additional estimates from commenters of $18,982 and $20,000.[480] We have taken these comments into account for purposes of developing the PRA burden hours and cost estimates. Additionally, a few commenters indicated that there was not an adequate basis for relying on an estimated cost per proposal of $150,000 in calculating the PRA burden estimate.[481] Other commenters, however, noted that a cost range of $87,000 to $150,000 was ''directionally accurate.'' [482] Overall, we believe that looking to a range of estimates, rather than relying on a single figure, is appropriate for purposes of informing the PRA burden hours and cost estimates and yields a more comprehensive estimation. For this reason, we believe it is appropriate to use the $150,000 cost estimate as one data point for purposes of the PRA.

Another commenter stated that the burden estimate does not adequately account for additional paperwork burdens on shareholders associated with the proposed ownership thresholds, one-proposal limit, and Momentum Requirement.[483] This commenter also stated that ''certain shareholders will respond to the proposed amendments to Rule 14a-8 by increasing their use of independent proxy solicitations in order to avoid the more restrictive requirements of the amended shareholder proposal rule,'' and that the burden estimate should consider the attendant paperwork costs.[484]

We are not revising our estimate in response to the commenter's suggestion to account for recordkeeping requirements related to the revised ownership requirements, one-proposal limit under Rule 14a–8(c), and Momentum Requirement. The commenter suggested that there would be an increased burden associated with the revised ownership requirements because ''shareholders' recordkeeping requirements under Rule 14a–8(b)(1)(i) will triple from one year to three years to determine whether they meet the $2,000 stock ownership requirement.'' We do not believe that the revised ownership requirements will result in this type of additional paperwork burden because Commission rules currently require a shareholder's broker to retain these records for a period that exceeds three years.[485] Thus, there should not be an additional burden for a shareholder-proponent associated with obtaining a broker letter verifying ownership for a two- or three-year period compared to a one-year period.

We also are not revising our assessment in response to the commenter's suggestion related to the one-proposal rule. The commenter stated that shareholders would ''have additional recordkeeping requirements to keep track of . . . their use of representatives under the proposed Rule 14a–8(c).'' [486] The commenter did not explain the basis for this statement, but we do not believe that there will be any additional paperwork burdens associated with keeping track of a shareholder-proponent's use of representatives. As explained in Section II.D, the amended rule will not unduly restrict a shareholder-proponent's options in selecting a representative because, while in some cases shareholder-proponents may need to submit a proposal on their own, they can otherwise enjoy all of the benefits of being represented by a representative of their choosing. Moreover, to the extent shareholder-proponents prepare and/or maintain paperwork in connection with their use of a representative, we believe the burden will be the same under the amendment as under the current rule.

We also are not revising our assessment in response to the commenter's suggestion related to the Momentum Requirement because we are not adopting that requirement. We have revised the estimate of the per-hour burden of the resubmission thresholds to reflect that the final amendments do not include the Momentum Requirement.

Finally, we are not revising our estimate in response to the commenter's suggestion that ''certain shareholders will respond to the proposed amendments to Rule 14a–8 by increasing their use of independent proxy solicitations in order to avoid the more restrictive requirements of the amended shareholder proposal rule.'' [487] We are not aware and this commenter did not provide evidence of this type of response to other amendments to Rule 14a–8. In addition, we believe that shareholders who are unable to use Rule 14a–8 as a result of the amendments will be more likely to engage with companies through alternative avenues rather than conduct their own proxy solicitation in light of the costs involved in conducting a non-exempt proxy solicitation. In addition, to the extent shareholders elect to engage in activities that do not require compliance with Commission rules or regulations ''in order to avoid the more restrictive requirements of the amended shareholder proposal rule,'' we note that those activities would not constitute a burden for purposes of the PRA.[488]

[477] *See* letters from AFL–CIO dated February 3, 2020; Interfaith Center on Corporate Responsibility dated January 27, 2020; Segal Marco Advisors dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[478] *See infra* note 490.

[479] *See supra* note 332.

[480] *See* letters from CalPERS dated February 3, 2020 (stating that the marginal cost of submitting a no-action request is less than $20,000); John Coates and Barbara Roper dated January 30, 2020 (stating that the cost estimate of $18,982 to print and mail a shareholder proposal ''is a relevant datum for estimating cost savings'').

[481] *See* letters from Interfaith Center on Corporate Responsibility dated January 27, 2020; Segal Marco Advisors dated February 3, 2020; UAW Retiree Medical Benefits Trust dated January 30, 2020.

[482] *See* letter from General Motors Company dated February 25, 2020. *See also* letter from Center for Capital Markets Competitiveness dated January 31, 2020.

[483] *See* letter from AFL–CIO dated February 3, 2020.

[484] *Id.*

[485] *See* 17 CFR 240.17a–3 and 17a–4.

[486] *See* letter from AFL–CIO dated February 3, 2020.

[487] *See* letter from AFL–CIO dated February 3, 2020.

[488] *See* 44 U.S.C. 3502(2); 5 CFR 1320.3(b).

We have modified the overall burden estimates to reflect the most current collections of information data from OMB and updated estimates on the effects of the amendments.

C. Summary of the Amendments' Impact on Collections of Information

In this section, we summarize the amendments and their general impact on the paperwork burden associated with Regulation 14A.

PRA TABLE 1—ESTIMATED PAPERWORK BURDEN EFFECTS OF THE FINAL AMENDMENTS

Final amendments	Estimated effect
Rule 14a–8(b)(1)(i):	
• Revise the ownership requirements that shareholders must satisfy to be eligible to submit proposals to be included in an issuer's Schedule 14A proxy statement to the following levels: ○ ≥$2K to <$15K for at least 3 years; ○ ≥$15K to <$25K for at least 2 years; or ○ ≥$25K for at least 1 year.	28% decrease in the number of shareholder proposal submissions,[489] resulting in a reduction in the average burden per response of 5.08 hours.[490]
Rule 14a–8(b)(1)(iii):	
• Require shareholders to provide the company with a written statement that they are able to meet with the company in person or via teleconference no less than 10 calendar days nor more than 30 calendar days after submission of the shareholder proposal, and to provide contact information as well as business days and specific times that they are available to discuss the proposal with the company.	Increase in the average burden per response of 0.04 hours.[491]
Rule 14a–8(b)(1)(iv):	
• Require shareholders to provide certain written documentation to companies if the shareholder appoints a representative to act on its behalf in submitting a proposal under the rule.	Increase in the average burden per response of 0.01 hours.[492]
Rule 14a–8(b)(1)(vi):	
• Disallow aggregation of holdings for purposes of satisfying the ownership requirements.	No change in the number of shareholder proposal submissions,[493] resulting in no change in the average burden per response.
Rule 14a–8(c):	
• Provide that shareholders and other persons cannot submit, directly or indirectly, more than one proposal for the same shareholders' meeting.	2% decrease in the number of shareholder proposal submissions,[494] resulting in a reduction in the average burden per response of 0.36 hours.[495]
Rule 14a–8(i)(12):	
• Increase the prior vote thresholds for resubmission of a proposal that addresses substantially the same subject matter as a proposal previously included in company's proxy materials within the preceding 5 calendar years if the most recent vote occurred within the preceding 3 calendar years to: ○ Less than 5% of the votes cast if previously voted on once; ○ less than 15% of the votes cast if previously voted on twice; or ○ less than 25% of the votes cast if previously voted on three or more times.	5% reduction in the number of shareholder proposals by reducing the number of resubmissions,[496] resulting in a reduction in the average burden per response of 0.90 hours.[497]
Total	Net decrease in the average burden per response of 6.29 hours.[498]

D. Incremental and Aggregate Burden and Cost Estimates for the Final Amendments

The paperwork burden estimate for Regulation 14A includes the burdens

[489] *See supra* note 322. We estimate that the decrease in the number of shareholder proposals could range from 0 to 56%, depending on proponents' holding periods. For purposes of the PRA, we assume an estimated decrease of 28%. The estimated decrease in the number of shareholder proposals takes into account the limitation on aggregation for purposes of satisfying the ownership thresholds.

[490] *See* Proposing Release at 66510 n.312. *See also* letters from Business Roundtable dated February 3, 2020 (noting that several member companies ''reported costs ranging from $50,000 to $100,000 or more per proposal'' and that ''costs for first-time proposals are generally higher than those incurred for resubmitted proposals''); CalPERS dated February 3, 2020 (stating that the marginal cost of submitting a no-action request is less than $20,000); Center for Capital Markets Competitiveness dated January 31, 2020 (stating that its members reported that $87,000 to $150,000 per proposal is a fair cost estimate, with some exceeding the high end of the range); John Coates and Barbara Roper dated January 30, 2020 (stating that the cost estimate of $18,982 to print and mail a shareholder proposal ''is a relevant datum for estimating cost savings''); Exxon Mobil Corporation dated February 3, 2020 (estimating the direct cost of each shareholder proposal included in its proxy statement to be ''at least $100,000''); General Motors Company dated February 25, 2020 (stating that a cost estimate of $87,000 to $150,000 is ''directionally accurate'').

At an estimated hourly cost of $400 per hour, these estimated costs would correspond to the following estimated burden hours: 47.5 hours ($18,982/$400 = 47.5), 50 hours ($20,000/$400 = 50), 125 hours ($50,000/$400 = 125), 218 hours ($87,000/$400 = 218), 250 hours ($100,000/$400 = 250), and 375 hours ($150,000/$400 = 375).

As in the Proposing Release, we continue to estimate that the burden hours for a company associated with considering and printing and mailing a shareholder proposal (not including burdens associated with the no-action process) would be 100 hours (80 hours associated with activities unrelated to printing and mailing, and 20 hours associated with printing and mailing). In addition, we estimate that the burden hours associated with seeking no-action relief would be 50 hours. *See* Proposing Release at 66510 n.312. In arriving at these estimates, we took into consideration the hourly burdens corresponding to the cost estimates provided by commenters, noted above, as well as data provided in response to a July 2009 survey of Business Roundtable companies. *See* 2009 BRT Letter, *supra* note 332. We believe it is useful to consider the Business Roundtable survey in estimating the burden hours for a company associated with considering and printing and mailing a shareholder proposal because it provides specific burden hour and cost estimates with respect to preparing a no-action request and printing and mailing a single shareholder proposal.

In the Proposing Release, we estimated that 40% of proposals are included in the proxy statement without seeking no-action relief, 16% are included after seeking no-action relief, 15% are excluded after seeking no-action relief, and 29% are withdrawn. *See* Proposing Release at 66510 n.312. No commenters provided alternative estimates on this point or expressed disagreement with these percentage estimates. Thus, for purposes of this PRA analysis, we estimate 107 burden hours associated with a company's receipt of a shareholder proposal, calculated as follows:

100 hours for 40% of proposals (*i.e.,* proposals that are included in the proxy statement without seeking no-action relief);

150 hours for 16% of proposals (*i.e.,* proposals that are included in the proxy statement after seeking no-action relief);

130 hours for 15% of proposals (*i.e.,* proposals that are excluded from the proxy statement after seeking no-action relief); and

80 hours for 29% of proposals (*i.e.,* proposals that are withdrawn).

The reduction in the average burden per response of 5.08 hours is calculated by multiplying the expected reduction in proposals (28%) by the average number of proposals received between 1997 and 2018 (946) for a reduction in the total number of proposals of 265. This reduction in the number of proposals (265) is then multiplied by the estimated burden hours per proposal (107) for a total of 28,355 burden hours. This total number of burden hours (28,355) is then divided by the total number of responses (5,586) for a reduction in the average burden per response of 5.08 hours.

[491] The increase in the average burden per response of 0.04 hours is calculated by multiplying

Continued

imposed by our rules that may be incurred by all parties involved in the proxy process leading up to and associated with the filing of a Schedule 14A. This would include both the time that a shareholder-proponent spends to prepare its proposals for inclusion in a company's proxy statement, as well as the time that the company spends to respond to such proposals. Our incremental and aggregate reductions in paperwork burden as a result of the proposed amendments represent the average burden for all respondents, including shareholder-proponents and large and small registrants. In deriving our estimates, we recognize that the burdens would likely vary among individual proponents and registrants based on a number of factors, including the propensity of a particular shareholder-proponent to submit proposals, or the number of shareholder proposals received by a particular company, which may be related to its line of business or industry or other factors.

As shown in PRA Table 1, the burden estimates were calculated by estimating the number of parties expected to expend time, effort, and/or financial resources to generate, maintain, retain, disclose, or provide information required by the amendments and then multiplying by the estimated amount of time, on average, each of these parties would devote in response to the amendments. For purposes of the PRA, the burden is to be allocated between internal burden hours and outside professional costs. For Regulation 14A we estimate that 75% of the burden is carried by the company or the shareholder-proponent internally and that 25% of the burden of preparation is carried by outside professionals retained by the company or the shareholder-proponent at an average cost of $400 per hour.[499]

PRA TABLE 2—CALCULATION OF THE INCREMENTAL CHANGE IN BURDEN ESTIMATES OF CURRENT RESPONSES RESULTING FROM THE FINAL AMENDMENTS

Number of estimated responses	Burden hour reduction per response	Reduction in burden hours for responses	Reduction in internal hours for responses	Reduction in professional hours for responses	Reduction in professional costs for responses
(A)[500]	(B)	(C) = (A) × (B)[501]	(D) = (C) × 0.75	(E) = (C) × 0.25	(F) = (E) × $400
5,586	6.29	35,136	26,352	8,784	$3,513,600

The following table summarizes the requested paperwork burden, including the estimated total reporting burdens and costs, under the final amendments.

PRA TABLE 3—REQUESTED PAPERWORK BURDEN UNDER THE FINAL AMENDMENTS

Current burden			Program change			Revised burden		
Current annual responses	Current burden hours	Current cost burden	Number of affected responses	Reduction in internal hours	Reduction in professional costs	Annual responses	Burden hours	Cost burden
(A)	(B)	(C)	(D)	(E)[502]	(F)[503]	(G) = (A)	(H) = (B) − (E)	(I) = (C) − (F)
5,586	551,101	$73,480,012	5,586	26,352	$3,513,600	5,586	524,749	$69,966,412

the expected amount of time to provide this information (20 minutes) by the expected average number of expected proposals after taking account of the total reduction in proposals submitted as a result of the proposed amendments (644) for a total increase of 215 hours. This increase in burden hours (215 hours) is then divided by the total number of responses (5,586) for an increase in the average burden per response of 0.04 hours.

[492] The increase in the average burden per response of 0.01 hours is calculated by multiplying the expected amount of time to provide this information (20 minutes) by the expected number of proposals submitted by a representative that would be subject to the amendment. We estimate that approximately 14% of proposals are submitted by such representatives; thus, we multiply the average number of expected proposals after taking into account the reduction in proposals as a result of the proposed amendments (644) by 14% for a total of 90 proposals submitted by such representatives. The number of proposals (90) is multiplied by the estimated amount of time to provide this information (20 minutes) for a total of 30 hours. This increase in burden hours (30 hours) is then divided by the total number of responses (5,586) for an increase in the average burden per response of 0.01 hours.

[493] *See supra* note 322. The effect of this amendment is accounted for in the above entry for Rule 14a–8(b)(1)(i).

[494] *See* Proposing Release at 66497 and *supra* tbl.1.

[495] The reduction in the average burden per response of 0.36 hours is calculated by multiplying the expected reduction in proposals (2%) by the average number of proposals received between 1997 and 2018 (946) for a reduction in the total number of proposals of 19. This reduction in the number of proposals (19) is then multiplied by the estimated burden hours per proposal (107) for a total of 2,033 burden hours. This total number of burden hours (2,033) is then divided by the total number of responses (5,586) for a reduction in the average burden per response of 0.36 hours.

[496] *See supra* tbl.1 for a discussion regarding the estimated decrease in resubmitted proposals. The estimated 5% reduction in the number of resubmissions is lower than the estimated reduction in the Proposing Release because the proposed Momentum Requirement is not being adopted.

[497] The reduction in the average burden per response of 0.90 hours is calculated by multiplying the expected reduction in proposals (5%) by the average number of proposals received between 1997 and 2018 (946) for a reduction in the total number of proposals of 47. This reduction in the number of proposals (47) is then multiplied by the estimated burden hours per proposal (107) for a total of 5,029 burden hours. This total number of burden hours (5,029) is then divided by the total number of responses (5,586) for a reduction in the average burden per response of 0.90 hours.

[498] (5.08 + 0.00 + 0.36 + 0.90) − (0.04 + 0.01) = 6.29 hours decrease in average burden per response.

[499] We recognize that the costs of retaining outside professionals may vary depending on the nature of the professional services, but for purposes of this PRA analysis, we estimate that such costs would be an average of $400 per hour. This estimate is based on consultations with several issuers, law firms, and other persons who regularly assist issuers in preparing and filing reports with the Commission.

[500] The number of estimated affected responses is based on the number of responses in the Commission's current OMB PRA filing inventory. The OMB PRA filing inventory represents a three-year average. We do not expect that the final amendments will materially change the number of responses in the current OMB PRA filing inventory.

[501] The estimated reductions in Columns (C), (D), and (E) are rounded to the nearest whole number.

VII. Final Regulatory Flexibility Act Analysis

This Final Regulatory Flexibility Act (''FRFA'') has been prepared in accordance with the Regulatory Flexibility Act (''RFA'').[504] It relates to amendments to Rule 14a–8. An Initial Regulatory Flexibility Analysis (''IRFA'') was prepared in accordance with the RFA and was included in the Proposing Release.

A. Need for, and Objectives of, the Final Amendments

Rule 14a–8 facilitates the proxy process for shareholders seeking to have proposals considered at a company's annual or special meeting; however, the burdens associated with this process are primarily borne by issuers and their shareholders. The amendments are intended to appropriately consider shareholders' ability to submit proposals as well as the attendant burdens for companies and other shareholders associated with the inclusion of such proposals in a company's proxy statement. The reasons for, and objectives of, the final amendments are discussed in more detail in Sections I and II above.

B. Significant Issues Raised by Public Comments

In the Proposing Release, we requested comment on any aspect of the IRFA, including how the proposed amendments can achieve their objective while lowering the burden on small entities, the number of small entities that would be affected by the proposed amendments, the existence or nature of the potential effects of the proposed amendments on small entities discussed in the analysis, and how to quantify the effects of the proposed amendments. We also requested comment on the number of shareholder-proponents that may be considered small entities.

One commenter stated that the amendments will raise costs on smaller shareholders.[505] Another commenter stated that the Commission should exempt small entities from the amended ownership requirements of $25,000 for one year or $15,000 for two years because, in the commenter's view, ''the existing $2,000 requirement for one year is appropriate given that small entities by definition have small investment portfolios of less than $5 million.'' [506]

C. Small Entities Subject to the Final Amendments

The amendments would affect some small entities that are either: (i) Shareholder-proponents that submit Rule 14a–8 proposals, or (ii) issuers subject to the federal proxy rules that receive Rule 14a–8 proposals. The RFA defines ''small entity'' to mean ''small business,'' ''small organization'' or ''small governmental jurisdiction.'' [507] The definition of ''small entity'' does not include individuals. For purposes of the RFA, under our rules, an issuer of securities or a person, other than an investment company, is a ''small business'' or ''small organization'' if it had total assets of $5 million or less on the last day of its 2018 fiscal year.[508] We estimate that there are approximately 835 issuers that are subject to the federal proxy rules, other than investment companies, that may be considered small entities. We are unable to estimate the number of potential shareholder-proponents that may be considered small entities.[509]

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

As noted above, the primary purpose of the amendments is to appropriately consider shareholders' ability to submit proposals as well as the attendant burdens for companies and other shareholders associated with the inclusion of such proposals. The amendments will likely reduce the number of proposals required to be included in the proxy statements of issuers subject to the federal proxy rules, including small entities. In turn, the amendments will likely reduce the costs to these issuers of complying with Rule 14a–8. The proposed amendments may reduce the number of proposals that shareholder-proponents that are small entities will be permitted to submit to issuers for inclusion in their proxy statements. In turn, these small entities may experience an increase in shareholder-engagement costs to the extent these small entities elect to increase their investment to meet the eligibility criteria or pursue alternative methods of engagement, such as conducting their own proxy solicitation. We are not exempting shareholders that are small entities from the amended ownership requirements of $25,000/one-year and $15,000/two-years, as suggested by one commenter. The amended rule will continue to allow shareholders holding at least $2,000 of a company's securities to submit a proposal as long as they have held their shares for at least three years. In addition, we are adopting a transition provision that will exempt certain existing shareholders from the new ownership thresholds, which is expected to help with compliance burdens for those shareholders.

The amendments that will require shareholder-proponents to provide written documentation regarding their ability to meet with the issuer and relating to the appointment of a representative will slightly increase the compliance burden for shareholder-proponents, including those that are small entities. Compliance with the amendments may require the use of professional skills, including legal skills. The amendments are discussed in detail in Section II, above. We discuss the economic impact, including the estimated costs and benefits, of the amendments to all affected entities, including small entities, in Section V and Section VI, above.

E. Agency Action To Minimize Effect on Small Entities

The Regulatory Flexibility Act directs us to consider alternatives that would accomplish our stated objectives, while minimizing any significant adverse impact on small entities. In connection with the proposed amendments, we considered the following alternatives:

- Establishing different compliance or reporting requirements that take into account the resources available to small entities;
- Clarifying, consolidating, or simplifying compliance and reporting requirements under the rules for small entities;
- Using performance rather than design standards; and
- Exempting small entities from all or part of the requirements.

Rule 14a–8 generally does not impose different standards or requirements based on the size of the issuer or shareholder-proponent. We do not believe that establishing different compliance or reporting obligations in conjunction with the amendments or exempting small entities from all or part of the requirements is necessary. While we note that one commenter suggested that the Commission provide regulatory relief from the proposed amendments

[502] From Column (D) in PRA Table 2.

[503] From Column (F) in PRA Table 2.

[504] 5 U.S.C. 601 *et seq.*

[505] *See* letter from Council of Institutional Investors dated January 30, 2020.

[506] *See* letter from AFL–CIO dated February 3, 2020.

[507] 5 U.S.C. 601(6).

[508] 17 CFR 240.0–10(a).

[509] For the purposes of our Economic Analysis, we estimate that there were 22.2 million retail accounts that held shares of U.S. public companies during calendar year 2017. There were 170 unique proponents that submitted proposals that were included in a company's proxy statement as lead proponent or co-proponent during calendar year 2018. Out of these 170 unique proponents, 38 were individuals and 132 were non-individuals. *See supra* Section V.B.3. Thus, no more than 132 of these unique proponents would be considered small entities.

by, for example, exempting small entities from the amended ownership requirements of $25,000 for one year or $15,000 for two years, we do not believe that such an exemption is necessary because the amended rule will continue to allow shareholders holding at least $2,000 of a company's securities to submit a proposal as long as they have held their shares for at least three years and we do not believe that holding $2,000 of a company's securities for up to an additional two years in order to submit a proposal will have a significant effect on small entities. We believe the amendments are equally appropriate for shareholder-proponents of all sizes seeking to engage with issuers through the Rule 14a–8 process. While we do anticipate a moderate increase in burden for some shareholder-proponents, we do not believe that imposing different standards or requirements based on the size of the shareholder-proponent will accomplish the purposes of the proposed amendments, and may result in additional costs associated with ascertaining whether a particular shareholder-proponent may avail itself of such different standards. For issuers, the amendments will not impose any significant new compliance obligations. To the contrary, they will reduce the compliance costs of affected issuers, including small entities, by decreasing the number of shareholder proposals that may be submitted. For these reasons, we are not adopting differing compliance or reporting requirements or timetables for issuers that are small entities, or an exception for small entities.

We believe that the amendments do not need further clarification, consolidation, or simplification for small entities. The amendments generally use design standards rather than performance standards in order to promote uniform submission requirements for all shareholder-proponents, and we do not believe that there are aspects of the amendments for which performance standards would be appropriate.

VIII. Statutory Authority

The final amendments contained in this release are being adopted under the authority set forth in Sections 3(b), 14, and 23(a) of the Exchange Act, as amended.

List of Subjects in 17 CFR Part 240

Brokers, Confidential business information, Fraud, Reporting and recordkeeping requirements, Securities.

Text of the Final Amendments

In accordance with the foregoing, we are amending title 17, chapter II, of the Code of Federal Regulations as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The authority citation for part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78dd, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.,* and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; Pub. L. 111–203, 939A, 124 Stat. 1376 (2010); and Pub. L. 112–106, sec. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

■ 2. Amend § 240.14a–8 by:
■ i. Revising paragraphs (b)(1) and (2);
■ ii. Effective January 4, 2021, through January 1, 2023, adding paragraph (b)(3);
■ iii. Revising paragraph (c); and
■ iv. Revising paragraph (i)(12).

The revisions and addition read as follows:

§ 240.14a–8 Shareholder proposals.

* * * * *

(b) * * *

(1) To be eligible to submit a proposal, you must satisfy the following requirements:

(i) You must have continuously held:

(A) At least $2,000 in market value of the company's securities entitled to vote on the proposal for at least three years; or

(B) At least $15,000 in market value of the company's securities entitled to vote on the proposal for at least two years; or

(C) At least $25,000 in market value of the company's securities entitled to vote on the proposal for at least one year; or

(D) The amounts specified in paragraph (b)(3) of this section. This paragraph (b)(1)(i)(D) will expire on the same date that § 240.14a–8(b)(3) expires; and

(ii) You must provide the company with a written statement that you intend to continue to hold the requisite amount of securities, determined in accordance with paragraph (b)(1)(i)(A) through (C) of this section, through the date of the shareholders' meeting for which the proposal is submitted; and

(iii) You must provide the company with a written statement that you are able to meet with the company in person or via teleconference no less than 10 calendar days, nor more than 30 calendar days, after submission of the shareholder proposal. You must include your contact information as well as business days and specific times that you are available to discuss the proposal with the company. You must identify times that are within the regular business hours of the company's principal executive offices. If these hours are not disclosed in the company's proxy statement for the prior year's annual meeting, you must identify times that are between 9 a.m. and 5:30 p.m. in the time zone of the company's principal executive offices. If you elect to co-file a proposal, all co-filers must either:

(A) Agree to the same dates and times of availability, or

(B) Identify a single lead filer who will provide dates and times of the lead filer's availability to engage on behalf of all co-filers; and

(iv) If you use a representative to submit a shareholder proposal on your behalf, you must provide the company with written documentation that:

(A) Identifies the company to which the proposal is directed;

(B) Identifies the annual or special meeting for which the proposal is submitted;

(C) Identifies you as the proponent and identifies the person acting on your behalf as your representative;

(D) Includes your statement authorizing the designated representative to submit the proposal and otherwise act on your behalf;

(E) Identifies the specific topic of the proposal to be submitted;

(F) Includes your statement supporting the proposal; and

(G) Is signed and dated by you.

(v) The requirements of paragraph (b)(1)(iv) of this section shall not apply to shareholders that are entities so long as the representative's authority to act on the shareholder's behalf is apparent and self-evident such that a reasonable person would understand that the agent has authority to submit the proposal and otherwise act on the shareholder's behalf.

(vi) For purposes of paragraph (b)(1)(i) of this section, you may not aggregate your holdings with those of another shareholder or group of shareholders to meet the requisite amount of securities necessary to be eligible to submit a proposal.

(2) One of the following methods must be used to demonstrate your eligibility to submit a proposal:

(i) If you are the registered holder of your securities, which means that your

name appears in the company's records as a shareholder, the company can verify your eligibility on its own, although you will still have to provide the company with a written statement that you intend to continue to hold the requisite amount of securities, determined in accordance with paragraph (b)(1)(i)(A) through (C) of this section, through the date of the meeting of shareholders.

(ii) If, like many shareholders, you are not a registered holder, the company likely does not know that you are a shareholder, or how many shares you own. In this case, at the time you submit your proposal, you must prove your eligibility to the company in one of two ways:

(A) The first way is to submit to the company a written statement from the ''record'' holder of your securities (usually a broker or bank) verifying that, at the time you submitted your proposal, you continuously held at least $2,000, $15,000, or $25,000 in market value of the company's securities entitled to vote on the proposal for at least three years, two years, or one year, respectively. You must also include your own written statement that you intend to continue to hold the requisite amount of securities, determined in accordance with paragraph (b)(1)(i)(A) through (C) of this section, through the date of the shareholders' meeting for which the proposal is submitted; or

(B) The second way to prove ownership applies only if you were required to file, and filed, a Schedule 13D (§ 240.13d–101), Schedule 13G (§ 240.13d–102), Form 3 (§ 249.103 of this chapter), Form 4 (§ 249.104 of this chapter), and/or Form 5 (§ 249.105 of this chapter), or amendments to those documents or updated forms, demonstrating that you meet at least one of the share ownership requirements under paragraph (b)(1)(i)(A) through (C) of this section. If you have filed one or more of these documents with the SEC, you may demonstrate your eligibility to submit a proposal by submitting to the company:

(*1*) A copy of the schedule(s) and/or form(s), and any subsequent amendments reporting a change in your ownership level;

(*2*) Your written statement that you continuously held at least $2,000, $15,000, or $25,000 in market value of the company's securities entitled to vote on the proposal for at least three years, two years, or one year, respectively; and

(*3*) Your written statement that you intend to continue to hold the requisite amount of securities, determined in accordance with paragraph (b)(1)(i)(A) through (C) of this section, through the date of the company's annual or special meeting.

(3) If you continuously held at least $2,000 of a company's securities entitled to vote on the proposal for at least one year as of January 4, 2021, and you have continuously maintained a minimum investment of at least $2,000 of such securities from January 4, 2021 through the date the proposal is submitted to the company, you will be eligible to submit a proposal to such company for an annual or special meeting to be held prior to January 1, 2023. If you rely on this provision, you must provide the company with your written statement that you intend to continue to hold at least $2,000 of such securities through the date of the shareholders' meeting for which the proposal is submitted. You must also follow the procedures set forth in paragraph (b)(2) of this section to demonstrate that:

(i) You continuously held at least $2,000 of the company's securities entitled to vote on the proposal for at least one year as of January 4, 2021; and

(ii) You have continuously maintained a minimum investment of at least $2,000 of such securities from January 4, 2021 through the date the proposal is submitted to the company.

(iii) This paragraph (b)(3) will expire on January 1, 2023.

(c) *Question 3:* How many proposals may I submit? Each person may submit no more than one proposal, directly or indirectly, to a company for a particular shareholders' meeting. A person may not rely on the securities holdings of another person for the purpose of meeting the eligibility requirements and submitting multiple proposals for a particular shareholders' meeting.

* * * * *

(i) * * *

(12) *Resubmissions.* If the proposal addresses substantially the same subject matter as a proposal, or proposals, previously included in the company's proxy materials within the preceding five calendar years if the most recent vote occurred within the preceding three calendar years and the most recent vote was:

(i) Less than 5 percent of the votes cast if previously voted on once;

(ii) Less than 15 percent of the votes cast if previously voted on twice; or

(iii) Less than 25 percent of the votes cast if previously voted on three or more times.

* * * * *

By the Commission.

Dated: September 23, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–21580 Filed 11–3–20; 8:45 am]

BILLING CODE 8011–01–P

FEDERAL REGISTER

Vol. 85 Wednesday,
No. 214 November 4, 2020

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, et al.
Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, 414, 424, and 484

[CMS–1730–F, CMS–1744–IFC, and CMS–5531–IFC]

RIN 0938–AU06, 0938–AU31, and 0938–AU32

Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the home health prospective payment system (HH PPS) payment rates and wage index for calendar year (CY) 2021. This final rule also implements the changes to the home health regulations regarding the use of telecommunications technology in providing services under the Medicare home health benefit as described in the ''Medicare and Medicaid Programs, Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (March 2020 COVID–19 IFC). In addition, this rule implements the permanent home infusion therapy services benefit and supplier enrollment requirements for CY 2021 and finalizes conforming regulations text changes excluding home infusion therapy services from coverage under the Medicare home health benefit. This rule also finalizes a policy to align the Home Health Value-Based Purchasing (HHVBP) Model data submission requirements with any exceptions or extensions granted for purposes of the Home Health Quality Reporting Program (HH QRP) during the COVID–19 PHE and also finalizes a policy for granting exceptions to the New Measures data reporting requirements during the COVID–19 PHE, as described in the ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' interim final rule with comment period (May 2020 COVID–19 IFC).

DATES: These regulations are effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Brian Slater (410) 786–5229, for home health and home infusion therapy payment inquiries.

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to: *HomehealthPolicy@cms.hhs.gov.*

For general information about home infusion payment, send your inquiry via email to: *HomeInfusionPolicy@cms.hhs.gov.*

For information about the Home Health Quality Reporting Program (HH QRP), send your inquiry via email to *HHQRPquestions@cms.hhs.gov.*

Mary Rossi-Coajou, (410) 786–6051, for condition of participation (CoP) OASIS requirements.

For information about the Home Health Value Based Model, send your inquiry via email to *HHVBPquestions@cms.hhs.gov.*

Joseph Schultz, (410) 786–2656, for information about home infusion therapy supplier enrollment requirements.

SUPPLEMENTARY INFORMATION: Wage index addenda will be available only through the CMS Coding and Billing Information website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.*

I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This final rule updates the payment rates for home health agencies (HHAs) for calendar year (CY) 2021, as required under section 1895(b) of the Social Security Act (the Act). This rule sets forth the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care in CY 2021; the CY 2021 fixed-dollar loss ratio (FDL); and the loss-sharing ratio for outlier payments (as required by section 1895(b)(5)(A) of the Act). Additionally, this rule adopts the revised Office of Management and Budget (OMB) statistical area delineations as described in the September 14, 2018 OMB Bulletin No. 18–04 [1] for the labor market delineations used in the home health wage index, effective beginning in CY 2021. This rule finalizes a cap on wage index decreases in excess of 5 percent and adopts the OMB statistical areas and the 5-percent cap on wage index decreases under the statutory discretion afforded to the Secretary under sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act. Lastly, this rule finalizes the changes to § 409.43(a) as set forth in the interim final rule with comment period that appeared in the April 6, 2020 **Federal Register** titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (PHE) (March 2020 COVID–19 IFC), to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system (85 FR 19230).

2. Home Health Quality Reporting Program (HH QRP)

We did not propose any changes for the HH QRP and therefore are not finalizing any policies in this final rule.

3. Changes to the Conditions of Participation (CoPs) OASIS Requirements

This final rule removes an obsolete provision that requires new HHAs that do not yet have a CMS certification number to conduct test OASIS data transmissions to the CMS data system as part of the initial certification process.

4. Reporting Under the Home Health Value Based Purchasing (HHVBP) Model During the COVID–19 PHE

This rule finalizes a policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP as well as a policy for granting exceptions to the New Measures data reporting requirements during the COVID–19 PHE, as described in the interim final rule with comment period that appeared in the May 8, 2020 **Federal Register** titled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27553) (May 2020 COVID–19 IFC).

5. Home Infusion Therapy Services

This final rule summarizes the home infusion therapy policies codified in the CY 2020 HH PPS final rule with comment period (84 FR 60615), as required by section 1834(u) of the Act. This rule also finalizes the exclusion of

[1] On March 6, 2020, OMB issued the most recent OMB Bulletin No. 20–01.

home infusion therapy services from coverage under the Medicare home health benefit as required by section 5012(c)(3) of the 21st Century Cures Act.

6. Enrollment Requirements for Qualified Home Infusion Therapy Suppliers

This final rule establishes Medicare provider enrollment policies for qualified home infusion therapy suppliers.

B. Summary of the Provisions of This Rule

In section III.A of this rule, we set the LUPA thresholds and the case-mix weights for CY 2021 equal to the CY 2020 LUPA thresholds and case-mix weights established for the first year of the Patient-Driven Groupings Model (PDGM). The PDGM is a new case-mix adjustment methodology used to adjust payments for home health periods of care beginning on or after January 1, 2020. The PDGM relies more heavily on clinical characteristics and other patient information to place patients into meaningful payment categories and eliminates the use of therapy service thresholds, as required by section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the Bipartisan Budget Act of 2018 (BBA of 2018).

Section III.B. of this rule adopts the OMB statistical area delineations outlined in a September 14, 2018, OMB bulletin No. 18–04. This rule also finalizes the transition with a 1-year cap on wage index decreases in excess of 5 percent, consistent with the policy finalized for other Medicare payment systems. This rule adopts the OMB statistical areas and the 5 percent cap on wage index decreases under the statutory discretion afforded to the Secretary under sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act.

In section III.C. of this rule, we update the home health wage index, the CY 2021 national, standardized 30-day period of care payment amounts and the CY 2021 national per-visit payment amounts by the home health payment update percentage. The home health payment update percentage for CY 2021 is 2.0 percent. Section III.D. of this rule describes the rural add-on payments as required by section 50208(a)(1)(D) of the BBA of 2018 for home health episodes or periods ending during CYs 2019 through 2022. Section III.E. of this rule maintains the fixed-dollar loss ratio at 0.56, as finalized for CY 2020, in order to ensure that outlier payments as a percentage of total payments is closer to, but no more than, 2.5 percent, as required by section 1895(b)(5)(A) of the Act.

Section III.F. of this rule finalizes the changes to § 409.43(a) as implemented in the March, 2020 COVID–19 IFC, to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system and that these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment, in accordance with section 1895(e)(1)(A) of the Act.

Section III.G. of this rule, finalizes conforming regulation text changes at §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 regarding allowed practitioner certification as a condition for payment for home health services.

Section IV.A and B. of this final rule discuss the HH QRP and changes to the Conditions of Participation (CoPs) OASIS requirements.

Section IV.C. of this final rule discusses final policies on reporting under the HHVBP Model during the COVID–19 PHE.

In sections V.A.1. and V.A.2. of this rule, we discuss the background and overview of the home infusion therapy services benefit, as well as review the payment policies we finalized in the CY 2020 HH PPS final rule with comment period for the CY 2021 implementation (84 FR 60628). Sections V.A.3. and V.A.4. describe the payment categories and payment amounts for home infusion therapy services for CY 2021, as well as payment adjustments for CY 2021 home infusion therapy services. In section V.A.5. of this rule, we finalize technical regulations text changes to exclude home infusion therapy services from coverage under the Medicare home health benefit, as required by section 5012(c)(3) of the 21st Century Cures Act, which amended section 1861(m) of the Act. In section V.B. of this rule, we discuss the home infusion therapy supplier enrollment requirements.

C. Summary of Costs, Transfers, and Benefits

BILLING CODE 4120–01–P

TABLE 1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2021 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated $390 million (1.9 percent) in increased payments to HHAs in CY 2021.	To ensure home health payments are consistent with statutory payment authority for CY 2021.
HH QRP	No proposals were made. Therefore, there are no costs or savings associated with this provision.		
OASIS	There are no costs associated with this provision.		Simplifies the submission process. HHAs are no longer limited to two users for submission of assessment data since VPN and CMSNet are no longer required.
Reporting Under the HHVBP Model During the COVID-19 PHE	We do not anticipate a change to Medicare expenditures as a result of this policy. However, we expect reduced burden on providers.	The overall economic impact of the HHVBP Model for CYs 2018 through 2022 is an estimated $378 million in total savings to Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.	Aligning HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID-19 PHE and implementing a policy for granting exceptions to the New Measures data reporting requirements during the COVID-19 PHE helps to provide HHAs with flexibility to respond to the COVID-19 PHE.
CY 2021 Payments for Home Infusion Therapy Services		The overall economic impact of updating the payment rates for home infusion therapy services, based on the proposed Physician Fee Schedule amounts for CY 2021, is a 0.7 percent decrease ($384,800) in payments to eligible home infusion therapy suppliers in CY 2021.	To ensure that payment for home infusion therapy services are consistent with statutory authority for CY 2021.
Home Infusion Therapy Supplier Enrollment	The estimated average annual burden associated with home infusion therapy supplier enrollment over the 3-year OMB approval period is 583 hours at a cost of $28,583.	We estimate a total application fee cost to enrollees of $364,800 (or 600 x $608) in the first year, $31,050 (or 50 x $621) in the second year, and $31,700 (or 50 x $634) in the third year. This constitutes an average annual figure over the first 3 years of this requirement of $142,517.	Enrollment ensures that home infusion therapy suppliers meet all applicable requirements.

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D. Issuance of the Proposed Rulemaking and Correction

In the CY 2021 HH PPS proposed rule that appeared in the June 30, 2020 **Federal Register** (85 FR 39408), we proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with under the HH PPS for CY 2021 and home infusion therapy services benefit for CY 2021. In addition, we set forth proposed changes to the reporting of OASIS requirements and requirements for home infusion therapy suppliers.

We note that Office of the Federal Register issued a correction to the comment period closing date for the CY 2021 HH PPS proposed rule in the July 20, 2020 **Federal Register** (85 FR 43805). The correct closing date for public comments was August 24, 2020.

We note that in response to the CY 2021 HH PPS proposed rule, we received approximately 162 timely pieces of correspondence from the

public, including from home health agencies, national and state provider associations, patient and other advocacy organizations, nurses, and other healthcare professionals. In the following sections, we summarize the proposed provisions and the public comments, and provide the responses to comments.

II. Overview of the Home Health Prospective Payment System (HH PPS)

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare home health services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system. Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled ''Prospective Payment for Home Health Services.'' Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. Section 1895(b)(2) of the Act required that, in defining a prospective payment amount, the Secretary will consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act required the following: (1) The computation of a standard prospective payment amount that includes all costs for home health services covered and paid for on a reasonable cost basis, and that such amounts be initially based on the most recent audited cost report data available to the Secretary (as of the effective date of the 2000 final rule); and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act requires the standard prospective payment amounts be annually updated by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of area wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act. Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Affordable Care Act revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable payment percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2.0 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) amended section 421(a) of the MMA to extend the 3 percent rural add-on payment for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) through January 1, 2018. In addition, section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that CY 2018 home health payments be updated by a 1.0 percent market basket increase. Section 50208(a)(1) of the BBA of 2018 again extended the 3.0 percent rural add-on through the end of 2018. In addition, this section of the BBA of 2018 made some important changes to the rural add-on for CYs 2019 through 2022.

Section 51001(a)(1)(B) of the BBA of 2018 amended section 1895(b) of the Act to require a change to the home health unit of payment to 30-day periods beginning January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service, furnished that end during the 12-month period beginning January 1, 2020, in a

budget neutral manner, such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before the application of the annual update to the standard prospective payment amount as required by section 1895(b)(3)(B) of the Act.

Additionally, section 1895(b)(3)(A)(iv) of the Act requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavior assumptions made in notice and comment rulemaking. CMS finalized these behavior assumptions in the CY 2019 HH PPS final rule with comment period (83 FR 56461).

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary to annually determine the impact of differences between assumed behavior changes as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases, based on retrospective behavior, to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year. And finally, section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for CY 2020 and subsequent years.

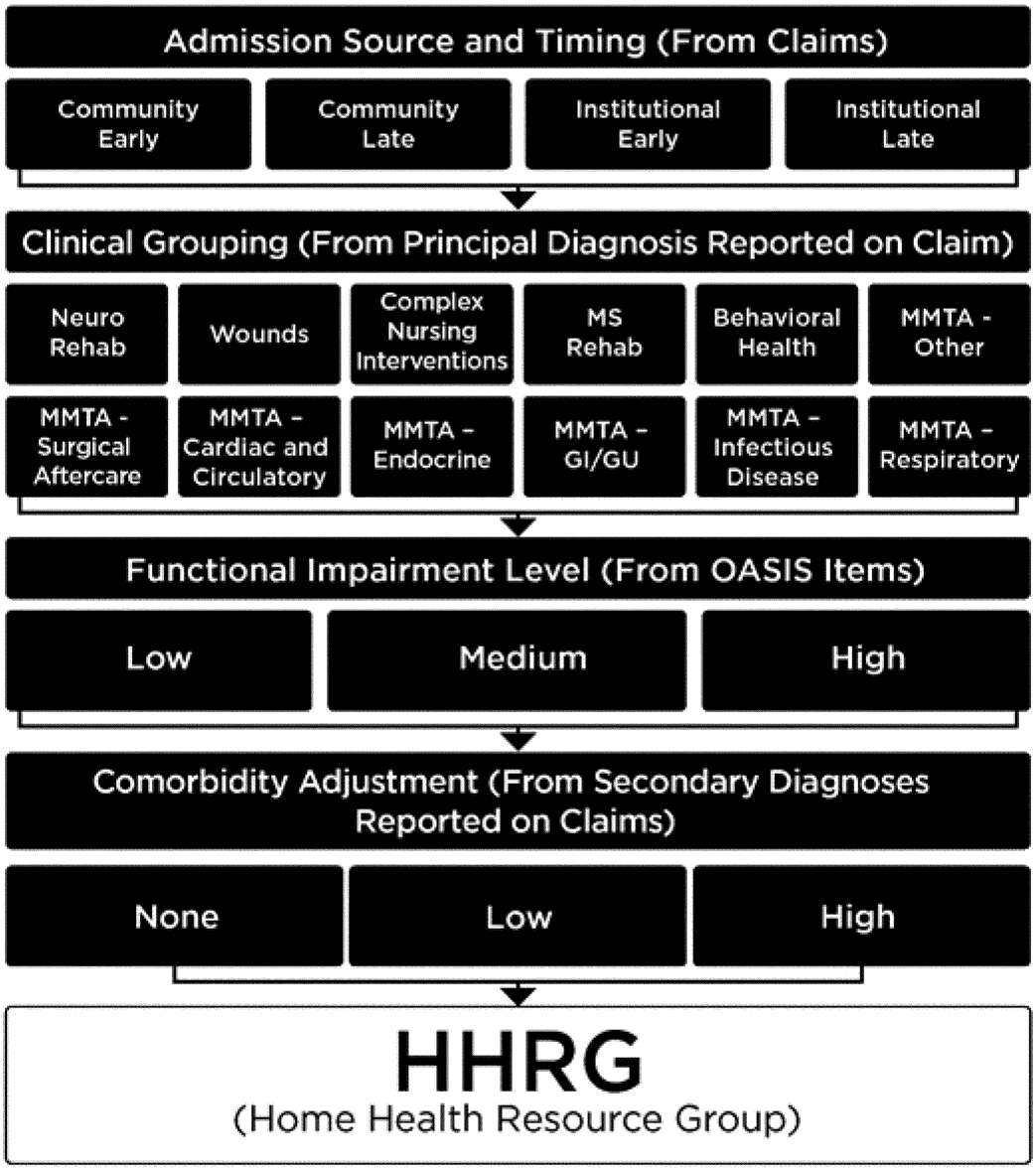
B. Current System for Payment of Home Health Services Beginning in CY 2020 and Subsequent Years

For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for the applicable case-mix and wage index in accordance with section 51001(a)(1)(B) of the BBA of 2018. The national, standardized 30-day period rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is now part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount and is not included in the national, standardized 30-day period payment amount.

To better align payment with patient care needs and ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized case-mix methodology refinements through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) assessment instrument. These 432 HHRGs represent the different payment groups based on five main case-mix variables under the PDGM, as shown in Figure 1, and subsequently described in more detail throughout this section. Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA) threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

Under this new case-mix methodology, case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of the five categories listed in this section of this final rule (admission source, timing clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. Below is a description of each of the case-mix variables under the PDGM.

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



1. Timing

Thirty-day periods of care are classified as ''early'' or ''late'' depending on when they occur within a sequence of 30-day periods. The first 30-day period of care is classified as early and all subsequent 30-day periods of care in the sequence (second or later) are classified as late. A 30-day period is not considered early unless there is a gap of more than 60 days between the end of one period of care and the start of another. Information regarding the timing of a 30-day period of care comes from Medicare home health claims data and not the OASIS assessment to determine if a 30-day period of care is ''early'' or ''late''. While the PDGM case-mix adjustment is applied to each 30-day period of care, other home health requirements continue on a 60-day basis. Specifically, certifications and re-certifications continue on a 60-day basis and the comprehensive assessment must still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, ''Condition of participation: Comprehensive assessment of patients.''

2. Admission Source

Each 30-day period of care is classified into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health. Thirty-day periods of care for beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF) stays, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long-term care hospital (LTCH) stays within 14-days prior to a home health admission are designated as institutional admissions.

The institutional admission source category also includes patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the ''admission date'' and ''from

date'' for the subsequent 30-day period of care do not match), as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge. However, we do not categorize post-acute care stays, meaning SNF, IRF, LTCH, or IPF stays, that occur during a previous 30-day period of care and within 14 days of a subsequent, contiguous 30-day period of care as institutional (that is, the ''admission date'' and ''from date'' for the subsequent 30-day period of care do not match), as HHAs should discharge the patient if the patient required post-acute care in a different setting, or inpatient psychiatric care, and then readmit the patient, if necessary, after discharge from such setting. All other 30-day periods of care would be designated as community admissions.

Information from the Medicare claims processing system determines the appropriate admission source for final claim payment. The OASIS assessment is not utilized in evaluating for admission source information. Obtaining this information from the Medicare claims processing system, rather than as reported on the OASIS, is a more accurate way to determine admission source information as HHAs may be unaware of an acute or post-acute care stay prior to home health admission. While HHAs can report an occurrence code on submitted claims to indicate the admission source, obtaining this information from the Medicare claims processing system allows CMS the opportunity and flexibility to verify the source of the admission and correct any improper payments as deemed appropriate. When the Medicare claims processing system receives a Medicare home health claim, the systems check for the presence of a Medicare acute or post-acute care claim for an institutional stay. If such an institutional claim is found, and the institutional claim occurred within 14 days of the home health admission, our systems trigger an automatic adjustment to the corresponding home health claim to the appropriate institutional category. Similarly, when the Medicare claims processing system receives a Medicare acute or post-acute care claim for an institutional stay, the systems will check for the presence of a home health claim with a community admission source payment group. If such home health claim is found, and the institutional stay occurred within 14 days prior to the home health admission, our systems trigger an automatic adjustment of the home health claim to the appropriate institutional category. This process may occur any time within the 12-month timely filing period for the acute or post-acute claim. For the purpose of a Request for Anticipated Payment (RAP), only the final claim will be adjusted to reflect the admission source. More information regarding the admission source reporting requirements for RAP and claims submission, including the use of admission source occurrence codes, can be found in the Medicare Claims Processing Manual, chapter 10.[2]

3. Clinical Groupings

Each 30-day period of care is grouped into one of 12 clinical groups that describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The clinical grouping is based on the principal diagnosis reported on home health claims. The 12 clinical groups are listed and described in Table 2.

TABLE 2: CLINICAL GROUPS FOR CASE-MIX ADJUSTMENT

Clinical Groups	The Primary Reason for the Home Health Encounter is to Provide:
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke
Wounds – Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric and substance abuse conditions
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions including IV, TPN, enteral nutrition, ventilator, and ostomies
Medication Management, Teaching and Assessment (MMTA)	
MMTA –Surgical Aftercare	Assessment, evaluation, teaching, and medication management for surgical aftercare
MMTA – Cardiac/Circulatory	Assessment, evaluation, teaching, and medication management for cardiac or other circulatory related conditions
MMTA – Endocrine	Assessment, evaluation, teaching, and medication management for endocrine related conditions
MMTA – GI/GU	Assessment, evaluation, teaching, and medication management for gastrointestinal or genitourinary related conditions
MMTA – Infectious Disease/Neoplasms/Blood-forming Diseases	Assessment, evaluation, teaching, and medication management for conditions related to infectious diseases, neoplasms, and blood-forming diseases
MMTA –Respiratory	Assessment, evaluation, teaching, and medication management for respiratory related conditions
MMTA – Other	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the previously listed groups

If a home health claim is submitted with a principal diagnosis that is not assigned to a clinical group (for example, because the diagnosis code is vague, ill-defined, unspecified, or is subject to certain ICD–10–CM coding conventions), the claim is returned to the provider for more definitive coding. While these clinical groups represent

[2] Medicare Claims Processing Manual Chapter 10—Home Health Agency Billing. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf.*

the primary reason for home health services during a 30-day period of care, this does not mean that they represent the only reason for home health services. Home health remains a multidisciplinary benefit and payment is bundled to cover all necessary home health services identified on the individualized home health plan of care. Therefore, regardless of the clinical group assignment, HHAs are required, in accordance with the home health CoPs at § 484.60(a)(2), to ensure that the individualized home health plan of care addresses all care needs, including the disciplines to provide such care. Under the PDGM, the clinical group is just one variable in the overall case-mix adjustment for a home health period of care. Moreover, it is possible for the principal diagnosis to change between the first and second 30-day period of care and the claim for the second 30-day period of care would reflect the new principal diagnosis. HHAs would not change the claim for the first 30-day period.

4. Functional Impairment Level

Each 30-day period of care will be placed into one of three functional impairment levels, low, medium, or high, based on responses to certain OASIS functional items associated with grooming, bathing, dressing, ambulating, transferring, and risk for hospitalization. The specific OASIS items that are used for the functional impairment level are found in Table 7 in the CY 2020 HH PPS final rule with comment period (84 FR 60490). Responses to these OASIS items are grouped together into response categories with similar resource use and each response category has associated points. A more detailed description as to how these response categories were established can be found in the technical report, ''Overview of the Home Health Groupings Model'', which is posted on our HHA web page.[3] The sum of these points' results in a functional impairment level score used to group 30-day periods of care into a functional impairment level with similar resource use. The scores associated with the functional impairment levels vary by clinical group to account for differences in resource utilization. The functional impairment level will remain the same for the first and second 30-day periods of care unless there has been a significant change in condition which warranted an ''other follow-up'' assessment prior to the second 30-day period of care. For each 30-day period of care, the Medicare claims processing system will look for the most recent OASIS assessment based on the claims ''from date.''

5. Comorbidity Adjustment

Thirty-day periods will receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use, meaning the secondary diagnoses have at least as high as the median resource use and represent more than 0.1 percent of 30-day periods of care. Home health 30-day periods of care can receive a comorbidity adjustment under the following circumstances:

- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.
- *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to if they were reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.
- *No comorbidity adjustment:* A 30-day period of care will receive no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria for a low or high comorbidity adjustment. A 30-day period of care can have a low comorbidity adjustment or a high comorbidity adjustment, but not both. A 30-day period of care can receive only one low comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the individual comorbidity subgroups or one high comorbidity adjustment regardless of the number of comorbidity group interactions, as applicable. The low comorbidity adjustment amount will be the same across the subgroups and the high comorbidity adjustment will be the same across the subgroup interactions.

[3] Overview of the Home Health Groupings Model. November 18, 2016. *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

III. Payment Under the Home Health Prospective Payment System (HH PPS)

A. CY 2021 PDGM Low-Utilization Payment Adjustment (LUPA) Thresholds and PDGM Case-Mix Weights

1. CY 2021 PDGM LUPA Thresholds

Under the HH PPS, low utilization payment adjustments (LUPAs) are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. The approach to calculating the LUPA thresholds under the PDGM changed to account for the 30-day unit of payment. Therefore, in order to target the same percentage of LUPA periods as under the previous 153-group case-mix system (that is, approximately 7–8 percent of 30-day periods would be LUPAs), in the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized that the LUPA thresholds would be set at the 10th percentile of visits or 2 visits, whichever is higher, for each payment group. This means that the LUPA threshold for each 30-day period of care varies depending on the PDGM payment group to which it is assigned. If the LUPA threshold for the payment group is met under the PDGM, the 30-day period of care will be paid the full 30-day period case-mix adjusted payment amount. If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment will be made using the CY 2021 per-visit payment amounts as described in section III.C.3.c. of this final rule. For example, if the LUPA visit threshold is four, and a 30-day period of care has four or more visits, it is paid the full 30-day period payment amount; if the period of care has three or less visits, payment is made using the per-visit payment amounts.

In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds for each PDGM payment group would be reevaluated every year based on the most current utilization data available at the time of rulemaking. However, CY 2020 was the first year of the new case-mix adjustment methodology and 30-day unit of payment and at this time we do not have sufficient CY 2020 data in which to make any changes to the LUPA thresholds for CY 2021. We believe that making any changes to the LUPA thresholds for CY 2021 based off 2019 utilization using the 153-group model would result in little change in the LUPA thresholds from CY 2020 to CY 2021 and would result in additional burden to HHAs and software vendors in revising their internal billing software

to reflect only minor changes. Therefore, we proposed to maintain the LUPA thresholds finalized and shown in Table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. We will repost the LUPA thresholds (along with the case-mix weights) that will be used for CY 2021 on the HHA Center and PDGM web pages.

2. CY 2021 PDGM Case-Mix Weights

As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient and other characteristics, such as timing, admission source, clinical grouping using the reported principal diagnosis, functional impairment level, and comorbid conditions. The PDGM case-mix methodology results in 432 unique case-mix groups called HHRGs. We also finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56515) our policy to annually recalibrate the PDGM case-mix weights using a fixed effects model using the most recent, complete utilization data available at the time of annual rulemaking. However, as noted previously, we do not have sufficient CY 2020 data from the first year of the new case-mix methodology and because the 2019 data utilize the old 153-case-mix methodology and 60-day episodes of payment, such data are not appropriate for use to simulate 30-day periods under the PDGM in order to recalibrate the case-mix weights for CY 2021. Therefore, we proposed to maintain the PDGM case-mix weights finalized and shown in Table 16 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes.

We will repost the case-mix weights for CY 2021 on the HHA Center and PDGM web pages. As mentioned previously in this section, we believe this approach for CY 2021 is more accurate, given the limited utilization data for CY 2020; and that the approach will be less burdensome for HHAs and software vendors, who continue to familiarize themselves with this new case-mix methodology.

B. Home Health Wage Index Changes

1. Implementation of New Labor Market Delineations

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued, OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revisions to the delineation of MSAs, Micropolitan Statistical Areas, and Combines Statistical Areas, and guidance on uses of the delineation in these areas. A copy of the September 2018 bulletin is available at: *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.* We note that on March 6, 2020 OMB issued OMB Bulletin No. 20–01 (available at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.* Bulletin No. 18–04 states it ''provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published in the June 28, 2010, **Federal Register** (75 FR 37246 through 37252), and Census Bureau data.''

While the revisions OMB published on September 14, 2018, are not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2006, the September 14, 2018 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart. We believe it is important for the home health wage index to use the latest OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We further believe that using the September 2018 OMB delineations would increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. We have reviewed our findings and impacts relating to the new OMB delineations, and have concluded that there is no compelling reason to further delay implementation. We proposed to implement the new OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04 for the home health wage index effective beginning in CY 2021. As noted previously, the March 6, 2020 OMB Bulletin No. 20–01 was not available in time for development of the proposed rule. We will include any updates from OMB Bulletin No. 20–01 in any changes that would be adopted in future rulemaking.

(a) Micropolitan Statistical Areas

As discussed in the CY 2006 HH PPS proposed rule (70 FR 40788) and final rule (70 FR 68132), CMS considered how to use the Micropolitan statistical area definitions in the calculation of the wage index. OMB defines a ''Micropolitan Statistical Area'' as a ''CBSA'' associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as ''rural'' and include them in the calculation of each state's home health rural wage index (see 70 FR 40788 and 70 FR 68132). Thus, the HH PPS statewide rural wage index is determined using IPPS hospital data from hospitals located in non-Metropolitan Statistical Areas (MSA).

Based upon the 2010 Decennial Census data, a number of urban counties have switched status and have joined or became Micropolitan Areas, and some counties that once were part of a Micropolitan Area, have become urban. Overall, there are fewer Micropolitan Areas (542) under the new OMB delineations based on the 2010 Census than existed under the latest data from the 2000 Census (581). We believe that the best course of action would be to continue the policy established in the CY 2006 HH PPS final rule and include Micropolitan Areas in each state's rural wage index. These areas continue to be defined as having relatively small urban cores (populations of 10,000 to 49,999). Therefore, in conjunction with our proposal to implement the new OMB labor market delineations beginning in CY 2021 and consistent with the treatment of Micropolitan Areas under the IPPS, we proposed to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index.

(b) Urban Counties Becoming Rural

Under the new OMB delineations (based upon the 2010 decennial Census data), a total of 34 counties (and county equivalents) that are currently considered urban are considered rural beginning in CY 2021. Table 3 lists the 34 counties that are changing to rural

status with the implementation of the new OMB delineations.

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TABLE 3: COUNTIES CHANGING TO RURAL STATUS

County Name	State	CBSA	CBSA Name
BAKER	GA	10500	Albany, GA
NEWTON	TX	13140	Beaumont-Port Arthur, TX
GOLDEN VALLEY	MT	13740	Billings, MT
WALKER	AL	13820	Birmingham-Hoover, AL
SIOUX	ND	13900	Bismarck, ND
FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA
DE WITT	IL	14010	Bloomington, IL
FORD	IL	16580	Champaign-Urbana, IL
BUCKINGHAM	VA	16820	Charlottesville, VA
ARANSAS	TX	18580	Corpus Christi, TX
MC DONALD	MO	22220	Fayetteville-Springdale-Rogers, AR-MO
LE FLORE	OK	22900	Fort Smith, AR-OK
WELLS	IN	23060	Fort Wayne, IN
HOOD	TX	23104	Fort Worth-Arlington, TX
SOMERVELL	TX	23104	Fort Worth-Arlington, TX
HAMILTON	NE	24260	Grand Island, NE
BARRY	MI	24340	Grand Rapids-Wyoming, MI
KALAWAO	HI	27980	Kahului-Wailuku-Lahaina, HI
VAN BUREN	MI	28020	Kalamazoo-Portage, MI
SCOTT	IN	31140	Louisville/Jefferson County, KY-IN
TRIMBLE	KY	31140	Louisville/Jefferson County, KY-IN
BENTON	MS	32820	Memphis, TN-MS-AR
SIBLEY	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
HICKMAN	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
GULF	FL	37460	Panama City, FL
CUSTER	SD	39660	Rapid City, SD
CAROLINE	VA	40060	Richmond, VA
WEBSTER	LA	43340	Shreveport-Bossier City, LA
PLYMOUTH	IA	43580	Sioux City, IA-NE-SD
UNION	SC	43900	Spartanburg, SC
PEND OREILLE	WA	44060	Spokane-Spokane Valley, WA
COLUMBIA	WA	47460	Walla Walla, WA
PULASKI	GA	47580	Warner Robins, GA
KINGMAN	KS	48620	Wichita, KS

(c) Rural Counties Becoming Urban

Under the new OMB delineations (based upon the 2010 decennial Census data), a total of 47 counties (and county equivalents) that are currently designated rural and are considered urban beginning in CY 2021. Table 4 lists the 47 counties that are changing to urban status.

TABLE 4: COUNTIES CHANGING TO URBAN STATUS

County Name	State	CBSA	CBSA Name
GREENE	AL	46220	Tuscaloosa, AL
WASHINGTON	AL	33660	Mobile, AL
FRANKLIN	AR	22900	Fort Smith, AR-OK
LEVY	FL	23540	Gainesville, FL
STEWART	GA	17980	Columbus, GA-AL
TALBOT	GA	17980	Columbus, GA-AL
POWER	ID	38540	Pocatello, ID
FULTON	IL	37900	Peoria, IL
JOHNSON	IL	16060	Carbondale-Marion, IL
FRANKLIN	IN	17140	Cincinnati, OH-KY-IN
PARKE	IN	45460	Terre Haute, IN
WARREN	IN	29200	Lafayette-West Lafayette, IN
BOONE	IA	11180	Ames, IA
JASPER	IA	19780	Des Moines-West Des Moines, IA
GEARY	KS	31740	Manhattan, KS
CARTER	KY	26580	Huntington-Ashland, WV-KY-OH
ASSUMPTION	LA	12940	Baton Rouge, LA
MOREHOUSE	LA	33740	Monroe, LA
FRANKLIN	MA	44140	Springfield, MA
IONIA	MI	24340	Grand Rapids-Kentwood, MI
SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
LAKE	MN	20260	Duluth, MN-WI
COVINGTON	MS	25620	Hattiesburg, MS
HOLMES	MS	27140	Jackson, MS
STONE	MS	25060	Gulfport-Biloxi, MS
COOPER	MO	17860	Columbia, MO
HOWARD	MO	17860	Columbia, MO
STILLWATER	MT	13740	Billings, MT
ANSON	NC	16740	Charlotte-Concord-Gastonia, NC-SC
CAMDEN	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
GRANVILLE	NC	20500	Durham-Chapel Hill, NC
HARNETT	NC	22180	Fayetteville, NC
OTTAWA	OH	45780	Toledo, OH
CLARENDON	SC	44940	Sumter, SC
GIBSON	TN	27180	Jackson, TN
STEWART	TN	17300	Clarksville, TN-KY
HARRISON	TX	30980	Longview, TX
STERLING	TX	41660	San Angelo, TX
KING AND QUEEN	VA	40060	Richmond, VA
MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
JACKSON	WV	16620	Charleston, WV
MORGAN	WV	25180	Hagerstown-Martinsburg, MD-WV
LINCOLN	WI	48140	Wausau-Weston, WI
ADJUNTAS	PR	38660	Ponce, PR
LAS MARIAS	PR	32420	Mayagüez, PR

(d) Urban Counties Moving to a Different Urban CBSA

In addition to rural counties becoming urban and urban counties becoming rural, several urban counties are shifting from one urban CBSA to another urban CBSA upon implementation of the new OMB delineations (Table 5). In other cases, applying the new OMB delineations involves a change only in CBSA name or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) experiences both a change to its number and its name, and becomes CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties remain the same. In other cases, only the name of the CBSA is modified, and none of the currently assigned counties are reassigned to a different urban CBSA. We are not discussing these changes in this section because they are inconsequential changes with respect to the home health wage index.

TABLE 5: COUNTIES CHANGING NAME AND/ OR CBSA NUMBER

Proposed CBSA Code	Proposed CBSA Title	Current CBSA Code	Current CBSA Title
10540	Albany-Lebanon, OR	10540	Albany, OR
11500	Anniston-Oxford, AL	11500	Anniston-Oxford-Jacksonville, AL
12060	Atlanta-Sandy Springs-Alpharetta, GA	12060	Atlanta-Sandy Springs-Roswell, GA
12420	Austin-Round Rock-Georgetown, TX	12420	Austin-Round Rock, TX
13460	Bend, OR	13460	Bend-Redmond, OR
13980	Blacksburg-Christiansburg, VA	13980	Blacksburg-Christiansburg-Radford, VA
14740	Bremerton-Silverdale-Port Orchard, WA	14740	Bremerton-Silverdale, WA
15380	Buffalo-Cheektowaga, NY	15380	Buffalo-Cheektowaga-Niagara Falls, NY
19430	Dayton-Kettering, OH	19380	Dayton, OH
24340	Grand Rapids-Kentwood, MI	24340	Grand Rapids-Wyoming, MI
24860	Greenville-Anderson, SC	24860	Greenville-Anderson-Mauldin, SC
25060	Gulfport-Biloxi, MS	25060	Gulfport-Biloxi-Pascagoula, MS
25540	Hartford-East Hartford-Middletown, CT	25540	Hartford-West Hartford-East Hartford, CT
25940	Hilton Head Island-Bluffton, SC	25940	Hilton Head Island-Bluffton-Beaufort, SC
28700	Kingsport-Bristol, TN-VA	28700	Kingsport-Bristol-Bristol, TN-VA
31860	Mankato, MN	31860	Mankato-North Mankato, MN
33340	Milwaukee-Waukesha, WI	33340	Milwaukee-Waukesha-West Allis, WI
34940	Naples-Marco Island, FL	34940	Naples-Immokalee-Marco Island, FL
35660	Niles, MI	35660	Niles-Benton Harbor, MI
36084	Oakland-Berkeley-Livermore, CA	36084	Oakland-Hayward-Berkeley, CA
36500	Olympia-Lacey-Tumwater, WA	36500	Olympia-Tumwater, WA
38060	Phoenix-Mesa-Chandler, AZ	38060	Phoenix-Mesa-Scottsdale, AZ
39150	Prescott Valley-Prescott, AZ	39140	Prescott, AZ
23224	Frederick-Gaithersburg-Rockville, MD	43524	Silver Spring-Frederick-Rockville, MD
44420	Staunton, VA	44420	Staunton-Waynesboro, VA
44700	Stockton, CA	44700	Stockton-Lodi, CA
45940	Trenton-Princeton, NJ	45940	Trenton, NJ
46700	Vallejo, CA	46700	Vallejo-Fairfield, CA
47300	Visalia, CA	47300	Visalia-Porterville, CA
48140	Wausau-Weston, WI	48140	Wausau, WI
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	48424	West Palm Beach-Boca Raton-Delray Beach, FL

However, in other cases, under the new OMB delineations, counties shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. In another type of change, some CBSAs have counties that split off to become part of or to form entirely new labor market areas. Finally, in some cases, a CBSA loses counties to another existing CBSA after implementing the new OMB delineations. Table 6 lists the urban counties moving from one urban CBSA to a newly or modified CBSA under the new OMB delineations.

TABLE 6: COUNTIES CHANGING TO A DIFFERENT CBSA

Previous CBSA	New CBSA	County	State
16974	16984	COOK	IL
16974	16984	DU PAGE	IL
16974	16984	GRUNDY	IL
16974	20994	KENDALL	IL
16974	16984	MC HENRY	IL
16974	16984	WILL	IL
20524	39100	DUTCHESS	NY
20524	35614	PUTNAM	NY
26580	16620	LINCOLN	WV
28940	34100	GRAINGER	TN
35084	35154	SOMERSET	NJ
35614	35154	MIDDLESEX	NJ
35614	35154	MONMOUTH	NJ
35614	35154	OCEAN	NJ
35614	39100	ORANGE	NY
38660	49500	GUANICA	PR
38660	49500	GUAYANILLA	PR
38660	49500	PENUELAS	PR
38660	49500	YAUCO	PR

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2. Transition Period

As discussed previously, overall, we believe that adopting the revised OMB delineations for CY 2021 results in HH PPS wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that some home health agencies would experience decreases in their area wage index values as a result of our proposal. We also realize that many home health agencies would have higher area wage index values under the new OMB delineations.

To mitigate the potential impacts of proposed policies on home health agencies, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. For example, we have proposed and finalized budget neutral transition policies to help mitigate negative impacts on home health agencies following the adoption of the new CBSA delineations based on the 2010 decennial census data in the CY 2015 home health final rule (79 FR 66032). Specifically, we implemented a 1-year 50/50 blended wage to the new OMB delineations. We applied a blended wage index for 1 year (CY 2015) for all geographic areas that would consist of a 50/50 blend of the wage index values using OMB's old area delineations and the wage index values using OMB's new area delineations. That is, for each county, a blended wage index was calculated equal to 50 percent of the CY 2015 wage index using the old labor market area delineation and 50 percent of the CY 2015 wage index using the new labor market area delineation, which resulted in an average of the two values. While we believed that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels, we also recognized that adopting such changes may cause some short-term instability in home health payments. Similar instability may result from the proposed wage policies herein, in particular for home health agencies that would be negatively impacted by the proposed adoption of the updates to the OMB delineations. We proposed a transition policy to help mitigate any significant negative impacts that home health agencies may experience due to our proposal to adopt the revised OMB delineations.

Specifically, for CY 2021 as a transition, we proposed to apply a 5 percent cap on any decrease in a geographic area's wage index value from the wage index value from the prior calendar year. This transition allows the effects of the adoption of the revised CBSA delineations to be phased in over 2 years, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in CY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (CY 2022)). We believe a 5 percent cap on the overall decrease in a geographic area's wage index value, regardless of the circumstance causing the decline, is an appropriate transition for CY 2021 as it provides predictability in payment levels from CY 2020 to the upcoming CY 2021 and additional transparency because it is administratively simpler than our prior 1-year 50/50 blended wage index approach. Consistent with the policy finalized under the IPPS and finalized in other Medicare settings, we believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in a geographic area's wage index value for CY 2021 that could result from the adoption of the new OMB delineations.

We believe a 1-year 5 percent cap provides home health agencies sufficient time to plan appropriately for CY 2022 and subsequent years. Because we believe that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels we proposed to include a cap on the overall decrease in a geographic area's wage index value.

While there are some minimal impacts on certain HHAs as a result of the 5 percent cap as shown in the regulatory impact analysis of this final rule, overall, the impact between the CY 2021 wage index using the old OMB delineations and the CY 2021 wage index using the new OMB delineations would be 0.0 percent due to the wage index budget neutrality factor, which ensures that wage index updates and revisions are implemented in a budget-neutral manner.

We received several comments on the FY 2021 home health wage index proposals from various stakeholders including home health agencies, national industry associations and MedPAC. A summary of these comments and our responses to those comments are as follows:

Comment: Commenters generally supported the adoption of the revised OMB delineations from the September 14, 2018 Bulletin No. 18–04 and the proposed transition methodology that would apply a 5 percent cap on decreases to a geographic area's wage index value relative to the wage index value from the prior calendar year.

Response: We appreciate the commenters' support of the adoption of the new OMB delineations and a 5 percent cap on wage index decreases for CY 2021 as an appropriate transition policy.

Comment: A few commenters recommended that CMS reconsider the implementation of the revised OMB delineations. A few commenters stated their concerns regarding potential wage index decreases in the newly created New Brunswick-Lakewood, NJ CBSA. A commenter suggested the redefinition of the New York-Jersey City-White Plains, NY–NJ CBSA will cause major Medicare reimbursement reductions across many hospitals and other providers, including Home Health Agencies, in New York and New Jersey.

Response: We appreciate the concerns sent in by the commenters regarding the impact of implementing the New Brunswick-Lakewood, NJ CBSA designation on their specific counties. While we understand the commenters' concern regarding the potential financial impact, we believe that implementing the revised OMB delineations will create more accurate representations of labor market areas nationally and result in home health wage index values being more representative of the actual costs of labor in a given area. Although this comment only addressed the negative impact on the commenter's geographic area, we believe it is important to note that there are many geographic locations and home health providers that will experience positive impacts upon implementation of the revised CBSA designations. We recognize there are areas that will experience a decrease in their wage index. As such, in the CY 2021 HH PPS proposed rule, we proposed a transition in order to mitigate the resulting short-term instability and negative impacts on certain providers and to provide time for providers to adjust to their new labor market delineations. We continue to believe that the 1-year 5 percent cap transition policy provides an adequate safeguard against any significant payment reductions in CY 2021 while improving the accuracy of the payment adjustment for differences in area wage levels. Therefore, we believe that it is appropriate to implement the new OMB delineations without further delay.

Comment: Several commenters stated that they were interested in gaining a deeper understanding of the impact of the 5 percent cap transition policy compared to the 50/50 blend transition that we have used in the past. These commenters recommended that CMS develop and make public an impact analysis of applying the previous transition approach in implementing new wage areas in the wage index where a 50/50 blend of old and new indexes was used. A commenter also suggested that for CY 2021, both the 50/50 blend transition and the 5 percent cap on reductions should be used for this transition.

Response: We thank the commenters for their recommendations. We continue to believe that the 5 percent cap on wage index decreases is the best transition approach for CY 2021. We note that the use of a 50/50 blended wage index transition or a combination of the 50/50 blend and the 5 percent cap would be more administratively burdensome as it would affect a larger number of CBSAs and rural areas as a transition wage index value for such areas would need to be used. Likewise, the 5 percent cap on wage index decreases will help effectively mitigate any significant decreases in wage index values for CY 2021 for those HHAs in CBSAs where there would be decreases in the wage index due to the adoption of the new OMB delineations. Finally, we believe that it is important to remain consistent with the other Medicare payment systems such as Hospice, SNF, IRF and IPF where the 5 percent cap transition was finalized for FY 2021 to ensure consistency and parity in the wage index methodology used by Medicare.

Comment: A few commenters, including MedPAC, suggested alternatives to the 5 percent cap transition policy. MedPAC suggested that the 5 percent cap limit should apply to both increases and decreases in the wage index so that no provider would have its wage index value increase or decrease by more than 5 percent for CY 2021. A commenter suggested that wage index decreases should be capped at 3 percent instead of 5 percent. Finally, several commenters recommended that CMS consider implementing a 5 percent cap, similar to that which we proposed for CY 2021, for years beyond the implementation of the revised OMB delineations.

Response: We appreciate MedPAC's suggestion that the cap on wage index changes of more than 5 percent should be applied to increases in the wage index. However, as we discussed in the proposed rule, the purpose of the proposed transition policy is to help mitigate the significant negative impacts of certain wage index changes. Additionally, we believe that the 5 percent cap on wage index decreases is an adequate safeguard against any significant payment reductions and do not believe that capping wage index decreases at 3 percent instead of 5 percent is appropriate. We believe that 5 percent is a reasonable level for the cap rather than 3 percent because it would more effectively mitigate any significant decreases in a home health agency's wage index for CY 2021, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Furthermore, a 5 percent cap on wage index decreases in CY 2021 provides a degree of predictability in payment changes for providers and allows providers time to adjust to any significant decreases they may face in CY 2022, after the transition period has ended. Finally, with regards to the comments recommending that CMS consider implementing this type of transition in future years, we believe that this would be counter to the purpose of the wage index, which is used to adjust payments to account for local differences in area wage levels. While we believe that a transition is necessary to help mitigate the negative

impact from the revised OMB delineations in the first year of implementation, this transition must be balanced against the importance of ensuring accurate payments.

Final Decision: We are finalizing our proposal to adopt the revised OMB delineations from the September 14, 2018 OMB Bulletin 18–04 and apply a 1-year 5 percent cap on wage index decreases as proposed, meaning the counties impacted will receive a 5 percent cap on any decrease in a geographic area's wage index value from the wage index value from the prior calendar year for CY 2021 effective January 1, 2021.

Due to the way that the transition wage index is calculated, some Core Based Statistical Areas (CBSAs) and statewide rural areas will have more than one wage index value associated with that CBSA or rural area. For example, some counties that change OMB designations will have a wage index value that is different than the wage index value associated with the CBSA or rural area they are moving to because of the transition. However, each county will have only one wage index value. For counties that correspond to a different transition wage index value, the CBSA number will not be able to be used for CY 2021 claims. In these cases, a number other than the CBSA number will be needed to identify the appropriate wage index value for claims for home health care provided in CY 2021. These numbers are five digits in length and begin with ''50''. These special 50xxx codes are shown in the last column of the CY 2021 home health wage index file. For counties located in CBSAs and rural areas that do not correspond to a different transition wage index value, the CBSA number will still be used. More information regarding the counties that will receive the transition wage index will be provided in the Home Health Payment Update Change Request (CR) located at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2020-Transmittals.*

The final wage index applicable to CY 2021 can be found on the CMS website at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.* The final HH PPS wage index for CY 2021 will be effective January 1, 2021 through December 31, 2021.

The wage index file posted on the CMS website provides a crosswalk between each state and county and its corresponding wage index along with the previous CBSA number, the new CBSA number or alternate identification number, and the new CBSA name.

C. CY 2021 Home Health Payment Rate Updates

1. CY 2021 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2021 be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. In the CY 2019 HH PPS final rule with comment period (83 FR 56425), we finalized a policy rebasing the home health market basket to reflect 2016 Medicare cost report (MCR) data, the latest available and complete data on the actual structure of HHA costs. As such, based on the rebased 2016-based home health market basket, we finalized our policy that the labor-related share will be 76.1 percent and the non-labor-related share is 23.9 percent. A detailed description of how we rebased the HHA market basket is available in the CY 2019 HH PPS final rule with comment period (83 FR 56425 through 56436).

Section 1895(b)(3)(B) of the Act requires that in CY 2015 and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), and CY 2020 (under section 53110 of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115–123, enacted February 9, 2018)), the market basket percentage under the HHA prospective payment system, as described in section 1895(b)(3)(B) of the Act, be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please visit *http://www.bls.gov/mfp,* to obtain the BLS historical published MFP data.

Consistent with our historical practice and our proposal, we estimate the market basket increase and the MFP adjustment based on IHS Global Inc.'s (IGI) forecast using the most recent available data. In the CY 2021 HH PPS proposed rule (85 FR 39421), we proposed to establish a home health payment update percentage for CY 2021 of 2.7 percent, based on the best available data at that time (that is, the estimated HHA market basket percentage increase of 3.1 percent, less the MFP adjustment of 0.4 percentage point). Consistent with our historical practice, we also proposed to use a more recent estimate of the home health market basket update and the MFP adjustment, if appropriate, to determine the home health payment update percentage for CY 2021 in the final rule.

For this final rule based on IGI's third-quarter 2020 forecast (with historical data through second-quarter 2020), the home health market basket percentage increase for CY 2021 is, as specified at section 1895(b)(3)(B)(iii) of the Act, 2.3 percent. We note that the first quarter 2020 forecast used for the proposed home health market basket percentage increase was developed prior to the economic impacts of the COVID–19 PHE. This lower update (2.3 percent) for CY 2021, relative to the proposed rule (3.1 percent), is primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets are expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery. Compensation costs account for 76 percent of the 2016-based HHA market basket and other labor-related costs account for an additional 12 percent of the 2016-based HHA market basket.

The CY 2021 home health market basket percentage increase of 2.3 percent is then reduced by a MFP adjustment, as mandated by the section 3401 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148). Based on the more recent data available for this final rule, the current estimate of the 10-year moving average growth of MFP for CY 2021 is 0.3 percentage points. This MFP is based on the most recent forecast of the macroeconomic outlook from IGI at the time of rulemaking (released September 2020) in order to reflect more current historical economic data. IGI produces monthly macroeconomic forecasts, which include projections of all of the economic series used to derive MFP. In contrast, IGI only produces forecasts of the more detailed price proxies used in the HHA market basket on a quarterly basis. Therefore, IGI's third quarter 2020 forecast is the most recent forecast of the HHA market basket percentage increase.

We note that it has typically been our practice to base the projection of the market basket price proxies and MFP in the final rule on the third quarter IGI forecast. For this final rule, we are using

the IGI September 2020 macroeconomic forecast for MFP because it is a more recent forecast, and it is important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID–19 PHE. However, we also note that the 10-year moving average of MFP based on the third quarter 2020 forecast is also 0.3 percentage points.

Therefore, the final CY 2021 home health payment update percentage for CY 2021 is 2.0 percent (HHA market basket percentage increase of 2.3 percent less 0.3 percentage points MFP adjustment). Section 1895(b)(3)(B)(v) of the Act requires that the home health payment update percentage be decreased by 2.0 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2021, the home health payment update percentage would be 0.0 percent (2.0 percent minus 2.0 percentage points).

Comment: Nearly all commenters supported the proposed 2.7 percent increase for a market basket update. Several commenters stated concerns regarding additional costs of personal protective equipment (PPE) and other infection control measures due to the COVID–19 PHE, and recommended CMS to include a PPE cost add-on to the 2020 30-day period payment and per visit payment rates. Additionally, a few commenters requested to use the proposed 2.7 percent increase as a floor and urged CMS to not make any downward adjustments to the market basket in the final rule. Finally, a commenter recommended the same approach to the MFP adjustment as used in other rulemaking this year to more accurately capture the impacts of the COVID–19 PHE on economic productivity.

Response: CMS thanks the commenters for their comments on the market basket percentage and appreciates their concerns regarding additional costs, such as PPE, due to the COVID–19 PHE. However, we do not yet have the claims and cost report data to conduct the analysis needed for a possible add-on payment to account for any increased costs for PPE. Historically, payments under the HH PPS have been higher than costs, and in its March 2020 Report to Congress, MedPAC estimates HHAs to have projected average Medicare margins of 17 percent in 2020.[4] Therefore, it is anticipated that HHAs have sufficient payment to account for the costs of PPE. However, we can examine overall costs once we have complete claims and cost report data for CY 2020.

Consistent with our proposal and prior HHA PPS final rules, as well as other FY 2021 Medicare PPS final rules, we believe it is appropriate to determine the home health payment update percentage for CY 2021 for the final rule based on the most recent forecast (at the time of rulemaking) of the HHA market basket percentage increase and MFP adjustment.

Final Decision: After consideration of public comments, CMS is finalizing the home health payment update percentage for CY 2021 based on the most recent forecast of the HHA market basket percentage increase and MFP adjustment at the time of rulemaking. Based on IGI's third-quarter 2020 forecast (with historical data through second-quarter 2020) of the HHA market basket percentage increase and IGI's September 2020 macroeconomic forecast of MFP, the home health payment update percentage for CY 2021 will be 2.0 percent (2.3 percent HHA market basket percentage increase less 0.3 percentage point MFP adjustment) for HHAs that submit the required quality data and 0.0 percent (2.0 percent minus 2.0 percentage points) for HHAs that do not submit quality data as required by the Secretary.

2. CY 2021 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to home health payments. We proposed to continue this practice for CY 2021, as we continue to believe that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. As discussed previously, we proposed to use the FY 2021 pre-floor, pre-reclassified hospital wage index with the September 2018 OMB delineations as the CY 2021 wage adjustment to the labor portion of the HH PPS rates. For CY 2021, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2016, and before October 1, 2017 (FY 2017 cost report data). We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2021 HH PPS wage index, we proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we proposed to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we proposed to continue to use the most recent wage index previously available for that area. The most recent wage index previously available for rural Puerto Rico is 0.4047. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2021, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). The CY 2021 new delineations wage index value for Hinesville, GA is 0.8388.

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted OMB's area delineations using a 1-year transition.

On August 15, 2017, OMB issued Bulletin No. 17–01 in which it announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. The new CBSA (46300) comprises the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The CY 2021 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8668. Bulletin No. 17–01 is available at *https://www.whitehouse.gov/sites/*

[4] Home Health Services, Chapter 9. MedPAC. March 2020. *http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch9_sec.pdf.*

whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.[5]

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/09/Bulletin-18-04.pdf.*

As discussed previously the most recent OMB Bulletin (No. 20–01) was published on March 6, 2020 and is available at *https://www.whitehouse.gov/wpcontent/uploads/2020/03/Bulletin-20-01.pdf.* This bulletin was not available in time for development of the CY 2021 proposed rule, however we will include any updates from OMB Bulletin No. 20–01 in future rulemaking.

A summary of the general comments on the home health wage index and our responses to those comments are as follows:

Comment: Many commenters recommended more far-reaching revisions and reforms to the wage index methodology used under Medicare fee-for-service. A few commenters recommended a home health specific wage index. MedPAC recommended that Congress repeal the existing hospital wage index and instead implement a market-level wage index for use across the inpatient prospective payment system and other prospective payment systems, including certain post-acute care providers. A commenter recommended a home health floor similar to the floor used in hospice. Finally, a few commenters recommended that the home health wage index utilize geographic reclassification and a rural floor like the hospital wage index.

Response: While we thank the commenters for their recommendations, these comments are outside the scope of the proposed rule. Any changes to the way we adjust home health payments to account for geographic wage differences, beyond the wage index proposals discussed in the CY 2021 HH PPS proposed rule, would have to go through notice and comment rulemaking. While CMS and other stakeholders have explored potential alternatives to using OMB's statistical area definitions, no consensus has been achieved regarding how best to implement a replacement system. We believe that in the absence of home health specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for home health payments. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification. The reclassification provision found in section 1886(d)(10) of the Act is specific to IPPS hospitals only. Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that state. This is the rural floor provision and it is only specific to IPPS hospitals. Additionally, the application of the hospice floor is specific to hospices and does not apply to HHAs. The hospice floor was developed through a negotiated rulemaking advisory committee, under the process established by the Negotiated Rulemaking Act of 1990 (Pub. L. 101– 648). Committee members included representatives of national hospice associations; rural, urban, large, and small hospices; multi-site hospices; consumer groups; and a government representative. The Committee reached consensus on a methodology that resulted in the hospice wage index. Because the reclassification provision and the hospital rural floor applies only to hospitals, and the hospice floor applies only to hospices, we continue to believe the use of the pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the home health payment rates. This position is longstanding and consistent with other Medicare payment systems (for example, SNF PPS, IRF PPS, and Hospice).

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed previously, we are finalizing our proposal to use the FY 2021 pre-floor, pre-reclassified hospital wage index data as the basis for the CY 2021 HH PPS wage index. The final CY 2021 wage index is available on the CMS website at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

3. CY 2021 Annual Payment Update

(a) Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), and as described in the CY 2020 HH PPS final rule with comment period (84 FR 60478), the unit of home health payment changed from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020. As set forth in § 484.220, we adjust the national, standardized prospective payment rates by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. In the CY 2019 HH PPS final rule with comment period (83 FR 56435), we finalized rebasing the home health market basket to reflect 2016 MCR data, the latest available and most complete data on the actual structure of HHA costs. We also finalized a revision to the labor-related share to reflect the 2016-based home health market basket compensation (Wages and Salaries plus Benefits) cost weight. We finalized that for CY 2019 and subsequent years, the labor-related share would be 76.1 percent and the non-labor-related share would be 23.9 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period rates for CY 2021:

- Multiply the national, standardized 30-day period rate by the patient's applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (76.1 percent) and a non-labor portion (23.9 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 30-day period rate, subject to any additional applicable adjustments.

We provide annual updates of the HH PPS rate in accordance with section 1895(b)(3)(B) of the Act. Section 484.225

[5] ''Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas''. OMB Bulletin No. 17–01. August 15, 2017. *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(c), for an HHA that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 30-day period rate is equal to the rate for the previous calendar year increased by the applicable home health payment update, minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

The final claim that the HHA submits for payment determines the total payment amount for the period and whether we make an applicable adjustment to the 30-day case-mix and wage-adjusted payment amount. The end date of the 30-day period, as reported on the claim, determines which calendar year rates Medicare will use to pay the claim.

We may adjust a 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A partial payment adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

(b) CY 2021 National, Standardized 30-Day period Payment Amount

Section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, requires us to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new PDGM case-mix adjustment methodology, to annually determine the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. In the CY 2021 HH PPS proposed rule, we stated that we would continue to monitor the impact of these changes on patient outcomes and Medicare expenditures, but that we believed it would be premature to release any information related to these issues based on the amount of data currently available and in light of the COVID–19 PHE. Therefore, for CY 2021, we did not propose to make any additional changes to the national, standardized 30-day period payment rate other than the routine rate updates outlined in the proposed rule. We stated that in future rulemaking, we plan to determine whether any changes need to be made to the national, standardized 30-day period payment rate based on the analysis of the actual versus assumed behavior change.

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget-neutral manner. To determine the CY 2021 national, standardized 30-day period payment rate, we apply a wage index budget neutrality factor and the home health payment update percentage discussed in section III.C.2. of this final rule.

To calculate the wage index budget neutrality factor, we simulated total payments, using CY 2019 Medicare claims data for episodes ending on or before December 31, 2019 for which we had a linked OASIS assessment, for non-LUPA 30-day periods using the CY 2021 wage index and compared it to our simulation of total payments for non-LUPA 30-day periods using the CY 2020 wage index. By dividing the total payments for non-LUPA 30-day periods using the CY 2021 wage index by the total payments for non-LUPA 30-day periods using the CY 2020 wage index, we obtain a wage index budget neutrality factor of 0.9999. We apply the wage index budget neutrality factor of 0.9999 to the calculation of the CY 2021 national, standardized 30-day period payment rate.

We note that in past years, a case-mix budget neutrality factor was annually applied to the HH PPS base rates to account for the change between the previous year's case-mix weights and the newly recalibrated case-mix weights. Since CY 2020 was the first year of PDGM, we did not propose to recalibrate the PDGM case-mix weights and; therefore, a case-mix budget neutrality factor is not needed. However, in future years under the PDGM, we would apply a case-mix budget neutrality factor with the annual payment update in order to account for the change between the previous year's PDGM case-mix weights and the new recalibrated PDGM case-mix weights.

Next, we update the 30-day payment rate by the CY 2021 home health payment update percentage of 2.0 percent. The CY 2021 national, standardized 30-day period payment rate is calculated in Table 7.

TABLE 7: CY 2021 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2020 30-day Budget Neutral (BN) Standard Amount	Wage Index Budget Neutrality Factor	CY 2021 HH Payment Update	CY 2021 National, Standardized 30-Day Period Payment
$1,864.03	X 0.9999	X 1.020	$1,901.12

The CY 2021 national, standardized 30-day period payment rate for an HHA that does not submit the required quality data is updated by the CY 2021 home health payment update of 2.0 percent minus 2 percentage points and is shown in Table 8.

TABLE 8: CY 2021 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2020 National, Standardized 30-Day Budget Neutral (BN) Period Payment	Wage Index Budget Neutrality Factor	CY 2021 HH Payment Update Minus 2 Percentage Points	CY 2021 National, Standardized 30-Day Period Payment
$1,864.03	X 0.9999	X 1.000	$1,863.84

Comments regarding the update to the CY 2021 national, standardized 30-day period payment amount are summarized in this section of this final rule. In addition, although we did not propose any changes the national, standardized 30-day period payment rate for CY 2021, except for the statutorily-required routine payment rate update, we received numerous comments regarding the behavior assumptions adjustment and these are summarized in this section of this final rule.

Comment: Commenters generally supported the home health payment updates for CY 2021. MedPAC stated that it recognizes that the public health emergency has had an effect on the home health benefit and will continue to monitor its effects, but still felt that many HHAs have been able to mitigate the negative impacts of the public health emergency through various mechanisms, including accessing funds through the Payroll Protection Program. MedPAC reiterated its recommendation from its March 2020 report to the Congress to reduce home health payments by 7 percent in CY 2021.

Response: Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2021 be increased by a factor equal to the applicable home health market basket percentage increase reduced by the MFP adjustment, and as such, we have no statutory or regulatory discretion in this matter.

Comment: Several commenters recommended that CMS reduce or eliminate the 4.36 percent behavior assumption reduction, finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60511–60519)), to the national, standardized 30-day period payment rate for the remainder of CY 2020 and for CY 2021 rate setting. Commenters stated that the effects of the COVID–19 PHE, in tandem with a new home health payment system, has brought about changes in patient mix, decreased utilization of home health services, and changing demands from patients in need of care. These commenters stated that the impact on payment to home health agencies would make it highly unlikely that Medicare home health spending in CY 2020 would be budget neutral in comparison to the level of spending that would have occurred if the PDGM and the change to a 30-day unit of payment had not been implemented.

Response: We thank the commenters for their recommendations and while we did not propose any changes for CY 2021 relating to the behavior assumptions finalized in the CY 2019 HH PPS final rule with comment period (84 FR 56461), or to the 4.36 percent behavior assumption reduction, finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60519), we want to respond with what CMS is required to do by law. Under section 1895(b)(3)(A)(iv) of the Act, we were required to calculate a 30-day payment amount for CY 2020 in a budget-neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 would be equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of payment. Section 1895(b)(3)(A)(iv) of the Act also required that in calculating a 30-day payment amount in a budget-neutral manner the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the case-mix adjustment factors established under 1895(b)(4)(B) of the Act. We were also required to calculate a budget-neutral 30-day payment amount before the provisions of section 1895(b)(3)(B) of the Act were applied; that is, before the home health applicable percentage increase, the adjustment if quality data are not reported, and the productivity adjustment.

In the CY 2020 HH PPS final rule with comment period, we stated that applying the previously finalized clinical group and comorbidity coding assumptions, and the LUPA threshold assumption, as required by section 1895(b)(3)(A)(iv) of the Act, would result in the need to decrease the CY 2020 30-day payment amount by 8.389 percent to maintain budget neutrality. However, commenters stated that CMS overestimated the magnitude of the behavior changes that would occur as HHAs transitioned to a new case-mix methodology and a change to a 30-day unit of payment. Commenters stated that behavior change would not occur 100 percent of the time for all 30-day periods of care. Therefore, in response to comments as to the frequency of the assumed behaviors during the first year of the transition to a new unit of payment and case-mix adjustment methodology, we finalized to apply the three behavior change assumptions, as finalized in the CY 2019 HH PPS final rule with comment period, to only half of the 30-day periods for purposes of calculating the CY 2020 30-day payment rate. As such, in the CY 2020 HH PPS final rule with comment period, we finalized a ×4.36 percent behavior assumption adjustment in order to calculate the 30-day payment rate in a budget-neutral manner for CY 2020 (84 FR 60511–60519).

Additionally, section 1895(b)(3)(D) of the Act requires the Secretary to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology under the PDGM, to annually determine the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures and, at a time and manner determined appropriate by the Secretary, make permanent and temporary adjustments to the 30-day payment amounts. This means that if CMS underestimates the reductions to the 30-day payment amount necessary to offset behavior changes and maintain budget neutrality, larger adjustments to the 30-day payment amount would be required in the future to ensure budget neutrality. Likewise, if CMS overestimates the reductions, we are required to make the appropriate payment adjustments accordingly. In the CY 2019 HH PPS final rule with

comment period (83 FR 56459), we stated that any adjustment to the payment amount resulting from differences between assumed versus actual behavior changes would not be related to increases in the number of beneficiaries utilizing Medicare home health services. The same would hold true for any decreases in the number of beneficiaries utilizing Medicare home health services. That is to say, the law required that CMS calculate the 30-day payment amount for CY 2020 to ensure that the aggregate expenditures during CY 2020 under the new case-mix methodology and 30-day unit of payment would be the same as if the 153-group model was still in place in CY 2020. Therefore, any future payment adjustment required by section 1895(b)(3)(D) of the Act, must be based on the difference in aggregate payments between the assumed versus actual behavior change and not because of utilization changes resulting from the COVID–19 PHE. However, CMS issued several IFCs, as described throughout this final rule, to provide flexibilities to ensure that HHAs could provide care to Medicare beneficiaries in the least burdensome manner during the COVID–19 PHE. These flexibilities include:

- Allowing HHAs to provide more services to beneficiaries using telecommunications technology within the 30-day period of care, so long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care;
- Allowing the face-to-face encounter for home health to be conducted via telehealth (*i.e.,* 2-way audio-video telecommunications technology);
- Extending the 5-day completion requirement for the comprehensive assessment to 30 days;
- Waiving the 30-day OASIS submission requirement (though HHAs must submit OASIS data prior to submitting their final claim in order to receive Medicare payment);
- Waiving the requirements in 42 CFR 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may only perform the initial and comprehensive assessment when only therapy services are ordered; and
- Changing the home health regulations to include physician assistants, nurse practitioners, and clinical nurse specialists as individuals who can certify the need for home health services and order services.

These flexibilities were provided to help mitigate commenters' concerns about the provision of home health services during the COVID–19 PHE. Moreover, as we stated in the CY 2021 HH PPS proposed rule, we believed it would be premature to propose any changes to the CY 2021 payment rate based on the data available at the time of CY 2021 rulemaking and in light of the ongoing COVID–19 PHE. Finally, any changes to the national, standardized 30-day period payment rates to account for differences in assumed versus actual behavior change are required to go through notice and comment rulemaking, as required by 1895(b)(3)(D)(ii) and (iii) of the Act.

Comment: Several commenters stated that the first eight months of the PDGM cannot be understood as an accurate representation of the new payment model given the public health emergency. These commenters stated that the short and long-term effects are not yet fully known and therefore, there should be no changes to the payment system for CY 2021.

Response: We thank commenters for their recommendation and we did not propose any changes to the home health prospective payment system, other than the routine payment updates, for CY 2021.

(c) CY 2021 National Per-Visit Rates for 30-Day Periods of Care

The national per-visit rates are used to pay LUPAs and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health discipline. The six home health disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the CY 2021 national per-visit rates, we started with the CY 2020 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA 30-day periods of care using the CY 2021 wage index and comparing it to simulated total payments for LUPA 30-day periods using the CY 2020 wage index. By dividing the total payments for LUPA 30-day periods using the CY 2021 wage index by the total payments for LUPA 30-day periods using the CY 2020 wage index, we obtained a wage index budget neutrality factor of 0.9997. Lastly, the per-visit rates for each discipline are updated by the CY 2021 home health payment update percentage of 2.0 percent. The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weight budget neutrality factor is needed to ensure budget neutrality for LUPA payments.

The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for 30-day periods that occur as the only 30-day period or the initial period in a sequence of adjacent 30-day periods. The CY 2021 national per-visit rates for HHAs that submit the required quality data are shown in Table 9.

TABLE 9: CY 2021 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2020 Per-Visit Payment	Wage Index Budget Neutrality Factor	CY 2021 HH Payment Update	CY 2021 Per-Visit Payment
Home Health Aide	$67.78	X 0.9997	X 1.020	$69.11
Medical Social Services	$239.92	X 0.9997	X 1.020	$244.64
Occupational Therapy	$164.74	X 0.9997	X 1.020	$167.98
Physical Therapy	$163.61	X 0.9997	X 1.020	$166.83
Skilled Nursing	$149.68	X 0.9997	X 1.020	$152.63
Speech-Language Pathology	$177.84	X 0.9997	X 1.020	$181.34

The CY 2021 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2020 home health payment update percentage of 2.0 percent minus 2.0 percentage points and are shown in Table 10.

TABLE 10: CY 2021 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2020 Per-Visit Rates	Wage Index Budget Neutrality Factor	CY 2021 HH Payment Update Minus 2 Percentage Points	CY 2021 Per-Visit Rates
Home Health Aide	$67.78	X 0.9997	X 1.000	$67.76
Medical Social Services	$239.92	X 0.9997	X 1.000	$239.85
Occupational Therapy	$164.74	X 0.9997	X 1.000	$164.69
Physical Therapy	$163.61	X 0.9997	X 1.000	$163.56
Skilled Nursing	$149.68	X 0.9997	X 1.000	$149.64
Speech- Language Pathology	$177.84	X 0.9997	X 1.000	$177.79

In the CY 2021 HH PPS proposed rule (85 FR 39424), we reminded stakeholders of the policies finalized in the CY 2020 HH PPS final rule with comment (84 FR 60544) with regards to the submission of Requests for Anticipated Payment (RAPs) for CY 2021 and the implementation of a new one-time Notice of Admission (NOA) process starting in CY 2022. In that final rule, we finalized the reduction in up-front payment made in response to a RAP to zero percent for all 30-day periods of care beginning on or after January 1, 2021 (84 FR 60544). For CY 2021, all HHAs (both existing and newly-enrolled HHAs) will submit a RAP at the beginning of each 30-day period to establish the home health period of care in the common working file and also to trigger the consolidated billing edits. With the removal of the upfront RAP payment for CY 2021, we relaxed the required information for submitting the RAP for CY 2021 and stated that the information required for submitting an NOA for CYs 2022 and subsequent years would mirror that of the RAP in CY 2021. Starting in CY 2022, HHAs will submit a one-time NOA that establishes the home health period of care and covers all contiguous 30-day periods of care until the individual is discharged from Medicare home health services. In addition, for both the submission of the RAP in CY 2021 and the one-time NOA for CYs 2022 and subsequent years, we finalized a payment reduction if the HHA does not submit the RAP for CY 2021 or NOA for CYs 2022 and subsequent years within 5 calendar days from the start of care. That is, if an HHA fails to submit a timely RAP for CY 2021 or fails to submit a timely NOA for CYs 2022 and subsequent years, the reduction in payment amount would be equal to a one-thirtieth reduction to the wage and case-mix adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submitted the RAP or NOA. In other words, the one-thirtieth reduction would be to the 30-day period adjusted payment amount, including any outlier payment, that the HHA otherwise would have received absent any reduction. For LUPA 30-day periods of care in which an HHA fails to submit a timely RAP or NOA, no LUPA payments would be made for days that fall within the period of care prior to the submission of the RAP or NOA. We stated that these days would be a provider liability, the payment reduction could not exceed the total payment of the claim, and that the provider may not bill the beneficiary for these days. For more in-depth information regarding the finalized policies associated with RAPs and the new one-time NOA process, we refer readers to the CY 2020 HH PPS final rule with comment (84 FR 60544).

Though we did not solicit comments on the previously finalized split percentage payment approach for CY 2021 or the NOA process for CY 2022, we did receive several comments on various components of the finalized policy. While most of the comments were out of scope of the proposed rule because we did not propose to make any changes, we did receive a few technical comments regarding the implementation of the finalized policy, which are summarized in this section of this final rule.

Comment: A commenter requested clarification on the methodology used to calculate the non-timely submission payment reduction. This commenter asked whether the reduction begins on day 1 or day 6. Another commenter recommended an alternative to the non-timely submission payment reduction. This commenter recommended that no RAP/NOA be considered late until day 6 of the 30-day period. The commenter suggested making the reduction one 25th for each day that it is late beyond day 5 (days 6–30).

Response: For purposes of determining if a ''no-pay'' RAP is timely-filed, the ''no-pay'' RAP must be submitted within 5 calendar days after the start of each 30-day period of care. For example, if the start of care for the first 30-day period is January 1, 2021, the ''no-pay'' RAP would be considered timely-filed if it is submitted on or before January 6, 2021.

Example:

1/1/2021 = Day 0 (start of the first 30-day period of care)

1/6/2021 = Day 5 (A ''no-pay'' RAP submitted on or before this date would be considered ''timely-filed''.)

1/7/2021 and after = Day 6 and beyond (A ''no-pay'' RAP submitted on and after this date will trigger the penalty.)

In the event that the ''no-pay'' RAP is not timely-filed, the penalty is calculated from the first day of that 30-day period (in the example, the penalty calculation would begin with the start of care date of January 1, 2021, counting as the first day of the penalty) until the date of the submission of the ''no-pay''

RAP. As finalized in the CY 2020 HH PPS final rule with comment period, Medicare does not pay for those days of home health services based on the ''from date'' on the claim to the date of filing of the RAP. Therefore, in CY 2021, the wage and case-mix adjusted 30-day payment amount is reduced by 1/30th for each day from the home health based on the ''from date'' on the claim until the date of filing of the RAP. For example, if an HHA submits their ''no-pay'' RAP one day late (with a submission 6 days after the start of care), the result would be a 20 percent reduction to the 30-day payment amount. Additionally, the finalized policy states that no LUPA payments are made that fall within the late period; the payment reduction cannot exceed the total payment of the claim; the non-covered days are a provider liability; and the provider must not bill the beneficiary for the non-covered days. And finally, in the CY 2020 HH PPS final rule with comment period (84 FR 60546), we stated that the ''no-pay'' RAP submission in CY 2021 and the NOA process beginning in CY 2022 would be similar to the hospice Notice of Election (NOE) process and where the penalty is calculated beginning with the start of care date. Therefore, we do not believe that the penalty calculation should begin on day 6 as the commenters recommended.

Comment: A few commenters provided several scenarios in which the HHA believed that the patient was covered under Medicare Advantage or another payer only to find out that the patient was actually covered under traditional Medicare and this could create a situation in which the RAP submission would be submitted after the timely-filing requirement. A commenter stated that agencies struggle with ascertaining beneficiary eligibility against inaccurate information in the Common Working File (CWF) as there can be significant lag time between a beneficiary's enrollment/disenrollment date and CWF update and that several days can pass before the plan provides any eligibility and/or authorization information on the beneficiary. Therefore, the commenter is concerned that agencies could be at risk for missing the 5-day window while seeking to confirm a beneficiary's insurance coverage. These commenters asked if there would be claim payment penalties for the periods that are being updated and re-billed to reflect the retroactive enrollment in Original Medicare.

Response: In the CY 2020 HH PP final rule with comment period, we finalized exceptions to the timely filing consequences of the RAP requirements at § 484.205(g)(4). Specifically, we finalized that CMS may waive the consequences of failure to submit a timely-filed RAP if it is determined that a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence. As finalized in the CY 2020 HH PPS final rule with comment period and as set forth in regulation at § 484.205(g)(4), an exceptional circumstance may be due to, but is not limited to the following:

- Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.
- A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.
- A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.
- Other situations determined by CMS to be beyond the control of the home health agency.

If an HHA believes that there is a circumstance that may qualify for an exception, the home health agency must fully document and furnish any requested documentation to CMS for a determination of exception. The scenarios provided by commenters may fall into one of the established timely filing exceptions.

(d) Low-Utilization Payment Adjustment (LUPA) Add-On Factors

Prior to the implementation of the 30-day unit of payment, LUPA episodes were eligible for a LUPA add-on payment if the episode of care was the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, we stated that the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occurred as the only episode or as an initial episode in a sequence of adjacent episodes were adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount.

In the CY 2019 HH PPS final rule with comment period (83 FR 56440), in addition to finalizing a 30-day unit of payment, we finalized our policy of continuing to multiply the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only 30-day period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM. For example, using the finalized CY 2021 per-visit payment rates for those HHAs that submit the required quality data, for LUPA periods that occur as the only period or an initial period in a sequence of adjacent periods, if the first skilled visit is SN, the payment for that visit would be $281.62 (1.8451 multiplied by $152.63), subject to area wage adjustment. We did not receive any comments on the LUPA add-on factors.

Final Decision: After considering the comments received in response to the proposed CY 2021 annual payment update and for the reasons discussed previously, we are finalizing the CY 2021 national, standardized 30-day payment rates, the per-visit payment rates and the home health payment update percentage of 2.0 percent for CY 2021 as proposed. We are not making any changes to the policies previously finalized in the CY 2020 HH PPS final rule regarding the behavior assumptions adjustment. In accordance with section 1895(b)(3)(D) of the Act, we will analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology under the PDGM, to annually determine the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures and, at a time and manner determined appropriate by the Secretary, make permanent and temporary adjustments to the 30-day payment amounts. Any future changes to the national, standardized 30-day period payment rates to account for differences in assumed versus actual behavior change, as a result of the implementation of the 30-day unit of payment and the case-mix adjustment methodology under the PDGM, are required to go through notice and comment rulemaking as required by 1895(b)(3)(D)(ii) and (iii) of the Act. We are not making any changes to the split-percentage payment policy finalized in the CY 2020 HH PPS final rule. That is,

for CY 2021, all HHAs will submit a ''no-pay'' RAP at the beginning of each 30-day period to allow the beneficiary to be claimed in the CWF and also to trigger the consolidated billing edits.

D. Rural Add-On Payments for CY 2021 and CY 2022

1. Background

Section 421(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) required, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent. Section 5201 of the Deficit Reduction Act of 2003 (DRA) (Pub. L. 108–171) amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016. Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 50208(a) of the BBA of 2018 amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2019.

2. Rural Add-On Payments for CYs 2019 Through CY 2022

Section 50208(a)(1)(D) of the BBA of 2018 added a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes or visits ending during CYs 2019 through 2022. It also mandated implementation of a new methodology for applying those payments. Unlike previous rural add-ons, which were applied to all rural areas uniformly, the extension provided varying add-on amounts depending on the rural county (or equivalent area) classification by classifying each rural county (or equivalent area) into one of three distinct categories: (1) Rural counties and equivalent areas in the highest quartile of all counties and equivalent areas based on the number of Medicare home health episodes furnished per 100 individuals who are entitled to, or enrolled for, benefits under Part A of Medicare or enrolled for benefits under Part B of Medicare only, but not enrolled in a Medicare Advantage plan under Part C of Medicare (the ''High utilization'' category); (2) rural counties and equivalent areas with a population density of 6 individuals or fewer per square mile of land area and are not included in the ''High utilization'' category (the ''Low population density'' category); and (3) rural counties and equivalent areas not in either the ''High utilization'' or ''Low population density'' categories (the ''All other'' category).

In the CY 2019 HH PPS final rule with comment period (83 FR 56443), CMS finalized policies for the rural add-on payments for CY 2019 through CY 2022, in accordance with section 50208 of the BBA of 2018. The CY 2019 HH PPS proposed rule (83 FR 32373) described the provisions of the rural add-on payments, the methodology for applying the new payments, and outlined how we categorized rural counties (or equivalent areas) based on claims data, the Medicare Beneficiary Summary File and Census data. The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of this rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html.* In addition, an Excel file containing the rural county or equivalent area name, their Federal Information Processing Standards (FIPS) state and county codes, and their designation into one of the three rural add-on categories is available for download.

The HH PRICER module, located within CMS' claims processing system, will increase the CY 2021 30-day base payment rates, described in section III.C.3.b. of this final rule, by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments. The CY 2019 through CY 2022 rural add-on percentages outlined in law are shown in Table 11.

TABLE 11: HH PPS RURAL ADD-ON PERCENTAGES, CYs 2019-2022

Category	CY 2019	CY 2020	CY 2021	CY 2022
High utilization	1.5%	0.5%	None	None
Low population density	4.0%	3.0%	2.0%	1.0%
All other	3.0%	2.0%	1.0%	None

Though we did not make any proposals regarding the rural add-on percentages in the CY 2021 HH PPS proposed rule, we did receive some comments as summarized in this section of this final rule.

Comment: While commenters understood the rural add-on payments decrease has been mandated by the BBA of 2018, many expressed continued concern and frustration of the reduction in support for access to rural beneficiaries. Several requested for stakeholders and CMS to work together with Congress to establish legislation to extend the 3 percent rural add-on payment. A few commenters recommended to continue monitoring utilization during the post-implementation period and to extend or modify the rural add-on as necessary. Some commenters had specific concerns about HHAs serving patients that reside in counties in the rural add-on high utilization category and such category losing its rural add-on payment in CY 2021. A commenter had concerns

regarding the change in the OMB delineations and how the new CBSA re-designation would affect any rural add-on payments. Specifically, the commenter asked if a rural add-on payment would be paid in CY 2021 if an HHA changed from an urban to a rural CBSA and whether the rural add-on payment would no longer be paid if an HHA changed from a rural to an urban CBSA in CY 2021 based on the new OMB delineations. A few commenters expressed support for the proposed rural add-on payment for CY 2021 and the methodology used to implement Section 50208 of the BBA of 2018, but recommended that CMS work with both stakeholders and Congress on long-term solutions for rural safeguards, given the cost and population health differences in rural America. Finally, a commenter recommended that, with the sunset of the rural add-on payment, CMS should include telehealth or virtual visits as a billable visit to help offset the financial burden of rural HHAs.

Response: We thank commenters for their recommendations. We understand commenter concerns about the phase-out of rural add-on payments and potential effects on rural HHAs. However, because the current rural add-on policy is statutory, we have no regulatory discretion to modify or extend it. However, CMS will continue to monitor patient access to home health services and the costs associated with providing home health care in rural versus urban areas. In response to the comment regarding the new OMB delineations and the potential effect on the rural add-on payment, section 50208(a)(1)(D) of the BBA of 2018 (revising section 421 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)) states that the designation for the rural add-on payment shall be made a single time and shall apply for the duration of the period to which the subsection applies. That is to say, that each county had a one-time designation as described CY 2019 HH PPS final rule with comment period (83 FR 56443) and the rural add-on payment is made based on that designation regardless of any change in CBSA status based on the new OMB delineations. In response to comments regarding the inclusion of telehealth services as billable visits, we refer readers to section III.F. of this final rule for a summary of comments and our responses on the use of telecommunications technology under the Medicare home health benefit.

Final Decision: Policies for the provision of rural add-on payments for CY 2019 through CY 2022 were finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56443), in accordance with section 50208 of the BBA of 2018. The data used to categorize each county or equivalent area are available in the downloads section associated with the publication of this rule at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html.* In addition, an Excel file containing the rural county or equivalent area name, their Federal Information Processing Standards (FIPS) state and county codes, and their designation into one of the three rural add-on categories is available for download.

E. Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or partial episode payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the home health FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act to require that the Secretary reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act, which capped outlier payments as a percent of total payments for each HHA for each year at 10 percent.

As such, beginning in CY 2011, we reduced payment rates by 5 percent and targeted up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we targeted up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10-percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold; and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the

amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

We will publish the cost-per-unit amounts for CY 2021 in the rate update change request, which is issued after the publication of the CY 2021 HH PPS final rule. We note that in the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, we noted that the per unit rates used to estimate an episode's cost will be updated by the home health payment update percentage each year, meaning we would start with the national per visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We note that we will continue to monitor the visit length by discipline as more recent data become available, and we may propose to update the rates as needed in the future.

In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of the PDGM beginning in CY 2020 and that we will calculate payment for high-cost outliers based upon 30-day periods of care.

2. Fixed Dollar Loss (FDL) Ratio for CY 2021

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of periods that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier periods. Alternatively, a lower FDL ratio means that more periods can qualify for outlier payments, but outlier payments per period must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio, which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs that exceed the outlier threshold amount. In the CY 2020 HH PPS final rule with comment period, given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we finalized a FDL ratio of 0.56 for 30-day periods of care in CY 2020. For CY 2021, we proposed to maintain the same fixed-dollar loss ratio finalized for CY 2020.

Comment: A commenter remarked on the proposed FDL ratio of 0.63 that was in the CY 2021 HH PPS proposed rule and stated that the FDL ratio that was finalized for CY 2020 was 0.56. This commenter requested clarification as to this discrepancy and asked that CMS clearly state in the final rule the correct FDL ratio for CY 2021.

Response: We apologize for the typographical error in the CY 2021 HH PPS proposed rule regarding the FDL ratio for CY 2021. This commenter is correct, and as noted previously, the FDL ratio for CY 2021 will be 0.56.

Comment: A commenter supports the methodology used in the outlier provision and the per unit basis is appropriate to account for utilization and accompanying resources allocations by HHAs.

Response: We thank the commenter for their support.

Comment: A few commenters recommended to end the outlier provision entirely and reinstate the 5 percent withheld into regular reimbursements.

Response: Section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS. We believe that outlier payments are beneficial in that they help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care.

Final Decision: We are finalizing the fixed-dollar loss ratio of 0.56 for CY 2021 to ensure that total outlier payments not exceed 2.5 percent of the total payments estimated to be made under the HH PPS.

F. The Use of Telecommunications Technology Under the Medicare Home Health Benefit

In the CY 2021 HH PPS proposed rule (85 FR 39427), we discussed the plan of care requirements at § 409.43(a), revised on an interim basis, as outlined in the March 2020 COVID–19 IFC (85 FR 19230). For the purposes of Medicare payment during the COVID–19 PHE, this revision requires the plan of care to include any provision of remote patient monitoring or other services furnished via a telecommunications system and must describe how the use of such technology is tied to the patient-specific needs as identified in the comprehensive assessment and will help to achieve the goals outlined on the plan of care. The amended plan of care requirements at § 409.43(a) also state that these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment, in accordance with section 1895(e)(1)(A) of the Act. We stated that we believed that this change will help to increase access to technologies, such as telemedicine and remote patient monitoring, during the COVID–19 PHE (85 FR 19250).

Additionally, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136) included section 3707 related to encouraging use of telecommunications systems for home health services furnished during the COVID–19 PHE. Specifically, section 3707 of the CARES Act requires, with respect to home health services furnished during the COVID–19 PHE, that the Secretary consider ways to encourage the use of telecommunications systems, including for remote patient monitoring as described in § 409.46(e) and other communications or monitoring services, consistent with the plan of care for the individual, including by clarifying guidance and conducting outreach, as appropriate. In the CY 2021 HH PPS proposed rule (85 FR 39427), we stated that we believe that the policies finalized on an interim basis meet the requirements of section 3707 of the CARES Act.

We also discussed hearing from stakeholders about the various applications of technologies that are currently in use by HHAs in the delivery of appropriate home health services outside of the COVID–19 PHE (85 FR 39427). We stated that although section 1895(e)(1)(A) of the Act prohibits payment for services furnished via a telecommunications system if such services substitute for in-person home

health services ordered as part of a plan of care, we understand that there are ways in which technology can be further utilized to improve patient care, better leverage advanced practice clinicians, and improve outcomes while potentially making the provision of home health care more efficient.

For these reasons, we proposed to finalize the amendment to § 409.43(a) as set out in the March 2020 COVID–19 IFC (85 FR 19230) beyond the period of the COVID–19 PHE. We also proposed to allow HHAs to continue to report the costs of telehealth/telemedicine as allowable administrative costs on line 5 of the home health agency cost report. We proposed to modify the instructions regarding this line on the cost report to reflect a broader use of telecommunications technology. Specifically, we proposed to amend § 409.46(e) to include not only remote patient monitoring, but other communication or monitoring services, consistent with the plan of care for the individual.

We also reminded stakeholders that access to telecommunications technology must be accessible, including for patients with disabilities. Section 504 of the Rehabilitation Act, section 1557 of the Patient Protection and Affordable Care Act (ACA), and the Americans with Disabilities Act (ADA) protect qualified individuals with disabilities from discrimination on the basis of disability in the provision of benefits and services. Concerns related to potential discrimination issues under section 504, section 1557 of the ACA, and Title II of the ADA [6] should be referred to the Office of Civil Rights for further review. Likewise, we reminded HHAs that the home health CoPs at § 484.50(f)(1) require that information be provided to persons with disabilities in plain language and in a manner that is accessible and timely, including accessible websites and the provision of auxiliary aids and services at no cost to the individual in accordance with the ADA, section 1557 of the ACA, and section 504 of the Rehabilitation Act. This means that the HHA must meet these requirements to ensure access to and use of telecommunications as required by law. Appendix B of the State Operations Manual (regarding home health services) provides detailed examples of ''auxiliary aids and services''.[7]

We also reiterated the expectation that services provided by telecommunications technology are services that could also be provided through an in-person visit. We stated that if there is a service that cannot be provided through telecommunications technology (for example, wound care which requires in-person, hands-on care), the HHA must make an in-person visit to furnish such services (85 FR 39428). We also stated that an HHA couldn't discriminate against any individual who is unable (including because of other forms of discrimination), or unwilling to receive home health services provided via telecommunications technology. In those circumstances, the HHA must provide such services through in-person visits. Section 1861(m) of the Act defines ''home health services'' to mean the furnishing of items and services *on a visiting basis in an individual's home* (emphasis added).

We received comments on the March 2020 COVID–19 IFC (85 FR 19230) regarding the interim amendment to § 409.43(a), allowing the use of telecommunications technology to be included as part of the home health plan of care as long as the use of such technology does not substitute for in-person visits ordered on the plan of care during the COVID–19 PHE, as well as comments on our proposal in the CY 2021 HH PPS proposed rule to finalize the amendment to § 409.43(a) in the March 2020 COVID–19 IFC (85 FR 19247). We also received comments on our proposal in the CY 2021 HH PPS proposed rule to amend the language at § 409.46(e), allowing a broader use of telecommunications technology to be reported as an allowable administrative cost on the home health agency cost report. A summary of the comments and our responses are as follows:

Comment: Commenters overwhelmingly supported CMS' acknowledgment that telecommunications technology has a place in home health for public health emergencies and beyond. Many commenters supported the amendment to § 409.43(a), allowing the use of telecommunications technology to be included as part of the home health plan of care during both the COVID–19 PHE, as well as beyond this time period, under the Medicare home health benefit. Commenters also supported amending the language at § 409.46(e) allowing a broader use of telecommunications technology to be reported as allowable administrative costs on the home health cost report. Specifically, a commenter stated that in rural areas, ''telehealth services help to increase access to home health services that patients may otherwise forego due to challenges they face accessing care.'' This commenter stated that home health delivery through telecommunications technologies may help alleviate some of these access challenges and will provide greater flexibility for both patients and home health providers. Another commenter noted that these changes would ensure patient access to the latest technology and give home health agencies the confidence that they can continue to use telecommunications technology as part of patient care beyond the COVID–19 PHE. This commenter noted that allowing services via telecommunications technology is especially useful for certain vulnerable subsets of Medicare patients, such as cancer patients who may be immunocompromised, by helping to reduce unnecessary exposure to all illnesses, not just COVID–19. A few commenters noted that the decision to provide services via telecommunications technology should be based on the individual's needs as identified during the comprehensive assessment, making the proposal to incorporate these services into the plan of care essential. This may be especially important for individuals with dementia whose services may be more appropriately delivered solely through in-person care.

Response: We thank commenters for their support.

Comment: A few commenters noted that, while helpful for many home health patients, especially those with chronic conditions, CMS should put safeguards in place to ensure that in-person visits are not being replaced by telecommunications technology and that in-person visits remain at adequate levels. They reiterated the importance of ensuring patient choice for those patients that are appropriate candidates for remote patient monitoring or other services furnished via telecommunications technology. Additionally, a commenter noted that the policy changes might provide incentive for patient selection, causing agencies to favor patients who benefit from these services and avoid those who do not benefit. These commenters suggested that CMS monitor and analyze the effects of these policy changes on beneficiary care and program costs prior to extending them beyond the COVID–19 PHE. A commenter stated that monitoring might be difficult because there is no requirement for HHAs to report on

[6] Discrimination on the Basis of Disability. *https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.*

[7] State Operations Manual Appendix B—Guidance to Surveyors: Home Health Agencies, Tab G490. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf.*

claims or patient assessments when an episode includes the provision of services via telecommunications technology. This commenter also stated that a new category of broadly defined services could also reduce the accuracy of home health agency cost reports, potentially resulting in erroneous reporting and distorting the financial information that CMS uses to set and analyze payment weights, and suggested that CMS indicate how, in the absence of patient-level reporting, the agency plans to assess the impact of ''other services provided via telecommunications'' and ensure access to and quality of care while maintaining program integrity.

Response: We appreciate the commenters' concerns regarding how these changes will affect the delivery of home health care beyond the period of the COVID–19 PHE. We agree with the importance of ensuring that any services furnished via telecommunications technology and/or remote patient monitoring do not replace in-person visits as ordered on the plan of care as this is prohibited by statute. However, we believe that the use of telecommunications technology in furnishing services in the home has the potential to improve efficiencies, expand the reach of healthcare providers, allow more specialized care in the home, and allow HHAs to see more patients or to communicate with patients more often. We expect physicians and allowed practitioners to only order services to be furnished via telecommunications technology, including remote patient monitoring, when it is in the best interest of each individual patient and after it has been determined that the patient would benefit from services furnished in this manner, as in-person care in the patient's home is the hallmark of the home health benefit. We proposed that the use of the technology must be related to the skilled services being furnished in order to optimize the services furnished during the home visit and included on the plan of care, along with a description of how the use of such technology is tied to the patient-specific needs as identified in the comprehensive assessment and how it will help to achieve the goals outlined on the plan of care. Implementing this as a condition for payment is a patient safeguard to ensure that HHAs are carefully evaluating not only whether a patient is an appropriate candidate for services furnished via telecommunications technology, but also that once implemented into the patient's care, it is benefitting the patient. We plan to monitor and analyze the cost report data and, as with all allowable administrative costs, we expect HHAs to be diligent and accurate in their reporting of these costs. We will also consider potential options regarding collecting data on the use of telecommunications technology on home health claims in order to expand monitoring efforts and evaluation.

Comment: Several commenters expressed concern about the proposed plan of care requirement, stating that without some flexibility in this requirement, HHAs may be at risk for unreasonable claim denials. Commenters suggested that CMS should permit documentation throughout the medical record to be used to support the use of telecommunications technology, and limit the plan of care requirement to the physician's order that permits the HHA to use the telecommunications technology.

Response: In accordance with the home health CoPs at § 484.60 the individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. This includes the types of services, supplies, and equipment required to meet these needs. Requiring that services furnished through telecommunications technology be incorporated into the plan of care, rather than simply requiring a physician's or allowed practitioner's order, acknowledges that each plan of care is unique to the individual. It is not our intent to simply promote the use of telecommunications technology without ensuring that furnishing the service in this way is beneficial to the individual patient.

We believe it is essential to ensure that each patient is evaluated during the comprehensive assessment and care planning process for appropriateness of the use of services furnished via telecommunications technology. The patient care plan would then identify and distinguish goals and expected outcomes, outline nursing observations and interventions needed for documentation, and include instructions the patient or caregiver may require. These tailored objectives are exceptionally important when furnishing services in a manner that may be new or unfamiliar to patients and family members and help to provide consistency among caregivers; however, we do understand that this information may be documented more extensively throughout the medical record, along with more detail regarding how the patient is benefitting from the technology. We maintain that the provision of remote patient monitoring or other services furnished via a telecommunications system must be on the plan of care and such services must be tied to the patient-specific needs as identified in the comprehensive assessment; however, in response to comments from the public, we are not requiring as part of the plan of care, a description of how the use of such technology will help to achieve the goals outlined on the plan of care. Instead, we would expect information regarding how such services will help to achieve the goals outlined on the plan of care to be in the medical record documentation for the patient.

Comment: Several commenters stated that because these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment, the new flexibilities will be of little benefit to HHAs and Medicare beneficiaries. These commenters requested that CMS work with Congress to amend Social Security Act section 1895(e)(1)(A) to allow payment for services furnished via a telecommunications system when those services substitute for in-person home health services ordered as part of a plan of care. Other commenters requested that Medicare reimburse the HHA for telehealth services that are included in the plan of care on the physician fee schedule or at the current low utilization payment adjustment rates per discipline of service, or explore ways to reimburse telehealth furnished by home health agencies in a way that supplements in-person visits, recognizing the statutory impediment. Commenters suggested that CMS develop a model for claims reporting and payment for home health visits provided by telecommunications systems. Additionally, a few commenters stated that CMS should permit telecommunication technologies to include audio only (telephonic) technology beyond the period of the COVID–19 PHE.

Response: By law, services furnished via a telecommunications system cannot be considered a home health visit for purposes of eligibility or payment; however, we disagree that this means these services will offer little benefit to HHAs and beneficiaries for the reasons discussed in previously in this section of this final rule. As stated previously, we believe utilizing telecommunications technology to furnish home health

services has the potential to improve efficiencies, expand the reach of healthcare providers, allow more specialized care in the home, and allow HHAs to see more patients or to communicate with patients more often. We will consider potential options for collecting data regarding the use of telecommunications technology on home health claims. We believe that using any available form of telecommunications technology or audio-only technology (*i.e.,* telephone calls), for certain home health services is imperative during the period of the COVID–19 PHE, and did not propose to restrict its usage beyond this timeframe. Therefore, we are clarifying in the regulations that audio-only technology may continue to be utilized to furnish skilled home health services (though audio-only telephone calls are not considered a visit for purposes of eligibility or payment and cannot replace in-person visits as ordered on the plan of care) after the expiration of the PHE. Like telecommunications technology, if audio-only services are ordered by the physician or allowed practitioner to furnish a skilled service, this must be included on the plan of care. The home health agency and patient's physician/practitioner must determine whether such audio-only technology can meet the patient's needs. Unlike telecommunications technology, audio-only technology (that is, telephones) is reported as a ''general'' expense and would not be reported on line 5 of the home health cost report as an allowed administrative expense for telecommunications technology.

Comment: A commenter recommended that CMS consider applying a PHE policy that was established for skilled nursing facilities to the Part A home health benefit, which would allow services provided on the premises, though not necessarily in the same room as the patient, to be considered in-person services.

Response: It is unclear how the skilled nursing facility policy finalized during the COVID–19 PHE would translate to the home health benefit beyond the PHE. It does not seem cost effective to furnish a home visit at the patient's house conducted via a telecommunications system, when the use of telecommunications technology cannot be considered a visit for purposes of payment or eligibility, as outlined in statute at section 1895(e) of the Act. However, we do appreciate the commenter exploring ways in which these services could be utilized to limit potential exposure to COVID–19.

Final Decision: We are finalizing the proposal to require that any provision of remote patient monitoring or other services furnished via a telecommunications system or audio-only technology must be included on the plan of care and cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for the purposes of eligibility or payment. We will still require that the use of such telecommunications technology or audio-only technology be tied to the patient-specific needs as identified in the comprehensive assessment, but we will not require as part of the plan of care, a description of how such technology will help to achieve the goals outlined on the plan of care. We expect to see documentation of how such services will be used to help achieve the goals outlined on the plan of care throughout the medical record when such technology is used. We are also finalizing the regulation text changes allowing a broader use of telecommunications technology to be considered allowable administrative costs on the home health cost report.

G. Care Planning for Medicare Home Health Services

Section 3708 of the CARES Act, amended section 1861(aa)(5) of the Act, allowing the Secretary regulatory discretion regarding the requirements for nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs). That is, NPs, CNSs, and PAs (as those terms are defined in section 1861(aa) of the Act), would be able to practice at the top of their state licensure to certify eligibility for home health services, as well as establish and periodically review the home health plan of care. In accordance with section 1861(aa)(5) of the Act, NPs, CNSs, and PAs are required to practice in accordance with state law in the state in which the individual performs such services. HHAs or other practitioners should check with the relevant state licensing authority websites to ensure that practitioners are working within their scope of practice and prescriptive authority.

As stated in the May 2020 COVID–19 IFC, we amended the regulations at parts 409, 424, and 484 to define an NP, a CNS, and a PA (as such qualifications are defined at §§ 410.74 through 410.76) as an ''allowed practitioner'' (85 FR 27572). This means that in addition to a physician, as defined at section 1861(r) of the Act, an ''allowed practitioner'' may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. Additionally, we amended the regulations to reflect that we would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed non-physician practitioner (NPP), as set forth in § 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying practitioner may be different from the provider performing the face-to-face encounter. These regulation changes were not time limited to the period of the COVID–19 PHE.

We inadvertently did not update §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 in the regulations when implementing the requirements set forth in the CARES Act in the May 2020 COVID–19 IFC regarding the ''allowed practitioners'' who can certify and establish home health services. Therefore, in this final rule we are finalizing conforming regulation text changes at §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 regarding allowed practitioner certification as a condition for payment for home health services. Although these changes were not proposed in the CY 2021 HH PPS proposed rule, we are adopting the changes here under a ''good cause'' waiver of proposed rulemaking, as described in section VI of this final rule. The specific changes we are making in the regulations are simply conforming regulations text changes to an already implemented policy required by section 3708 of the CARES Act, and do not reflect any additional substantive changes. Therefore, we find that undertaking further notice and comment procedures to incorporate these changes into this final rule is unnecessary and contrary to the public interest. We received a few comments on the regulation changes finalized in the May 2020 COVID–19 IFC.

Comment: Commenters gave their overall support for PAs and advanced practice registered nurses (APRNs) to order, certify, and recertify home health services. A commenter requested that CMS review and modify the language and definition of PAs and APRNs for home health services, specifically suggesting that CMS defer to state rules that govern the practice of NPs and CNSs with respect to collaboration with the physician and remove references to ''working in collaboration with the physician'' in the NP and CNS definitions.

Response: We amended the regulations at parts 409, 424, and 484 to define an NP, a CNS, and a PA as such

qualifications are defined at §§ 410.74 through 410.76. These sections specify that the services performed by these entities are only covered if the entity performs the services in accordance with state law and state scope of practice rules for PAs, NPs, and CNSs in the state in which such practitioner's professional services are furnished. Section 1861(aa)(5) of the Act allows the Secretary regulatory discretion regarding the requirements for NPs, CNSs, and PAs, and as such, we believe that we should align, for Medicare home health purposes, the definitions for such practitioners with the existing definitions in regulation at §§ 410.74 through 410.76, for consistency across the Medicare program and to ensure that Medicare home health beneficiaries are afforded the same standard of care. Therefore, we are not revising the definitions at this time. As stated in the May 2020 COVID–19 IFC, HHAs or other practitioners should check with the relevant state licensing authority websites to ensure that practitioners are working within their scope of practice and prescriptive authority.

IV. Other Home Health Related Provisions

A. Home Health Quality Reporting Program (HH QRP)

1. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that, for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary shall reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and further reduction of the increase by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

For more information on the policies we have adopted for the HH QRP, we refer readers to the following:

- CY 2007 HH PPS final rule (71 FR 65888 through 65891).
- CY 2008 HH PPS final rule (72 FR 49861 through 49864).
- CY 2009 HH PPS update notice (73 FR 65356).
- CY 2010 HH PPS final rule (74 FR 58096 through 58098).
- CY 2011 HH PPS final rule (75 FR 70400 through 70407).
- CY 2012 HH PPS final rule (76 FR 68574).
- CY 2013 HH PPS final rule (77 FR 67092).
- CY 2014 HH PPS final rule (78 FR 72297).
- CY 2015 HH PPS final rule (79 FR 66073 through 66074).
- CY 2016 HH PPS final rule (80 FR 68690 through 68695).
- CY 2017 HH PPS final rule (81 FR 76752).
- CY 2018 HH PPS final rule (82 FR 51711 through 51712).
- CY 2019 HH PPS final rule with comment period (83 FR 56547).
- CY 2020 HH PPS final rule with comment period (84 FR 60554).

2. General Considerations Used for the Selection of Quality Measures for the HH QRP

For a detailed discussion of the considerations we historically use for measure selection for the HH QRP quality, resource use, and others measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696). In the CY 2019 HH PPS final rule with comment (83 FR 56548 through 56550) we also finalized the factors we consider for removing previously adopted HH QRP measures.

3. Quality Measures Currently Adopted for the CY 2022 HH QRP

The HH QRP currently includes 20 measures for the CY 2022 program year.[8]

[8] The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

TABLE 12: MEASURES CURRENTLY ADOPTED FOR THE CY 2022 HH QRP

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Bathing	Improvement in Bathing (NQF #0174).
Bed Transferring	Improvement in Bed Transferring (NQF # 0175).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation Of Care (NQF #0526).
TOH - Provider	Transfer of Health Information to Provider-Post-Acute Care
TOH - Patient	Transfer of Health Information to Patient-Post-Acute Care
Claims-based	
ACH	Acute Care Hospitalization During the First 60 Days of HH (NQF #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (NQF #3477)
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
HHCAHPS-based	
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (NQF #0517) - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

There were no proposals or updates for the Home Health Quality Reporting Program (HH QRP). We received several comments on the HH QRP.

Comment: Several commenters provided feedback on the Home Health Quality Reporting Program. A commenter recommended that CMS expedite development of new measures to address pain management after the recent removal of the Improvement in Pain Interfering with Activity quality measure from the HH QRP. Another commenter suggested the need to develop measures to address maintenance of functional status for patients who may not improve. A number of commenters expressed support for CMS's waivers related to quality reporting for quarters affected by the COVID–19 PHE. These commenters also suggested that CMS continue monitoring the effects of the public health epidemic on home health agencies' performance on all quality measures during the PHE. A commenter suggested adding new measures to the HH QRP to address advanced care planning and timely referral to hospice care. Another commenter noted support for the continued inclusion of the Influenza Immunization Received for the Current Flu Season quality measure and suggested the addition of the new composite adult immunizations measure being tested by the National Committee on Quality Assurance.

Response: We appreciate these suggestions. These comments are outside the scope of the CY HH PPS 2021 proposed rule but we will consider them, as applicable, in future rulemaking.

We recognize the importance of pain management as part of home health. We

would like to note that in the CY 2020 Home Health PPS final rule with comment period (84 FR 60592 through 60594), CMS finalized the Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements as standardized patient assessment data elements This will allow HHAs to continue to collect information on patient pain that could support care planning, quality improvement, and potential quality measurement, including risk adjustment. HHAs must begin collecting data on the Pain Interference (Pain Effect on Sleep, Pain Interference With Therapy Activities, and Pain Interference With Day-to-Day Activities) SPADE on January 1st of the year that is at least one full calendar year after the end of the COVID–19 PHE (85 FR 27595 through 27596). In addition, the HHS Roadmap [9] emphasizes non-pharmacological options for managing pain as critical in the efforts to reduce over-reliance on and misuse of opioids.

We appreciate the suggestions and we will continue to monitor the performance of home health agencies on quality measures and will consider the issues raised by commenters in future measure development efforts.

B. Change to the Conditions of Participation (CoPs) OASIS Requirements

Section 484.45(c)(2) of the home health agency conditions of participation (CoPs) requires that new home health agencies must successfully transmit test data to the Quality Improvement & Evaluation System (QIES) or CMS OASIS contractor as part of the initial process for becoming a Medicare-participating home health agency. The previous data submission system limited HHAs to only two users who had permission to access the system, and required the use of a virtual private network (VPN) to access CMSNet. New HHAs do not yet have a CMS Certification Number (CCN). Therefore, they used a fake or test CCN in order to transmit test data to the Quality Improvement & Evaluation System Assessment Submission & Processing (QIES ASAP) System or CMS OASIS contractor.

CMS recently enhanced the system that HHAs use to submit OASIS data to be more user friendly. The new CMS data submission system, internet Quality Improvement & Evaluation System (iQIES), is now internet-based. Therefore, HHAs are no longer limited to two users for submission of assessment data since VPN and CMSNet are no longer required. These factors make the data submission process simpler. In addition, the new iQIES data submission system requires users to include a valid CCN with their iQIES user role request that will allow them to submit their OASIS assessment data to CMS; the new data system no longer supports the use of test or fake CCNs, making it impossible for new HHAs that do not yet have a CCN to submit test data.

The transition to the new data submission system, the simpler data submission process and the inability to use test or fake CCNs has rendered the requirement at § 484.45(c)(2) obsolete. Therefore, we proposed to remove the requirement at § 484.45(c)(2). HHAs must be able to submit assessments in order for the claims match process to occur and relay the data needed for payment under the PDGM system. This link to the payment process gives HHAs strong incentive to ensure that they can successfully submit their OASIS assessments in the absence of this regulatory requirement.

We received two timely public comments on our proposed change to remove the OASIS requirement at § 484.45(c)(2). Commenters included an industry association and an accreditation organization. Overall, the commenters were supportive of the removal of the provisions related to test transmission of OASIS data by a new HHA, because the provision is now obsolete due to changes in our data submission system. Summaries of the comments received and our responses are as follows.

Comment: The commenters supported CMS's proposal to remove the provisions related to test transmission of OASIS data by a new HHA at § 484.45(c)(2). Commenters agreed that as a result of the implementation of the internet Quality Improvement & Evaluation System (iQIES), they support removing the requirement at § 484.45(c)(2) in accordance with improved online connectivity for reporting OASIS data.

Response: We appreciate the unanimous support in deleting the OASIS requirement at § 484.45(c)(2). Therefore, we are finalizing the removal of this requirement at § 484.45(c)(2) for HHAs to successfully transmit test data to the QIES ASAP System or CMS OASIS contractor.

C. Finalization of the Provisions of the May 2020 Interim Final Rule With Comment Period Relating to the Home Health Value-Based Purchasing Model (HHVBP)

1. Background

In the interim final rule with comment period that appeared in the May 8, 2020 **Federal Register** (May 2020 COVID–19 IFC) (85 FR 27553 through 27554), we implemented a policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP as well as a policy for granting exceptions to the New Measures data reporting requirements during the COVID–19 PHE. The comment period for that rule closed on July 7, 2020. In this section, we summarize these provisions of the May 2020 COVID–19 IFC, summarize and respond to the comments we received, and finalize these policies.

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process. All Medicare certified HHAs providing services in Arizona, Florida, Iowa, Nebraska, North Carolina, Tennessee, Maryland, Massachusetts, and Washington are required to compete in the Model. The HHVBP Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act based on the competing HHAs' performance on applicable measures. The maximum payment adjustment percentage increases incrementally over the course of the HHVBP Model in the following manner, upward or downward: (1) 3 percent in CY 2018; (2) 5 percent in CY 2019; (3) 6 percent in CY 2020; (4) 7 percent in CY 2021; and (5) 8 percent in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year (PY), which is comprised of performance on: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS), completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and select claims data elements; and (2) three New

[9] CMS Roadmap, Strategy to Fight the Opioid Crisis. June 2020. *https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.*

Measures for which points are achieved for reporting data.

2. Reporting Under the HHVBP Model for CY 2020 During the COVID–19 PHE

In the May 2020 COVID–19 IFC, we established a policy to align the HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID–19 PHE. We also established a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for COVID–19. Specifically, during the COVID–19 PHE, to the extent that the data that participating HHAs in the nine HHVBP Model states are required to report are the same data that those HHAs are also required to report for the HH QRP, HHAs are required to report those data for the HHVBP Model in the same time, form and manner that HHAs are required to report those data for the HH QRP. As such, if CMS grants an exception or extension that either excepts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and/or extensions apply to the submission of those same data for the HHVBP Model. In addition, we adopted a policy to allow exceptions or extensions to New Measure reporting for HHAs participating in the HHVBP Model during the PHE for COVID–19.

In the May 2020 COVID–19 IFC, we explained that the HHVBP Model utilizes some of the same quality measure data that are reported by HHAs for the HH QRP, including HHCAHPS survey data. The other HHVBP measures are calculated using OASIS data, which are still required to be reported during the PHE; however, we have given providers additional time to submit OASIS data (*https://www.cms.gov/files/document/covid-home-health-agencies.pdf*); claims-based data extracted from Medicare fee-for-service (FFS) claims; and New Measure data. To assist HHAs while they direct their resources toward caring for their patients and ensuring the health and safety of patients and staff, we adopted a policy for the HHVBP Model to align the HHVBP data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID–19 PHE. For the same reason, we also established a policy for granting exceptions to New Measure reporting requirements for HHAs participating in the HHVBP Model during the COVID–19 PHE.

We explained that under this policy, to the extent CMS has granted an exception to the HH QRP (for 2019 Q4 and 2020 Qs 1 and 2 as noted in the May 2020 COVID–19 IFC and below in this section), or may grant any future exceptions or extensions under this same program for other CY 2020 reporting periods, HHAs in the nine HHVBP Model states do not need to separately report these measures for purposes of the HHVBP Model, and those same exceptions apply to the submission of those same data for the HHVBP Model. In accordance with this policy, we stated that if CMS grants an exception or extension under the HH QRP that either excepts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and/or extensions apply to the submission of those same data for the HHVBP Model.

In response to the COVID–19 PHE, on March 27, 2020, we issued public guidance (*https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*) excepting HHAs from the requirement to report any HH QRP data for the following quarters:

- October 1, 2019–December 31, 2019 (Q4 2019).
- January 1, 2020–March 31, 2020 (Q1 2020).
- April 1, 2020–June 30, 2020 (Q2 2020).

Under our policy to align HHVBP data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID–19 PHE, HHAs in the nine HHVBP Model states are not required to separately report measure data for these quarters for purposes of the HHVBP Model. We noted that with regard to the exception from the requirement to report Q4 2019 HH QRP data, we do not anticipate any issues in calculating the TPSs based on CY 2019 data under the HHVBP Model because HHAs were able to submit these Q4 2019 data on a rolling basis prior to the COVID–19 PHE.

In addition, to ensure that HHAs are able to focus on patient care in lieu of data submission during the COVID–19 PHE, we established a policy to allow us to grant exceptions to New Measure reporting for HHAs participating in the HHVBP Model during the COVID–19 PHE. We also specified that we were codifying these changes at § 484.315(b). In accordance with this policy, we granted an exception to all HHAs participating in the HHVBP Model for the following New Measure reporting requirements:

- April 2020 New Measures submission period (data collection period October 1, 2019–March 31, 2020).
- July 2020 New Measures submission period (data collection period April 1, 2020–June 30, 2020).

We noted in the May 2020 COVID–19 IFC that although the data collection period for the April 2020 New Measures submission period began in 2019, the data collected during this period are used for the calculation of the TPSs based on CY 2020, not CY 2019, data. We further noted that HHAs may optionally submit part or all of these data by the applicable submission deadlines. We stated that if we make the determination to grant an exception to New Measure data reporting for periods beyond the April and July 2020 submission periods, for example if the PHE for COVID–19 extends beyond the New Measure submission periods we had listed in the IFC, we would communicate this decision through routine communication channels to the HHAs participating in the HHVBP Model, including but not limited to issuing memos, emails and posting on the HHVBP Connect site (*https://app.innovation.cms.gov/HHVBPConnect*).

We acknowledged that the exceptions to the HH QRP reporting requirements, as well as the modified submission deadlines for OASIS data and our exceptions for the New Measures reporting requirements, may impact the calculation of performance under the HHVBP Model for PY 2020. We also noted that while we are able to extract the claims-based data from submitted Medicare FFS claims, we may need to assess the appropriateness of using the claims data submitted for the period of the PHE for COVID–19 for purposes of performance calculations under the HHVBP Model. We further explained that we are evaluating possible changes to our payment methodologies for CY 2022 in light of this more limited data, such as whether we would be able to calculate payment adjustments for participating HHAs for CY 2022, including those that continue to report data during CY 2020, if the overall data is not sufficient, as well as whether we may consider a different weighting methodology given that we may have sufficient data for some measures and not others. Further, we are also evaluating possible changes to our public reporting of CY 2020 performance year data. We stated that we intend to address any such changes to our payment methodologies for CY 2022 or public reporting of data in future rulemaking.

The following is a summary of public comments received and our responses:

Comment: Several commenters supported the policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for COVID–19.

Response: We thank the commenters for their support.

Comment: Several commenters inquired about CMS's utilization of data from the last performance year of the Model (CY 2020). Commenters suggested that we examine how the PHE has affected operations and relative performance and how that might impact 2020 performance calculations for the HHVBP Model. Several commenters requested that we not use any performance data from CY 2020 and terminate or suspend the model early. Another commenter requested that we extend reporting exceptions for Quarters 3 and 4 of CY 2020, stating that this would continue to provide regulatory relief for quality reporting programs across Medicare Fee-for-Service payment systems.

Response: We thank the commenters for their comments. As we discussed in the May 2020 COVID–19 IFC, we acknowledge that the exceptions to the reporting requirements and modified submission deadlines may impact the calculation of performance under the HHVBP Model, and also that we may need to assess the appropriateness of using certain data submitted for the period of the PHE for purposes of performance calculations. CMS will continue to examine these issues as it reviews the data collected during CY 2020. We intend to address possible changes to our CY 2022 payment methodologies through rulemaking in the CY 2022 HH PPS proposed rule. With respect to the request to extend the reporting exceptions for additional quarters, we note that we did not grant any further exceptions under the HH QRP beyond Q2 of 2020 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Spotlight-and-Announcements*). As previously described, our policy is to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for COVID–19. For this same reason, we also did not grant further exceptions to HHVBP Model New Measure data submission periods beyond the July 2020 submission period.

Final Decision: After consideration of the comments received, we are finalizing without modification the policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID–19 PHE, as described in the May 2020 COVID–19 IFC. We are also finalizing without modification the policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the COVID–19 PHE, including the codification of these changes at § 484.315(b), as described in the May 2020 COVID–19 IFC.

V. Home Infusion Therapy

A. Medicare Coverage of Home Infusion Therapy Services

1. Background and Overview

(a) Background

Section 5012 of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255), which amended sections 1834(u), 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit. The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education not otherwise covered under the durable medical equipment benefit, remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries.

Section 50401 of the BBA of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of most of the same items and services, as defined in section 1861(iii)(2)(A) and (B) of the Act, related to the administration of home infusion drugs. The temporary transitional payment began on January 1, 2019 and will end the day before the full implementation of the home infusion therapy services benefit on January 1, 2021, as required by section 5012 of the 21st Century Cures Act.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized the implementation of temporary transitional payments for home infusion therapy services to begin on January 1, 2019. In addition, we implemented the establishment of regulatory authority for the oversight of national accrediting organizations (AOs) that accredit home infusion therapy suppliers, and their CMS-approved home infusion therapy accreditation programs.

(b) Overview of Infusion Therapy

Infusion drugs can be administered in multiple health care settings, including inpatient hospitals, skilled nursing facilities (SNFs), hospital outpatient departments (HOPDs), physicians' offices, and in the home. Traditional fee-for-service (FFS) Medicare provides coverage for infusion drugs, equipment, supplies, and administration services. However, Medicare coverage requirements and payment vary for each of these settings. Infusion drugs, equipment, supplies, and administration are all covered by Medicare in the inpatient hospital, SNFs, HOPDs, and physicians' offices.

Under the various Part A prospective payment systems, Medicare payment for the drugs, equipment, supplies, and services are bundled, meaning a single payment is made based on expected costs for clinically-defined episodes of care. For example, if a beneficiary is receiving an infusion drug during an inpatient hospital stay, the Part A payment for the drug, supplies, equipment, and drug administration is included in the diagnosis-related group (DRG) payment to the hospital under the Medicare inpatient prospective payment system. Beneficiaries are liable for the Medicare inpatient hospital deductible and no coinsurance for the first 60 days. Similarly, if a beneficiary is receiving an infusion drug while in a SNF under a Part A stay, the payment for the drug, supplies, equipment, and drug administration are included in the SNF prospective payment system payment. After 20 days of SNF care, there is a daily beneficiary cost-sharing amount through day 100 when the beneficiary becomes responsible for all costs for each day after day 100 of the benefit period.

Under Medicare Part B, certain items and services are paid separately while other items and services may be packaged into a single payment together. For example, in an HOPD and in a physician's office, the drug is paid separately, generally at the average sales price (ASP) plus 6 percent (77 FR 68210). Medicare also makes a separate payment to the physician or hospital outpatient departments (HOPD) for administering the drug. The separate payment for infusion drug

administration in an HOPD and in a physician's office generally includes a base payment amount for the first hour and a payment add-on that is a different amount for each additional hour of administration. The beneficiary is responsible for the 20 percent coinsurance under Medicare Part B.

Medicare FFS covers outpatient infusion drugs under Part B, ''incident to'' a physician's service, provided the drugs are not usually self-administered by the patient. Drugs that are ''not usually self-administered,'' are defined in our manual according to how the Medicare population as a whole uses the drug, not how an individual patient or physician may choose to use a particular drug. For the purpose of this exclusion, the term ''usually'' means more than 50 percent of the time for all Medicare beneficiaries who use the drug. The term ''by the patient'' means Medicare beneficiaries as a collective whole. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is generally excluded from Part B coverage. This determination is made on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.[10] The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.[11]

Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home. Certain drugs can be infused in the home, but the nature of the home setting presents different challenges than the settings previously described. Generally, the components needed to perform home infusion include the drug (for example, antivirals, immune globulin), equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are usually necessary to train and educate the patient and caregivers on the safe administration of infusion drugs in the home. Visiting nurses often play a large role in home infusion. These nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to assess the infusion site and provide dressing changes. Depending on patient acuity or the complexity of the drug administration, certain infusions may require more training and education, especially those that require special handling or pre-or post-infusion protocols. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies.

With regard to payment under traditional Medicare, most home infusion drugs are generally covered under Part B or Part D. Certain infusion pumps, supplies (including home infusion drugs and the services required to furnish the drug, (that is, preparation and dispensing), and nursing are covered in some circumstances through the Part B durable medical equipment (DME) benefit, the Medicare home health benefit, or some combination of these benefits. In accordance with section 50401 of the BBA of 2018, beginning on January 1, 2019, for CYs 2019 and 2020, Medicare implemented temporary transitional payments for home infusion therapy services furnished in coordination with the furnishing of transitional home infusion drugs. This payment, for home infusion therapy services, is only made if a beneficiary is furnished certain drugs and biologicals administered through an item of covered DME, and payable only to suppliers enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies (including the drug). With regard to the coverage of the home infusion drugs, Medicare Part B covers a limited number of home infusion drugs through the DME benefit if: (1) the drug is necessary for the effective use of an external infusion pump classified as DME and determined to be reasonable and necessary for administration of the drug; and (2) the drug being used with the pump is itself reasonable and necessary for the treatment of an illness or injury.

Only certain types of infusion pumps are covered under the DME benefit. In order for the infusion pump to be covered under the DME benefit, it must be appropriate for use in the home (§ 414.202). The Medicare National Coverage Determinations Manual, chapter 1, part 4, section 280.14 describes the types of infusion pumps that are covered under the DME benefit.[12] For DME external infusion pumps, Medicare Part B covers the infusion drugs and other supplies and services necessary for the effective use of the pump. Through the Local Coverage Determination (LCD) for External Infusion Pumps (L33794), the DME Medicare administrative contractors (MACs) specify the details of which infusion drugs are covered with these pumps. Examples of covered Part B DME infusion drugs include, among others, certain IV drugs for heart failure and pulmonary arterial hypertension, immune globulin for primary immune deficiency (PID), insulin, antifungals, antivirals, and chemotherapy, in limited circumstances.

(c) Home Infusion Therapy Legislation

(1). 21st Century Cures Act

Effective January 1, 2021, section 5012 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) created a separate Medicare Part B benefit category under section 1861(s)(2)(GG) of the Act for coverage of home infusion therapy services needed for the safe and effective administration of certain drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual, through a pump that is an item of DME. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the Part B DME benefit. Section 1861(iii)(2) of the Act defines home infusion therapy to include the following items and services: The professional services, including nursing services, furnished in accordance with the plan, training and education (not otherwise paid for as DME), remote monitoring, and other monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier, which are furnished in the individual's home. Section 1861(iii)(3)(B) of the Act defines the patient's home to mean a place of residence used as the home of an individual as defined for purposes of section 1861(n) of the Act. As outlined in section 1861(iii)(1) of the Act, to be eligible to receive home infusion therapy services under the home infusion therapy services benefit, the patient must be under the care of an applicable provider (defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant), and the patient must be under a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. The plan of care must be periodically reviewed by the physician in coordination with the

[10] Medicare Benefit Policy Manual, Chapter 15, ''Covered Medical and Other Health Services'', section 50.2—Determining Self-Administration of Drug or Biological. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[11] Self-Administered Drug (SAD) Exclusion List Report. *www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D.*

[12] National Coverage Determinations Manual. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.html.*

furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C) of the Act). Section 1861(iii)(3)(C) of the Act defines a ''home infusion drug'' under the home infusion therapy services benefit as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the patient's home, through a pump that is an item of DME as defined under section 1861(n) of the Act. This definition does not include insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list.

Section 1861(iii)(3)(D)(i) of the Act defines a ''qualified home infusion therapy supplier'' as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. The provision specifies that qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an organization designated by the Secretary; and meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage (MA) plans under Part C and in the private sector. The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of medical services, in order to meet these requirements.

Section 1834(u)(1) of the Act requires the Secretary to implement a payment system under which, beginning January 1, 2021, a single payment is made to a qualified home infusion therapy supplier for the items and services (professional services, including nursing services; training and education; remote monitoring, and other monitoring services). The single payment must take into account, as appropriate, types of infusion therapy, including variations in utilization of services by therapy type. In addition, the single payment amount is required to be adjusted to reflect geographic wage index and other costs that may vary by region, patient acuity, and complexity of drug administration. The single payment may be adjusted to reflect outlier situations, and other factors as deemed appropriate by the Secretary, which are required to be done in a budget-neutral manner. Section 1834(u)(2) of the Act specifies certain items that ''the Secretary may consider'' in developing the home infusion therapy payment system: ''the costs of furnishing infusion therapy in the home, consult[ation] with home infusion therapy suppliers, . . . payment amounts for similar items and services under this part and Part A, and . . . payment amounts established by Medicare Advantage plans under Part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy)''. Section 1834(u)(3) of the Act specifies that annual updates to the single payment are required to be made, beginning January 1, 2022, by increasing the single payment amount by the percent increase in the Consumer Price Index for all urban consumers (CPI–U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). Under section 1834(u)(1)(A)(iii) of the Act, the single payment amount for each infusion drug administration calendar day, including the required adjustments and the annual update, cannot exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services if furnished in a physician's office. This statutory provision limits the single payment amount so that it cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Section 1834(u)(4) of the Act also allows the Secretary discretion, as appropriate, to consider prior authorization requirements for home infusion therapy services. Finally, section 5012(c)(3) of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the HH PPS beginning on January 1, 2021.

(2). Bipartisan Budget Act of 2018

Section 50401 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs, beginning January 1, 2019. This payment covers the same items and services as defined in section 1861(iii)(2)(A) and (B) of the Act, furnished in coordination with the furnishing of transitional home infusion drugs. Section 1834(u)(7)(A)(iii) of the Act defines the term ''transitional home infusion drug'' using the same definition as ''home infusion drug'' under section 1861(iii)(3)(C) of the Act, which is a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME as defined under section 1861(n) of the Act. The definition of ''home infusion drug'' excludes ''a self-administered drug or biological on a self-administered drug exclusion list'' but the definition of ''transitional home infusion drug'' notes that this exclusion shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of 1834(u)(7)(C) of the Act. Section 1834(u)(7)(C) of the Act sets out the Healthcare Common Procedure Coding System (HCPCS) codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794),[13] as the drugs covered during the temporary transitional period. In addition, section 1834(u)(7)(C) of the Act states that the Secretary shall assign to an appropriate payment category drugs which are covered under the DME LCD for External Infusion Pumps (L33794) [14] and billed under HCPCS codes J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified), or billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in subregulatory guidance as a home infusion drug.

Section 1834(u)(7)(E)(i) of the Act states that payment to an eligible home infusion supplier or qualified home infusion therapy supplier for an infusion drug administration calendar day in the individual's home refers to payment only for the date on which professional services, as described in section 1861(iii)(2)(A) of the Act, were furnished to administer such drugs to such individual. This includes all such drugs administered to such individual on such day. Section 1842(u)(7)(F) of the Act defines ''eligible home infusion supplier'' as a supplier who is enrolled in Medicare as a pharmacy that provides external infusion pumps and external infusion pump supplies, and that maintains all pharmacy licensure requirements in the State in which the

[13] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

[14] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

applicable infusion drugs are administered.

As set out at section 1834(u)(7)(C) of the Act, identified HCPCS codes for transitional home infusion drugs are assigned to three payment categories, as identified by their corresponding HCPCS codes, for which a single amount will be paid for home infusion therapy services furnished on each infusion drug administration calendar day. Payment category 1 includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 includes subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment category 3 includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals. The payment category for subsequent transitional home infusion drug additions to the DME LCD for External Infusion Pumps (L33794) and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the DME MACs.

In accordance with section 1834(u)(7)(D) of the Act, each payment category is paid at amounts in accordance with the Physician Fee Schedule (PFS) for each infusion drug administration calendar day in the individual's home for drugs assigned to such category, without geographic adjustment. Section 1834(u)(7)(E)(ii) of the Act requires that in the case that two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category will be made.

(d) Summary of CY 2019 and CY 2020 Home Infusion Therapy Provisions

In the CY 2019 HH PPS final rule with comment period (83 FR 56579) we finalized the implementation of the home infusion therapy services temporary transitional payments under paragraph (7) of section 1834(u) of the Act, for CYs 2019 and 2020. These services are furnished in the individual's home to an individual who is under the care of an applicable provider (defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant) and where there is a plan of care established and periodically reviewed by a physician (defined at section 1861(r)(1) of the Act), prescribing the type, amount, and duration of infusion therapy services. Only eligible home infusion suppliers can bill for the temporary transitional payments. Therefore, in accordance with section 1834(u)(7)(F) of the Act, we clarified that this meant that in addition to other DME suppliers, existing DME suppliers that were enrolled in Medicare as pharmacies that provided external infusion pumps and external infusion pump supplies, who complied with Medicare's DME Supplier and Quality Standards, and maintained all pharmacy licensure requirements in the State in which the applicable infusion drugs were administered, could be considered eligible home infusion suppliers for purpose of the temporary home infusion therapy benefit.

Section 1834(u)(7)(C) of the Act assigns transitional home infusion drugs, identified by the HCPCS codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794),[15] into three payment categories, for which we established a single payment amount per category in accordance with section 1834(u)(7)(D) of the Act. This section states that each single payment amount per category will be paid at amounts equal to the amounts determined under the PFS established under section 1848 of the Act for services furnished during the year for codes and units of such codes, without geographic adjustment. Therefore, we created a new HCPCS G-code for each of the three payment categories and finalized the billing procedure for the temporary transitional payment for eligible home infusion suppliers. We stated that the eligible home infusion supplier would submit, in line-item detail on the claim, a G-code for each infusion drug administration calendar day. We stated that the claim should include the length of time, in 15-minute increments, for which professional services were furnished. The G-codes could be billed separately from, or on the same claim as, the DME, supplies, or infusion drug, and would be processed through the DME MACs. On August 10, 2018, we issued Change Request: R4112CP: Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020[16] outlining the requirements for the claims processing changes needed to implement this payment.

And lastly, we finalized the definition of ''infusion drug administration calendar day'' in regulation as the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel (42 CFR 486.505). Section 1834(u)(7)(E)(i) of the Act clarifies that this definition is with respect to the furnishing of ''transitional home infusion drugs'' and ''home infusion drugs'' to an individual by an ''eligible home infusion supplier'' and a ''qualified home infusion therapy supplier.'' The definition of ''infusion drug administration calendar day'' applies to both the temporary transitional payment in CYs 2019 and 2020 and the permanent home infusion therapy services benefit to be implemented beginning in CY 2021.

2. Summary of Home Infusion Therapy Services for CY 2021 and Subsequent Years

Upon completion of the temporary transitional payments for home infusion therapy services at the end of CY 2020, we will be implementing the permanent payment system for home infusion therapy services under section 5012 of the 21st Century Cures Act (Pub. L. 114–255) beginning January 1, 2021. In the CY 2020 HH PPS final rule with comment period, we finalized provisions regarding payment for home infusion therapy services for CY 2021 and subsequent years in order to allow adequate time for eligible home infusion therapy suppliers to make any necessary software and business process changes for implementation on January 1, 2021.

(a) Scope of Benefit and Conditions for Payment

Section 1861(iii) of the Act establishes certain provisions related to home infusion therapy with respect to the requirements that must be met for Medicare payment to be made to qualified home infusion therapy suppliers. These provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services, outlining beneficiary qualifications and plan of care requirements, and establishing who can bill for payment under the benefit.

[15] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=83&Date=05%2f15%2f2019&DocID=L33794&bc=iAAAABAAAAAA&.*

[16] Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020. August 10, 2018. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf*

(1). Home Infusion Drugs

In the CYs 2019 and 2020 HH PPS proposed rules (83 FR 32466 and 84 FR 34690) we discussed the relationship between the home infusion therapy services benefit and the DME benefit. We stated that, as there is no separate Medicare Part B DME payment for the professional services associated with the administration of certain home infusion drugs covered as supplies necessary for the effective use of external infusion pumps, we consider the home infusion therapy services benefit to be a separate payment in addition to the existing payment for the DME equipment, accessories, and supplies (including the home infusion drug) made under the DME benefit. We stated that, consistent with the definition of ''home infusion therapy,'' the home infusion therapy services payment explicitly and separately pays for the professional services related to the administration of the drugs identified on the DME LCD for External Infusion Pumps (L33794),[17] when such services are furnished in the individual's home. For purposes of the temporary transitional payments for home infusion therapy services in CYs 2019 and 2020, the term ''transitional home infusion drug'' includes the HCPCS codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794).[18] We also noted that although section 1834(u)(7)(A)(iii) of the Act defines the term ''transitional home infusion drug,'' section 1834(u)(7)(A)(iii) of the Act does not specify the HCPCS codes for ''home infusion drugs'' for which home infusion therapy services would be covered beginning in CY 2021.

Section 1861(iii)(3)(C) of the Act defines ''home infusion drug'' as a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. This definition not only specifies that the drug or biological must be administered through a pump that is an item of DME, but references the statutory definition of DME at 1861(n) of the Act. This means that ''home infusion drugs'' are drugs and biologicals administered through a pump that is covered under the Medicare Part B DME benefit. Therefore, in the CY 2020 HH PPS final rule with comment period (84 FR 60618), we stated that this means that ''home infusion drugs'' are defined as parenteral drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME covered under the Medicare Part B DME benefit, pursuant to the statutory definition set out at section 1861(iii)(3)(C) of the Act, and incorporated by cross reference at section 1834(u)(7)(A)(iii) of the Act.

(2). Patient Eligibility and Plan of Care Requirements

Subparagraphs (A) and (B) of section 1861(iii)(1) of the Act set forth beneficiary eligibility and plan of care requirements for ''home infusion therapy.'' In accordance with section 1861(iii)(1)(A) of the Act, the beneficiary must be under the care of an applicable provider, defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant. In accordance with section 1861(iii)(1)(B) of the Act, the beneficiary must also be under a plan of care, established by a physician (defined at section 1861(r)(1) of the Act), prescribing the type, amount, and duration of infusion therapy services that are to be furnished, and periodically reviewed, in coordination with the furnishing of home infusion drugs under Part B. Based on these statutory requirements, and in accordance with the standards at § 486.520, we finalized the home infusion therapy services conditions for payment at 42 CFR part 414, subpart P via the CY 2020 HH PPS final rule with comment period (84 FR 60618).

(3). Qualified Home Infusion Therapy Suppliers and Professional Services

Section 1861(iii)(3)(D)(i) of the Act defines a ''qualified home infusion therapy supplier'' as a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider of services or supplier furnishes items or services. The qualified home infusion therapy supplier must: Furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour a-day basis; be accredited by an organization designated by the Secretary; and meet such other requirements as the Secretary determines appropriate.

Section 1861(iii)(2) of the Act defines home infusion therapy to include the following items and services: The professional services, including nursing services, furnished in accordance with the plan, training and education (not otherwise paid for as DME), remote monitoring, and other monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier, which are furnished in the individual's home. Section 1861(iii)(2) of the Act does not define home infusion therapy services to include the pump, home infusion drug, or related services. Therefore, in the CY 2020 HH PPS final rule with comment period, we noted that the infusion pump, drug, and other supplies, and the services required to furnish these items (that is, the compounding and dispensing of the drug) remain covered under the DME benefit.

We stated in the CY 2020 HH PPS proposed rule that we did not specifically enumerate a list of ''professional services'' for which the qualified home infusion therapy supplier is responsible in order to avoid limiting services or the involvement of providers of services or suppliers that may be necessary in the care of an individual patient (84 FR 34692). However, we noted that, under section 1862(a)(1)(A) of the Act, no payment can be made for Medicare services under Part B that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, unless explicitly authorized by statutes. We stated that this means that the qualified home infusion therapy supplier is responsible for the reasonable and necessary services related to the administration of the home infusion drug in the individual's home. These services may require some degree of care coordination or monitoring outside of an infusion drug administration calendar day. However, payment for these services is built into the bundled payment for an infusion drug administration calendar day.

Payment to a qualified home infusion therapy supplier is for an infusion drug administration calendar day in the individual's home, which, in accordance with section 1834(u)(7)(E) of the Act, refers to payment only for the date on which professional services were furnished to administer such drugs

[17] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

[18] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

to such individual. Ultimately, the qualified home infusion therapy supplier is the entity responsible for furnishing the necessary services to administer the drug in the home and, as we noted in the CY 2019 HH PPS final rule with comment period (83 FR 56581), ''administration'' refers to the process by which the drug enters the patient's body. Therefore, it is necessary for the qualified home infusion therapy supplier to be in the patient's home, on occasions when the drug is being administered in order to provide an accurate assessment to the physician responsible for ordering the home infusion drug and services. The services provided would include patient evaluation and assessment; training and education of patients and their caretakers, assessment of vascular access sites and obtaining any necessary bloodwork; and evaluation of medication administration. However, visits made solely for the purposes of venipuncture on days where there is no administration of the infusion drug would not be separately paid because the single payment includes all services for administration of the drug. Payment for an infusion drug administration calendar day is a bundled payment, which reflects not only the visit itself, but any necessary follow-up work (which could include visits for venipuncture), or care coordination provided by the qualified home infusion therapy supplier. Any care coordination, or visits made for venipuncture, provided by the qualified home infusion therapy supplier that occurs outside of an infusion drug administration calendar day would be included in the payment for the visit (83 FR 56581).

Additionally, section 1861(iii)(1)(B) of the Act requires that the patient be under a plan of care established and periodically reviewed by a physician, in coordination with the furnishing of home infusion drugs. The physician is responsible for ordering the reasonable and necessary services for the safe and effective administration of the home infusion drug, as indicated in the patient plan of care. In accordance with this section, the physician is responsible for coordinating the patient's care in consultation with the DME supplier furnishing the infusion pump and the home infusion drug. We recognize that collaboration between the ordering physician and the DME supplier furnishing the home infusion drug is imperative in providing safe and effective home infusion. Payment for physician services, including any home infusion care coordination services, are separately paid to the physician under the PFS and are not covered under the home infusion therapy services benefit. However, payment under the home infusion therapy services benefit to eligible home infusion therapy suppliers is for the professional services that inform collaboration between physicians and home infusion therapy suppliers. Care coordination between the physician and DME supplier, although likely to include review of the services indicated in the home infusion therapy supplier plan of care, is paid separately from the payment under the home infusion therapy services benefit.

As discussed in the CY 2020 HH PPS proposed rule, the DME quality standards require the supplier to review the patient's record and consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s) (84 FR 34692). Follow-up services to the beneficiary and/or caregiver(s), must be consistent with the type(s) of equipment, item(s) and service(s) provided, and include recommendations from the prescribing physician or healthcare team member(s).[19] Additionally, DME suppliers are required to communicate directly with patients regarding their medications.

In summary, the qualified home infusion therapy supplier is responsible for the reasonable and necessary services related to the administration of the home infusion drug in the individual's home. These services may require some degree of care coordination or monitoring outside of an infusion drug administration calendar day; payment for these services is built into the bundled payment for an infusion drug administration calendar day. Furthermore, as we noted in the CY 2019 HH PPS proposed rule, we consider the home infusion benefit principally to be a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the home infusion therapy services (83 FR 32466). Therefore, the professional services covered under the DME benefit are not covered under the home infusion benefit. While the two benefits exist in tandem, the services are unique to each benefit and billed and paid for under separate payment systems. While we did not make any proposals regarding policies finalized in the CY 2020 HH PPS final rule with comment period as they relate to the implementation of the permanent home infusion therapy services in CY 2021, we did receive comments making suggestions to change certain aspects of the finalized policies. As we did not make any proposals in the CY 2021 proposed rule, we view these comments outside of the scope of this rule. However, we will keep these comments in mind for future rulemaking.

[19] Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/Final-DMEPOS-Quality-Standards-Eff-01-09-2018.pdf.*

(4). Home Infusion Therapy and Interaction With the Home Health Benefit

Because a qualified home infusion therapy supplier is not required to become accredited as a Part B DME supplier or to furnish the home infusion drug, and because payment is determined by the provision of services furnished in the patient's home, we acknowledged in the CY 2019 HH PPS proposed rule the potential for overlap between the new home infusion therapy services benefit and the home health benefit (83 FR 32469). We stated that a beneficiary is not required to be considered homebound in order to be eligible for the home infusion therapy services benefit; however, there may be instances where a beneficiary under a home health plan of care also requires home infusion therapy services. Additionally, because section 5012 of the 21st Century Cures Act amends section 1861(m) of the Act to exclude home infusion therapy from home health services effective on January 1, 2021; we stated that a beneficiary may utilize both benefits concurrently.

Furthermore, because both the home health agency and the qualified home infusion therapy supplier furnish services in the individual's home, and may potentially be the same entity, the best process for payment for furnishing home infusion therapy services to beneficiaries who qualify for both benefits is as outlined in the CY 2019 HH PPS proposed rule (83 FR 32469). If a patient receiving home infusion therapy is also under a home health plan of care, and receives a visit that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS and billed on the home health claim. When the home health agency furnishing home health services is also the qualified home infusion therapy supplier furnishing home infusion therapy services, and a home visit is exclusively for the purpose of furnishing items and services related to

the administration of the home infusion drug, the home health agency would submit a home infusion therapy services claim under the home infusion therapy services benefit. If the home visit includes the provision of other home health services in addition to, and separate from, home infusion therapy services, the home health agency would submit both a home health claim under the HH PPS and a home infusion therapy services claim under the home infusion therapy services benefit. However, the agency must separate the time spent furnishing services covered under the HH PPS from the time spent furnishing services covered under the home infusion therapy services benefit. DME is excluded from the consolidated billing requirements governing the HH PPS (42 CFR 484.205) and therefore, the DME items and services (including the home infusion drug and related services) will continue to be paid for outside of the HH PPS. If the qualified home infusion therapy supplier is not the same entity as the home health agency furnishing the home health services, the home health agency would continue to bill under the HH PPS on the home health claim, and the qualified home infusion therapy supplier would bill for the services related to the administration of the home infusion drugs on the home infusion therapy services claim.

The summarized comments and responses related to the separation of home infusion therapy services benefit from the HH PPS are found in section V.A.5 .

(b) Notification of Infusion Therapy Options Available Prior To Furnishing Home Infusion Therapy Services

Section 1834(u)(6) of the Act requires that prior to the furnishing of home infusion therapy services to an individual, the physician who establishes the plan described in section 1861(iii)(1) of the Act for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

We recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy options. We solicited comments in the CY 2020 PFS proposed rule (84 FR 40716) and the CY 2020 HH PPS proposed rule (84 FR 34694), regarding the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment options available to his/her patient for the furnishing of infusion therapy (home or otherwise) under Medicare Part B. We also invited comments on any additional interpretations of this notification requirement. We summarized the comments received in the CY 2020 PFS final rule (84 FR 62568) and the CY 2020 HH PPS final rule with comment period (84 FR 60478), and we stated we would take these comments into consideration as we continue developing future policy through notice-and-comment rulemaking.

Many commenters stated that physicians already routinely discuss the infusion therapy options with their patients and annotate these discussions in their patients' medical records. For home infusion therapy services effective beginning CY 2021, physicians are to continue with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. We did not propose to create a mandatory form nor did we otherwise propose to require a specific manner or frequency of notification of options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care, as we believe that current practice provides appropriate notification. However, we stated that if current practice is later found to be insufficient in providing appropriate notification to patients of the available infusion options under Part B, we might consider additional requirements regarding this notification in future rulemaking.

Comment: One commenter supported the current practice of physicians discussing all infusion therapy options with their patients, especially in regard to understanding the costs.

Response: We appreciate the commenter's support of maintaining this current practice.

Final Decision: At this time, we will not create a mandatory form nor require a specific manner or frequency of notification of options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care, as we believe that current practice provides appropriate notification. However, if current practice is later found to be insufficient in providing appropriate notification to patients of the available infusion options under Part B, we may consider additional requirements regarding this notification in future rulemaking.

3. Payment Categories and Payment Amounts for Home Infusion Therapy Services for CY 2021

Section 1834(u)(1) of the Act provides the authority for the development of a payment system for Medicare-covered home infusion therapy services. In accordance with section 1834(u)(1)(A)(i) of the Act, the Secretary is required to implement a payment system under which a single payment is made to a qualified home infusion therapy supplier for items and services furnished by a qualified home infusion therapy supplier in coordination with the furnishing of home infusion drugs. Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment under this payment system is for each infusion drug administration calendar day in the individual's home, and requires the Secretary, as appropriate, to establish single payment amounts for different types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the PFS (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting. Furthermore, such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. This permanent payment system would become effective for home infusion therapy items and services furnished on or after January 1, 2021.

In accordance with section 1834(u)(1)(A)(ii) of the Act, a unit of single payment for each infusion drug administration calendar day in the individual's home must be established for types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Furthermore, section 1834(u)(1)(B)(ii) of the Act requires that the payment amount reflect factors such as patient acuity and complexity of drug administration. We believe that the best way to establish a single payment amount that varies by utilization of nursing services and reflects patient acuity and complexity of drug administration, is to group home infusion drugs by J-code into payment categories reflecting similar therapy types. Therefore, each payment category would reflect variations in infusion drug administration services.

Section 1834(u)(7)(C) of the Act established three payment categories, with the associated J-code for each transitional home infusion drug (see

Table 13), for the home infusion therapy services temporary transitional payment. Payment category 1 comprises certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including, but not limited to, antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 comprises subcutaneous infusions for therapy or prophylaxis, including, but not limited to, certain subcutaneous immunotherapy infusions. Payment category 3 comprises intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

(a) CY 2021 Payment Categories for Home Infusion Therapy Services

In the CY 2020 HH PPS final rule with comment period (84 FR 60478), we finalized our proposal to maintain the three payment categories utilized under the temporary transitional payments for home infusion therapy services. Maintaining the three current payment categories, with the associated J-codes as set out at section 1834(u)(7)(C) of the Act, utilizes an already established framework for assigning a unit of single payment (per category), accounting for different therapy types, as required by section 1834(u)(1)(A)(ii) of the Act. The payment amount for each of these three categories is different, though each category has its associated single payment amount. The single payment amount (per category) would thereby reflect variations in nursing utilization, complexity of drug administration, and patient acuity, as determined by the different categories based on therapy type. Retaining the three current payment categories maintains consistency with the already established payment methodology and ensures a smooth transition between the temporary transitional payments and the permanent payment system to be implemented beginning in 2021.

Table 13 provides the list of J-codes associated with the infusion drugs that fall within each of the payment categories. There are some drugs that are paid for under the transitional benefit but would not be defined as a home infusion drug under the permanent benefit beginning with 2021. Section 1861(iii)(3)(C) of the Act defines a home infusion drug as a parenteral drug or biological administered intravenously or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. Such term does not include the following: (1) Insulin pump systems; and (2) a self-administered drug or biological on a self-administered drug exclusion list. Hizentra®, a subcutaneous immunoglobulin, is not included in this definition of ''home infusion drugs'' because it is listed on a self-administered drug (SAD) exclusion list by the MACs. This drug was included as a transitional home infusion drug since the definition of such drug in section 1834(u)(7)(A)(iii) of the Act does not exclude self-administered drugs or biologicals on a SAD exclusion list under the temporary transitional payment. Therefore, although home infusion therapy services related to the administration of Hizentra® are covered under the temporary transitional payment, because it is currently on a SAD exclusion list, services related to the administration of this biological are not covered under the benefit in 2021; however, if it is removed from all the SAD lists, it could be added to the home infusion drugs list in the future. Similarly, in accordance with the definition of ''home infusion drug'' as a parenteral drug or biological administered intravenously or subcutaneously, home infusion therapy services related to the administration of ziconotide and floxuridine are also excluded, as these drugs are given via intrathecal and intra-arterial routes respectively and therefore do not meet the definition of ''home infusion drug''. Likewise, home infusion therapy services related to the intrathecal administration of morphine, identified by HCPCS code J2274, is excluded because intrathecal administration does not meet the definition of a ''home infusion drug'' under the permanent benefit.

It is important to note that the list of home infusion drugs is maintained by the DME MACs and the drugs or their respective payment categories do not need to be updated through rulemaking every time a new drug is added to the DME LCD for External Infusion Pumps (L33794).[20] We acknowledge, however, that two immune-globulins, Xembify® and Cutaquig®, have been added to the DME LCD for External Infusion Pumps (L33794).[21] Consistent with the definition of ''home infusion drug'', the home infusion therapy services will be covered under payment category 2 for these two subcutaneously infused drugs. Xembify® is identified by HCPCS code J1558 and Cutaquig® is currently identified by the not otherwise classified (NOC) code J7799 until it is assigned a unique HCPCS code.

The payment category may be determined by the DME MAC for any subsequent home infusion drug additions to the DME LCD for External Infusion Pumps (L33794) [22] as identified by the following NOC codes: J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified). Payment category 1 would include any appropriate subsequent intravenous infusion drug additions, payment category 2 would include any appropriate subsequent subcutaneous infusion drug additions, and payment category 3 would include any appropriate subsequent intravenous chemotherapy or other highly complex drug or biologic infusion additions.

[20] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

[21] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

[22] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

TABLE 13: INFUSION DRUG J-CODES ASSOCIATED WITH HOME INFUSION THERAPY SERVICE PAYMENT CATEGORIES FOR CY 2021

J-Code	Drug
Category 1	
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	
J1555 JB*	Injection, immune globulin (cuvitru), 100 mg
J1558 JB*	Injection, immune globulin (xembify), 100 mg
J1561 JB*	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562 JB*	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB*	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB*	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Category 3	
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

*The JB modifier indicates that the route of administration is subcutaneous.

Comment: We received comments expressing concerns regarding home infusions of the cytotoxic chemotherapy drugs that are on the list of home infusion drugs, especially if they are mishandled or administered incorrectly. Commenters noted that certain safety standards that exist for outpatient clinics may be difficult to satisfy when infusing such drugs in the home environment and thus infusing such drugs at home could potentially put patients and health care personnel at increased risk of dangerous adverse effects such as genotoxicity, teratogenicity, acute anaphylactic reactions, carcinogenicity, and reproductive risks for patients and the potential for mishandling of the drugs by health care personnel among others. We also received comments with requests for the current list of transitional home infusion drugs to be grandfathered into the list of home infusion drugs for the permanent benefit in effort to continue payment for services related to certain drugs, such as Hizentra® and ziconotide, which do not meet the definition of ''home infusion drugs'' according to section 1861(iii)(3)(C) of the Act. Other comments suggested adding certain antibiotics and central nervous system agents to the list of home infusion drugs, especially in consideration for beneficiaries whose previous commercial insurance may have covered home infusion services related to such drugs. Many commenters specifically suggested including two subcutaneously infused immune-globulins, Xembify® and Cutaquig®, on

the list of home infusion drugs. Another commenter suggested revising the requirement that home infusion drugs must be identified by the DME LCD for External Infusion Pumps (L33794) [23] in an effort to expand the list of home infusion drugs more quickly than via the existing LCD reconsideration process.

Response: We appreciate the commenters' interests and concerns regarding the drugs associated with the permanent home infusion therapy services benefit, however, the home infusion therapy services benefit does not cover drugs, as they are covered under the durable medical equipment benefit. Rather, the home infusion therapy services benefit covers the professional services associated with drugs that meet the definition of home infusion drugs and are identified in the DME LCD for External Infusion Pumps (L33794).[24] We discussed the LCD Development Process in the CY 2020 HH PPS final rule in order to provide transparency to stakeholders on the criteria and process used to determine which items are included on the LCD for External Infusion Pumps (84 FR 60619). Any requests regarding additions to the DME LCD for External Infusion Pumps must be made to the DME MACs. Finally, as previously discussed, Xembify® and Cutaquig® were recently added to the DME LCD for External Infusion Pumps (L33794) [25] and meet the definition of a home infusion drug with coverage of home infusion therapy services under payment category 2.

Final Decision: We did not propose any changes, therefore we are maintaining the current definition of ''home infusion drugs'' as finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60618), pursuant to the statutory definition set out at section 1861(iii)(3)(C) of the Act, and incorporated by cross reference at section 1834(u)(7)(A)(iii) of the Act.

(b) CY 2021 Payment Amounts for Home Infusion Therapy Services

Section 1834(u)(1)(A)(ii) of the Act requires that the payment amount take into account variation in utilization of nursing services by therapy type. Additionally, section 1834(u)(1)(A)(iii) of the Act provides a limitation that the single payment shall not exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. Finally, section 1834(u)(1)(B)(ii) of the Act requires the payment amount to reflect patient acuity and complexity of drug administration.

Currently, as set out at section 1834(u)(7)(D) of the Act, each temporary transitional payment category is paid at amounts in accordance with six infusion CPT codes and units of such codes under the PFS. These payment category amounts are set equal to 4 hours of infusion therapy administration services in a physician's office for each infusion drug administration calendar day, regardless of the length of the visit. In the CY 2020 HH PPS final rule with comment period (84 FR 60478), we finalized that the payment amounts per category, for an infusion drug administration calendar day under the permanent benefit, be in accordance with the six PFS infusion CPT codes and units for such codes, as described in section 1834(u)(7)(D) of the Act. However, we set the amount equivalent to 5 hours of infusion in a physician's office, rather than 4 hours. Each payment category amount would be in accordance with the six infusion CPT codes identified in section 1834(u)(7)(D) of the Act and as shown in Table 14.

TABLE 14: PAYMENT CATEGORIES FOR HOME INFUSION THERAPY SERVICES PAYMENT FOR CY 2021

CPT CODE	DESCRIPTION	UNITS
	CATEGORY 1	
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- each additional hour	4
	CATEGORY 2	
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96370	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- each additional hour	4
	CATEGORY 3	
96413	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- up to one hour	1
96415	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- each additional hour	4

We also finalized the proposal to increase the payment amounts for each of the three payment categories for the first home infusion therapy visit by the qualified home infusion therapy supplier in the patient's home by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year, resulting in a small decrease to the payment amounts for the second and subsequent visits, using a budget neutrality factor. Effective January 1, 2021 there are changes to the office/outpatient E/M visit code set (CPT codes

[23] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

[24] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

[25] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA.*

99201 through 99215) used to calculate the initial and subsequent visit payment amounts for home infusion. These changes were adopted from the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA's CPT Editorial Panel (see *https://www.amaassn.org/practice-management/cpt/cptevaluation-and-management*) and include the deletion of code 99201 (Level 1 office/outpatient visit, new patient), and new values for CPT codes 99202 through 99215. The initial visit percentage increase will still be calculated using the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year; however, now only new patient E/M codes 99202 through 99205 will be used in the calculation. Using the proposed CY 2021 PFS rates, we estimate a 19 percent increase in the first visit payment amount and a 1.18 percent decrease in subsequent visit amounts. Table 15 shows the updated E/M visit codes and proposed PFS payment amounts for CY 2021, for both new and existing patients, used to determine the increased payment amount for the first visit. The final CY 2021 PFS amounts for E/M visits were not available at the time of publication for this final rule; however, we will post the final home infusion therapy services payment amounts on the PFS rate setting update.

TABLE 15: AVERAGE DIFFERENCE BETWEEN PFS E/M CODES FOR NEW AND EXISTING PATIENTS*

New Patient E/M Code	PFS Amount	Existing Patient E/M Code	PFS Amount	Percent Difference
		99211	$22.26	NA
99202	$69.04	99212	$54.20	27%
99203	$106.14	99213	$86.78	22%
99204	$159.37	99214	$122.91	30%
99205	$210.66	99215	$172.27	22%
Total	$545.21		$458.42	19%

Note: Rates are calculated using proposed CY 2021 PFS rates.

*This represents the average difference between the physician E/M payment amounts for new versus established patients: (the sum of the initial rates – the sum of the existing rates) (the sum of the existing rates) =19 percent.

Table 16 shows the 5-hour payment amounts (using proposed CY 2021 PFS rates) reflecting the increased payment for the first visit and the decreased payment for all subsequent visits. The payment amounts for this final rule are estimated using the proposed CY 2021 rates because the final CY 2021 PFS rates are not available at the time of this rule making. The final home infusion 5-hour payment amounts will be released on the Physician Fee Schedule when the final CY 2021 PFS rates are posted. We plan on monitoring home infusion therapy service lengths of visits, both initial and subsequent, in order to evaluate whether the data substantiates this increase or whether we should re-evaluate whether, or how much, to increase the initial visit payment amount.

TABLE 16: 5-HOUR PAYMENT AMOUNTS REFLECTING PAYMENT RATES FOR FIRST AND SUBSEQUENT VISITS

CPT Code	Description	Proposed 2021 PFS Amount	5-hour Payment - First Visit	5-hour Payment - Subsequent Visits
96365	Ther, Proph, Diag IV/IN infusion 1 hr	$72.26	$188.85 (category 1)	$156.83 (category 1)
96366	Ther, Proph, Diag IV/IN infusion add hr	$21.61		
96369	Sub Q Ther Inf 1 hr	$156.46	$256.83 (category 2)	$213.27 (category 2)
96370	Sub Q Ther Inf add hr	$14.84		
96413	Chemo Inf 1 hr	$146.14	$319.80 (category 3)	$265.57 (category 3)
96415	Chemo Inf add hr	$30.65		

Note: Rates are calculated using proposed CY 2021 PFS rates.

We did not propose any new policies related to the HIT services payment system, and did not receive any specific comments on the payment amounts posted in the proposed rule.

Final Decision: The payment policies for the permanent home infusion therapy services benefit were finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60478). We will maintain the three payment categories currently being utilized under the temporary transitional payments for home infusion therapy services and each category payment amount will be

in accordance with the six CPT infusion codes under the PFS and equal to 5 hours of infusion services in a physician's office. We will increase the payment amounts for each of the three payment categories for the first visit by the relative payment for a new patient rate over an existing patient rate using the Medicare physician evaluation and management (E/M) payment amounts for a given year, in a budget neutral manner, resulting in a small decrease to the payment amounts for any subsequent visits. Payment will be made for each infusion drug administration calendar day in accordance with the definition finalized in the CY 2019 final rule with comment period (83 FR 56583).

4. Payment Adjustments for CY 2021 Home Infusion Therapy Services

(a) Home Infusion Therapy Geographic Wage Index Adjustment

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted to reflect a geographic wage index and other costs that may vary by region. In the 2020 HH PPS final rule with comment period (84 FR 60478, 60629) we finalized the use of the Geographic Adjustment Factor (GAF) to adjust home infusion therapy payments based on differences in geographic wages. The GAF is a weighted composite of each PFS locality's work, practice expense (PE), and malpractice (MP) Geographic Price Cost Index (GPCIs) and represents the combined impact of the three GPCI components. The GAF is calculated by multiplying the work, PE, and MP GPCIs by the corresponding national cost share weight: work (50.886 percent), PE (44.839 percent), and MP (4.295 percent).[26] The GAF is not specific to any of the home infusion drug categories, so the GAF payment rate would equal the unadjusted rate multiplied by the GAF for each locality level, without a labor share adjustment. As such, based on locality, the GAF adjusted payment rate would be calculated using the following formula:

$$Rate_i^{GAF} = GAF * UnadjRate_i$$

The appropriate GAF value is applied to the home infusion therapy single payment amount based on the site of service of the beneficiary and the adjustment will happen on the PFS based on the beneficiary zip code submitted on the 837P/CMS–1500 professional and supplier claims form. We finalized that the application of the GAF will be budget neutral so there is no overall cost impact. However, this will result in some adjusted payments being higher than the average and others being lower. In order to make the application of the GAF budget neutral we will apply a budget-neutrality factor. If the rates were set using the proposed CY 2021 PFS rates the budget neutrality factor would be 0.9951. The GAF conversion factor equals the ratio of the estimated unadjusted national spending total to the estimated GAF-adjusted national spending total. Estimates of national spending totals are derived from a function of ''beneficiary counts,'' ''weeks of care,'' and ''estimated visits of care'' by home infusion therapy drug payment category, which were compiled from CY 2019 utilization data. We define home infusion therapy beneficiaries as Medicare beneficiaries with at least one home infusion therapy drug prescription fill in CY 2019, and weeks of care for each home infusion therapy beneficiary equal the number of weeks between (and including) the first prescription fill in CY 2019 and the last prescription fill in CY2019. Weeks of care are then transformed into ''estimated visits of care,'' where we assumed 2 visits for the initial week of care, with 1 visit per week for all subsequent weeks for categories 1 and 3, and we assumed 1 visit per month, or 12 visits per year, for category 2.

The list of GAFs by locality for this final rule is available as a downloadable file at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html.*

(b) Consumer Price Index

Subparagraphs (A) and (B) of section 1834(u)(3) of the Act specify annual adjustments to the single payment amount that are required to be made beginning January 1, 2022. In accordance with these sections we would increase the single payment amount by the percent increase in the Consumer Price Index for all urban consumers (CPI–U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). Accordingly, this may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

We did not propose any new policies related to the payment adjustments for HIT services, and did not receive any specific comments on the use of the GAF or the CPI–U.

Final Decision: As finalized in the CY 2020 HH PPS final rule (84 FR 60630), we will use the GAF to geographically adjust the home infusion therapy payment amounts in CY 2021 and subsequent calendar years. And beginning in CY 2022, we will annually update the single payment amount from the prior year for each home infusion therapy payment category by the percent increase in the Consumer Price Index for all urban consumers (CPI–U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) as required by section 1834(u)(3) of the Act.

5. Home Infusion Therapy Services Excluded From the Medicare Home Health Benefit

In the CY 2021 proposed rule (85 FR 39440) we discussed the services covered under the home infusion therapy services benefit as defined under section 1861(iii) of the Act. This section defines ''home infusion therapy'' as the items and services described in paragraph (2), furnished by a qualified home infusion therapy supplier which are furnished in the individual's home. In accordance with § 486.525, the required items and services covered under the home infusion therapy services benefit are as follows:

- Professional services, including nursing services, furnished in accordance with the plan.
- Training and education (not otherwise paid for as DME).
- Remote monitoring, and monitoring services for the provision of home infusion drugs furnished by a qualified home infusion therapy supplier.

We also noted that the CY 2019 HH PPS proposed rule described the professional and nursing services, as well as the training, education, and monitoring services included in the payment to a qualified home infusion therapy supplier for the provision of home infusion drugs (83 FR 32467). Additionally, while we did not outline an exhaustive list of services that are covered under the home infusion therapy services benefit, we did outline the scope of services covered under the home infusion therapy services benefit in sub-regulatory guidance.[27] This

[26] *GAF* = (0.50886 × Work GPCI) + (0.44839 × PE GPCI) + (0.04295 × MP GPCI).

[27] MLN Matters: SE19029: Medicare Part B Home Infusion Therapy Services With the Use of Durable Medical Equipment. December 13, 2019. *https://www.cms.gov/files/document/se19029.pdf.* And Temporary Transitional Payment FAQs. February 27, 2019. *https://www.cms.gov/Medicare/Medicare-*

Continued

guidance states that the home infusion therapy services benefit is intended to be a separate payment explicitly covering the professional services, training and education (not covered under the DME benefit), and monitoring and remote monitoring services for the provision of home infusion drugs. We state that these services may include, for example the following:

- Training and education on care and maintenance of vascular access devices—

++ Hygiene Education;

++ Instruction on what to do in the event of a dislodgement or occlusion;

++ Education on signs and symptoms of infection; and

++ Teaching and training on flushing and locking the catheter.

- Dressing changes and site care.
- Patient assessment and evaluation—

++ Review history and assess current physical and mental status, including obtaining vital signs;

++ Assess any adverse effects or infusion complications;

++ Evaluate family and caregiver support ;

++ Review prescribed treatment and any concurrent oral and/or over-the-counter treatments; and

++ Obtain blood for laboratory work

- Medication and disease management education—

++ Instruction on self-monitoring;

++ Education on lifestyle and nutritional modifications;

++ Education regarding drug mechanism of action, side effects, interactions with other medications, adverse and infusion-related reactions;

++ Education regarding therapy goals and progress;

++ Instruction on administering pre-medications and inspection of medication prior to use;

++ Education regarding household and contact precautions and/or spills;

- Remote monitoring services.
- Monitoring services—

++ Communicate with patient regarding changes in condition and treatment plan;

++ Monitor patient response to therapy; and

++ Assess compliance.

We stated that this list is not intended to be prescriptive or all-inclusive, as the physician is responsible for ordering the reasonable and necessary services for the safe and effective administration of the home infusion drug.

In the CY 2021 proposed rule, we also recognized that section 5012 of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the definition of home health services, effective January 1, 2021 (85 FR 39441). We clarified that while patients needing home infusion therapy are not required to be eligible for the home health benefit, they are not prohibited from utilizing both the home infusion therapy and home health benefits concurrently, and that it is likely that many home health agencies will become accredited and enroll as qualified home infusion therapy suppliers. Therefore, because a home health agency may furnish services for a patient receiving both home health services and home infusion therapy services, we stated that it is necessary to exclude in regulation the scope of professional services, training and education, as well as monitoring and remote monitoring services, for the provision of home infusion drugs, as defined at § 486.505, from the services covered under the home health benefit. We also noted that the home infusion therapy services distinct from those which are required and furnished under the home health benefit, are only for the provision of home infusion drugs. Therefore, when a home health agency is furnishing services to a patient receiving an infusion drug not defined as a home infusion drug at § 486.505, those services may still be covered as home health services.

In accordance with the conforming amendment in section 5012(c)(3) of the 21st Century Cures Act, which amended section 1861(m) of the Act to exclude home infusion therapy from the definition of home health services, we proposed to amend § 409.49 to exclude services covered under the home infusion therapy services benefit from the home health benefit. We stated that any services that are covered under the home infusion therapy services benefit as outlined at § 486.525, including any home infusion therapy services furnished to a Medicare beneficiary that is under a home health plan of care, are excluded from coverage under the Medicare home health benefit. Additionally, we clarified that excluded home infusion therapy services only pertain to the items and services for the provision of home infusion drugs, as defined at § 486.505. Services for the provision of drugs and biologicals not covered under this definition may continue to be provided under the Medicare home health benefit, and paid under the home health prospective payment system.

Additionally, in the proposed rule we reiterated the billing process as outlined in the CY 2019 HH PPS proposed rule (83 FR 32469). We stated that if a patient is under a home health plan of care, and a home health visit is furnished that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS and billed on the same home health claim. If the HHA providing services under the Medicare home health benefit is also the same entity furnishing services as the qualified home infusion therapy supplier, and a home visit is exclusively for the purpose of furnishing home infusion therapy services, the HHA would submit a claim for payment as a home infusion therapy supplier and receive payment under the home infusion therapy services benefit. If the home visit includes the provision of home health services in addition to, and separate from, items and services related to home infusion therapy, the HHA would submit both a home health claim and a home infusion therapy services claim, and must separate the time spent performing services covered under the HH PPS from the time spent performing services covered under the home infusion therapy services benefit.

Collectively, commenters expressed disagreement with the proposal to amend § 409.49 to exclude services covered under the home infusion therapy services benefit from the home health benefit. The following is our response.

Comment: Commenters suggested that CMS should use its authority to not enforce the prohibition for HHAs to provide the professional services associated with Part B infusion drugs under the home health benefit. Some commenters expressed concern that beneficiaries would receive fragmented care from multiple visits from various entities and would be required to pay a twenty percent coinsurance for the home infusion therapy services benefit when utilizing both concurrently, whereas they did not have a coinsurance previously under the home health benefit. One commenter expressed concern with the number of eligible entities that intend to enroll as home infusion therapy suppliers and whether there will be sufficient suppliers enrolled, particularly in rural areas. The commenter stated that there may be many HHAs that do not enroll as qualified home infusion therapy suppliers, and who plan to subcontract with a home infusion therapy supplier, but the availability of these suppliers is unknown; potentially creating a situation where there may be difficulties in finding qualified home infusion therapy suppliers. This commenter suggested that some HHAs would then

Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf.

be forced to provide unreimbursed care to patients receiving home infusion drugs.

Response: Section 5012 of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy services from the definition of home health services, effective January 1, 2021, therefore, we are statutorily precluded from making payment for home infusion therapy services to entities other than ''qualified home infusion therapy suppliers'' for services needed to administer ''home infusion drugs.'' As described in section V.B of the proposed rule (85 FR 39442), the overarching purpose of the enrollment process is to help ensure that providers and suppliers that seek to bill the Medicare program for services or items furnished to Medicare beneficiaries are qualified to do so under federal and state laws. This process helps to prevent unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. Therefore, an HHA must be accredited and enrolled in Medicare as a qualified home infusion therapy supplier in order to furnish and bill for home infusion therapy services under the home infusion therapy services benefit, which is statutorily required to be implemented by January 1, 2021. If an HHA does not become accredited and enrolled as a qualified home infusion therapy supplier and is treating a patient receiving a home infusion drug, the HHA must contract with a qualified home infusion therapy supplier to furnish the services related to the home infusion drug.

As we noted in the CY 2020 HH PPS final rule (84 FR 60624), it is already the responsibility of the HHA to arrange for the DME and related infusion services for patients under a home health plan of care. In accordance with the Medicare HH CoPs at 42 CFR 484.60, the home health agency must assure communication with all physicians involved in the plan of care, as well as integrate all orders and services provided by all physicians and other healthcare disciplines, such as nursing, rehabilitative, and social services. If the HHA also becomes accredited and enrolls in Medicare as a qualified home infusion therapy supplier, the HHA can either continue to furnish the services or contract with a qualified home infusion therapy supplier to meet these requirements. It is also important to note that the HHA can still provide all infusion services to patients under the home health benefit as home health services, for any drugs not considered home infusion drugs.

Final Decision: In accordance with the conforming amendment in section 5012(c)(3) of the 21st Century Cures Act, which amended section 1861(m) of the Act to exclude home infusion therapy from the definition of home health services, we are finalizing as proposed our amendment to § 409.49 to exclude services covered under the home infusion therapy services benefit from the home health benefit. Any services that are covered under the home infusion therapy services benefit as outlined at § 486.525, including any home infusion therapy services furnished to a Medicare beneficiary that is under a home health plan of care, are excluded from coverage under the Medicare home health benefit. Excluded home infusion therapy services only pertain to the items and services for the provision of home infusion drugs, as defined at § 486.505. Services for the provision of drugs and biologicals not covered under this definition may continue to be provided under the Medicare home health benefit, and paid under the home health prospective payment system.

B. Enrollment Requirements for Qualified Home Infusion Therapy Suppliers

As previously alluded to, regulatory provisions pertaining to home infusion therapy have been established in various parts of Title 42 of the CFR, such as in part 414, subpart P and in part 486, subpart I. Sections 486.520 and 486.525 outline standards for home infusion therapy while § 486.505 defines ''qualified home infusion therapy supplier.'' This latter term means a supplier of home infusion therapy that meets all of the following criteria, which are set forth at section 1861(iii)(3)(D)(i) of the Act:

- Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.
- Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.
- Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.
- Meets such other requirements as the Secretary determines appropriate.

Concerning this final criterion (which reflects section 1861(iii)(3)(D)(i)(IV) of the Act), one of CMS' principal oversight roles is to protect the Medicare program from fraud, waste, and abuse. This is accomplished in part through the careful screening and monitoring of prospective and existing providers and suppliers. In our view, section 1861(iii)(3)(D)(i)(IV) of the Act permits the Secretary to take steps in this direction with respect to home infusion therapy suppliers.

1. Background—Provider and Supplier Enrollment Process

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all federal and state requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare.

Since 2006, we have taken various steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereinafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges. One such requirement (outlined in § 424.510) is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, Provider Enrollment, Chain, and Ownership System) collects important information about the provider or supplier; such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider's or supplier's initial enrollment application, reviewing and confirming the information thereon, and determining whether the provider or supplier meets all applicable Medicare requirements, CMS or the MAC will either: (1) Approve the application and grant billing privileges to the provider or supplier (or, depending upon the provider or supplier type involved, simply recommend approval of the application and refer it to the state agency or to the CMS regional office, as applicable); or (2) deny enrollment under § 424.530.

We believe the Medicare provider and supplier enrollment screening process has greatly assisted CMS in executing its responsibility to prevent Medicare waste and abuse. As emphasized in the June 30, 2020 proposed rule, we believe the safeguards that Medicare enrollment furnishes are equally needed with respect to home infusion therapy suppliers.

2. Legal Bases for Home Infusion Therapy Supplier Enrollment

There are several legal bases for our proposed home infusion therapy supplier enrollment requirements. First, section 5012 of the Cures Act, which amended sections 1834(u), 1861(s)(2), and 1861(iii) of the Act, established a new Medicare home infusion therapy benefit. Second, section 1861(iii)(3)(D)(i)(IV) of the Act permits the Secretary to establish requirements for qualified home infusion therapy suppliers that the Secretary determines appropriate. In doing so, the Secretary shall take into account the standards of care for home infusion therapy established by Medicare Advantage plans under Part C and in the private sector. (However, we interpret this latter provision to apply strictly to the establishment of standards of care as opposed to the creation of enrollment requirements for home infusion therapy suppliers.) Third, section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Fourth, sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

3. Proposed Provisions

This section of this final rule outlines the proposed enrollment requirements for suppliers of home infusion therapy.

a. Definition

We proposed to establish a new § 424.68 that would encapsulate the preponderance of our home infusion therapy supplier enrollment provisions. In paragraph (a) thereof, we proposed to define ''home infusion therapy supplier'' (for purposes of § 424.68) as a supplier of home infusion therapy that meets all of the following requirements:

++ Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

++ Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

++ Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

++ Is enrolled in Medicare as a home infusion therapy supplier consistent with the provisions of § 424.68 and part 424, subpart P.

b. General Enrollment and Payment Requirement

In paragraph (b), we proposed that for a supplier to receive Medicare payment for the provision of home infusion therapy supplier services, the supplier must: (1) Qualify as a home infusion therapy supplier (as defined in § 424.68); and (2) be in compliance with all applicable provisions of § 424.68 and part 424, subpart P. (Proposed paragraph (b) would achieve consistency with § 424.505, which states that all providers and suppliers seeking to bill Medicare must enroll in Medicare and adhere to all of subpart P's enrollment requirements.)

c. Specific Requirements for Home Infusion Therapy Supplier Enrollment

(1) Submission of Form CMS–855 and Certification

In § 424.68(c)(1)(i), we proposed that a home infusion therapy supplier must complete in full and submit the Form CMS–855B application (''Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers'') (OMB Control No.: 0938–0685), or its electronic or successor application, to its applicable Medicare contractor. The Form CMS–855B is typically completed by suppliers other than individual physicians and practitioners. We thus believed that the Form CMS–855B was the most suitable enrollment application for home infusion therapy suppliers.

In § 424.68(c)(1)(ii), we proposed that the home infusion therapy supplier must certify via the Form CMS–855B that it meets and will continue to meet the specific requirements and standards for enrollment described in § 424.68 and part 424, subpart P. This was to help ensure that the home infusion therapy supplier fully understands its obligation to maintain constant compliance with the requirements associated with enrollment.

(2) Payment of Application Fee

Under § 424.514, prospective and revalidating institutional providers that are submitting an enrollment application generally must pay the applicable application fee. (For CY 2020, the fee amount is $595.) In § 424.502, we define an institutional provider as any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and non-physician practitioner organizations, which are exempt from the fee requirement if they are enrolling as a physician or non-physician practitioner organization), Form CMS–855S, Form CMS–20134, or an associated internet-based PECOS enrollment application. Since a home infusion therapy supplier would need to complete the Form CMS–855B to enroll in Medicare as such (and would not be enrolling as a physician/non-physician organization), we believed that a home infusion therapy supplier would meet the definition of an institutional provider at § 424.502. Therefore, we proposed in § 424.68(c)(2) that a home infusion therapy supplier would be subject to the application fee requirements of § 424.514.

(3) Accreditation

Consistent with section 1861(iii)(3)(D)(i)(III) of the Act (codified in § 486.505), we proposed in new § 424.68(c)(3) that a home infusion therapy supplier must be currently and validly accredited as such by a CMS-recognized home infusion therapy supplier accreditation organization in order to enroll and remain enrolled in Medicare.

(4) Home Infusion Therapy Supplier Standards

Certain provisions in part 486, subpart I, and in part 414, subpart P, outline important quality standards and conditions of payment applicable to home infusion therapy suppliers. To help tie these requirements to the home infusion therapy supplier enrollment process, we proposed the following:

- In new § 424.68(c)(4), we proposed that in order to enroll and maintain enrollment as a home infusion therapy supplier, the latter must be compliant with § 414.1515 and all provisions of 42 CFR part 486, subpart I.
- In § 414.1505, we proposed to add a new paragraph (c) stating that, along with the requirements for home infusion therapy payment in paragraphs § 414.1505(a) and (b), the home infusion therapy supplier must also be enrolled in Medicare consistent with the provisions of § 424.68 and part 424, subpart P.

(5) Categorical Risk Designation

Section 424.518 addresses enrollment application screening categories based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular type of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type

poses, the greater the level of scrutiny with which CMS screens and reviews providers or suppliers within that category.

There are three categories of screening in § 424.518: limited, moderate, and high. Irrespective of which category a provider or supplier type falls within, the MAC performs the following screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location:

- Verifies that the provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.
- Conducts state license verifications.
- Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels, however, must also undergo a site visit. Furthermore, for those in the high categorical risk level, the MAC performs a fingerprint-based criminal history record check of all individuals with a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

As explained in the June 30, 2020 proposed rule, we have no recent evidence to suggest that home infusion therapy suppliers (as a supplier type) pose an enhanced threat of fraud, waste, or abuse that would warrant their placement in the moderate or high screening level. We thus proposed to include home infusion therapy suppliers within the limited screening category. Our specific regulatory revisions in this regard were: (1) Re-designating existing § 424.518(a)(1)(vii) through (xvi) as, respectively, § 424.518(a)(1)(viii) through (xvii); (2) including home infusion therapy suppliers in revised § 424.518(a)(vii); and (3) stating in new § 424.68(c)(5) that home infusion therapy suppliers must successfully complete the limited categorical risk level of screening under § 424.518.

d. Denial of Enrollment and Appeals Thereof

In new § 424.68(d)(1)(i) and (ii), respectively, we proposed that CMS may deny a home infusion therapy supplier's enrollment application on either of the following grounds:

- The home infusion therapy supplier does not meet all of the requirements for enrollment outlined in § 424.68 and in part 424, subpart P of this chapter; or
- Any of the reasons for denial of a prospective provider's or supplier's enrollment application in § 424.530 applies.

In new § 424.68(d)(2), we proposed that a home infusion therapy supplier may appeal the denial of its enrollment application under 42 CFR part 498.

e. Continued Compliance, Standards, and Reasons for Revocation

For reasons identical to those behind § 424.68(c), we proposed several provisions in new § 424.68(e).

In paragraph (e)(1), we proposed that, upon and after enrollment, a home infusion therapy supplier—

- Must remain currently and validly accredited as described in § 424.68(c)(3); and
- Remains subject to, and must remain in full compliance with, all of the provisions of—
  - ++ Section 424.68;
  - ++ Part 424, subpart P;
  - ++ Section 414.1515; and
  - ++ Part 486, subpart I.

In paragraph (e)(2), we proposed that CMS may revoke a home infusion therapy supplier's enrollment if—

- The supplier does not meet the accreditation requirements as described in § 424.68(c)(3);
- The supplier does not comply with all of the provisions of—
  - ++ Section 424.68;
  - ++ Part 424, subpart P;
  - ++ Section 414.1515; and
  - ++ Part 486, subpart I; or
- Any of the revocation reasons in § 424.535 applies.

In new paragraph (e)(3), we proposed that a home infusion therapy supplier may appeal the revocation of its enrollment under part 498.

f. Effective and Retrospective Date of Home Infusion Therapy Supplier Billing Privileges

Section 424.520 outlines the effective date of billing privileges for certain provider and supplier types that are eligible to enroll in Medicare. Section 424.520(d) sets forth the applicable effective date for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs. This effective date is the later of: (1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the supplier first began furnishing services at a new practice location. In a similar vein, § 424.521(a) states that physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs may retrospectively bill for services when the supplier has met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to—

- Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

To clarify the effective date of billing privileges for home infusion therapy suppliers and to account for circumstances that could prevent a home infusion therapy supplier's enrollment prior to the furnishing of Medicare services, we proposed to include newly enrolling home infusion therapy suppliers within the scope of both §§ 424.520(d) and 424.521(a). We believed that the effective and retrospective billing dates addressed therein achieve a proper balance between the need for the prompt provision of home infusion therapy services and the importance of ensuring that each prospective home infusion therapy enrollee is carefully and closely screened for compliance with all applicable requirements.

4. Comments Received and Responses

We received 12 comments from stakeholders regarding our proposed home infusion therapy supplier enrollment requirements. Summaries of these comments and our responses thereto are as follows:

Comment: Several commenters expressed concern that CMS will not accept Medicare enrollment applications from home infusion therapy suppliers until after this final rule is issued. They stated that this will give these suppliers only 2 months to complete the enrollment process before the home infusion therapy supplier benefit commences on January 1, 2021, thus delaying the provision of these services to beneficiaries.

Response: We recognize the limited timeframe between the issuance of this rule and January 1, 2021. However, we cannot accept applications from a new Medicare supplier type before any final regulatory provisions pertaining thereto have been made public. To permit suppliers to submit applications based on proposed regulatory provisions could lead to confusion for stakeholders,

especially if the final rule's provisions ultimately differ from those that we proposed. Nevertheless, and as with all incoming provider and supplier enrollment applications, Form CMS–855B submissions from home infusion therapy suppliers will be processed as expeditiously as feasible. We also note that our previously mentioned proposals to revise §§ 424.520(d) and 424.521(a) would permit home infusion therapy suppliers to back bill for certain services furnished prior to the date on which the MAC approved the supplier's enrollment application.

Comment: Several commenters stated that a number of home health agencies and hospices do not intend to enroll as Part B home infusion therapy suppliers. The commenters believed this could result in an insufficient number of such suppliers, especially in rural areas.

Response: We acknowledge the possibility that some entities that might otherwise qualify as home infusion therapy suppliers will elect not to pursue enrollment as such. This is the entity's independent choice. However, based on feedback received from the home infusion therapy community, we are confident that an adequate number of suppliers will enroll in Medicare, therefore helping to ensure beneficiary access to these services.

Comment: A commenter supported our establishment of measures designed to prevent fraudulent and unqualified home infusion therapy suppliers from entering Medicare. However, the commenter urged CMS to ensure that the measures are reasonable and equitable.

Response: We appreciate the commenter's support. We emphasize that our proposed enrollment requirements (for example, including home infusion therapy suppliers within the limited risk screening category rather than the moderate or high risk category) were carefully tailored to balance the need to protect the Trust Funds and beneficiaries from unqualified suppliers with the importance of limiting supplier burden to the extent possible.

Comment: A commenter agreed with CMS' proposal to place home infusion therapy suppliers in the limited risk screening category under § 424.518.

Response: We appreciate the commenter's support.

Comment: Several commenters asked CMS to clarify the specific supplier type that the enrolling home infusion therapy supplier should indicate on the Form CMS–855B.

Response: Until the Form CMS–855B is revised to include a specific supplier type category for home infusion therapy suppliers, such suppliers should, in the appropriate section of the current Form CMS–855B: (1) Indicate a supplier type of ''Other''; and (2) list ''home infusion therapy supplier'' in the space next thereto.

Comment: A number of commenters requested that CMS outline the enrollment and licensure requirements for home infusion therapy suppliers that—(1) operate in multiple jurisdictions; and/or (2) perform certain services through subcontractors. Regarding the first issue, several commenters contended that home infusion therapy suppliers should not be required to enroll in each MAC jurisdiction in which it performs services; besides being overly burdensome, they believed this would require the supplier to have a physical presence in each such jurisdiction (and perhaps even in each state that the MAC covers). These commenters requested that home infusion therapy suppliers be permitted to bill all MACs from a single location: (1) Without having to maintain fixed sites in every applicable MAC jurisdiction or state; and (2) with a single National Provider Identifier (NPI).

Response: It has long been general provider enrollment policy that Medicare providers and suppliers must be enrolled in each MAC jurisdiction (and, as applicable, licensed or certified in each state) in which it performs services, even if the provider or supplier does not have a physical practice location in that MAC and/or state. To illustrate, suppose a supplier has a single practice location in State X. The supplier sends its personnel out from this site to perform services in States X, Y, and Z; each of these states falls within a different MAC jurisdiction. The supplier must separately enroll with all three MACs if it wishes to receive Medicare payments for services provided in States X, Y, and Z. The purpose of this policy is to ensure that the applicable MAC can: (1) Verify the provider's or supplier's compliance with the state's requirements; and (2) make accurate payments. For this important reason, we believe home infusion therapy suppliers should be subject to this requirement as well.

Concerning the maintenance of fixed practice locations in each MAC jurisdiction in which services are performed, we recognize that home infusion therapy suppliers will often operate out of only one central location, with services occasionally furnished in homes located in various MAC jurisdictions and/or states. We will issue subregulatory guidance to address this issue for home infusion therapy suppliers in more detail.

As for the specific NPI situation the commenters raised, we refer the latter to the 2004 NPI Final Rule (*https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand/downloads/NPIfinalrule.pdf*), the NPI regulations at 45 CFR part 162, subpart D, and the ''Medicare Expectations Subpart Paper'' (the text of which is in CMS Publication 100–08, Medicare Program Integrity Manual, Chapter 15, section 15.3, at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf*.) In short, and based solely on the very general circumstances the commenters presented, the home infusion therapy supplier would not be required to obtain a separate NPI for each enrollment application it submits to each Part A/B MAC. Nonetheless, the facts of each case may differ, and we strongly encourage the commenters to review the aforementioned NPI Final Rule, NPI regulations, and Medicare Expectations Subpart Paper for more detailed guidance on how divergent scenarios should be handled.

As for home infusion therapy suppliers that subcontract the provision of certain services to another party, the enrolled supplier is ultimately responsible for ensuring that it meets and operates in compliance with all Medicare requirements, enrollment or otherwise.

Comment: A commenter expressed support for our proposal in § 424.68(b)(3) that a home infusion therapy supplier must be accredited in order to enroll in Medicare.

Response: We appreciate the commenter's support.

Comment: Several commenters stated that some pharmacies are enrolled in Medicare as suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) via the Form CMS–855S (OMB Control No. 0938–1056) in order to furnish external infusion pump items. (The National Supplier Clearinghouse (NSC) is the Medicare contractor that processes Form CMS–855S applications. Durable Medicare Equipment Medicare Administrative Contractors (DME MACs) process DMEPOS claims.) The commenters requested that such pharmacies also enrolling via the Form CMS–855B as home infusion therapy suppliers be able to use their existing NPI (that is, the same NPI utilized for their DMEPOS enrollment) when doing so. A commenter further requested that pharmacies enrolled as DMEPOS suppliers be permitted to have a single enrollment as a qualified home infusion therapy supplier; the commenter

believed this would enable pharmacies to submit all claims for items (for example, drugs and durable medical equipment) and services to the Part A/B MAC alone rather than to the DME MAC and the Part A/B MAC.

Response: Similar to our response to a previous NPI-related comment, we encourage these commenters to review the NPI Final Rule, NPI regulations, and Medicare Expectations Subpart Paper for guidance concerning the acquisition and use of NPIs. We do note (and subject to the provisions of the NPI Final Rule, NPI regulations, and the Medicare Expectations Subpart Paper) that there is no express prohibition against using the same NPI for enrollment with the NSC as a DMEPOS supplier and enrollment with the Part A/B MAC as another provider or supplier type (such as a home infusion therapy supplier). On the other hand, this does not mean that such dually-enrolled providers and suppliers can use a single Form CMS–855 to encompass both their NSC enrollment and their Part A/B MAC enrollment. The Forms CMS–855S and CMS–855B are separate applications specifically tailored to capture certain information unique to the different provider and supplier types they pertain to; as an illustration, allowing an entity to enroll as a DMEPOS supplier via the Form CMS–855B (as opposed to the DMEPOS-specific Form CMS–855S) would deprive the NSC of important data needed to verify the entity's compliance with all DMEPOS enrollment standards and requirements. Accordingly, we must respectfully decline the commenter's request for joint enrollment with the NSC and the Part A/B MAC via a single application.

5. Final Provisions

After reviewing the comments received, we are finalizing our provisions pertaining to home infusion therapy supplier enrollment as proposed.

VI. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment before the provisions of a rule take effect in accordance with section 4 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule (5 U.S.C. 553(b)(B)). We amended §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 to include a provision requiring ''allowed practitioners'' to certify and establish home health services as a condition for payment under the home health benefit. These changes are simply additional regulation text changes that were inadvertently left out of the final regulations text changes in the first IFC (85 FR 27550) and do not reflect any substantive changes in policy. Additionally, this regulatory change was subject to notice and comment rulemaking following the issuance of the first IFC. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into the CY 2021 final rule is unnecessary and contrary to the public interest, as these regulation text changes are required by section 3708 of the CARES Act.

VII. 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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. The Use of Telecommunications Technology Under the Medicare Home Health Benefit

As discussed in III.F. of this final rule, we finalized the proposal to require that any provision of remote patient monitoring or other services furnished via a telecommunications system must be included on the plan of care and cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for the purposes of eligibility or payment. We will still require the use of such telecommunications technology to be tied to the patient-specific needs as identified in the comprehensive assessment, but we will not require a description of how such technology will help to achieve the goals outlined on the plan of care. We also stated that we expect to see documentation of how such services will be used to help achieve the goals outlined on the plan of care throughout the medical record when such technology is used. The expectation to see such documentation in the medical record does not create any additional burden for HHAs given that information describing how home health services help achieve established goals is traditionally documented in the clinical record. Likewise, documenting in the clinical record is a usual and customary practice as described in the supporting statement for the Paperwork Reduction Act Submission, Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies, OMB Control No. 0938–1299.

B. Enrollment

This section discusses our proposed burden estimates for the enrollment of home infusion therapy suppliers as well as the PRA exemption we are claiming for the appeals process. As discussed in section V.B.3 of this final rule, home infusion therapy suppliers would be required to enroll in Medicare via the paper or internet-based version of the Form CMS–855B (''Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers'') (OMB Control Number: 0938–0685), or its electronic or successor application, and pay an application fee in accordance with § 424.514.

Using existing accreditation statistics and our internal data, we generally estimated that approximately: (1) 600 home infusion therapy suppliers would be eligible for Medicare enrollment under our provisions, all of whom would enroll in the initial year thereof; and (2) 50 home infusion therapy suppliers would annually enroll in Year 2 and in Year 3. This results in a total of 700 home infusion therapy suppliers enrolling over the next 3 years.

According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2019 (see *http://www.bls.gov/oes/current/oes_nat.htm*), the mean hourly wages for the following categories are:

TABLE 17: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Healthcare Diagnosing or Treating Practitioners	29-1000	49.26	49.26	98.52
Medical Secretaries and Administrative Assistants	43-6013	18.31	18.31	36.62

Consistent with Form CMS–855B projections made in recent rulemaking efforts, it would take each home infusion therapy supplier an average of 2.5 hours to obtain and furnish the information on the Form CMS–855B. Per our experience, the home infusion therapy supplier's medical secretary would secure and report this data, a task that would take approximately 2 hours. Additionally, a health diagnosing and treating practitioner of the home infusion therapy supplier would review and sign the form, a process we estimate takes 30 minutes. Therefore, we projected a first-year burden of 1,500 hours (600 suppliers × 2.5 hrs) at a cost of $73,500 (600 suppliers × ((2 hrs × $36.62/hr) + (0.5 hrs × $98.52/hr)), a second-year burden of 125 hours (50 suppliers × 2.5 hrs) at a cost of $6,125 (50 suppliers × ((2 hrs × $36.62/hr) + (0.5 hrs × $98.52/hr)), and a third-year burden of 125 hours (50 suppliers × 2.5 hrs) at a cost of $6,125 (50 suppliers × ((2 hrs × $36.62/hr) + (0.5 hrs × $98.52/hr)). In aggregate, we estimated a burden of 1,750 hours (1,500 hrs + 125 hrs + 125 hrs) at a cost of $85,750. When averaged over the typical 3-year OMB approval period, we estimate an annual burden of 583 hours (1,750 hrs/3) at a cost of $28,583 ($85,750/3).

We received no public comments on the foregoing burden estimates and are therefore finalizing them as proposed.

C. Appeals

As mentioned previously in this final rule, proposed § 424.68(d)(2) and (e)(3) state that a home infusion therapy supplier may appeal, respectively, the denial or revocation of its enrollment application under 42 CFR part 498. While there are information collection requirements associated with the appeals process, we believe they are exempt from the PRA. In accordance with the implementing regulations of the PRA at 5 CFR 1320.4(a)(2), the information collection requirements associated with the appeals process are subsequent to an administrative action (specifically, the denial or revocation of a home infusion therapy supplier enrollment application). Therefore, we have not developed burden estimates. We also noted our belief that any costs associated with home infusion therapy supplier appeals would, in any event, be *de minimis;* this is because we would anticipate, based on past experience, there would be comparatively few denials and revocations of home infusion therapy supplier enrollments.

We received no public comments on burden estimates related to the appeals provisions and are therefore finalizing them as proposed.

D. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule, please visit the CMS website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at (410) 786–1326.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. Home Health Prospective Payment System (HH PPS)

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the applicable home health percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act requires the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Section 50208 of the BBA of 2018 (Pub. L. 115–123) requires the Secretary to implement a new methodology used to determine rural add-on payments for CYs 2019 through 2022.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, required the Secretary to implement a 30-day unit of service, for 30-day periods beginning on and after January 1, 2020. The HH PPS wage index utilizes the wage adjustment factors used by the Secretary for purposes of Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act for hospital wage adjustments. In this final rule, we are adopting the new OMB delineations and applying a 5-percent cap only in CY 2021 on any decrease in a geographic

area's wage index value from the wage index value from the prior calendar year. This transition allows the effects of our adoption of the revised CBSA delineations to be phased in over 2 years, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in CY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (CY 2022)).

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 801(a)(1)(B)(i)), 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 1 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. Given that, we note the following costs associated with the provisions of this final rule:

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The net transfer impact related to the changes in payments under the HH PPS for CY 2021 is estimated to be $390 million (1.9 percent). Therefore, we estimate that this rule 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 presents our best estimate of the costs and benefits of this rule.

C. Anticipated Effects

1. HH PPS

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has 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. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs and home infusion therapy suppliers are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies in this final rule would not result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS final rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule is not applicable to hospitals. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $156 million or more.

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. We have reviewed this final rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

2. HH QRP

We did not propose any changes to the HH QRP. Therefore, we are not providing any estimated impacts.

3. Change to the CoP OASIS Requirement

No impact was assessed for this provision in the January 13, 2017 final rule titled ''Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies (82 FR 4504). Therefore, we do not believe that there are any burden reductions to be assessed when removing this requirement.

4. Reporting Under the Home Health Value Based Purchasing (HHVBP) Model During the COVID–19 PHE

Section IV.C of this rule finalizes a policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID–19 PHE, as well as a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the COVID–19 PHE. We do not anticipate a change to Medicare expenditures as a result of this policy. The overall economic impact of the HHVBP Model for CYs 2018 through 2022 is an estimated $378 million in total savings to Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality

improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model as a result of this policy.

5. Payment for Home Infusion Therapy Services

In the CY 2020 HH PPS final rule with comment period, we estimated that the implementation of the permanent home infusion therapy benefit would result in a 3.6 percent decrease ($2 million) in payments to home infusion therapy suppliers in CY 2021 (84 FR 60639). This decrease reflects the exclusion of statutorily-excluded drugs and biologicals, and is representative of a wage-adjusted 4-hour payment rate, compared to a wage-adjusted 5-hour payment rate.

There were no new proposals related to payments for home infusion therapy services in CY 202l. The CY 2021 final PFS amounts were not available at the time of rulemaking; however any impact to the CY 2021 home infusion therapy payment amounts are be attributed to changes in the PFS amounts for 2021. The impact of updating the payment rates for home infusion therapy services for CY 2021, based on the proposed PFS amounts for CY 2021, is a 0.7 percent decrease ($384,800) in payments to eligible home infusion therapy suppliers in CY 2021.

6. Home Infusion Therapy Supplier Requirements

As stated previously, we proposed that home infusion therapy suppliers be required to enroll in Medicare and pay an application fee at the time of enrollment in accordance with § 424.514.

The application fees for each of the past 3 calendar years were or are $569 (CY 2018), $586, (CY 2019), and $595 (CY 2020). Consistent with § 424.514, the differing fee amounts are predicated on changes/increases in the Consumer Price Index (CPI) for all urban consumers (all items; United State city average, CPI–U) for the 12-month period ending on June 30 of the previous year. Although we could not predict future changes to the CPI, the fee amounts between 2018 and 2020 increased by an average of $13 per year. We believed this was a reasonable barometer with which to establish estimates (strictly for purposes of the final rule) of the fee amounts in the first 3 CYs of this rule (that is, 2021, 2022, and 2023). Thus, we projected a fee amount of $608 in 2021, $621 for 2022, and $634 for 2023.

Applying these prospective fee amounts to the number of projected applicants in the rule's first 3 years, we estimated a total application fee cost to enrollees of $364,800 (or 600 × $608) in the first year, $31,050 (or 50 × $621) in the second year, and $31,700 (or 50 × $634) in the third year. (This constituted an average annual figure of $142,517 over the first 3 years of this rulemaking). As referenced in Table 1 of this final rule, this would represent a transfer from home infusion therapy suppliers to the federal government. We received no comments concerning our projected application fee transfers and are therefore finalizing them as proposed.

As noted in Table 1 and section VII.B. of this final rule, the estimated average annual burden associated with home infusion therapy supplier enrollment over the 3-year OMB approval period is 583 hours at a cost of $28,583.

7. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique reviewers of this year's final rule would be the similar to the number of reviewers on this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. While we solicited comments on the approach in estimating the number of entities which would review the proposed rule and the assumption of how much of the rule reviewers would read, we did not receive any comments.

Therefore, using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 1.80 hours for the staff to review half of this final rule, which consists of approximately 54,079 words. For each HHA that reviews the rule, the estimated cost is $199.33 (1.80 hours × $110.74). Therefore, we estimate that the total cost of reviewing this final rule is $32,291 ($199.33 × 162 reviewers). For purposes of this estimate, the number of reviewers of this year's rule is equivalent to the number of comments received for the CY 2021 HH PPS proposed rule.

D. Detailed Economic Analysis

This rule finalizes updates to Medicare payments under the HH PPS for CY 2021. The impact analysis of this final rule presents the estimated expenditure effects of policy changes finalized in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case mix. This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based primarily on Medicare claims data for episodes ending on or before December 31, 2019. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 18 represents how HHA revenues are likely to be affected by the policy changes in this final rule for CY 2021. For this analysis, we used an analytic file with linked CY 2019 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2019. The first column of Table 18 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of updating to the CY 2021 wage index. The fourth column shows the effects of

moving from the old OMB delineations to the new OMB delineations with a 5 percent cap on wage index decreases. The fifth column shows the payment effects of the CY 2021 rural add-on payment provision in statute. The sixth column shows the payment effects of the CY 2021 home health payment update percentage and the last column shows the combined effects of all the policies finalized in this rule.

Overall, it is projected that aggregate payments in CY 2021 would increase by 1.9 percent. As illustrated in Table 18, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2021 wage index, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

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TABLE 18: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2021

	Number of Agencies	CY 2021 Updated Wage Index (CY 2020 Payments)	OMB Delineations with 5% Cap	CY 2021 Rural Add-On	CY 2021 HH Payment Update Percentage	Total
All Agencies	**9,808**	**0.0%**	**0.0%**	**-0.1%**	2.0%	**1.9%**
Facility Type and Control						
Free-Standing/Other Vol/NP	970	0.0%	0.0%	-0.1%	2.0%	1.9%
Free-Standing/Other Proprietary	7,910	0.0%	0.0%	-0.1%	2.0%	1.9%
Free-Standing/Other Government	198	0.3%	0.1%	-0.4%	2.0%	2.0%
Facility-Based Vol/NP	511	0.1%	0.1%	-0.2%	2.0%	2.0%
Facility-Based Proprietary	58	-0.1%	0.4%	-0.3%	2.0%	2.0%
Facility-Based Government	161	-0.2%	0.1%	-0.4%	2.0%	1.5%
Subtotal: Freestanding	9,078	0.0%	0.0%	-0.1%	2.0%	1.9%
Subtotal: Facility-based	730	0.1%	0.1%	-0.2%	2.0%	2.0%
Subtotal: Vol/NP	1,481	0.0%	0.0%	-0.2%	2.0%	1.8%
Subtotal: Proprietary	7,968	0.0%	0.0%	-0.1%	2.0%	1.9%
Subtotal: Government	359	0.0%	0.1%	-0.4%	2.0%	1.7%
Facility Type and Control: Rural						
Free-Standing/Other Vol/NP	234	0.3%	0.0%	-0.8%	2.0%	1.5%
Free-Standing/Other Proprietary	817	0.1%	0.0%	-0.5%	2.0%	1.6%
Free-Standing/Other Government	133	0.1%	0.1%	-0.9%	2.0%	1.3%
Facility-Based Vol/NP	232	0.0%	0.0%	-0.8%	2.0%	1.2%
Facility-Based Proprietary	26	0.5%	0.5%	-0.7%	2.0%	2.3%
Facility-Based Government	123	0.2%	0.0%	-0.8%	2.0%	1.4%
Facility Type and Control: Urban						
Free-Standing/Other Vol/NP	736	-0.1%	0.0%	-0.1%	2.0%	1.8%
Free-Standing/Other Proprietary	7,093	0.0%	0.0%	-0.1%	2.0%	1.9%
Free-Standing/Other Government	65	0.4%	0.1%	-0.1%	2.0%	2.4%
Facility-Based Vol/NP	279	0.1%	0.1%	-0.1%	2.0%	2.1%
Facility-Based Proprietary	32	-0.4%	0.3%	-0.1%	2.0%	1.8%
Facility-Based Government	38	-0.5%	0.1%	-0.1%	2.0%	1.5%
Facility Location: Urban or Rural						
Rural	1,565	0.1%	0.0%	-0.6%	2.0%	1.5%
Urban	8,243	0.0%	0.0%	-0.1%	2.0%	1.9%
Facility Location: Region of the Country (Census Divisions)						
New England	336	-1.0%	-0.1%	-0.1%	2.0%	0.8%
Mid Atlantic	452	0.7%	0.2%	-0.1%	2.0%	2.8%
East North Central	1,750	0.2%	-0.1%	-0.2%	2.0%	1.9%
West North Central	652	-0.6%	0.0%	-0.3%	2.0%	1.1%
South Atlantic	1,569	0.0%	0.0%	-0.1%	2.0%	1.9%
East South Central	381	0.0%	0.0%	-0.3%	2.0%	1.7%
West South Central	2,387	0.1%	0.0%	-0.1%	2.0%	2.0%
Mountain	689	-0.3%	-0.1%	-0.1%	2.0%	1.5%
Pacific	1,552	0.0%	0.1%	0.0%	2.0%	2.1%
Outlying	40	-1.2%	-0.2%	-0.1%	2.0%	0.5%

	Number of Agencies	CY 2021 Updated Wage Index (CY 2020 Payments)	OMB Delineations with 5% Cap	CY 2021 Rural Add-On	CY 2021 HH Payment Update Percentage	Total
Facility Size (Number of 60-day Episodes)						
< 100 episodes	2,491	-0.1%	0.0%	-0.1%	2.0%	1.8%
100 to 249	1,989	-0.1%	0.0%	-0.1%	2.0%	1.8%
250 to 499	2,044	-0.1%	0.0%	-0.1%	2.0%	1.8%
500 to 999	1,687	-0.1%	0.0%	-0.1%	2.0%	1.8%
1,000 or More	1,597	0.0%	0.0%	-0.1%	2.0%	1.9%

Source: CY 2019 Medicare claims data for episodes ending on or before December 31, 2019 for which we had a linked OASIS assessment (as of July 13, 2020).

Notes: Impacts were calculated using 8,744,171 simulated 30-day periods. This analysis omits 721,240 simulated 30-day periods not grouped under the PDGM (either due to a missing Start of Care (SOC) OASIS, because they could not be assigned to a clinical grouping, or had missing therapy/nursing visits). Additionally, another 42,998 periods were excluded with missing wage index information, a further 7 periods were excluded with missing NRS weights, and 2,074 periods with a missing urban/rural indicator. The standard 30-day payment amount used to achieve impact neutrality does not incorporate any behavioral assumptions. PDGM impacts were modeled using CY2020 payment parameters, wage indexes, and rural add-on policy, with a 30-day standard amount of $1,864.03.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York;
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
Pacific=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

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E. Alternatives Considered

For the CY 2021 HH PPS proposed rule, we considered alternatives to the proposals articulated in section III.B. of this final rule. We considered not adopting the OMB delineations. However, we have historically adopted the latest OMB delineations as we believe that implementing the new OMB delineations would result in wage index values being more representative of the actual costs of labor in a given area. Additionally, we considered not implementing the 1-year 5-percent cap on wage index decreases. While there are some minimal impacts on certain HHAs as a result of this 5-percent cap as shown in the regulatory impact analysis of this final rule, we decided that the 5-percent cap was a better option for the transition because it would mitigate potential negative impacts from the transition to the new OMB delineations and allow providers the opportunity to adjust to the changes in their wage index values gradually.

F. Accounting Statement and Tables

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 19, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2021 HH PPS provisions of this rule.

TABLE 19: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2020 TO 2021

Category	Transfers
Annualized Monetized Transfers	$390 million
From Whom to Whom?	Federal Government to HHAs

G. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled ''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. It has been determined that this final rule is an action that primarily results in transfers and does not impose more than de minimis costs as described previously and thus is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

H. Conclusion

In conclusion, we estimate that the provisions in this final rule would result in an estimated net increase in HH payments of 1.9 percent for CY 2021 ($390 million). The $390 million increase in estimated payments for CY 2021 reflects the effects of the CY 2021 home health payment update percentage of 2.0 percent ($410 million increase) and an estimated −0.1 percent decrease in payments due to the rural add-on percentages mandated by the Bipartisan Budget Act of 2018 for CY 2021 ($20 million decrease).

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements

42 CFR Part 424

Emergency medical centers, Health facilities, Health professions, Medicare, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

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

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

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 409.43 is amended by revising paragraphs (a) introductory text, (a)(1), and (3) to read as follows:

§ 409.43 Plan of care requirements.

(a) *Contents.* An individualized plan of care must be established and periodically reviewed by the certifying physician or allowed practitioner.

(1) The HHA must be acting upon a plan of care that meets the requirements of this section for HHA services to be covered.

* * * * *

(3)(i) The plan of care must include all of the following:

(A) The identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in § 484.60(a) of this chapter that establish the need for such services.

(B) Any provision of remote patient monitoring or other services furnished via telecommunications technology (as defined in § 409.46(e)) or audio-only technology. Such services must be tied to the patient-specific needs as identified in the comprehensive assessment, cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for the purposes of patient eligibility or payment.

(ii) All care provided must be in accordance with the plan of care.

* * * * *

■ 3. Section 409.46 is amended by revising paragraph (e) to read as follows:

§ 409.46 Allowable administrative costs.

* * * * *

(e) *Telecommunications technology.* Telecommunications technology, as indicated on the plan of care, can include: remote patient monitoring, defined as the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient or caregiver or both to the home health agency; teletypewriter (TTY); and 2-way audio-video telecommunications technology that allows for real-time interaction between the patient and clinician. The costs of any equipment, set-up, and service related to the technology are allowable only as administrative costs. Visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the technology, without the provision of a skilled service, are not separately billable.

■ 4. Section 409.49 is amended by adding paragraph (h) to read as follows:

§ 409.49 Excluded services.

* * * * *

(h) *Services covered under the home infusion therapy benefit.* Services that are covered under the home infusion therapy benefit as outlined at § 486.525 of this chapter, including any home infusion therapy services furnished to a Medicare beneficiary that is under a home health plan of care, are excluded from coverage under the Medicare home health benefit. Excluded home infusion therapy services pertain to the items and services for the provision of home infusion drugs, as defined at § 486.505 of this chapter. Services for the provision of drugs and biologicals not covered under this definition may continue to be provided under the Medicare home health benefit.

■ 5. Section 409.64 is amended by revising paragraph (a)(2)(ii) to read as follows:

§ 409.64 Services that are counted toward allowable amounts.

* * * * *

(a) * * *

(2) * * *

(ii) The hospital, CAH, SNF, or home health agency had submitted all necessary evidence, including physician or allowed practitioner certification of need for services when such certification was required;

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 6. The authority citation for part 410 continues to read as follows:

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

■ 7. Section 410.170 is amended by revising paragraph (b) to read as follows:

§ 410.170 Payment for home health services, for medical and other health services furnished by a provider or an approved ESRD facility, and for comprehensive outpatient rehabilitation facility (CORF) services: Conditions.

* * * * *

(b) *Physician or allowed practitioner certification.* For home health services, a physician or allowed practitioner provides certification and recertification in accordance with § 424.22 of this chapter.

* * * * *

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

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

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

■ 9. Section 414.1505 is amended by adding paragraph (c) to read as follows:

§ 414.1505 Requirement for payment.

* * * * *

(c) The home infusion therapy supplier must be enrolled in Medicare consistent with the provisions of § 424.68 and part 424, subpart P of this chapter.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 10. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 11. Section 424.68 is added to subpart E to read as follows:

§ 424.68 Enrollment requirements for home infusion therapy suppliers.

(a) *Definition.* For purposes of this section, a home infusion therapy supplier means a supplier of home infusion therapy that meets all of the following requirements:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Is enrolled in Medicare as a home infusion therapy supplier consistent with the provisions of this section and subpart P of this part.

(b) *General requirement.* For a supplier to receive Medicare payment for the provision of home infusion therapy supplier services, the supplier must qualify as a home infusion therapy supplier (as defined in this section) and be in compliance with all applicable provisions of this section and of subpart P of this part.

(c) *Specific requirements for enrollment.* To enroll in the Medicare program as a home infusion therapy supplier, a home infusion therapy supplier must meet all of the following requirements:

(1)(i) Fully complete and submit the Form CMS–855B application (or its electronic or successor application) to its applicable Medicare contractor.

(ii) Certify via the Form CMS–855B that the home infusion therapy supplier meets and will continue to meet the specific requirements and standards for enrollment described in this section and in subpart P of this part.

(2) Comply with the application fee requirements in § 424.514.

(3) Be currently and validly accredited as a home infusion therapy supplier by a CMS-recognized home infusion therapy supplier accreditation organization.

(4) Comply with § 414.1515 of this chapter and all provisions of part 486, subpart I of this chapter.

(5) Successfully complete the limited categorical risk level of screening under § 424.518.

(d) *Denial of enrollment.* (1) Enrollment denial by CMS. CMS may deny a supplier's enrollment application as a home infusion therapy supplier on either of the following grounds:

(i) The supplier does not meet all of the requirements for enrollment outlined in § 424.68 and in subpart P of this part.

(ii) Any of the applicable denial reasons in § 424.530.

(2) Appeal of an enrollment denial. A supplier may appeal the denial of its enrollment application as a home infusion therapy supplier under part 498 of this chapter.

(e) *Continued compliance, standards, and reasons for revocation.* (1) Upon and after enrollment, a home infusion therapy supplier—

(i) Must remain currently and validly accredited as described in paragraph (c)(3) of this section.

(ii) Remains subject to, and must remain in full compliance with, all of the provisions of—

(A) This section;

(B) Subpart P of this part;

(C) Section 414.1515 of this chapter; and

(D) Part 486, subpart I of this chapter.

(2) CMS may revoke a home infusion therapy supplier's enrollment on any of the following grounds:

(i) The supplier does not meet the accreditation requirements as described in paragraph (c)(3) of this section.

(ii) The supplier does not comply with all of the provisions of—

(A) This section;

(B) Subpart P of this part;

(C) Section 414.1515 of this chapter; and

(D) Part 486, subpart I of this chapter; or

(iii) Any of the revocation reasons in § 424.535 applies.

(3) A home infusion therapy supplier may appeal the revocation of its enrollment under part 498 of this chapter.

■ 12. Section 424.518 is amended by redesignating paragraphs (a)(1)(vii) through (xvi) as paragraphs (a)(1)(viii) through (xvii) and adding a new paragraph (a)(1)(vii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(a) * * *

(1) * * *

(vii) Home infusion therapy suppliers.

* * * * *

■ 13. Section 424.520 is amended by revising paragraph (d) introductory text to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) *Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers.* The effective date for billing privileges for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers is the later of—

* * * * *

■ 14. Section 424.521 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 424.521 Request for payment by physicians, non-physician practitioners, physician and non-physician organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers.

(a) Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers may retrospectively bill for services when the physician, non-physician practitioner, physician or non-physician organization, ambulance supplier, opioid treatment program, or home infusion therapy supplier has met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to—

* * * * *

PART 484—HOME HEALTH SERVICES

■ 15. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 484.45 [Amended]

■ 16. Section 484.45 is amended by—
■ a. Removing paragraph (c)(2); and
■ b. Redesignating paragraphs (c)(3) and (4) as paragraphs (c)(2) and (3), respectively.

■ 17. Section 484.110 is amended by revising the introductory text and paragraph (a)(1) to read as follows:

§ 484.110 Condition of participation: Clinical records.

The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) or allowed practitioner(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

(a) * * *

(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician or allowed practitioner orders;

* * * * *

Dated: October 23, 2020.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 26, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–24146 Filed 10–29–20; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 85 Wednesday,

No. 214 November 4, 2020

Part IV

Department of Health and Human Services

Centers for Medicare and Medicaid Services

42 CFR Part 414

Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS); Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1738–P]

RIN 0938–AU17

Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish methodologies for adjusting the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule amounts using information from the Medicare DMEPOS competitive bidding program for items furnished on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Social Security Act, whichever is later; application evaluation processes and other procedures related to Healthcare Common Procedure Coding System (HCPCS) Level II code applications; and procedures for making benefit category and payment determinations for new items and services that are durable medical equipment (DME), prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B. In addition, this rule proposes to classify continuous glucose monitors (CGMs) as DME under Medicare Part B and establish fee schedule amounts for these items and related supplies and accessories. Also, this proposed rule would expand the scope of the Medicare Part B benefit for DME by revising the interpretation of the ''appropriate for use in the home'' requirement in the definition of DME specifically for certain drugs or biologicals infused in the home using an external infusion pump. This proposed rule would also make conforming changes to the regulations related to implementation of section 106 of the Further Consolidated Appropriations Act, 2020.

DATES: To be assured consideration, comments must be received at one of the addresses specified in the **ADDRESSES** section, no later than 5 p.m. on January 4, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1738–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1738–P, P.O. Box 8013, Baltimore, MD 21244–8010.

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–1738–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: *DMEPOS@cms.hhs.gov* or Alexander Ullman, 410–786–9671, for issues related to the DMEPOS payment policy.

HCPCS@cms.hhs.gov or Kim Campbell, 410–786–2289, for issues related to HCPCS.

HomeInfusionPolicy@cms.hhs.gov for issues related to home infusion therapy services payment policy.

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.

I. Executive Summary

A. Purpose

This proposed rule contains proposals related to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Amounts to ensure access to items and services in rural areas, procedures for making benefit category and payment determinations for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations to prevent delays in coverage of new items and services, classification and payment for CGMs under the Part B benefit for DME to establish the benefit category and payment rules for these items, and the HCPCS Level II code application process to increase transparency and gather public input on proposed code application procedures. This proposed rule would expand the scope of the Medicare Part B benefit for DME by revising the interpretation of the ''appropriate use in the home'' requirement in the definition of DME at 42 CFR 414.202. External infusion pumps used to administer certain drugs or biologicals in the home would meet the definition of DME in cases where assistance in the patient's home from a skilled home infusion therapy supplier is necessary during the infusion and these home infusion therapy services are separately covered and paid for by Medicare under the home infusion therapy services benefit. This proposed rule would also make conforming changes to the regulations related to implementation of section 106 of the Further Consolidated Appropriations Act, 2020.

1. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

The purpose of this proposal is to establish the methodologies for adjusting the fee schedule payment amounts for DMEPOS items and services furnished in non-competitive bidding areas (non-CBAs) on or after April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (the Act) (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later. The emergency period we are referring to is the Public Health Emergency (PHE) for coronavirus disease 2019 (COVID–19). We refer readers to section II.A.6. of this rule for details regarding the DMEPOS fee schedule changes CMS has already made as a result of the PHE for COVID–19. CMS previously established transition rules for phasing in the fee schedule adjustments under 42 CFR 414.210(g)(9), and these rules address the phase in of the fee schedule adjustments for items furnished through

December 31, 2020. The purpose of this proposal is to establish revised DMEPOS fee schedule adjustment methodologies for items and services furnished in non-CBAs on or after April 1, 2021 or the date immediately following the duration of the PHE for COVID–19, whichever is later.

2. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

The purpose of this section is to address our intent to finalize and address comments received on the May 11, 2018 interim final rule (83 FR 21912) entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To provide Relief in Rural Areas and Non-Contiguous Areas'' including comments related to the conforming amendment excluding infusion drugs from the DMEPOS CBP.

3. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

CMS establishes and maintains certain codes under the HCPCS Level II and is responsible for making decisions about additions, revisions, and discontinuations to those codes. This proposed rule proposes application procedures and evaluation processes for external HCPCS Level II code applications related to drug or biological products, and non-drug, non-biological items and services, as defined in this proposed rule.

4. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, or Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

The purpose of this proposal is to establish procedures for making benefit category and payment determinations for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations that permit public consultation through public meetings. Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) requires the Secretary to establish procedures for coding and payment determinations for new DME under part B of title XVIII of the Act that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for ICD–9–CM (which has since been replaced with ICD–10–CM as of October 1, 2015). CMS decided to expand these procedures to all new items and services in 2005. We are proposing to codify in regulation procedures for making benefit category determinations and payment determinations for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations. Consistent with current CMS practice, the proposed procedures will incorporate public consultation on these determinations.

Whether or not an item or service falls under a Medicare benefit category, such as the Medicare Part B benefit category for DME, is a necessary step in determining whether an item may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the items and services. If the item is excluded from coverage by the Act or does not fall within the scope of a defined benefit category, the item cannot be covered under Title XVIII. On the other hand, if the item is not excluded from coverage by the Act and is found to fall within a benefit category, we will need to determine what payment rules would apply to the item if other statutory criteria for coverage of the item are met, such as whether the item or service meets the reasonable and necessary criteria under section 1862(a)(1)(A) of the Act.

Therefore, we are proposing procedures for use in determining if items and services fall under the Medicare Part B benefit categories for DME, prosthetic devices, orthotics, and prosthetics, surgical dressings, splints, casts and other devices for the reduction of fractures or dislocations, or therapeutic shoes and inserts, in order to promote transparency, continue our longstanding practice of establishing coverage and payment for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations soon after they are identified through the HCPCS code application process, and prevent delays in access to new technologies that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations.

5. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

The purpose of this proposed rule is to address classification and payment for CGMs under the Medicare Part B benefit for DME.

6. Expanded Classification of External Infusion Pumps as DME

The purpose of this proposed rule is to revise our interpretation of the ''appropriate for use in the home'' requirement at 42 CFR 414.202 as it applies to certain external infusion pumps. We are proposing that an external infusion pump would be considered ''appropriate for use in the home'' if: (1) The Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both; (2) a qualified home infusion therapy supplier (as defined at § 486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at § 486.505); and (3) the FDA-required labeling specifies infusion via an external infusion pump as a route of administration, at least once per month, for the drug. The home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump. Under our proposal, if an individual or caregiver is unable to safely and effectively administer certain infusion drugs, such drugs could be covered as supplies necessary for the effective use of an external infusion pump under the DME benefit if the criteria listed previously is satisfied (and, presumably, the external infusion pump satisfies all other relevant statutory and regulatory requirements for DME).

7. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs From the CBP

Section 106 of the Further Consolidated Appropriations Act, 2020 excludes complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories from the DMEPOS CBP as well as from fee schedule adjustments based on

information from the DMEPOS CBP. This provision became effective January 1, 2020, and we are currently implementing this provision through program instructions, as authorized by section 106 of the Further Consolidated Appropriations Act, 2020. This rule proposes to make conforming changes to the regulations to reflect section 106 of the Further Consolidated Appropriations Act, 2020.

B. Summary of the Major Provisions

1. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

This rule proposes to revise § 414.210(g)(2) and (9) to establish the fee schedule adjustment methodologies for items and services furnished on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, in non-CBAs.

2. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

We indicate in this rule our plan to finalize the May 11, 2018 interim final rule (83 FR 21912) entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To provide Relief in Rural Areas and Non-Contiguous Areas'' that resumed the transitional 50/50 blended rates for items furnished in rural areas and noncontiguous areas from June 1, 2018 through December 31, 2018, including the conforming amendment to exclude infusion drugs from the DMEPOS CBP.

3. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

This proposed rule proposes application procedures and evaluation processes for external HCPCS Level II code applications:

- *Coding cycles for code applications:* This rule proposes specific coding cycles for drug or biological products, and non-drug, non-biological items and services, as defined in this proposed rule, including timeframes for application submission and final decisions; and additional procedures and exceptions to these proposed processes.
- *Processes for Evaluating Coding Applications:* This rule proposes processes that CMS would use to evaluate code applications to determine whether to add, revise, or discontinue a code for drug or biological products, and non-drug, non-biological items and services, as defined in this proposed rule.

4. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, or Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

This proposed rule would establish procedures for making benefit category and payment determinations for items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations for which a HCPCS Level II code has been requested. Specifically, the purpose of the procedure would be to determine whether the product for which a HCPCS code has been requested meets the Medicare definition of DME, a prosthetic device, an orthotic or prosthetic, a surgical dressing, splint, cast, or other device used for reducing fractures or dislocations, or a therapeutic shoe or insert and is not otherwise excluded under Title XVIII, to determine how payment for the item of service would be made, and to obtain public consultation on these determinations.

5. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

This rule proposes to classify all CGMs as DME and addresses the payment for different types of CGMs, as well as supplies and accessories used with CGMs. Additional determinations regarding whether a CGM is covered in accordance with section 1862(a)(1)(A) of the Act, or is otherwise excluded under Title XVIII, will be made by DME MACs using the local coverage determination process or during the Medicare claim-by-claim review process.

6. Expanded Classification of External Infusion Pumps as DME

We propose to interpret the ''appropriate for use in the home'' requirement within the definition of DME at 42 CFR 414.202 to be met for certain external infusion pump if: (1) The Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both; (2) a qualified home infusion therapy supplier (as defined at § 486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at § 486.505); and (3) the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug. The home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump.

7. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs From the DMEPOS CBP

This rule proposes to revise the definition of ''item'' under the CBP at 42 CFR 414.402 to exclude complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories as required by section 106(a) of the Further Consolidated Appropriations Act, 2020.

C. Summary of Cost and Benefits

1. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

We estimate that the payment methodologies described in section I.B.1. of this proposed rule would have no fiscal impact because the Office of the Actuary has determined that this provision neither increases nor decreases spending from what is assumed in the FY 2021 President's Budget.

2. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

As we are signaling an intent to finalize an IFC that was already promulgated in 2018, there would be no fiscal impacts associated with this policy. The fiscal impacts of this IFC are considered to have already occurred.

3. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

This rule proposes to continue certain existing code application policies and processes and proposes certain new coding policies and procedures. All proposed policies and procedures are assumed to have no fiscal impact when

considered against the FY 2021 President's Budget baseline.

4. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, or Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

This rule proposes to establish a process for making benefit category and payment determinations for items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations and is assumed to have an indeterminable fiscal impact due to the unique considerations given to establishing payment for specific items.

5. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

This rule proposes to classify all CGMs as DME and addresses the payment for different types of CGMs. This classification is assumed to have no fiscal impact when considered against the FY 2021 President's Budget baseline.

6. Expanded Classification of External Infusion Pumps as DME

This rule proposes that an external infusion pump would be considered ''appropriate for use in the home'' in accordance with the definition of DME at 42 CFR 414.202 if: (1) The Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both; (2) a qualified home infusion therapy supplier (as defined at § 486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at § 486.505); and (3) the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug. The home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump. This expanded classification is assumed to be a small savings to Medicare in CY 2021 when considered against the FY 2021 President's Budget baseline.

7. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs From the DMEPOS CBP

This rule proposes to revise the definition of ''item'' at 42 CFR 414.402 to exclude complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories as required by section 106(a) of the Further Consolidated Appropriations Act, 2020 and is assumed to have no fiscal impact. These conforming changes to the regulations have no impact since the exclusion of these items from the CBP is mandated by the statute.

II. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

A. Background

1. DMEPOS Competitive Bidding Program

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), mandates the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) for contract award purposes in order to furnish certain competitively priced DMEPOS items and services subject to the CBP:

- Off-the-shelf (OTS) orthotics, for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment, and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

Section 1847(a) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement CBPs in competitive bidding areas (CBAs) throughout the U.S. Section 1847(a)(1)(B)(i) of the Act mandates that the programs be phased into 100 of the largest metropolitan statistical areas (MSA) by 2011 and additional areas after 2011. Thus far, CBAs have been either an MSA or a part of an MSA. Under the Office of Management and Budget (OMB) standards for delineating MSAs, MSAs have at least one urbanized area that has a population of at least 50,000. The MSA comprises the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county or counties as measured through commuting.[1] OMB updates MSAs regularly and the most recent update can be found in OMB Bulletin No. 20–01.[2] The statute allows us to exempt rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service, from the CBP. We may also exempt from the CBP items and services for which competitive acquisition is unlikely to result in significant savings.

We refer to areas in which the CBP is not or has not been implemented as non-competitive bidding areas (non-CBAs). There are currently no CBAs due to a gap period in the DMEPOS CBP, however, we use the term ''former CBAs'' to refer to the areas that were formerly CBAs prior to the gap in the CBP, in order to distinguish those areas from ''non-CBAs.'' More information on why there are currently no CBAs can be found in the November 14, 2018 final rule entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS,'' (83 FR 56922) (hereinafter CY 2019 ESRD PPS DMEPOS final rule).

Non-CBAs include rural areas, non-rural areas, and non-contiguous areas. A rural area is defined in 42 CFR 414.202 as a geographic area represented by a postal ZIP code, if at least 50 percent of the total geographic area of the area included in the ZIP code is estimated to be outside any MSA. A rural area also includes a geographic area represented by a postal ZIP code that is a low population density area excluded from a CBA in accordance with section 1847(a)(3)(A) of the Act at the time the rules in § 414.210(g) are applied. Non-contiguous areas refer to areas outside the contiguous U.S.—that is, areas such as Alaska, Guam, and Hawaii (81 FR 77936).

[1] OMB 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas; Notice, June 28, 2010 (75 FR 37252).

[2] *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf?#.*

2. Payment Methodology for CBAs

In the DMEPOS CBP, suppliers bid for contracts for furnishing multiple items and services, identified by HCPCS codes, under several different product categories. In the CY 2019 ESRD PPS DMEPOS final rule, we made significant changes to how we calculate single payment amounts (SPAs) under the DMEPOS CBP. Prior to these changes, for individual items within each product category in each CBA, the median of the winning bids for each item was used to establish the SPA for that item in each CBA. As a result of the changes we made in the CY 2019 ESRD PPS DMEPOS final rule, SPAs are calculated for the lead item in each product category (per § 414.402, the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition) based on the maximum winning bid (the highest of bids submitted by winning suppliers) in each CBA. Per § 414.416(b)(3), the SPA for each non-lead item in a product category (all items other than the lead item) is calculated by multiplying the SPA for the lead item by the ratio of the average of the 2015 fee schedule amounts for all areas for the non-lead item to the average of the 2015 fee schedule amounts for all areas for the lead item.

For competitively bid items and services furnished in a CBA, the SPAs replace the Medicare allowed amounts established using the lower of the supplier's actual charge or the fee schedule payment amount recognized under sections 1834(a)(2) through (7) of the Act. Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is made on an assignment-related basis and is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act.

3. Fee Schedule Adjustment Methodology for Non-CBAs

Section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information on the payment determined under the Medicare DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs on or after January 1, 2016. Section 1834(a)(1)(F)(iii) of the Act requires the Secretary to continue to make these adjustments as additional covered items are phased in under the CBP or information is updated as new CBP contracts are awarded. Similarly, sections 1842(s)(3)(B) and 1834(h)(1)(H)(ii) of the Act authorize the Secretary to use payment information from the DMEPOS CBP to adjust the fee schedule amounts for enteral nutrition and OTS orthotics, respectively, furnished in all non-CBAs. Section 1834(a)(1)(G) of the Act requires the Secretary to specify the methodology to be used in making these fee schedule adjustments by regulation, and to consider, among other factors, the costs of items and services in non-CBAs (where the adjustments would be applied) compared to the payment rates for such items and services in the CBAs.

In accordance with the requirements of Section 1834(a)(1)(G) of the Act, we conducted notice-and-comment rulemaking in 2014 to specify methodologies for adjusting the fee schedule amounts for DME, enteral nutrition, and OTS orthotics in non-CBAs in 42 CFR 414.210(g). We will provide a summary of these methodologies, but also refer readers to the July 11, 2014 proposed rule entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,'' (79 FR 40208) (hereinafter CY 2015 ESRD PPS DMEPOS proposed rule), and the November 6, 2014 final rule entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,'' (79 FR 66120 ( ) (hereinafter CY 2015 ESRD PPS DMEPOS final rule) for additional details.

The methodologies set forth in § 414.210(g) account for regional variations in prices, including for rural and non-contiguous areas of the U.S. In accordance with § 414.210(g)(1), CMS determines regional adjustments to fee schedule amounts for each state in the contiguous U.S. and the District of Columbia, based on the definition of region in § 414.202, which refers to geographic areas defined by the Bureau of Economic Analysis in the Department of Commerce for economic analysis purposes (79 FR 66226). Under § 414.210(g)(1)(i) through (iv), adjusted fee schedule amounts for areas within the contiguous U.S. are determined based on regional prices limited by a national ceiling of 110 percent of the regional average price and a floor of 90 percent of the regional average price (79 FR 66225). Under § 414.210(g)(1)(v), adjusted fee schedule amounts for rural areas are based on 110 percent of the national average of regional prices. Under § 414.210(g)(2), fee schedule amounts for non-contiguous areas are adjusted based on the higher of the average of the SPAs for CBAs in non-contiguous areas in the U.S., or the national ceiling amount.

For items and services that have been included in no more than 10 CBPs, § 414.210(g)(3) specifies adjustments based on 110 percent of the average of the SPAs. In cases where the SPAs from DMEPOS CBPs that are no longer in effect are used to adjust fee schedule amounts, § 414.210(g)(4) requires that the SPAs be updated by an inflation adjustment factor on an annual basis based on the Consumer Price Index for all Urban Consumers update factors from the mid-point of the last year the SPAs were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect.

Under § 414.210(g)(5), in situations where a HCPCS code that describes an item used with different types of base equipment is included in more than one product category in a CBA, a weighted average of the SPAs for the code is computed for each CBA prior to applying the other payment adjustment methodologies in § 414.210(g). Under § 414.210(g)(6), we will adjust the SPAs for certain items prior to using those SPAs to adjust fee schedule amounts for items and services if price inversions have occurred under the DMEPOS CBP. Price inversions occur when one item in a grouping of items in a product category includes a feature that another similar item in the product category does not, and the average of the 2015 fee schedule amounts for the item with the feature is higher than the average of the 2015 schedule amounts for the item without the feature, but following a CBP competition, the SPA for the item with the feature is lower than the SPA for the item without the feature. For groupings of similar items where price inversions have occurred, the SPAs for the items in the grouping are adjusted to equal the weighted average of the SPAs for the items in the grouping.[3]

[3] For further discussion regarding adjustments to SPAs to address price inversions, we refer readers to the CY 2017 ESRD PPS DMEPOS final rule, entitled Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model, 81 FR 77937 (November 4, 2016).

In § 414.210(g)(8), the adjusted fee schedule amounts are revised each time a SPA for an item or service is updated following one or more new DMEPOS CBP competitions and as other items are added to the DMEPOS CBP. The fee schedule amounts that are adjusted using SPAs are not subject to the annual DMEPOS covered item update and are only updated when SPAs from the DMEPOS CBP are updated or, in accordance with § 414.210(g)(10), when there are temporary gaps in the DMEPOS CBP. Updates to the SPAs may occur as contracts are recompeted. In the CY 2015 ESRD PPS DMEPOS final rule, we established § 414.210(g)(9) to provide for a transitional phase-in period of the DMEPOS fee schedule adjustments. We established a 6-month transition period for blended rates from January 1 through June 30, 2016 (79 FR 66228 through 66229). In establishing a transition period, CMS agreed with commenters that phasing in the adjustments to the fee schedule amounts would allow time for suppliers to adjust to the new payment rates, and further noted that CMS would monitor the impact of the change in payment rates on access to items and services and health outcomes using real time claims data and analysis (79 FR 66228). Under § 414.210(g)(9)(i), we specified that the fee schedule adjustments for items and services furnished between January 1, 2016 through June 30, 2016 would be based on a blend of 50 percent of the unadjusted fee schedule amount and 50 percent of the adjusted fee schedule amount. Under § 414.210(g)(9)(ii), we specified that for items and services furnished with dates of service on or after July 1, 2016, the fee schedule amounts would be fully adjusted in accordance with the rules specified in § 414.210(g)(1) through § 414.210(g)(8).

4. 21st Century Cures Act

Section 16007(a) of the 21st Century Cures Act (Cures Act) was enacted on December 13, 2016, and extended the transition period for the phase-in of fee schedule adjustments at § 414.210(g)(9)(i) by an additional 6 months from July 1, 2016 through December 31, 2016. In the May 11, 2018 interim final rule with comment period entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas,'' 83 FR 21912 through 21925 (hereinafter 2018 Interim Final Rule), we amended § 414.210(g)(9)(i) to implement the 6 month extension to the initial transition period, as mandated by section 16007(a) of the Cures Act. Accordingly, the fee schedule amounts were based on blended rates until December 31, 2016, with full implementation of the fee schedule adjustments applying to items and services furnished with dates of service on or after January 1, 2017 (83 FR 21915). Section 16008 of the Cures Act amended section 1834(a)(1)(G) of the Act to require that the Secretary take into account certain factors when making any fee schedule adjustments under sections 1834(a)(1)(F)(ii) or (iii), 1834(h)(i)(H)(ii), or 1842(s)(3)(B) of the Act for items and services furnished on or after January 1, 2019. Specifically, the Secretary was required to take into account: (1) Stakeholder input solicited regarding adjustments to fee schedule amounts using information from the DMEPOS CBP; (2) the highest bid by a winning supplier in a CBA; and (3) a comparison of each of the following factors with respect to non-CBAs and CBAs: The average travel distance and cost associated with furnishing items and services in the area, the average volume of items and services furnished by suppliers in the area, and the number of suppliers in the area.

5. Extension of DMEPOS Fee Schedule Transition Period & Revised Methodology

In the 2018 Interim Final Rule (83 FR 21918), we expressed an immediate need to resume the transitional, blended fee schedule amounts in rural and non-contiguous areas, noting strong stakeholder concerns about the continued viability of many DMEPOS suppliers, our finding of a decrease in the number of suppliers furnishing items and services subject to the fee schedule adjustments, as well as the Cures Act mandate to consider additional information material to setting fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished on or after January 1, 2019. We explained that resuming these transitional blended rates would preserve beneficiary access to needed DME items and services in a contracting supplier marketplace, while also allowing CMS time to address the adequacy of the fee schedule adjustment methodology, as required by section 16008 of the Cures Act. As a result, we amended § 414.210(g)(9) by adding § 414.210(g)(9)(iii) to resume the fee schedule adjustment transition rates for items and services furnished in rural and non-contiguous areas from June 1, 2018 through December 31, 2018. We explained that resuming these transitional blended rates would allow additional time for suppliers serving rural and non-contiguous areas to adjust their businesses, prevent suppliers that beneficiaries may rely on for access to items and services in rural and non-contiguous areas from exiting the business, and allow additional time for CMS to monitor the impact of the blended rates. We also amended § 414.210(g)(9)(ii) to reflect that for items and services furnished with dates of service from January 1, 2017 to May 31, 2018, fully adjusted fee schedule amounts would apply (83 FR 21922). In addition, we added § 414.210(g)(9)(iv) to specify that fully adjusted fee schedule amounts would apply for items furnished in non-CBAs other than rural and non-contiguous areas from June 1, 2018 through December 31, 2018 (83 FR 21920). We explained that we would use the extended transition period to further analyze our findings and consider the information required by section 16008 of the Cures Act in determining whether changes to the methodology for adjusting fee schedule amounts for items furnished on or after January 1, 2019 are necessary (83 FR 21918 through 21919).

In the CY 2019 ESRD PPS DMEPOS final rule, we finalized changes to bidding and pricing methodologies under the DMEPOS CBP for future competitions (83 FR 57020 through 57025). Specifically, we finalized lead item pricing for all product categories under the DMEPOS CBP, which would use the bid for the lead item to establish the SPAs for both the lead item and all other items in the product category (the non-lead items). We explained that this change would reduce the burden on suppliers since they would no longer have to submit bids on numerous items in a product category. We also finalized changes to the methodology for calculating SPAs under the DMEPOS CBP based on lead item pricing using maximum winning bids for lead items in each product category. We finalized revisions to §§ 414.414 and 414.416 to reflect our changes to the bidding and pricing methodologies, and revised the definitions of bid, composite bid, and lead item in § 414.402.

Also in the CY 2019 ESRD PPS DMEPOS final rule, we established fee schedule adjustment transition rules for items and services furnished from January 1, 2019 through December 31, 2020. We decided to make these fee schedule adjustment transition rules effective for a 2-year period only, for two reasons. First, we believed that we must proceed cautiously when adjusting fee schedules in the short term in an effort to protect access to items, while we continued to monitor health outcomes, assignment rates, and other information (83 FR 57029). Second, as

part of the final rule, we made significant changes to the way bids are submitted and SPAs are calculated under the CBP. We stated in the final rule these changes could warrant further changes to the fee schedule adjustment methodologies in the future (83 FR 57030). Consistent with the requirements of Section 16008 of the Cures Act, we set forth our analysis and consideration of stakeholder input solicited on adjustments to fee schedule amounts using information from the DMEPOS CBP, the highest bid by a winning supplier in a CBA, and a comparison of the various factors with respect to non-CBAs and CBAs. We noted stakeholder concerns that the adjusted payment amounts constrained suppliers from furnishing items and services to rural areas, and their request for an increase to the adjusted payment amounts for these areas (83 FR 57025). In reviewing highest winning bids, we found no pattern indicating that maximum bids were higher for areas with lower volume than for areas with higher volume (83 FR 57026). In our consideration of the Cures Act factors with respect to non-CBAs and CBAs, we found higher costs for non-contiguous areas, an increased average travel distance in certain rural areas, a significantly lower average volume per supplier in non-CBAs, especially in rural and non-contiguous areas, and a decrease in the number of non-CBA supplier locations. Based on our consideration of the foregoing, we expressed our belief that the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all rural or non-contiguous areas should be based on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amounts in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g) (83 FR 57029). We also expressed our belief that the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are non-CBAs, but are not rural or non-contiguous areas, should be based on 100 percent of the adjusted fee schedule amounts in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g) (83 FR 57029). We finalized amendments to the transition rules at § 414.210(g)(9) to reflect these fee schedule adjustment methodologies for items and services furnished from January 1, 2019 through December 31, 2020 (83 FR 57039; 83 FR 57070 through 57071).

6. The Coronavirus Aid, Relief, and Economic Security Act

The Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116–136) was enacted on March 27, 2020. Section 3712 of the CARES Act specifies the payment rates for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs through the duration of the emergency period described in section 1135(g)(1)(B) of the Social Security Act. Section 3712(a) of the CARES Act continues our policy of paying the 50/50 blended rates for items furnished in rural and non-contiguous non-CBAs through December 31, 2020, or through the duration of the emergency period, if longer. Section 3712(b) of the CARES Act increased the payment rates for DME and enteral nutrients, supplies, and equipment furnished in areas other than rural and non-contiguous non-CBAs through the duration of the emergency period. Beginning March 6, 2020, the payment rates for DME and enteral nutrients, supplies, and equipment furnished in these areas are based on 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount, which results in higher payment rates as compared to the full fee schedule adjustments that were previously required under § 414.210(g)(9)(iv). We made changes to the regulation text at § 414.210(g)(9), consistent with section 3712 of the CARES Act, in an interim final rule with comment period that we published in the May 8, 2020 **Federal Register** entitled ''Medicare and Medicaid Programs; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency.''

B. Current Issues

We are now proposing the fee schedule adjustment methodologies for items and services furnished in non-CBAs on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later. Though the transition rules under 42 CFR 414.210(g)(9) expire on December 31, 2020, we believe that the rest of the current fee schedule adjustment rules at 414.210(g) would continue to be in effect should the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B) expire after January 1, 2021, and before April 1, 2021. In other words, in the event that the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) expires before April 1, 2021, the current fee schedule adjustment rules at § 414.210(g)(1) through (8) would be used to adjust fee schedule amounts for items and services furnished in non-CBAs and the current fee schedule adjustment rule at 414.210(g)(10) would be used to adjust fee schedule amounts for items and services furnished in CBAs or former CBAs until March 31, 2021.

1. Section 16008 of the Cures Act Analysis

As discussed, section 16008 of the Cures Act requires that we take into account a number of factors in making any fee schedule adjustments for items and services furnished on or after January 1, 2019, including: (1) Stakeholder input we have solicited on adjustments to fee schedule amounts using information from the DMEPOS CBP; (2) the highest bid by a winning supplier in a CBA; and (3) a comparison of the factors outlined in section 16008 of the Cures Act with respect to non-CBAs and CBAs. Our analysis of the Cures Act factors focuses on the effect we believe increased payment levels have had in rural and non-contiguous non-CBAs, and the effect we believe fully adjusted fees have had in non-rural contiguous non-CBAs. We also provide our analysis of other metrics we believe are important in measuring the impacts of our payment policies.

a. Stakeholder Input Gathered in Accordance With Section 16008 of the Cures Act

Section 16008 of the Cures Act requires us to solicit and take into account stakeholder input in making fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished on or after January 1, 2019. On March 23, 2017, we hosted a national provider call to solicit stakeholder input regarding adjustments to fee schedule amounts using DMEPOS CBP information (83 FR 57025 through 57026). More than 330 participants called in, with 23 participants providing oral comments during the call. We also received 125 written comments from stakeholders in response to our request for written comments. Our announcement of this call, a copy of our presentation, the audio recording of the call, and its transcript can be found at the following link on the CMS website.[4]

In general, the commenters were mostly suppliers located in MSAs, but also included manufacturers, trade

[4] *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-03-23-DMEPOS.*

organizations, and healthcare providers such as physical and occupational therapists. For additional details about the national provider call and a summary of oral and written comments received, we refer readers to the CY 2019 ESRD PPS/DMEPOS proposed rule (83 FR 57026). For a summary of public comments received on the CY 2019 ESRD PPS DMEPOS proposed rule and our responses, we refer readers to the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57030 through 57036). While the stakeholder input from 2017 did not quantify the degree to which costs of furnishing items in CBAs versus rural areas or any other non-CBAs, the comments we received in response to our 2014 proposed rule (79 FR 40208) indicated that the adjusted fee schedule amounts for rural areas should be equal to 120 to 150 percent of the average of the regional single payment amounts (RSPAs) rather than 110 percent of the average of the RSPAs. In addition, a 2015 industry survey of suppliers of respiratory equipment indicated that the cost of furnishing respiratory equipment in ''super rural'' areas is 17 percent higher than the cost of furnishing respiratory equipment in CBAs.[5] The term ''super rural'' refers to areas identified as ''qualified rural areas'' under the ambulance fee schedule statute at section 1834(l)(12)(B) of the Act (as implemented at 42 CFR 414.610(c)(5)(ii)). For the purposes of the fee schedule for ambulance services, rural areas are defined at 42 CFR 414.605 as areas located outside an urban area (MSA), or a rural census tract within an MSA as determined under the most recent version of the Goldsmith modification as determined by the Federal Office of Rural Health Policy at the Health Resources and Services Administration (HRSA). The most recent version of the Goldsmith Modification are the Rural-Urban Commuting Area (RUCA) codes, which are a method of determining rurality.[6] Under 42 CFR 414.610(c)(5)(ii), for ground ambulance services furnished during the period July 1, 2004 through December 31, 2022, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. CMS refers to this as the ''super rural'' bonus, and the areas that receive this super rural bonus as ''super rural'' areas.[7] For purposes of payment under the Medicare ambulance fee schedule, a ''super rural'' area is thus a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. DMEPOS industry stakeholders have recommended that this differential in payment between super rural areas and MSAs may be adopted in the DMEPOS fee schedule payment context as well.

In general, we continue to receive feedback from industry stakeholders expressing their belief that the fully adjusted fee schedule amounts are too low and are having an adverse impact on beneficiary access to items and services furnished in rural areas. Industry stakeholders have also stated that the fully adjusted fee schedule amounts are insufficient to cover the supplier's costs, particularly for delivering items in rural areas.

We have been closely monitoring beneficiary health outcomes and access to DMEPOS items. There has been no decline in allowed services for items subject to the fee schedule adjustments at any point in time, including 2017 and the first half of 2018 when payment in rural and non-contiguous areas was based on the fully adjusted fee schedule amounts. Traditional Medicare or fee-or-service allowed services for items subject to the fee schedule adjustments rose from 24,882,018 in 2015 to 25,604,836 in 2016, 26,065,601 in 2017, and 26,481,002 in 2018. This increase in allowed services occurred even though beneficiary fee-for-service enrollment dropped by 0.6 percent from 33.7 million in 2016 to 33.5 million 2018 while Medicare Advantage beneficiary enrollment rose by 16.0 percent from 18.4 million in 2016 to 21.3 million in 2018. During this time, suppliers accepted assignment (Medicare payment in full) for most items and services (99.79 percent in 2017 and 99.81 percent in 2018). This rate of assignment remained extremely high (99.68 percent in 2017 and 99.70 percent in 2018) even after removing claims for Medicare participating suppliers and suppliers furnishing items to beneficiaries with dual (Medicare and Medicaid) eligibility, where assignment is mandatory. In addition, we have continued to monitor over one thousand health metrics (emergency room visits, physician office visits, nursing home and hospital admissions, length of need, deaths, etc.) and have not detected any negative impact of the fee schedule adjustments on health outcomes. When analyzing the 2015 monthly average health outcome rates for beneficiaries in non-CBAs, which was the last year we did not make any fee schedule adjustments in non-CBAs, we have seen reductions in both 2017 and 2018 in mortality rates, hospitalization rates, physician visits, SNF admissions, and monthly days in the hospital. The percentage of beneficiaries with emergency room visits increased slightly from 3.6 to 3.9 percent and monthly days in nursing homes remained unchanged. Finally, we note that beneficiary inquiries and complaints related to DMEPOS items and services have steadily declined since 2016 and have not increased.

b. Highest Winning Bids in CBAs Analysis

Section 16008 of the Cures Act requires us to take into account the highest amount bid by a winning supplier in a CBA when making fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished on or after January 1, 2019. As discussed earlier, in the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57026), we found no pattern indicating that maximum bids are higher for areas with lower volume than for areas with higher volume. For additional details, we refer readers to the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34360 through 34367).

c. Travel Distance Analysis

Section 16008 of the Cures Act also requires us to take into account a comparison of the average travel distance and costs associated with furnishing items and services in CBAs and non-CBAs. In the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34367 through 34371), we compared the average size of different non-CBAs nationally and found that the CBAs had much larger service areas than the non-CBAs. We also compared the average travel distances for suppliers in the different areas using claims data for items and services subject to the fee schedule adjustments. From our analysis, we found that the average distance traveled in CBAs was generally greater than in most non-CBAs. However, in reviewing certain non-CBAs, such as Frontier and Remote (FAR) areas,[8] Outside Core Based

[5] *https://www.cqrc.org/img/CQRCCostSurvey WhitePaperMay2015Final.pdf.*

[6] *https://www.hrsa.gov/rural-health/about-us/definition/index.html.*

[7] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/afspuf.*

[8] A Frontier and Remote (FAR) area is statistically delineated by the Health Resources and Services Administration (HRSA) based on remoteness and population sparseness. HRSA Methodology for Designation of Frontier and Remote Areas, 79 FR 25599 through 25603 (May 5, 2014).

Statistical Areas (OCBSAs),[9] and super rural areas,[10] we found that suppliers generally must travel farther distances to beneficiaries located in those areas than for beneficiaries located in CBAs and other non-CBAs. For additional details on our previous travel distance analysis, we refer readers to the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34367 through 34371).

We have updated some of the travel distance data used in our previous travel distance analysis with data from 2018, which is the most recent full year of data with CBAs. In reviewing the data from 2018, we found that the same trends we presented in the CY 2019 ESRD PPS DMEPOS proposed rule, which were based on 2016 data, apply. Similar to our previous travel distance analysis, to prevent the data from being skewed in certain ways, we only included claims where the supplier billing address is in the same or adjoining state as the beneficiary address, and we excluded claims from suppliers with multiple locations that always use the same billing address. These data restrictions left in place 96 percent of allowed claims lines when looking at hospital beds, 97 percent when looking at oxygen, and 92 percent when looking at all items.

TABLE 1—2018 AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY *

Beneficiary area	Hospital beds	Oxygen	All items
CBAs	28	23	30
Non-CBA MSAs	24	22	28
Non-CBA Micro Areas	22	22	27
Non-CBA OCBSA	28	31	37
Super Rural	37	37	42
FAR level 1	27	31	36
FAR level 3	40	41	47

* Includes claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

We also reviewed travel distance data updated by partial 2019 data spanning January through November 2019. Average travel distances in former CBAs decreased, while average travel distances in rural and non-rural non-CBAs increased. Section 16008 of the Cures Act requires a comparison of average travel distance with respect to non-CBAs and CBAs. However, there are currently no CBAs due to the gap period in the DMEPOS CBP, allowing any Medicare-enrolled DMEPOS suppliers to furnish DMEPOS items and services. We still reviewed data from former CBAs, as we believe the decrease in average travel distance in the former CBAs is additional confirmation that travel distances are generally greater in CBAs while a CBP is in effect, when compared to non-CBAs. We believe average supplier travel distances in the former CBAs decreased for a variety of reasons. For one, CBP contract suppliers must furnish items and services to any beneficiary located in a CBA. Now that there is a gap period in the CBP, any supplier may furnish items and services to a beneficiary located in a former CBA and suppliers are no longer obligated to service a beneficiary who may be farther away from the supplier. Additionally, more suppliers can now furnish items and services to beneficiaries, so a beneficiary could also receive items and services furnished by a supplier located closer to the beneficiary.

Section 16008 of the Cures Act requires us to take into account a comparison of the average travel distance and costs associated with furnishing items and services in CBAs and non-CBAs. As a result, we believe a payment methodology should account for this factor, and the increased costs suppliers may face in reaching certain non-CBAs. When we say certain non-CBAs, we are referring to non-CBAs classified as either super rural, FAR, or OCBSA. This is because although we found that the average travel distance for suppliers in non-CBAs is generally lower than the average travel distance and costs for suppliers in CBAs while the CBP was in effect, we found that suppliers generally must travel farther distances to beneficiaries located in non-CBAs that are super rural, FAR or OCBSA than for beneficiaries located in CBAs and other non-CBAs. Still, industry stakeholders have expressed their belief that the fully adjusted fee schedule amounts are too low and have an adverse impact on beneficiary access to items and services furnished in rural non-CBAs. We have not seen evidence of this, but because stakeholder input is another factor in section 16008 of the Cures Act, we are also factoring stakeholder input into our payment methodology, and therefore believe a payment methodology should result in higher payments for DMEPOS suppliers that furnish items and services to all rural areas, instead of just those areas with greater travel distance than CBAs. We believe this errs on the side of caution and may incentivize suppliers to furnish items and services to all rural areas.

d. Cost Analysis

We presented our analysis of different sources of cost data in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34371 through 34377). Overall, in comparing CBAs to non-CBAs, we found that CBAs tended to have the highest costs out of the cost data we examined. For certain cost data, we also found that Alaska and Hawaii—both non-contiguous areas—tended to have higher costs than many contiguous areas of the U.S. We updated this analysis with more recent data and did not notice any significant differences in these overall findings.

We believe these findings support a payment methodology that considers such increased costs in non-contiguous areas.

We note that we also consider assignment rates as a source of cost data, and consider it a measure of the sufficiency of payment to cover a supplier's costs for furnishing items and services under the Medicare program. Assignment rates for items subject to the fee schedule adjustments have not varied significantly around the country, and they have consistently remained

[9] Outside Core Based Statistical Areas are delineated by OMB as counties that do not qualify for inclusion in a Core Based Statistical Area. OMB 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas; Notice, 75 FR 37245 (June 28, 2010).

[10] Under the Ambulance Fee schedule (AFS), temporary add-on payments known as the ''super rural bonus'' are available in relation to areas that are within the lowest 25 percentile of all rural areas arrayed by population density. 42 CFR 414.610(c)(5)(ii).

over 99 percent in all areas. Thus, for the overwhelming majority of claims for items and services furnished in the non-CBAs that were subject to the fee schedule adjustments, suppliers have decided to accept the Medicare payment amount in full, and have not needed to charge the beneficiary for any additional costs that the Medicare allowed payment amount did not cover. Of note, for the 17 months from January 2017 through May 2018 when Medicare paid at the fully adjusted fee level in all areas, or about 40 percent below the un-adjusted fee schedule amounts on average, the assignment rate did not dip below 99 percent for the items and services subject to the adjusted fee schedule amounts.

e. Average Volume of Items and Services Furnished by Suppliers in the Area Analysis

Section 16008 of the Cures Act requires that we take into account a comparison of the average volume of items and services furnished by suppliers in CBAs and non-CBAs. In the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34377), we found that in virtually all cases, the average volume of items and services furnished by suppliers is higher in CBAs than non-CBAs. In reviewing updated data from 2018, we found that in most cases, the average volume of items and services furnished by suppliers was higher in CBAs than in non-CBAs. We reviewed the number of allowed claim lines on a national level for 15 different product categories subject to the fee schedule adjustments. In doing so, we found that non-CBAs had more allowed claim lines than CBAs for 4 of the 15 product categories that we reviewed (nebulizer, oxygen, seat lifts, and transcutaneous electrical nerve stimulation (TENS) devices). Rural non-CBAs had more allowed claim lines than CBAs for 2 of the 15 product categories that we reviewed (seat lifts and TENS). Finally, non-rural non-CBAs had more allowed claims lines than CBAs for those same two product categories (seat lifts and TENS).

Additionally, total services per supplier continued to increase in 2018 and 2019 in all non-CBAs. Thus, we found that the average volume per supplier in non-CBAs continues to increase while assignment rates are 99 percent or higher, and overall utilization remains steady or is increasing. We believe these findings support a payment methodology that takes into account and ensures beneficiary access to items and services in non-CBAs with relatively low volume.

f. Number of Suppliers Analysis

Section 16008 of the Cures Act requires us to take into account a comparison of the number of suppliers in the area.

The number of suppliers billing Medicare Fee-for-Service (FFS) for items subject to fee schedule adjustments in all non-CBAs declined from June 2018 through the end of 2019, which is the time period in which we paid the fully adjusted fees in non-rural, contiguous non-CBAs and the blended rates in rural and non-contiguous non-CBAs, in accordance with 42 CFR 414.210(g)(9)(iii) and (iv). More specifics about this decline can be found in Table 2. We note that the decline in the number of billing suppliers is part of a long-term trend that preceded the adjustment of the fee schedule amounts beginning in 2016, but we are still concerned about this trend, particularly for rural and non-contiguous areas, because beneficiaries could have trouble accessing items and services in these lower population areas if more suppliers decide to stop serving these areas.

We studied supplier numbers and found that when looking at a sample of HCPCS codes for high volume items subject to fee schedule adjustments (E1390 for oxygen concentrators, E0601 for CPAP machines, E0260 for semi-electric hospital beds, and B4035 for enteral nutrition supplies), that the average volume of items furnished by suppliers before they stopped billing Medicare is very small compared to the average volume of items furnished by suppliers who continued to bill. Data shows that large national chain suppliers are accepting a large percentage of the beneficiaries who were previously served by the smaller suppliers that exited the Medicare market. In addition, the average volume per supplier continues to increase (as the number of suppliers who bill Medicare decline, the suppliers that still bill Medicare are picking up more volume), while overall services continue to grow, suggesting industry consolidation rather than any type of access issue for DME. Therefore, the decline in the number of supplier locations is largely a result of the consolidation of suppliers furnishing items subject to the fee schedule adjustments rather than a decline in beneficiary access to items subject to the fee schedule adjustments. In addition, this trend in consolidation is matched by an increase in the average volume of items furnished per supplier, increasing economies of scale for these suppliers, although this does decrease the number of overall suppliers beneficiaries can choose from to provide DMEPOS items.

However, to determine what effect, if any, our payment amounts have had on the number of billing suppliers, we also examined supplier numbers during defined timeframes in which we paid suppliers the unadjusted and adjusted fees, and the 50/50 blended rates (50 percent unadjusted and 50 percent adjusted). The declines in the number of billing suppliers in both rural and non-rural non-CBAs were very similar, even when we increased payment levels to the blended rates in rural and non-contiguous non-CBAs, and continued paying the fully adjusted fees in non-rural/contiguous non-CBAs. We did not see an appreciable difference in supplier reductions between the two areas. We note that non-contiguous non-CBAs exhibited a slightly different trend than other non-CBAs, as the number of billing suppliers in these areas increased from 2015 to 2016 when we paid the unadjusted fees, and January 2017 to May 2018 when we paid the fully adjusted fees, but subsequently declined between June 2018 to November 2019 when we paid the blended rates.

For this analysis, we reviewed the following timeframes and noted the payment policies in effect at that time:

- Period 1: January 2015–December 2015: Unadjusted fees in all non-CBAs
- Period 2: January 2016–December 2016: Blended rates in all non-CBAs (as noted previously, Congress passed section 16007 of the Cures Act on December 13, 2016, which made the blended rates effective retroactively in all non-CBAs from June 30 through December 31, 2016)
- Period 3: January 2017–May 2018: Fully adjusted fees in all non-CBAs
- Period 4: June 2018–November 2019: Blended rates in rural and non-contiguous non-CBAs, fully adjusted fees in non-rural non-CBAs in the contiguous U.S.

TABLE 2—NUMBER OF SUPPLIERS WHO BILLED FOR DME SUBJECT TO THE FEE SCHEDULE ADJUSTMENTS

Period	CBA	% Change	Non-CBA non-rural	% Change	Non-CBA rural	% Change	Non-CBA non-contiguous	% Change
Jan 2015–Dec 2015	12,717	.....	10,694	.....	11,491	.....	1,150	.....
Jan 2016–Dec 2016	11,698	−8.0	10,103	−5.5	10,772	−6.3	1,229	6.9
Jan 2017–May 2018 (fully adjusted)	9,127	−22.0	9,520	−5.8	10,173	−5.6	1,295	5.4
Jun 2018–Nov 2019	10,381	13.7	8,778	−7.8	9,401	−7.6	1,238	−4.4

*Claims data through 2019/11/29 (2019 Week 48), Provider Enrollment, Chain, and Ownership System (PECOS) data through 2019/09/17.

As we noted in our previous analysis (83 FR 34380), we believe that oxygen and oxygen equipment is one of the most critical items subject to the fee schedule adjustments in terms of beneficiary access. If access to oxygen and oxygen equipment is denied to a beneficiary who needs oxygen, serious health implications can result. Oxygen and oxygen equipment are also items that must be delivered to the beneficiary, and set up and used properly in the home for safety reasons. Access to oxygen and oxygen equipment in remote areas thus remains critical and has been stressed by stakeholders. To determine if there were pockets of the country where access to oxygen and oxygen equipment was in jeopardy, we reviewed data depicting how many non-CBA counties are being served by only one oxygen supplier. From 2016 to 2018, there was a total of 2,691 non-CBA counties with beneficiaries receiving Medicare-covered oxygen supplies. For each year, there were approximately 38 to 39 counties being served by only one oxygen supplier, serving approximately 68 to 78 beneficiaries receiving approximately 736 to 896 services (annually) in those areas. Among the counties with only one oxygen supplier, the majority had only one oxygen user during that year. All counties with a single oxygen supplier from 2016 to 2018 had 100 percent assignment rates for oxygen services, and more than half of the single-supplier counties were in Puerto Rico.

We believe this shows that access to oxygen and oxygen equipment is not in jeopardy. If there are oxygen claims for only one beneficiary in the area, then only one billing supplier would show up in the data. This does not mean that the supplier submitting the claims for this one beneficiary is the only supplier available to furnish oxygen and oxygen equipment in the area. There may be other suppliers able to serve these areas as well and this would show up in the claims data if there were more beneficiaries using oxygen in these areas and these beneficiaries used more than one supplier. This also shows how non-CBAs can have far less volume and fewer billing suppliers than CBAs. Thus, we believe paying more money to suppliers serving rural and non-contiguous non-CBAs takes into account those factors specified in Section 16008 of the Cures Act (volume and number of suppliers), and it errs on the side of caution in seeking to prevent beneficiary access issues.

2. DMEPOS Fee Schedule Adjustment Impact Monitoring Data

In addition to the various Cures Act factors, we have also been monitoring other metrics we believe are important in measuring the impacts of our payment policies. In reviewing claims data processed through mid-November in 2018 and 2019, we found that assignment rates for all claims for DMEPOS items and services subject to fee schedule adjustments went up slightly from 2018 to 2019 in both non-rural non-CBAs (from 99.826 percent or 12,948,603 assigned services out of 12,971,110 to 99.833 percent or 11,594,547 assigned services out of 11,613,970) and rural non-CBAs (from 99.79 percent or 13,285,838 assigned services out of 13,313,575 to 99.81 percent or 11,863,434 assigned services out of 11,885,683). Keep in mind that the 2019 claims data is not yet complete, so the number of allowed services will be greater than what is reported here, but the final rate of assignment will likely not change much if at all.

We have also been monitoring other claims data from non-CBAs, and we have not observed any trends indicating an increase in adverse beneficiary health outcomes. We monitor mortality rates, hospitalization rates, ER visit rates, SNF admission rates, physician visit rates, monthly days in hospital, and monthly days in SNF. Except for death information, which comes from the Medicare Enrollment Database, all other outcomes are derived from claims (inpatient, outpatient, Part B carrier, and SNF). Our monitoring materials cover historical and regional trends in these health outcome rates across a number of populations, allowing us to observe deviations that require further drilldown analyses. We monitor health outcomes in the enrolled Medicare population (Medicare Parts A and B), dual Medicare and Medicaid population, long-term institutionalized population, as well as various DME utilizers and access groups. This helps paint a complete picture of whether an increase in an outcome is across the board (not linked to DME access), or is unique to certain populations. Specifically, we focus on any increases that are unique to the DME access groups, which include beneficiaries who are likely to use certain DME based on their diagnoses, and we would conduct drilldown analyses and policy research to pinpoint potential reasons for such increases. In addition, we examined what effect, if any, paying the blended rates in rural and non-contiguous non-CBAs had on utilization of DME. We compared the utilization of oxygen equipment between June 2017 through December 2017, and June 2018 through December 2018. We compared these two time periods, because we paid the blended rates in rural and non-contiguous non-CBAs from June 1, 2018 through December 31, 2018, in accordance with the 2018 Interim Final Rule (83 FR 21915). During the 2017 time period, we paid the fully adjusted fees in all non-CBAs. During the 2018 time period, we paid the blended rates in rural and non-contiguous non-CBAs and the fully adjusted fees in the non-rural contiguous non-CBAs from June 1, 2018 through December 31, 2018. We specifically studied oxygen utilization in rural areas without Micropolitan Statistical Areas, that is OCBSAs, as these counties have the least populated urban areas, and as we stated in the CY 2019 ESRD PPS DMEPOS final rule, one reason for paying higher rates was to ensure beneficiary access in rural and remote areas (83 FR 57029). We found that the number of allowed units in OCBSAs decreased comparably in all areas. Payment at the blended rates between June 1, 2018 and December 31, 2018 increased allowed charges in OCBSAs by 42 percent, but this had no apparent effect on increasing services in OCBSAs. Additionally, the significant reduction of liquid oxygen equipment allowed services trend continued in OCBSAs as well as in all areas. The decline in the number of oxygen concentrators that were furnished

declined at the same rate in OCBSAs as in all areas. Access to oxygen equipment in OCBSAs was unchanged, despite a 49 percent increase in unit prices.

In sum, we do not believe our payment rates had a discernible impact on any trends that were already occurring before we paid the higher fees, and we did not see any appreciable differences between the areas in which we paid the higher 50/50 blended rates in rural and non-contiguous non-CBAs and the areas in which we pay the fully adjusted fees in non-rural/contiguous non-CBAs. In addition, assignments rates are still high in all non-CBAs—over 99 percent—, which means over 99 percent of suppliers are accepting Medicare payment as payment in full and not balance billing beneficiaries for the cost of the DME.

We seek comments on all of our findings.

TABLE 3—SUMMARY OF OUR ANALYSIS OF THE SECTION 16008 CURES ACT FACTORS

Section 16008 Cures Act factors	Summary of our analysis
Stakeholder input	• Most of the input we have received has come from the DMEPOS industry, such as DMEPOS suppliers, expressing that the fully adjusted fee schedule amounts are too low, and that CMS should increase how much Medicare pays DMEPOS suppliers to furnish items and services to beneficiaries in non-CBAs. These stakeholders expressed concerns that the level of the adjusted payment amounts constrains suppliers from furnishing items and services to rural areas. • Stakeholder input that did not support such payment increases included input from the Medicare Payment Advisory Commission (MedPac), which believed any adjustment for rural and non-contiguous areas should be limited to only the amount needed to ensure access, targeted at areas and products for which an adjustment is needed, and that CMS should consider taking steps to offset the cost of any adjustments. MedPac supported setting fee schedule rates in urban, contiguous non-CBAs based 100 percent on information from the CBP.*
Highest Winning Bid	• In the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57026), we found no pattern indicating that maximum bids are higher for areas with lower volume than for areas with higher volume.
Travel Distance	• Average travel distance between the supplier and beneficiary is generally higher in CBAs than in non-CBAs, except for non-CBAs classified as FAR, super rural, or OCBSA.
Cost	• We examined four sources of cost data: (1) The Practice Expense Geographic Practice Cost Index (PE GPCI), (2) delivery driver wages from the Bureau of Labor Statistics (BLS), (3) real estate taxes from the U.S. Census Bureau's American Community Survey (ACS), and (4) gas and utility prices from the Consumer Price Index (CPI). • Overall, in comparing CBAs to non-CBAs, CBAs tended to have the highest costs out of the cost data we examined. For certain cost data, we also found that Alaska and Hawaii—both non-contiguous areas—tended to have higher costs than many contiguous areas of the U.S. Assignment rates, which we consider to be a measure of the sufficiency of payment to cover a supplier's costs for furnishing items and services under the Medicare program, have consistently remained high at over 99 percent (out of 100) in non-CBAs, meaning over 99 percent of suppliers furnishing items subject to fee schedule adjustments in the non-CBAs are accepting the Medicare payment in full.
Volume	• CBAs generally have higher volume than non-CBAs. • Total services per supplier continued to increase in 2018 and 2019 in non-CBAs.
Number of Suppliers	• The number of suppliers billing Medicare for furnishing items and services subject to fee schedule adjustments in the non-CBAs has been declining for several years, and this downward trend started years before CMS started adjusting fee schedule amounts in the non-CBAs in 2016. • When looking at a sample of HCPCS codes for high volume items subject to fee schedule adjustments, the average volume of items furnished by suppliers before they stopped billing Medicare is very small compared to the average volume of items furnished by suppliers who continued to bill. Data shows that large national chain suppliers are accepting a large percentage of the beneficiaries who were previously served by the smaller suppliers that exited the Medicare market. In addition, the average volume per supplier continues to increase (as the number of suppliers who bill Medicare decline, the suppliers that still bill Medicare are picking up more volume), while overall services continue to grow, suggesting industry consolidation rather than any type of access issue for DME. Therefore, the decline in the number of supplier locations is largely a result of the consolidation of suppliers furnishing items subject to the fee schedule adjustments rather than a decline in beneficiary access to items subject to the fee schedule adjustments. • When looking at different timeframes over the last several years in which we paid different fee schedule amounts (unadjusted fees, adjusted fees, and the 50/50 blended rates), we did not see an appreciable effect that these payment changes had on stemming the reduction in the number of suppliers billing Medicare. • All counties with a single oxygen supplier from 2016 to 2018 had 100 percent assignment rates for oxygen services, and more than half of the single-supplier counties were in Puerto Rico.

* *http://www.medpac.gov/docs/default-source/commentletters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf?sfvrsn=0.*

C. Provisions of the Proposed Regulations

After reviewing updated information that must be taken into consideration in accordance with section 1834(a)(1)(G) of the Act in determining adjustments to DMEPOS fee schedule amounts, we are proposing to revise § 414.210(g) to establish three different methodologies for adjusting fee schedule amounts for DMEPOS items and services included in more than ten competitive bidding programs furnished in non-CBAs on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later. We are proposing three different fee schedule adjustment methodologies, based on the non-CBA in which the items are furnished: (1) One fee schedule adjustment methodology for items and services furnished in non-contiguous non-CBAs; (2) another adjustment methodology for items and services furnished in non-CBAs within the contiguous United States that are defined as rural areas at § 414.202; and (3) a third adjustment methodology for items and services furnished in all other non-CBAs (non-rural areas within the contiguous United States). With respect to items and services furnished in no more than ten competitive bidding programs, we are proposing to continue using the methodology in § 414.210(g)(3) to adjust the fee schedule amounts for these items furnished on or after April 1, 2021. The rest of the discussion that follows addresses the fee schedule adjustments for items and services that have been included in more than ten competitive bidding programs.

First, we are proposing to continue paying the 50/50 blended rates in non-contiguous non-CBAs, but are proposing that the 50/50 blend will no longer be a transition rule under § 414.210(g)(9), and will instead be the fee schedule adjustment methodology for items and services furnished in these areas under § 414.210(g)(2) unless revised in future rulemaking. We are proposing that the fee schedule amounts for items and services furnished on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, in non-contiguous non-CBAs be adjusted so that they are equal to a blend of 50 percent of the greater of the average of the SPAs for the item or service for CBAs located in non-contiguous areas or 110 percent of the national average price for the item or service determined under § 414.210(g)(1)(ii) and 50 percent of the unadjusted fee schedule amount for the area, which is the fee schedule amount in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment. We explained our rationale for a methodology that incorporates 110 percent of the national average price in our CY 2015 ESRD PPS DMEPOS final rule. We stated that we believe that a variation in payment amounts both above and below the national average price should be allowed, and we believe that allowing for the same degree of variation (10 percent) above and below the national average price is more equitable and less arbitrary than allowing a higher degree of variation (20 percent) above the national average price than below (10 percent), as in the case of the national ceiling and floor for the Prosthetic & Orthotic fee schedule, or allowing for only 15 percent variation below the national average price, as in the case of the national ceiling and floor for the DME fee schedule.

Second, we are proposing to continue paying the 50/50 blended rates in rural contiguous areas, but are proposing that the 50/50 blend will no longer be a transition rule under § 414.210(g)(9), and will instead be the fee schedule adjustment methodology for items and services furnished in these areas under § 414.210(g)(2) unless revised in future rulemaking. We are proposing that the fee schedule amounts for items and services furnished in rural contiguous areas on or after April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, be adjusted so that they are equal to a blend of 50 percent of 110 percent of the national average price for the item or service determined under § 414.210(g)(1)(ii) and 50 percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment. We are also revising § 414.210(g)(1)(v) to address the period before April 1, 2021, to say that for items and services furnished before April 1, 2021, the fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section. We decided to propose a policy of paying a 50/50 blend of adjusted and unadjusted rates in non-contiguous non-CBAs and in rural non-CBAs, as opposed to a different ratio (such as a 75/25 blend, which is an alternative we considered and discuss further in this section), because past stakeholder input from the DME industry has expressed support for this 50/50 blend. For instance, we proposed paying the 50/50 blend for rural and non-contiguous non-CBAs from January 1, 2019 through December 31, 2020 in our CY 2019 ESRD PPS DMEPOS proposed rule, and we finalized this policy in our CY 2019 ESRD PPS DMEPOS final rule. Most of the comments we received on this proposal were from commenters in the DME industry, such as homecare associations, DME manufacturers, and suppliers, and these commenters generally supported the 50/50 blended rates proposal.

Third, for items and services furnished on or after April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, in all other non-rural non-CBAs within the contiguous United States, we are proposing that the fee schedule amounts be equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv).

Accordingly, we are proposing to add paragraph § 414.210(g)(9)(vi) to say that for items and services furnished in all areas with dates of service on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, based on the fee schedule amount for the area is equal to the adjusted payment amount established under § 414.210(g).

Thus under our proposal, CMS would continue paying suppliers significantly higher rates for furnishing items and services in rural and non-contiguous areas as compared to items and services furnished in other areas because of stakeholder input indicating higher costs in these areas, greater travel distances and costs in certain non-CBAs compared to CBAs, the unique logistical challenges and costs of furnishing items to beneficiaries in the non-contiguous areas, significantly lower volume of items furnished in these areas versus

CBAs, and concerns about financial incentives for suppliers in surrounding urban areas to continue including outlying rural areas in their service areas. Previous feedback from industry stakeholders expressed concern regarding beneficiary access to items and services furnished in rural and remote areas.

Furthermore, in our analysis, we found that suppliers must travel farther distances to deliver items to beneficiaries located in super rural areas and areas outside both MSAs and micropolitan statistical areas than the distances they must travel to deliver items to beneficiaries located in CBAs (while the CBP was in effect). We also found that certain non-contiguous areas tended to have higher costs, and had smaller numbers of oxygen suppliers and beneficiaries. Rural and non-contiguous areas also have much lower volume of DMEPOS items furnished by suppliers than in CBAs, and we are also concerned that national chain suppliers or suppliers in higher populated urban areas that are currently serving rural areas may abandon these areas if they are less profitable markets due to fee schedule adjustments and may instead concentrate on the larger markets only. We believe that this feedback as well as these findings supports a payment methodology that errs on the side of caution and ensures adequate payment for items and services furnished to beneficiaries in all rural and non-contiguous non-CBAs. We also believe that the proposed fee schedule adjustment methodologies would create an incentive for suppliers to continue serving areas where fewer beneficiaries reside and will therefore further ensure beneficiary access to items and services in these areas. We believe that this proposal, which proposes to continue paying the 50/50 blended rates in rural and non-contiguous non-CBAs, and 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv) in non-rural non-CBAs in the contiguous U.S., takes into account stakeholder feedback as well as information from our previous and updated analyses of the Cures Act factors.

The purpose of the 50/50 blend is to ensure payment rates are sufficient to maintain access to DME in areas where suppliers often furnish a lower volume of DME, such as rural areas of the country and non-contiguous areas.

The proposed fee schedule adjustment methodologies rely on SPAs generated by the CBP. CMS recently announced that it will only award Round 2021 CBP contracts to bidders in the OTS back braces and OTS knee braces product categories.[11] CMS will not award Round 2021 CBP contracts to bidders that bid in any other product categories that were included in round 2021 of the CBP, therefore, CMS will not have any new SPAs for these items and services. As a result, we are seriously considering whether to simply extend application of the current fee schedule adjustment transition rules for all of the items and services that were included in Round 2021 of the CBP but have essentially been removed from Round 2021 of the CBP. That is, for non-CBAs, the fee schedule adjustment transition rules at § 414.210(g)(9) and, for CBAs and former CBAs (CBAs where no CBP contracts are in effect), the fee schedule adjustment rules at § 414.210(g)(10), would be extended until a future round of the CBP. More specifically, for non-CBAs, we would extend the transition rules at § 414.210(g)(9)(iii) and (v) for items and services included in product categories other than the OTS back and knee brace product categories, and, for these same items and services furnished in CBAs or former CBAs, we are considering extending the rules at § 414.210(g)(10), until such product categories are competitively bid again in a future round of the CBP. In this situation, the proposed fee schedule adjustments discussed previously in this proposed rule would only apply to OTS back braces and OTS knee braces furnished in non-CBAs on or after April 1, 2021.

In short, beginning on April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, there would be several different fee schedule adjustment methodologies in effect, depending on where an item or service is furnished, and whether CMS has awarded Round 2021 CBP contracts for that item or service. For OTS back braces and OTS knee braces included in Round 2021 of the CBP and furnished in CBAs, payment would be made in accordance with the methodologies described in 42 CFR 414.408. For OTS back braces and OTS knee braces included in Round 2021 of the CBP and furnished in rural and non-contiguous non-CBA areas, payment would be made in accordance with the methodologies we are proposing in this proposed rule in § 414.210(g)(2). For OTS back braces and OTS knee braces included in Round 2021 of the CBP furnished in non-rural and contiguous non-CBA areas, payment would be made using the methodologies described in 42 CFR 414.210(g)(1)(iv).

For items and services included in the product categories that have essentially been removed from Round 2021 of the CBP, payment would be based on the methodologies described in 42 CFR 414.210(g)(10) when such items and services are furnished in CBAs or former CBAs. When such items and services are furnished in rural and non-contiguous non-CBAs, payment would be based on the methodologies we proposed at 42 CFR 414.210(g)(2) and the methodology at 42 CFR 414.210(g)(4). In non-rural and contiguous non-CBA areas, payment for these items and services would be based on the methodologies described in 42 CFR 414.210(g)(1)(iv) and the methodology at (g)(4). CMS welcomes comment on whether the transition rules at § 414.210(g)(9) and fee schedule adjustment rules at § 414.210(g)(10) should continue for these items and services that have essentially been removed from Round 2021 of the CBP. Specifically, we invite comment on whether we should extend the transition rules at § 414.210(g)(9)(iii) and (v) for items and services furnished in non-CBAs and included in product categories other than the OTS back and knee brace product categories, and, for these same items and services furnished in CBAs or former CBAs, whether we should extend the rules at § 414.210(g)(10), until such product categories are competitively bid again in a future round of the CBP.

3. Alternatives Considered But Not Proposed

We considered, but are not proposing, three alternatives to our proposals and we are seeking comments on these alternatives:

a. Adjust Fee Schedule Amounts for Super Rural Areas and Non-Contiguous Areas Based on 120 Percent of the Fee Schedule Amounts for Non-Rural Areas

Under the first alternative, we considered prior suggestions from stakeholders to use the ambulance fee schedule concept of a ''super rural area'' when determining fee schedule adjustments for non-CBAs. Specifically, we considered proposing to eliminate the definition of rural area at § 414.202 and 42 CFR 414.210(g)(1)(v), which brings the adjusted fee schedule amounts for rural areas up to 110 percent of the national average price determined under section 414.210(g)(1)(ii). In place of this definition and rule, we considered proposing an adjustment to the fee schedule amounts for DMEPOS items and services furnished in super rural

[11] The link to the announcement is *https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf.*

non-CBAs within the contiguous U.S. equal to 120 percent of the adjusted fee schedule amounts determined for other, non-rural non-CBAs within the same state. For example, the adjusted fee schedule amount for super rural, non-CBAs within Minnesota would be based on 120 percent of the adjusted fee schedule amount (in this case, the regional price) for Minnesota established in accordance with section 414.210(g)(1)(i) through (iv). Consistent with the ambulance fee schedule rural adjustment factor at § 414.610(c)(5)(ii), we considered defining ''super rural'' as a rural area determined to be in the lowest 25 percent of rural population arrayed by population density, where a rural area is defined as an area located outside an urban area (MSA), or a rural census tract within an MSA as determined under the most recent version of the Goldsmith modification as determined by the Federal Office of Rural Health Policy at the Health Resources and Services Administration. Per this definition and under this alternative rule, certain areas within MSAs would be considered super rural areas whereas now they are treated as non-rural areas because they are located in counties that are included in MSAs. For all other non-CBAs, including areas within the contiguous U.S. that are outside MSAs but do not meet the definition of super rural area, we considered adjusting the fee schedule amounts using the current fee schedule adjustment methodologies under § 414.210(g)(1) and § 414.210(g)(3) through (8).

In addition to addressing past stakeholder input, this alternative approach would provide a payment increase that is somewhat higher than, but similar to the 17 percent payment differential identified by stakeholders in 2015 based on a survey of respiratory equipment suppliers.[12] In addition, we have received input from suppliers that serve low population density areas within MSAs that are not CBAs. These stakeholders claim that they are serving low population density areas that are not near to or served by suppliers located in the urban core areas of the MSA and believe they should receive higher payments than suppliers serving the higher population density areas of the MSA. Under the alternative fee schedule adjustment methodology, if these low population density areas were to meet the definition of super rural area, they would receive a 20 percent higher payment than areas that are not super rural areas. This alternative payment rule would address these concerns with how the current payment rules and definition of rural area affect these areas, and would target payments for those rural areas that are low population density areas, regardless of whether they are located in an MSA or not. This approach would also address concerns raised from stakeholders on the March 23, 2017 call regarding the cost of traveling long distances to serve far away, remote areas.

Under this alternative, § 414.210(g)(2), which addresses fee schedule adjustments for DMEPOS items and services furnished in non-contiguous areas, would be replaced with a new rule that adjusts the fee schedule amounts for non-contiguous areas based on the higher of 120 percent of the average of the SPAs for the item or service in CBAs outside the contiguous U.S. (currently only Honolulu, Hawaii), or the national average price determined under § 414.210(g)(1)(ii).

b. Establish Additional Phase-In Period for Fully Adjusted Fee Schedule Amounts for Rural Areas and Non-Contiguous Areas

We considered proposing an alternative fee schedule adjustment methodology that would establish an additional transition period to allow us to determine the impact of the new SPAs and monitor the impact of adjusted fee schedule amounts. Under this alternative, we considered adjusting the fee schedule amounts for items and services furnished in rural areas and non-contiguous non-CBAs based on a 75/25 blend of adjusted and unadjusted rates for the 3-year period from April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, through December 31, 2023. Such a phase-in would bring the fee schedule payment amounts down closer to the fully adjusted fee levels and allow for a 3-year period to monitor the impact of the lower rates on access to items and services in these areas before potentially phasing in the fully adjusted rates in 2024.

c. Extend Current Fee Schedule Adjustments for Items and Services Furnished in Non-CBAs, CBAs, and Former CBAs That Were Included in Product Categories Removed From Round 2021 of the CBP

CMS recently announced that it will only award Round 2021 CBP contracts to bidders in the OTS back braces and OTS knee braces product categories. CMS will not award Round 2021 CBP contracts to bidders that bid in any other product categories that were included in Round 2021 of the CBP, therefore, CMS will not have any new SPAs for these items and services. As a result, under this alternative, we are seriously considering whether to simply extend application of the current fee schedule adjustment rules for all of the items and services that were included in Round 2021 of the CBP but have essentially been removed from Round 2021 of the CBP. Specifically, for items and services included in product categories that have essentially been removed from Round 2021 of the CBP, CMS would consider extending the transition rules at § 414.210(g)(9)(iii) and (v) for items and services furnished in non-CBAs and the fee schedule adjustment rules at § 414.210(g)(10) for items and services furnished in CBAs or former CBAs until such product categories are competitively bid again in a future round of the CBP. Under this alternative, we would consider adjusting the fee schedule amounts for items and services furnished in areas other than rural areas and non-contiguous non-CBAs in accordance with § 414.210(g)(9)(v) based on 100 percent of the adjusted rates beginning on April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, through the date immediately preceding the effective date of the next round of CBP contracts. The fee schedule amounts for items and services removed from the CBP and furnished in rural and non-contiguous non-CBAs would continue to be adjusted based on a 50/50 blend in accordance with § 414.210(g)(9)(iii) through the date immediately preceding the effective date of the next round of CBP contracts. For items and services included in product categories that have essentially been removed from Round 2021 of the CBP, the fee schedule amounts for items and services furnished in CBAs or former CBAs would continue to be adjusted in accordance with § 414.210(g)(10) through the date immediately preceding the effective date of the next round of CBP contracts. In contrast, for items and services that are included in Round 2021 of the CBP, CMS would adjust the fee schedule amounts for such items and services in accordance with the adjustment methodologies outlined in this proposed rule; CMS would pay the 50/50 blended rates in rural and non-contiguous non-CBAs, and 100 percent of the adjusted payment amount established under

[12] *https://www.cqrc.org/img/CQRCCostSurveyWhitePaperMay2015Final.pdf.*

§ 414.210(g)(1)(iv) in non-rural non-CBAs in the contiguous U.S.

We are seeking comments on these alternative methodologies and our proposed methodologies. For instance, we would be interested to learn if there are benefits or downsides to our proposals that we did not consider or discuss in this proposed rule.

III. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

On May 11, 2018 we published an interim final rule (83 FR 21912) in the **Federal Register** entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To provide Relief in Rural Areas and Non-Contiguous Areas'' (which we will refer to as the ''2018 Interim Final Rule''). We solicited comments on the 2018 Interim Final Rule, but because we have not yet responded to the comments we received, we are signaling our intent to do so in the final rule.

Section 5004(b) of the Cures Act amended section 1847(a)(2)(A) of Act to exclude drugs and biologicals described in section 1842(o)(1)(D) of the Act from the DMEPOS CBP. In the 2018 Interim Final Rule, we made conforming changes to the regulation to reflect the exclusion of infusion drugs, described in section 1842(o)(1)(D) of Act, from items subject to the DMEPOS CBP.

As discussed in section II. of this rule, in the 2018 Interim Final Rule, we also expressed an immediate need to resume the transitional, blended fee schedule amounts in rural and non-contiguous areas, noting strong stakeholder concerns about the continued viability of many DMEPOS suppliers, our finding of a decrease in the number of suppliers furnishing items and services subject to the fee schedule adjustments, as well as the Cures Act mandate to consider additional information material to setting fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished on or after January 1, 2019 (83 FR 21918). We amended § 414.210(g)(9) by adding § 414.210(g)(9)(iii) to resume the fee schedule adjustment transition rates for items and services furnished in rural and non-contiguous areas from June 1, 2018 through December 31, 2018. We also amended § 414.210(g)(9)(ii) to reflect that for items and services furnished with dates of service from January 1, 2017 to May 31, 2018, fully adjusted fee schedule amounts would apply (83 FR 21922). We also added § 414.210(g)(9)(iv) to specify that fully adjusted fee schedule amounts would apply for certain items furnished in non-CBAs other than rural and non-contiguous areas from June 1, 2018 through December 31, 2018 (83 FR 21920). We explained that we would use the extended transition period to further analyze our findings and consider the information required by section 16008 of the Cures Act in determining whether changes to the methodology for adjusting fee schedule amounts for items furnished on or after January 1, 2019 are necessary (83 FR 21918 through 21919). We intend to respond to the comments we received on these issues in the final rule.

IV. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

A. Background

1. Origin and Purpose of HCPCS

Section 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under Medicare Part B unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under that part. In order to process claims and determine payment for items and services under Medicare, we need a way to appropriately identify the items and services billed. As discussed later in this section, we have established certain codes for providers and suppliers to use to identify items and services on claims. Medicare receives over 1 billion electronic claims per year.

The Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of Current Procedural Terminology (CPT®) codes.[13] The HCPCS Level II code set is used primarily to identify items, services, supplies, and equipment that are not identified by CPT® codes. The HCPCS Level II codes were originally created for use by government insurers including Medicare.[14] On August 17, 2000, HHS published a final rule (65 FR 50312) in which it adopted HCPCS Level II codes as the standard code set to be used by all payers for, among other things, health care equipment and supplies not described by CPT® codes, for use in Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions (45 CFR 162.1002).[15] The HCPCS Level II coding system was selected as the standard code set, in part, because of its wide acceptance among both public and private insurers. With few exceptions,[16] HCPCS Level II codes are maintained by CMS, which is responsible for making decisions about additions, revisions, and discontinuations to the codes. CMS maintains the code set for Medicare but, because HCPCS Level II is a standard code set designated for use under HIPAA by all payers, CMS also considers the needs of other payers, including both government and private insurers, in establishing and maintaining codes.

The procedures by which the public submits and CMS evaluates external code applications to modify the HCPCS Level II code set have been primarily included in guidance documents released on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.* We update and release the HCPCS Level II dataset files to our contractors and the public via our website on a quarterly basis. Although the HCPCS Level II code set is a coding system used to identify categories of items and services, it is not a methodology or system for making coverage or payment determinations for individual items and services, and the existence or absence of a code does not, of itself, determine coverage or non-

[13] The CPT® is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Decisions regarding the addition, deletion, or revisions of CPT® codes are made and published by the American Medical Association (AMA) through the CPT® Editorial Panel. More information on CPT® codes can be found at *www.ama-assn.org/about/cpt-editorial-panel/cpt-code-process.*

[14] The code set was previously called the HCFA (Health Care Financing Administration) Common Procedure Coding System, after the previous name of the Agency, before it became known as the Healthcare Common Procedure Coding System as it is known today.

[15] Through subtitle F of Title II of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191), Congress added to Title XI of the Social Security Act a new Part C, entitled ''Administrative Simplification.'' HIPAA requires the Secretary to adopt standards for code sets for the electronic transactions, including health care claims transactions, for which the Secretary has adopted a standard.

[16] The Code on Dental Procedures and Nomenclature (CDT® code) represents a separate medical code set adopted under HIPAA. See 45 CFR 162.1002. Based on alpha-numeric format, they are considered HCPCS Level II series D-codes but are maintained, copyrighted, licensed and published separately by the American Dental Association. More information on CDT® codes can be found at *https://www.ada.org/en/publications/cdt.*

coverage for the corresponding item or service.

HCPCS Level II codes are alpha-numeric codes that begin with an alphabetical letter followed by four numeric digits. Currently, there are almost 8,000 HCPCS Level II codes that represent categories of like items and services. Each code includes a text descriptor (code text) that identifies the category of items and services encompassed in the code. HCPCS Level II codes are generally organized into lettered categories that loosely describe the types of codes under that letter; [17] however the lettered categories are not dispositive, meaning that they are not all inclusive of the types of items and services described in the heading for each lettered category.

2. External HCPCS Level II Code Applications

Interested parties seeking to modify the HCPCS Level II code set may submit an application, as available on CMS' website, that requests to add a code, revise an existing code, or discontinue an existing code. The types of items and services subject to the external HCPCS Level II code application procedures and evaluation processes proposed in this rule are described in section IV.B. of this proposed rule. The information collection activity is approved under OMB control number 0938–1042. In recent years, approximately 150 code applications typically have been submitted to CMS annually from the public. As part of our external HCPCS Level II code application process, we establish deadlines for when code applications need to be submitted by the public and post those deadlines on CMS' HCPCS website.

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) requires the Secretary to establish procedures for coding and payment determinations for new DME under Part B of Title XVIII of the Act that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for ICD–9–CM (which has since been replaced with ICD–10–CM as of October 1, 2015). In November 2001, we issued a notice announcing the establishment of public meetings for making coding and payment determinations for new DME beginning in 2002 (66 FR 58743 through 58745). We also issued a notice on March 25, 2005, stating that the public meeting process previously limited to DME was expanded to include all new public requests for revisions to the HCPCS Level II codes (70 FR 15340). This change was intended to provide more opportunities for the public to become aware of and provide comment on code applications and changes under consideration, as well as opportunities for CMS to gather public input. Given the expansion of the public meeting process, we scheduled additional annual public meetings for 2005 and subsequent years.

Public meetings have provided a forum for interested parties to make oral presentations and to submit written comments in response to preliminary HCPCS Level II coding recommendations [18] for new DME, as well as for other items and services included in the public meeting. The dates for the public meetings are announced in the **Federal Register**. Agenda items for the meetings are published in advance of the public meeting. The public meeting agendas generally have included descriptions of the coding requests under consideration, the applicant, the name of the item or service, our preliminary HCPCS Level II coding recommendations and rationale, as well as preliminary Medicare payment recommendations.[19] We publish the public meeting agendas on CMS' HCPCS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.*

Prior to 2020, CMS received and reviewed HCPCS Level II code applications and typically made related coding changes annually, including releasing updated coding files. However, CMS' quarterly systems release process gave CMS the flexibility to review applications and make codes effective quarterly in response to claims processing needs, which it used in very limited circumstances. In November 2019, we announced updates to our HCPCS Level II coding procedures to enable shorter and more frequent HCPCS Level II code application cycles beginning in January 2020 as part of our initiative to facilitate launching new products into the marketplace for providers and patients.[20] Specifically, we implemented a process whereby HCPCS Level II code applications for DMEPOS and other non-drug, non-biological items and services are submitted and reviewed no less frequently than bi-annually; and HCPCS Level II code applications for drugs and biological products are submitted and reviewed no less frequently than quarterly (hereinafter also referred to as bi-annual and quarterly coding cycles, respectively).[21]

Prior to 2020, we included code applications for drugs and biological products in the HCPCS public meeting process, even though not required under section 531(b) of BIPA. In order to achieve the additional time savings necessary to implement coding for the majority of drugs and biological products for which we receive code applications on a quarterly cycle, in November 2019, we updated our HCPCS Level II coding procedures such that beginning January 1, 2020, we no longer conduct public meetings as part of our HCPCS Level II code application process for drugs and biological products.[22] Although code applications for drugs and biological products are no longer included in the public meetings, the 2020 coding procedures provide an opportunity for applicants to resubmit a code application for a drug or biological product in a subsequent quarterly coding cycle, which offers individual applicants who are dissatisfied with our coding decisions in one quarterly cycle an opportunity to reapply in the next or a subsequent quarterly cycle.

We also announced that beginning in 2020, consistent with implementing shorter and more frequent HCPCS

[17] A-codes: Transportation Services, Medical and Surgical Supplies, Miscellaneous; B-codes: Enteral and Parenteral Therapy; C-codes: Hospital Outpatient Prospective Payment System; D-codes: Dental Procedures; E-codes: Durable Medical Equipment; G-codes: Temporary Codes for Procedures and Professional Services; H-codes: Rehabilitative Services; J-codes: Drugs Administered Other Than Oral Method, Chemotherapy Drugs; K-codes: Medicare National Codes for DMEPOS; L-codes: Orthotics, and Prosthetics; M-codes: Medical Services; P-codes: Pathology and Laboratory Services; Q-codes: Medicare National Codes; R-codes: Diagnostic Radiology Services; S-codes: Non-Medicare National Codes; T-codes: State Medicaid Agency Codes; U-codes: Clinical Laboratory Tests; and V-codes: Vision and Hearing Services.

[18] CMS has also previously referred to preliminary recommendations as preliminary decisions. Hereinafter, in section IV. of this proposed rule, we will use the term preliminary recommendation.

[19] Preliminary Medicare payment recommendations (also referred to as preliminary Medicare payment determinations) are discussed in more detail in section V.A.2. of this proposed rule.

[20] HCPCS—General Information. Announcement of Shorter Coding Cycle Procedures, Applications, and Deadlines for 2020. Available at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.*

[21] HCPCS—General Information. Announcement of Shorter Coding Cycle Procedures, Applications, and Deadlines for 2020, available at. *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo;* Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, Rev. September 16, 2020, available at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf.*

[22] Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, revised November 26, 2019.

coding cycles, we will release decisions on coding actions on a quarterly basis in the same format as we previously announced annual decisions.[23] These actions are available on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.* We note that each payer effectuates the changes to the code sets on its own timeframes. For Medicare, unless otherwise announced or specified, Table 4 sets forth the coding timeframes for the 2020 coding cycles. We refer readers to the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo* for the most recent updates and revisions to these timeframes.

TABLE 4—2020 SCHEDULE FOR HCPCS LEVEL II CODING CYCLES

Application topic	Coding cycle	Application deadline	Preliminary recommendation publication	Public meeting	Final decision publication	Coding changes effective date
DMEPOS and Other Non-Drug, Non-Biological Items and Services.	Bi-annual 1 ...	1/06/2020	May 2020	June 1 and 2, 2020**	July 2020	10/01/2020
DMEPOS and Other Non-Drug, Non-Biological Items and Services.	Bi-annual 2 ...	6/29/2020	Approximately 2 weeks prior to the Public Meeting in Fall 2020.	Fall 2020	January 2021 or earlier.	4/01/2021
Drugs and Biological Products	Q1	1/06/2020	N/A*	N/A*	April 2020	7/01/2020
Drugs and Biological Products	Q2	4/06/2020	N/A*	N/A*	July 2020	10/01/2020
Drugs and Biological Products	Q3	6/29/2020	N/A*	N/A*	October 2020	1/01/2021
Drugs and Biological Products	Q4	9/21/2020	N/A*	N/A*	January 2021 or earlier.	4/01/2021

** Announced in the **Federal Register** at 85 FR 21859.

* As further explained, although we previously included code applications for drugs and biological products in our HCPCS public meeting processes, we are not doing so in 2020 in order to achieve the additional time savings necessary to implement coding for the vast majority of drugs and biological products on a quarterly cycle.

As explained in more detail in section IV.B.2. of this proposed rule, there are three types of modifications to the HCPCS Level II code set that can be requested by the public under this process using the application form available on CMS' website: (1) The addition of a HCPCS Level II code; (2) a revision to the long descriptor language (code text) of an existing HCPCS Level II code; and (3) the discontinuation of an existing HCPCS Level II code. The current HCPCS Level II code application and instructions can be found on the CMS HCPCS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Application_Form_and_Instructions.*[24] Anyone may submit an application. We outline procedures we use to make coding decisions for certain items and services that are coded in the HCPCS Level II code set in a document entitled ''Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,'' available on our website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf.*[25] Summaries of external HCPCS code applications with our final coding decisions and rationale are made available on our website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.* Separately, Quarterly Update releases of the full HCPCS Level II code set are made available on our website at *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets.*

B. Proposals for HCPCS Level II Coding Procedures

To increase transparency and gather stakeholder input, we are proposing in this proposed rule to codify certain policies and procedures regarding the submission and evaluation of external HCPCS Level II code applications. Consistent with our current practices, the proposed external HCPCS Level II code application process applies to products paid separately as drugs or biologicals (defined later in the section and in proposed 42 CFR 414.8(a)(2)),[26] and non-drug, non-biological items and services (defined later in the section and in proposed 42 CFR 414.8(a)(1)).[27]

For purposes of section IV.B. of this proposed rule, the term ''products paid separately as drugs or biologicals'' refers to products that are separately payable by Medicare under Part B (and potentially by other payers, such as private insurers) as drugs or biologicals as that term is defined in section 1861(t) of the Act. These products typically fall into one or more of the following three categories: (1) Products furnished incident to a physician's services under sections 1861(s)(2)(A) and (B) of the Act, excluding products that are usually self-administered (for example, tablets, capsules, oral solutions, disposable inhalers); (2) products administered via a covered item of DME; and (3) other categories of products for which there is another Part B benefit category as specified by statute or regulations (for example, drug or biological products described elsewhere in section 1861(s) of the Act, such as immunosuppressive drugs (at section 1861(s)(2)(J) of the Act); hemophilia blood clotting factors (at section 1861(s)(2)(I) of the Act); certain oral anticancer drugs (at section 1861(s)(2)(Q) of the Act); certain oral antiemetic drugs (at section 1861(s)(2)(T) of the Act); pneumococcal pneumonia, influenza and hepatitis B vaccines (at section 1861(s)(10) of the Act)). For ease of reference, when discussing products paid separately as drugs or biologicals in this proposed rule, we will generally refer to these as ''drug or biological products.'' The proposed code application and evaluation processes for drug or biological products are described in section IV.B. of this proposed rule.

For purposes of the proposals regarding HCPCS Level II coding procedures in section IV.B. of this proposed rule, the term ''non-drug, non-

[23] Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, Rev. September 16, 2020, available at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf.*

[24] Updated September 2020.

[25] Updated September 2020.

[26] Note, in prior code documents on our website, we used the reference ''drugs and biological products'' (see ''Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,'' available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf*).

[27] Note, in prior code documents on the website, we used the reference ''DMEPOS and other non-drug, non-biological items and services'' in our ''Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,'' available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf.*

biological items and services'' refers to items and services that Medicare (and potentially other payers, such as private insurers) typically pay separately [28] and that are described in the following list,[29] as well as certain items and services that are not covered under Medicare (as described in the following list):

- Medical and surgical supplies, such as splints and casts described in section 1861(s)(5) of the Act and therapeutic shoes described in section 1861(s)(12) of the Act.
- Dialysis supplies and equipment such as those described in section 1861(s)(2)(F) of the Act.[30]
- Ostomy and urological supplies such as those described in section 1861(s)(8) of the Act.
- Surgical dressings such as those described in section 1861(s)(5) of the Act.
- Prosthetics (artificial legs, arms, and eyes) such as those described in section 1861(s)(9) of the Act and prosthetic devices such as those described in section 1861(s)(8) of the Act.
- Orthotics (leg, arm, back, and neck braces) such as those described in section 1861(s)(9) of the Act.
- Enteral/parenteral nutrition such as those described in section 1842(s)(2) of the Act.
- Durable Medical Equipment (and related accessories and supplies other than drugs), such as oxygen and oxygen equipment, wheelchairs, infusion pumps, and nebulizers such as those described in sections 1861(s)(6) and 1861(n) of the Act.
- Vision items and services, such as prosthetic lenses described in section 1861(s)(8) of the Act.
- Other items and services that are statutorily excluded from Medicare coverage for which CMS or other government or private insurers have identified a claims processing need for a HCPCS Level II code, such as hearing aids which are excluded from coverage by section 1862(a)(7) of the Act.

We note that these are the general categories of non-drug, non-biological items and services currently listed in the HCPCS Level II code application [31] on our website. For purposes of this proposed rule, the term non-drug, non-biological items and services does not include drugs covered under the DME benefit as supplies put directly into DME, such as a nebulizer or infusion pump, to achieve the therapeutic benefit of the DME (such drugs, as noted previously, are considered ''drug or biological products'' under this proposed rule), but does include gaseous or liquid oxygen put into oxygen equipment (tanks or other containers).

The proposed code application procedures and evaluation processes in section IV.B of this proposed rule would not apply to other items and services described in procedural codes for oral health and dentistry that begin with the letter ''D'' (CDT® codes), which are published, copyrighted, and licensed by the American Dental Association (ADA) and are not maintained by CMS, nor items and services coded by CMS internally that are not based on an external application request and are based exclusively on Medicare claims processing needs.

1. Proposed HCPCS Level II Coding Cycles and Related Policies

As discussed in section IV.A.2. of this proposed rule, beginning in January 2020, the following coding cycles for HCPCS Level II code applications apply: (1) For non-drug, non-biological items and services, coding cycles begin no less frequently than bi-annually; and (2) for drug or biological products, coding cycles begin no less frequently than quarterly. As discussed in more detail later in the section, we propose to codify these coding cycles and certain related policies for code applications for non-drug, non-biological items and services, and for drug or biological products. We propose to add new sections §§ 414.8 and 414.9 to set forth these proposed policies.

a. Coding Cycles for Non-Drug, Non-Biological Items and Services

We propose that for HCPCS Level II code applications for non-drug, non-biological items and services, we would continue to begin a new coding cycle for such code applications no less frequently than bi-annually. Subject to the exceptions proposed and explained later in this section, we also propose that for each coding cycle for non-drug, non-biological items and services, we would continue to: (1) Establish a deadline for submitting code applications in or around January or June each year (depending on the cycle) on the CMS website or in another manner; (2) issue preliminary recommendations (a preliminary recommendation may also include questions or requests for additional information that could help CMS in reaching a final decision) on code applications that will be addressed at the public meeting on the CMS website or in another manner prior to the relevant public meeting; (3) hold public meetings to provide the public with an opportunity to become aware of and provide input on code applications and preliminary recommendations under consideration for that coding cycle; and (4) issue final coding decisions on the CMS website or in another manner within approximately 6 months of the code application deadline. Consistent with our current practice, coding changes would become effective approximately 3 months after issuance of the final coding decision. We propose to add new § 414.8(b), (c), (d) and (e) to set forth these proposed procedures.

We currently post all of our final coding decisions on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.* We believe these proposed bi-annual coding cycles for non-drug, non-biological items and services allow us sufficient time to issue preliminary recommendations in advance of the public meetings and to meet the statutory requirement under section 531(b) of BIPA that we permit public consultation on coding determinations for new DME (which we currently accomplish through our public meetings), while also being responsive to previous stakeholder feedback requesting faster coding decisions. We note that even though section 531(b) of BIPA requires procedures for coding determinations for new DME that permit public consultation, as explained in section IV.A.2. of this proposed rule, we previously expanded public meetings to include all new HCPCS Level II code applications because we believe it is helpful to obtain public input on code applications for as many items and services as possible. Therefore, we are proposing at §§ 414.8(d) and 414.8(b), to continue to include not only code applications for new DME items and services in the public meetings, but also code applications for all non-drug, non-biological items and services and to

[28] Items and services that are separately payable would not be included in a bundled payment. We discuss this in more detail in section IV.B.2 of this proposed rule.

[29] The statutory citations and corresponding definitions are not intended to be strict definitions of the items and services in these categories or the categories themselves, but are intended for purposes of describing the types of non-drug, non-biological items and services that are subject to the HCPCS Level II code application process.

[30] Beginning January 1, 2011, all renal dialysis services defined under 42 CFR 413.171 are paid under the ESRD PPS, and therefore, we do not pay separately for most dialysis supplies and equipment. However, the transitional drug add-on payment adjustment (TDAPA) and the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES), available under the ESRD PPS (42 CFR 413.234 and 413.236), require separate coding for certain items and services that are eligible for a payment adjustment.

[31] HCPCS Code Application, Question #3.

follow the bi-annual coding cycle schedule for them.

We also considered proposing coding cycles of no less frequently than quarterly for non-drug, non-biological items and services. While quarterly cycles for non-drug, non-biological items and services could provide for faster coding decisions on these items and services and would align with our proposal for quarterly coding cycles for drug or biological products, as further discussed in section IV.B.1.b. of this proposed rule, we believe quarterly coding cycles would not allow us sufficient time to evaluate the applications for all non-drug, non-biological items and services, issue preliminary recommendations, hold public meetings, and issue final coding decisions. All of these activities would require more than 3 months to complete. As described earlier in this section, we are proposing to continue seeking public input at our public meetings on preliminary recommendations issued for all non-drug, non-biological items and services under consideration in a given bi-annual coding cycle, and not just for new DME items and services. In addition, in our experience, applications for non-drug, non-biological items and services tend to be more complex or require more research and review time than code applications for drug or biological products, and therefore we typically need more than 3 months for their evaluation. For example, non-drug and non-biological items and services may not be regulated by the Food and Drug Administration (FDA) and therefore, the manufacturer may not conduct clinical studies and in that case we may not receive clinical studies with the HCPCS Level II code application. Thus, applications for such items and services would require independent review and research by CMS to evaluate, for example, whether the item or service has functional or clinical differences compared to other similar items and services already described in the code set and thus, we would need more time to gather such information, if available, and review the code application. By contrast, as described in section IV.B.1.b. of this proposed rule, drug or biological products are regulated by the FDA and code applications for approved drug or biological products include detailed FDA documentation, which typically include clinical information and studies that assist us in evaluating the application. Thus, typically we require less time to assess such applications than many of the applications for non-drug, non-biological items and services. As a result, while we are proposing quarterly coding cycles for drug or biological products, we believe bi-annual cycles are more appropriate for applications for non-drug, non-biological items and services.

We also propose at § 414.8(e)(3), consistent with our current practice, that in circumstances where code applications for non-drug, non-biological items or services raise complex or significant issues or considerations and we determine that additional time is needed to evaluate such applications, we may delay issuing a preliminary recommendation and therefore delay the final coding decision. We note that a decision to delay a preliminary recommendation would have the effect of pushing the code application to the next coding cycle for further determination. In addition, after issuing a preliminary recommendation, we may delay issuing the final coding decision. These delays may be for one or more coding cycles (depending on the nature and timing of the issues raised). While we make every effort to complete our review and issue final coding decisions for all timely and complete code applications within the applicable coding cycle, there are occasions where additional time and evaluation are necessary to fully assess certain applications because the code application raises complex or significant issues or considerations. These circumstances would include, but are not limited to, situations where the code application involves a significant policy consideration (for example, a unique issue related to a specific item or service or group of items or services, such as appropriate coding for combination products that include a drug and a service component), involves a significant claims processing consideration (for example, operational issues arising from a coding action requiring significant revisions to the claims processing system, such as re-tooling to add another character to the price field to accommodate higher prices than contemplated when the system was established, including determining whether the claims processing system change could be made, and in what timeframe, to ensure that the coding solution would be viable, or whether an alternative solution needs to be implemented before publishing new codes), or requires in-depth clinical or other research.

We note that under our current process, we also may delay issuing preliminary recommendations and final coding decisions on code applications because we need additional time to evaluate the applications. We note that this occurs infrequently, and we believe it is important to continue this practice to allow us sufficient time to evaluate and determine appropriate coding actions on certain applications. While we expect to make a final coding decision within the next coding cycle in most instances where we determine such delays are necessary, we may further delay issuing a preliminary recommendation and final coding decision, or a final coding decision after a preliminary recommendation, to subsequent coding cycles. We expect extended delays would be rare and would only occur if necessary due to significant complexities arising from an application that requires additional consideration and time to come to a preliminary recommendation or final coding decision. We believe the ability to extend our evaluation of an application in limited circumstances for more than one bi-annual coding cycle may be necessary to account for potential significant complexities presented by individual applications, particularly in light of the proposed bi-annual coding cycles, so that we can continue to ensure we have sufficient time as well as information needed to determine the most appropriate coding action. Therefore, we propose that, where additional time and evaluation are necessary to fully assess an application (including in the circumstances described earlier), we may delay issuing a preliminary recommendation, and therefore, the final coding decision, or after making a preliminary recommendation, we may delay issuing a final coding decision alone, on the application for one or more coding cycles. We propose to add new § 414.8(e)(3) to set forth this proposed policy. We note that prior to a final coding decision, miscellaneous codes are available for assignment by insurers, if they deem appropriate, to allow suppliers to begin billing for an item or service as soon as it receives FDA marketing authorization for those items and services that require such marketing authorization, or as soon as it begins marketing for those items and services that do not require FDA marketing authorization, including during the HCPCS code application review process.

In cases in which we determine that we need additional time to make a preliminary recommendation, we propose that we would continue our current practice of issuing a determination that additional time is needed to evaluate a particular

application, either on the CMS website or in another manner, at the same time that we issue preliminary recommendations for other items and services included in that coding cycle (see proposed § 414.8(e)(3)(iii)). We also may seek additional information from the applicant or other sources or both as we continue to consider the application, which is consistent with our current practice.

In cases in which a preliminary recommendation is issued, but we later determine that we need additional time to come to a final coding decision, we propose to continue our current practice of issuing a determination that additional time is needed to evaluate a particular application, either on the CMS website or in another manner, at the same time that we issue final coding decisions for other items and services included in that coding cycle (see proposed § 414.8(e)(3)(iii)). In such cases, we propose to continue to evaluate that application in the next coding cycle and note that per proposed § 414.8(e)(3) it could be delayed into additional subsequent cycles. We may seek additional information from the applicant or other sources or both as we continue to consider the application.

b. Coding Cycles for Drug or Biological Products

We propose that for HCPCS Level II code applications for drug or biological products, we would continue to begin new coding cycles for such code applications no less frequently than quarterly. Subject to the exceptions proposed and explained later in this section, we also propose that for each coding cycle for applications for drug or biological products, we would continue to: (1) Establish (on the CMS website or in another manner) a deadline for submitting code applications, which would occur in or around January, April, June, or September each year depending on the cycle; and (2) issue final coding decisions on the CMS website or in another manner, within approximately 3 months of the code application deadline. Coding changes would become effective approximately 3 months after issuance of the final coding decisions. We currently post summaries of the applications with our final coding decisions on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.* We propose to codify these procedures at proposed § 414.8(b), (c)(2), and (e).

The proposed quarterly coding cycles for drug or biological products are responsive to previous stakeholder feedback requesting faster coding cycles for such products. We also believe that faster coding cycles may facilitate and expedite claims processing and launching new products into the marketplace for providers and patients. We believe that quarterly cycles are appropriate for most drug or biological product applications because it is our experience that drug or biological product applications tend to be more straightforward and take less time to assess than many of the applications for non-drug, non-biological items and services. Most separately paid Part B drugs are paid using the methodology in section 1847A of the Act, and the code evaluation process for many drug or biological products is based on Medicare statutory requirements consistent with section 1847A of the Act. Specifically, section 1847A of the Act requires different payment methodologies for single source drugs, multiple source drugs, and biological products (including biosimilar biological products), which, in turn, necessitates separate codes for purposes of facilitating separate payment amounts. The use of separate codes for this purpose is discussed further in subregulatory guidance published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*). In most cases, information pertaining to the need for separate payment amounts for drug or biological products under section 1847A is driven by factors such as the FDA approval pathway (for example, a Biologics License Application (BLA), New Drug Application (NDA), or Abbreviated New Drug Application (ANDA)) as well as Therapeutic Equivalence ratings as provided in section 1847A(c)(6)(C). Information on these factors is easy to obtain using public sources such as Daily Med (*https://dailymed.nlm.nih.gov/dailymed/index.cfm*), the Orange Book (*https://www.accessdata.fda.gov/scripts/cder/ob/*), and the Purple Book (*https://purplebooksearch.fda.gov/*). In addition, the FDA approval processes for drug or biological products, and the accompanying documentation provided with external HCPCS Level II code applications for those products, which includes clinical data, information relevant to the safety profile, clinical indications for use, contraindications, and appropriate use or dosing intervals and other information, helps us evaluate those applications faster and tends to allow CMS to make final coding decisions about the program need for a code and the information required for a code descriptor without the need for public input. The proposed procedures for evaluating drug or biological product code applications are discussed in more detail in section IV.B.2. of this proposed rule. For situations where more detailed information may be required to support coding decisions pertaining to an external code application, for example if we are not able to immediately establish whether the drug is separately payable under Part B, we may delay the final coding decision to a subsequent coding cycle as proposed later in this section.

Furthermore, except for code applications that are resubmitted for reevaluation as provided in proposed § 414.9(b), and code applications where a decision is delayed under proposed § 414.8(e)(3) that present program, policy, or implementation concerns or complexities, or otherwise raise questions that public input could help to address (see proposed § 414.8(d)(4)(ii)), we propose that, consistent with our current procedures, we would not hold public meetings or issue preliminary recommendations for drug or biological product code applications. Because of the additional time needed to prepare for and hold the public meetings, we believe it would not be feasible to include public meetings within the quarterly cycles. We note that there is no statutory requirement for public consultation on drug or biological product coding determinations. We propose to set forth this proposed policy at new § 414.8(d)(4). We refer readers to section IV.B.1.d. of this proposed rule where we propose to add drug or biological product applications to a bi-annual public meeting agenda if an applicant is dissatisfied with a prior final coding decision and submits an application for reevaluation. We refer readers to later in this section where we propose that we may add drug or biological product applications to a bi-annual public meeting if the code applications are delayed and present program, policy, or implementation concerns or complexities, or otherwise raise questions that public input could help to address.

We also considered coding cycles of no less frequently than bi-annually for applications for drug or biological products, which would align with our proposal for bi-annual coding cycles for non-drug, non-biological items and services discussed in section IV.B.1.a. of this proposed rule and enable us to include all drug or biological product applications in the public meeting process. While we understand there is value in providing an opportunity for the public to submit input and for CMS to consider public input on all applications, we also believe that by

expediting coding decisions for drug or biological products and the incorporation of such products in the claims processing system, quarterly coding cycles for drug or biological product applications may facilitate patient and provider access to new products. In addition, as explained previously, we believe that generally, we can make well-informed HCPCS Level II coding decisions for drug or biological products based on the information contained in the code applications without a public meeting given that applications for such products are largely evaluated based on Medicare statutory requirements consistent with section 1847A of the Act, and the code applications include detailed FDA documentation, as discussed earlier in this section. Given these considerations, we believe that more expeditious coding for these products outweighs the benefit of including such applications in the public meeting process.

As noted, the trade-off for conducting public meetings for applications for drug or biological products would be longer coding cycles, such as bi-annual cycles, to accommodate the time required to prepare preliminary recommendations and conduct public meetings, evaluate public input received from the public meetings, and reach final coding decisions for such applications. We seek comments on whether it would be appropriate or preferable to instead adopt coding cycles of no less frequently than bi-annually for drug or biological product code applications, which would enable us to issue preliminary recommendations and solicit public input at public meetings on all such products for a given coding cycle.

For applications for drug or biological products, we propose at § 414.8(e)(3) that, consistent with our current practice, in circumstances where the code application raises complex or significant issues or considerations and we determine that additional time is needed to evaluate the code application, we may delay issuing a final coding decision by one or more coding cycles. While we will make every effort to complete our review of all timely and complete code applications within the applicable coding cycle, there will be occasions where additional time and evaluation are necessary to fully assess certain applications because the application raises complex or significant issues or considerations. These circumstances would include, but are not limited to, situations where the code application involves a significant policy consideration (for example, a unique issue related to a specific drug or biological product or group of drug or biological products), or a significant claims processing consideration (for example, operational issues arising from a coding action requiring significant revisions to the claims processing system); or the code application requires in-depth clinical or other research (for example, if we are not able to immediately establish whether the drug is separately payable under Part B). Based on coding experience with Part B drugs since the implementation of section 1847A of the Act, we anticipate that these situations would be particularly rare for drug or biological product applications, which tend to be more straightforward than applications for non-drug, non-biological items and services, as explained earlier in this section. While in most instances where we determine such a delay is necessary we expect to make a final coding decision within the next coding cycle, we propose that in certain circumstances, we may further delay issuing a final coding decision into a subsequent coding cycle. We expect this would be a rare occurrence, and would only be done if necessary due to significant complexities arising from an application that requires additional consideration and time to come to a final coding decision. We believe the ability to extend our evaluation of an application in limited circumstances for more than one coding cycle may be necessary to account for potential significant complexities presented by individual applications, particularly in light of the proposed shorter coding cycles, so that we can continue to ensure we have sufficient time, as well as information needed, to determine the most appropriate coding action. We propose to set forth this proposed policy at new § 414.8(e)(3). As is our current practice, we also propose that we would continue to issue a determination that additional time is needed to evaluate a particular application on the CMS website or in another manner at the same time that we issue final coding decisions for drug or biological products included in that coding cycle, in the same way as described in section IV.B.1.a. of this proposed rule for non-drug, non-biological items and services (see proposed § 414.8(e)(3)(iii)). We reiterate that we believe such delays would occur infrequently, and we would make every effort to complete our review and issue final coding decisions for all timely and complete code applications within the applicable coding cycle.

Additionally, in some of these situations where we delay a final coding decision we propose at § 414.8(d)(4)(ii) that we may also add the application to the agenda for a public meeting, in order for CMS to obtain further input and public discussion of the application. We would add an application for a drug or biological product to a public meeting agenda only when we believe that an individual application requires additional consideration because it presents program, policy, or implementation concerns or complexities, or otherwise raises questions that public input could help to address, such as where we believe we may need input from other external sources such as clinicians or other users of the product. For example, we believe it may be helpful to gather public input when a request to code a new drug that is similar to other drugs categorized within existing HCPCS Level II codes would involve modifying, discontinuing existing codes, or replacing those existing codes with new ones. In these types of circumstances, gathering public input through the public meeting process could facilitate our review of the application and assist in reaching an appropriate coding decision. If an application is put on a public meeting, we propose that we would issue a preliminary recommendation prior to that public meeting. In order to provide sufficient time to prepare for the public meeting, we would not be able to include the application on a public meeting in the quarter in which it is submitted, even if regular bi-annual public meetings were held in that quarter. In other words, if an application for a drug or biological product is included in a public meeting it would need to follow the bi-annual cycle schedule and would also be subject to the proposals that allow for delay of preliminary recommendations and final coding decisions for one or more cycles under new § 414.8(e)(3). Given that including a drug or biological product code application on a public meeting agenda could result in delaying a final coding decision more than one quarterly cycle given the bi-annual public meeting timelines, we would weigh the benefit of and need for receiving public input with the interests of making final coding decisions as quickly as possible when deciding whether to put a drug or biological product code application on a public meeting agenda. For instance, while we may determine that we need to delay a final coding decision on an application for a drug or biological product to consider complexities or other concerns internally, if we do not

believe public input is needed, we may decide not to place the application on a public meeting agenda, which would give flexibility to potentially come to a final coding decision in the next quarterly coding cycle. For example, if an application is submitted by the deadline in the second quarterly coding cycle, which has an application deadline around April, and we decide to delay the final decision, if we also decide to put the application on a public meeting agenda, the earliest public meeting it could be placed on would be the public meeting for the second bi-annual cycle, which would necessarily delay the final decision at least two quarterly cycles. However, if the final decision is delayed but it is not placed on a public meeting agenda it may be possible to come to a final decision within the next quarterly cycle, depending on the circumstances. Our goal is to make every attempt to make final coding decisions as quickly as possible and avoid unnecessary delays. We note that any determination to include an application in a public meeting would be initiated by CMS based on the considerations described in this section and would not be granted based on requests from an applicant.

We also seek public comment on whether there may be other circumstances under which it may be appropriate for CMS to decide to include a drug or biological product application in a public meeting (for example, when an applicant requests to add such an application to the public meeting process; or other particular circumstances where a public meeting would be important). However, we note that unless the addition of an application for drug or biological product to a public meeting agenda is a rare occurrence, we believe that the operational burden of accommodating public meetings for these products could make it infeasible for CMS to carry out a quarterly coding review cycle for drug or biological product applications. Consequently, if stakeholders favor public meetings for the review of applications for drug or biological products on other than a very infrequent basis, it is likely that we would need to consider implementing bi-annual coding cycles for all drug or biological product applications, including a public meeting component.

As an alternative to including the code applications described at proposed § 414.8(d)(4)(ii) in a public meeting, we considered soliciting public input for such applications through the CMS website (rather than a public meeting). We considered that such a web-based public input process would occur bi-annually, as the public meetings do, and would include posting on CMS' HCPCS website either a preliminary HCPCS coding recommendation, one or more coding options for which we are seeking feedback, one or more questions, or other requests for comment or information that would help CMS formulate a coding decision. We considered that this process could be applied to the same types of code applications we propose at § 414.8(d)(4)(ii) to include in a public meeting, that is, where we determine to delay a decision on a code application and we determine the application requires additional consideration because it presents program, policy, or implementation concerns or complexities, or otherwise raises questions that public input could help to address. We considered that a 15-calendar day period for public input could be applied under such a process, with the comment window beginning on the date that the public would be invited to comment on the CMS website. We note that a 15-calendar day period is approximately the same amount of time we currently provide for submitting public input on preliminary recommendations issued for non-drug, non-biological code applications in the public meeting agenda (which is generally posted approximately two weeks prior to the associated public meeting), including written and oral comments related to public meetings, if received by the end of the public meeting at which the relevant application is discussed. Similar to the proposal to add select drug or biological product applications to the public meeting process, in order to provide sufficient time to prepare either a preliminary HCPCS coding recommendation, one or more coding options for which we are seeking feedback, one or more questions, or other requests for comment or information that would help CMS formulate a coding decision, we believe that we would not be able to put an application through such a web-based public input process in the same quarter in which the application is submitted and would need to follow the bi-annual cycle schedule. We considered that we would also similarly weigh the benefit of and need for receiving public input through such a web-based process with the interests of making final coding decisions as quickly as possible when deciding whether to put a drug or biological product code application through such a web-based public input process, given the potential that a final decision may be delayed more than two quarters depending on the timing of the bi-annual public input periods. While we are not proposing in § 414.8(d)(4)(ii) a web-based public input process for drug or biological product code applications described in that proposed provision, we seek comment on the alternative we considered (as discussed previously) to solicit public input for such drug or biological product applications through the CMS website (rather than in a public meeting). We also seek comment on whether there may be other specific circumstances in which public input via such a web-based public input process may be useful, considering that under the shorter coding cycles only a limited number of applications could be accommodated.

c. Proposed Requirements for Applications To Be Considered in a Coding Cycle

Consistent with our current procedures and requirements for HCPCS Level II code applications, we propose at new § 414.9(a) that to be considered in a given coding cycle, an application must be timely and complete. We further propose that an application that is not timely and complete would be declined by CMS but may be submitted by the applicant in a subsequent coding cycle. We propose at new § 414.9(a)(1) that an application is timely if it is submitted to CMS by the applicable code application submission deadline specified by CMS for each coding cycle, which CMS posts on its website or in another manner, or as specified in proposed § 414.9(a)(3). We propose at new § 414.9(a)(2)(i) that an application would be considered complete if it includes, by the applicable code application submission deadline, the applicable information and documentation required in proposed § 414.9, and meets the administrative elements as specified by the application instructions issued by CMS and posted on the CMS website (for example, it includes answers to all of the application questions, includes required FDA documentation, and is within the page limit). We also propose at new § 414.9(a)(2)(ii) that, consistent with our current practice, for an application to be complete, the applicant provide FDA documentation of the item's current classification, as applicable, as well as FDA marketing authorization documentation, or provide the regulation number under 21 CFR parts 862 through 892 for a device exempted from the premarket notification requirement. If a device exceeds the limitations to the exemptions under 21 CFR parts 862 through 892 of the device

classification regulations, the appropriate marketing authorization documentation must be submitted to CMS as part of the application. We propose that FDA documentation of the item's current classification, as applicable, and FDA marketing authorization documentation, or the regulation number under 21 CFR parts 862 through 892 for a device exempted from the 510(k) requirement would be required to be submitted with the code application by the relevant HCPCS Level II code application deadline, for an application to be complete.

Additionally, for biosimilar biological products, we propose to allow a 10-business day extension past the application deadline to provide a complete application, including FDA marketing authorization documentation, if the proposed criteria discussed later in this section are met. Under the annual coding cycle prior to 2020, for drug or biological product code applications, we provided a 3-month extension for submission of FDA marketing authorization documentation and to provide updates to the application based on the FDA marketing authorization documentation. However, the shorter quarterly coding cycles for drug or biological product applications cannot accommodate a 3-month extension for submission of FDA marketing authorization documentation and to update the application based on that documentation, as was previously offered under the annual coding cycle, and thus, beginning in 2020, we eliminated the 3-month extension to enable the quarterly coding cycles for drug or biological products. Therefore, currently, in order for an application to be complete, code applications must be submitted by the application deadline with the aforementioned FDA documentation. Under the shorter quarterly coding cycles, applicants who are unable to submit a complete application, including the required FDA marketing authorization documentation, by the application deadline for a given coding cycle would be able to submit the application and required FDA marketing authorization documentation for the next quarterly cycle, provided the application is complete by the next coding cycle's application deadline. We note that under our previous annual coding process prior to 2020, the next opportunity to submit was the next annual coding cycle.

Our recent changes to the coding cycles were designed to facilitate more rapid coding, which could be frustrated if required FDA documentation is unavailable for a large number of applications at the deadline because the items have not yet received FDA marketing authorization, or if a lengthy extension is allowed in order to provide such documentation. We have concerns about the impact of extending the submission deadline for required FDA marketing authorization documentation and the impact that not having the documentation would have on the ability to provide complete information in the rest of the application and how that could further compress the amount of time available to process applications. We also have concerns about allowing deadline extensions for all drug or biological product code applications given our resources and the compressed review timeframe under shorter quarterly coding cycles. If we were to consider extensions to accommodate submission of required FDA documentation for all drug or biological product code applications, we believe that this would potentially strain our resources and possibly hinder our ability to thoroughly evaluate applications and issue final coding decisions in a timely manner. Therefore, we do not believe an extension for the submission for required FDA documentation would be feasible for all drug or biological product applications. However, we recognize that there may be instances in which an extension to accommodate the submission of required FDA documentation past the quarterly application deadline for certain items and services could serve broader Medicare programmatic goals, particularly where expedited coding could facilitate and expedite claims processing, without straining our resources and possibly hindering our ability to thoroughly evaluate and issue final coding decisions for all the applications we receive in a given coding cycle.

Stakeholders have mentioned biosimilar biological products as a type of product that might warrant an extension for submitting required FDA documentation beyond the code application deadline while still allowing a coding decision to be made within a particular coding cycle to facilitate faster coding for such products. A biosimilar biological product is a biological product that is highly similar to and has no clinically meaningful differences in terms of safety, purity, and potency from an FDA-approved biological reference product.[32] In the Revisions to the Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018 final rule (CY 2018 PFS and Other Revisions to Part B final rule) (82 FR 53186) we finalized a policy to separately code and pay for biosimilar biological products under Medicare Part B. In that final rule, we noted that we were persuaded that there is a program need for assigning Part B biosimilar biological products into separate HCPCS codes, and specifically that the policy would address concerns about a stronger marketplace, access to these drugs in the United States marketplace, provider and patient choice and competition. As stated in the CY 2018 PFS and Other Revisions to Part B final rule (82 FR 53186), we believe that the change in policy encourages the innovation needed to bring more products to the market by encouraging greater manufacturer participation in the marketplace and the introduction of more biosimilar biological products, thus creating a stable and robust market, driving competition and decreasing uncertainty about access and payment. Additionally, we stated we believe that the policy provides physicians with greater certainty about biosimilar payment and that, in turn, that will affect utilization of biosimilar biological products, creating more demand that would help increase competition (82 FR 53186). We also anticipated greater access to biosimilar biological products and that more price competition between more products would occur. Finally, as stated in the CY 2018 PFS and Other Revisions to Part B final rule (82 FR 53186), we believed the change in policy could lead to additional savings for Medicare and its beneficiaries over the long-term by increasing the utilization of products that are less expensive than reference biologicals. We believe that providing a code application deadline extension for biosimilar biological products to accommodate the submission of required FDA documentation past the application deadline would similarly support the goal of a competitive market because it will facilitate faster assignment of a separate HCPCS code, which we believe will increase the availability of and access to biosimilar biological products. We also believe that providing an extension for submitting the required FDA documentation for biosimilar biological products will help further the President's initiative to promote access to generics and biosimilar biological products in order to lower prescription drug costs for all Americans.[33] We believe this 10-

[32] *See* section 351(i)(2) of the Public Health Service Act.

[33] *See* ''Increasing Access to Generics and Biosimilars in Medicare'' (Feb. 5, 2020) available at

Continued

business day extension would be helpful for manufacturers of biosimilar biological products seeking a HCPCS Level II code who receive their FDA marketing authorization just after the deadline for submitting an application in a given coding cycle, and because we do not currently receive many applications for biosimilar biological products, we do not believe this extension would impact our ability to review all the applications and issue final coding decisions in a particular coding cycle. We do not believe an extension longer than 10-business days would be feasible given the number of applications we receive in a coding cycle and the resources for evaluating those applications. We note that if we were to begin receiving a large number of applications for biosimilar biological products within the 10-business day extension period in a coding cycle, and the number of applications negatively impacted our timely review of all of the applications we received, we might decide to reconsider this proposed policy, if finalized.

Thus we propose to add a new policy at new § 414.9(a)(3) that would establish a 10-business day extension past the code application deadline for submitting a complete application, including FDA marketing authorization documentation, for biosimilar biological products. We propose that this extension would apply only if the following proposed criteria are met: (1) The marketing authorization documentation is dated between the first day of the extension period and no later than the last day of the extension period; and (2) the applicant submits a complete application to CMS by the last day of the extension period. We believe these proposed limitations are necessary to limit the deadline extension only to those applicants that receive marketing authorization after the regular quarterly application deadline and before the end of the extension period. We believe a 10-business day extension would be an adequate and reasonable amount of time for applicants, given the proposed shorter quarterly coding cycles, while still allowing enough time for CMS to evaluate the code application and generally make a final coding decision within the quarterly coding cycle. We also considered an extension of up to 3 weeks. Because there are only a limited number of days in the quarterly coding cycle to evaluate the applications and because we are usually already heavily involved in application review by that point, we believe it would be very difficult for us to provide an extension beyond 10 business days and still be able to make a final coding decision in the quarterly coding cycle. Given implementation of shorter, quarterly coding cycles, we believe it is reasonable to have applicants submit a full and complete application in the next coding cycle when complete documentation cannot be submitted by the 10-business day extension after the code application deadline. We also considered extensions shorter than 10 business days, but we believe shorter extensions might not make a meaningful difference for applicants to receive an FDA decision and submit the required documentation to CMS.

Also, while we do not believe an application deadline extension to accommodate later submission of required FDA documentation would be feasible for all drug or biological product applications given our resources and the compressed review timeframe under shorter coding cycles, we seek comment on other potential circumstances that could warrant such a deadline extension within the quarterly coding cycles (for example, for particular drugs or drug classes). We note however that our ability to accommodate any extension is based on our expectation that the extension would impact only a limited number of applications. If the number of applications that are submitted to CMS within an extension period becomes too large, we may need to reevaluate the policy, if finalized. We also seek comment on the appropriate length of an extension for those circumstances, taking into consideration that one possible approach to address requests for more lengthy extensions, or a higher volume of applications submitted within an extension period, may be a longer coding cycle (for example, a bi-annual coding cycle) for all drug or biological product applications. We also seek comment on the impact of product launch delays for biosimilar biological products once they are approved by the FDA. A number of biosimilar biological products have not been launched immediately after their approval by the FDA, thus we seek comment on whether a 10-day deadline extension is necessary.

Consistent with current practice, we also propose at new § 414.9(a)(2)(iii) that in order for applications for non-drug, non-biological items or services that are not subject to marketing authorization under the Federal Food Drug & Cosmetic Act (FD&C Act) or Public Health Service Act (PHSA) to be considered complete, the application must include evidence that the item or service is available in the U.S. market for use and purchase at the time of the relevant HCPCS Level II code application submission deadline specified by CMS. Prior to 2020, we had a requirement for 3 months of marketing activity at the time of the application deadline to create or revise a code for non-drug items, although an insurer could assign a miscellaneous code for use until such time as a coding decision is made.[34] Beginning in 2020, we adjusted the marketing criteria to only require evidence that the item or service is available in the U.S. market for use and purchase at the time of the relevant HCPCS Level II code application submission deadline, to improve the speed of beneficiary access to new items and services, and applied this policy to non-drug items that are not regulated by the FDA. We believe it is important that non-drug, non-biological items not subject to marketing authorization under the FD&C Act or PHSA be available in the U.S. market for use and purchase at the time of the relevant HCPCS Level II code application submission deadline as some measure of assurance that the item is available for prescription or use and thus is ready to receive a HCPCS Level II code. We believe this minimizes the chance of adding unnecessary codes or making updates to the code set that may not be useful, thus promoting administrative simplification and minimizing burden on insurers, providers, coders, and other users of the HCPCS code set. As discussed in more detail in section IV.B.2. of this proposed rule, a major goal of an effective code set is to strike a balance between sufficiently identifying and differentiating items and services and producing a manageable system and set of codes for users to efficiently submit and process claims. When a new code is added, updates

https://www.cms.gov/blog/increasing-access-generics-and-biosimilars-medicare.

[34] HCPCS Level II codes include ''miscellaneous/not otherwise classified'' codes. Historically, these codes have been used when a supplier is submitting a bill for an item or service for which there is no existing code that adequately describes the item or service being billed. If a supplier or manufacturer has been advised to use a miscellaneous code (also known as unlisted code, unclassified code, or not otherwise specified code) because there is no existing code that describes the item or service but the supplier or manufacturer believes that a new code is needed, then the supplier or manufacturer may submit an application to add a new HCPCS Level II code. Significantly, miscellaneous codes allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the FDA in the absence of a specific HCPCS code—including during the period when a request for a new code is being considered under the HCPCS code review process. In addition, to avoid the inefficiency and administrative burden of assigning distinct codes, miscellaneous codes also may be used for items or services that are rarely furnished or for which few claims are expected to be submitted.

must be disseminated, policies and coding manuals revised, and medical records, billing software, and other systems changes are necessary to accommodate the new and revised codes. In addition, coders, providers, and suppliers have to be educated on and prepared for changes in codes to ensure they are accurately utilizing the appropriate code that best describes a specific item or services. By contrast, given the rigorous FDA marketing authorization processes, requirements for clinical data, and the user fees generally associated with the FDA marketing authorization processes, CMS believes that manufacturers of items that are subject to FDA marketing authorization intend to market the product that is the subject of the code application and as such we do not require evidence that these items are available in the U.S. market for use and purchase at the time of the relevant code application deadline. We note however that even if an item or service that is subject to FDA marketing authorization is not available on the U.S. market at the time of the application submission deadline, as noted in proposed § 414.9(a)(2), all such code applications must include the applicable FDA documentation and other information outlined in § 414.9(a)(2), to be complete.

As described earlier in this subsection and at proposed § 414.9(a), we are proposing to decline applications received after the applicable deadline or that are incomplete. Applications that are declined because they are not submitted by the applicable deadline or are incomplete may be submitted in a subsequent coding cycle provided they are timely and complete by the applicable deadline for the subsequent coding cycle. We also considered allowing applicants to supplement incomplete applications after the application deadline for minor deficiencies or missing information that is insubstantial, such as a missing brochure or clinical study that is referenced by the applicant but not included as an attachment to the application. We weighed the benefits of accommodating the submission of such supplemental information within a coding cycle in cases where there are minor deficiencies, against the need for applicants to submit timely, complete applications. Given the shorter coding cycles we currently implement (which we propose to continue, as previously discussed), we believe it would be difficult to follow-up with numerous applicants within a cycle for missing information, and thus, we propose that an application must be timely and complete, in accordance with the criteria described earlier in this section, in order for the application to be considered and reviewed in a coding cycle. However, we seek comment on whether we should allow certain supplemental information to be submitted after the application deadline and in what circumstances (including requirements or timeframes we should impose for accepting additional information), recognizing that CMS would only have a limited amount of time and resources for following up about and obtaining missing information from applicants and may also have limited opportunities to consider supplemental information in the course of the coding review cycle. Please note that we would continue to allow applicants to supplement a complete application with additional materials up to the time of close of business on the date of the public meeting at which the application is discussed, as is our current policy.

d. Proposed Application Resubmission and Reevaluation

As outlined in the HCPCS Level II Coding Procedures document posted on our website at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS,* we currently allow any applicant who is dissatisfied with our final coding decision to resubmit an application for a previously considered item or service in a subsequent coding cycle for us to reevaluate the final coding decision. Under our current policy, we allow applicants to resubmit HCPCS Level II code applications without limitation for items and services on which we previously reached a final coding decision. Although we have stated in our past guidance that previously unavailable information, additional explanations, or significant new information that supports such a reevaluation request may be helpful in informing CMS about why the prior decision should be changed, many resubmitted applications do not contain new information or specify a clear basis for us to reevaluate the previously submitted information or reconsider the prior final coding decision. As a result, we have spent time and resources reviewing applications that are resubmitted with substantially similar information, without a clear understanding of whether there is something new or whether aspects of the information previously submitted should be considered differently, such that it would warrant a change to our prior final coding decision. We are proposing to continue to allow applicants to resubmit code applications for reevaluation of prior final coding decisions. However, in the interest of reaching an appropriate coding decision and supporting efficient and expeditious review of all code applications that are resubmitted, we are proposing certain limitations and additional policies related to reevaluations of coding decisions.

We propose at new § 414.9(b)(1) that an applicant who is dissatisfied with a final coding decision on an initial code application may resubmit their application for reevaluation by CMS no more than two times. We propose that any application resubmitted for reevaluation must be timely and complete as specified in proposed § 414.9(a) and must include—(1) a description of the previous application submission(s); (2) a copy of the prior final coding decision(s); and (3) an explanation of the applicant's reason for disagreement with the prior final coding decision(s). The first time an applicant resubmits an application for reevaluation by CMS, we would not require, but would strongly encourage, that the applicant submit new information with the application. As we state in our current guidance, previously unavailable information, additional explanations, or significant new information that supports such a reevaluation request may be helpful in informing CMS about why the prior decision should be changed.

In addition, at proposed § 414.9(b), we propose that if an applicant is dissatisfied after our initial reevaluation of our prior final coding decision, we would allow one additional opportunity for the applicant to resubmit the application for reevaluation of the first resubmission decision. For a second application resubmission and reevaluation, we propose at § 414.9(b)(2) that, in addition to the information and documentation required to be submitted with both resubmissions under proposed § 414.9(b)(1), the application also must include the following: (1) Significant new information, defined as information that was not previously submitted to CMS with respect to the application that directly relates to the reason for the prior final coding decision(s) and could potentially change the final coding decision, and (2) an explanation of how the significant new information addresses and directly relates to the reason(s) for the previous final coding decision(s) and supports the request for a different coding decision. By significant new information, we mean information not previously submitted to CMS (for example, it was not included in the

prior application, and not submitted as a supplement to the prior application or in response to a preliminary recommendation issued for a prior public meeting up to the time of close of business on the date of the CMS HCPCS public meeting at which the application is discussed), and that directly relates to the reason for the prior final coding decision(s) (for example, significant new information could be a newly published relevant clinical study that supports a claim of a significant therapeutic distinction made, but unsupported, in the prior code application, or additional information that supports a claim in an initial application that the product performs a significantly different clinical function not captured in the current code set). The nature of the prior final coding decisions also would be relevant in determining whether the new information submitted would be considered significant new information within the meaning of this proposal. As in the example described previously, a new or additional clinical study may be considered significant new information if the previous final coding decision(s) directly relates to an unsupported claim of significant therapeutic distinction. If significant new information is not submitted with the second resubmission, or if the applicant does not provide the other information required to be provided with both resubmissions (as set forth at proposed § 414.9(b)(1) and (2)), we would decline to reevaluate the application. We note that for an application to be considered for reevaluation it must be for the same item or service originally submitted, and it must be based on the same request made in the initial code application. For example, if an item receives a new indication that was not a part of the original application, a new and separate application would be required if the applicant seeks to address the new indication because the review of such an application would require new and different considerations.

We believe that requiring applicants to include significant new information (and satisfy the additional requirements at proposed § 414.9(b)(1) and (b)(2)) when an application is resubmitted for a second reevaluation balances our desire to afford applicants another opportunity to seek a reevaluation when they believe a final coding decision should be changed and the recognition that it takes time and resources to reevaluate applications that are submitted multiple times, especially when those applications are submitted without a clear indication of whether there is new information that should impact CMS's decision, or whether aspects of the information previously submitted to CMS may be considered differently. We believe that requiring significant new information and other information, as outlined in proposed § 414.9(b)(1) and (b)(2), would enhance the accuracy of our coding decisions and would enable us to focus our limited resources on maintaining continued efficiency and speed in processing applications.

We believe our limitation on the number of times an application can be resubmitted for reevaluation of a final coding decision is reasonable. In the past under the annual coding cycles, applicants have resubmitted applications multiple times in subsequent coding cycles for reevaluation. We believe that this could happen even more often under the shorter more frequent coding cycles, especially for drug or biological product code applications, given the shorter coding cycles. However, we do not believe it would be necessary or appropriate to allow for more than two resubmissions of a code application for reevaluation, especially since under our proposal, resubmissions would include additional information and materials as required by proposed § 414.9(b)(1) and (b)(2) (as previously discussed in this section) and the applications would go through a public meeting process with opportunity to comment on resubmissions (as discussed later in this section). Allowing further opportunities for applicants to resubmit applications after multiple evaluations of the prior coding decision(s) for the same item or service would strain our resources and is unlikely to result in a different decision (especially given that for the second resubmission, the applicant would be required to provide us with significant new information for our consideration). Therefore, we believe it is important to apply a reasonable limit to the number of times a code application for the same item or service can be resubmitted that takes into account prior opportunities for evaluation, conserves limited resources, and supports successful and timely implementation of shorter and more frequent coding cycles. We also believe that our proposal to place a limit on the number of resubmissions would encourage applicants to fully consider and robustly address the reason for the prior denial of their coding request before resubmitting. It also would decrease the likelihood of resubmission of applications without significant new information that could potentially change the prior coding decision. Therefore, we propose to limit the number of times an applicant may resubmit a code application for the same item or service for reevaluation by CMS to two resubmissions. This limitation would apply to resubmissions of applications for the same item or service with the same FDA marketing authorization submitted with the original application and would continue to apply to a code application for that item or service regardless of whether the applicant or manufacturer undergoes a change of ownership, a new manufacturer begins manufacturing the item or service at issue, there is a change of or new supplier of that item or service, or the item or service is renamed.

In addition, in order to ensure that we have the opportunity to receive and consider additional input that may be helpful for reevaluations, at proposed § 414.9(b)(3), we are proposing to include an application submitted for reevaluation on an agenda for a bi-annual public meeting and to issue a preliminary recommendation (provided the resubmitted application is timely and complete and meets all other proposed criteria and requirements for consideration under the HCPCS Level II external code application process). We note that this policy would also apply to resubmitted applications for drug or biological products as well as for non-drug and non-biological items and services. For resubmissions of code applications for drug or biological products, we propose at § 414.9(b)(3)(i) that the resubmitted application would not be included in a public meeting or receive a final decision in the quarterly cycle in which the application is submitted. Even if a public meeting falls within the quarterly cycle in which such an application was resubmitted, we would not include the application in a public meeting agenda or issue a preliminary recommendation on such application until at least the following bi-annual cycle. We believe this is necessary because we would need more than approximately 1-month to prepare the preliminary recommendation before including an application on a public meeting agenda. For example, if a drug or biological product application were submitted for reevaluation for the second quarterly cycle of the year (application deadline around April), the preliminary recommendation for the public meeting that falls in that cycle would need to be prepared for May, which we believe would not allow us sufficient time to complete a preliminary recommendation. In

addition, consistent with the policy that would apply to initial code applications, we propose at § 414.9(b)(3)(ii) that preliminary recommendations and final decisions for applications that are resubmitted for reevaluation may be delayed as described in § 414.8(e)(3).

We seek comments on the proposals discussed in this section.

2. Proposed Evaluation of HCPCS Level II Code Applications

As explained earlier in section IV.A.2. of this proposed rule, interested parties seeking to modify the HCPCS Level II code set may submit an external HCPCS Level II code application, as available on CMS' website, that requests to add a code, revise an existing code, or discontinue an existing code. An application to add a code may be submitted when the applicant believes it is appropriate for the item or service that is the subject of the code application to be separately identified by a new HCPCS Level II code. An applicant may submit an application to revise an existing code if the applicant believes that the descriptor of an existing HCPCS Level II code does not adequately describe the subject item or service, and that a modification to the long descriptor language (code text) would provide a more appropriate description of the category of items or services represented by the code. An application to discontinue an existing code may be submitted when the applicant believes that an existing HCPCS Level II code is duplicative of another code or has become obsolete and should be removed from the HCPCS Level II code set. Consistent with these procedures, we propose at § 414.10(b) that an applicant may submit an external HCPCS Level II code application to request the addition of a code, revision of an existing code, or discontinuation of an existing code.

We propose at § 414.10(c) that our evaluation of a code application would be based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made by or the evidence provided by the applicant. Our evaluation of a code application may result in a coding decision that reflects the applicant's coding request in whole, in part, or with modification. CMS may also deny the coding request. CMS's coding action would be set forth in the final coding decision. We propose at § 414.10(h) to continue these procedures. Examples of prior years' CMS HCPCS Level II coding decisions are publicly available on our HCPCS website at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.*

As set forth at proposed § 414.10(a), the code application evaluation procedures proposed in § 414.10 and described in this section would apply to CMS' evaluation of external HCPCS Level II code applications for drug or biological products and non-drug, non-biological items and services, as described in proposed § 414.8. In this section, we propose the processes by which we would evaluate code applications, depending on the subject of the application and type of modification to the code set requested. Our evaluation of all code applications, however, involves careful consideration of CMS's objectives of maintaining a code set that is manageable for users and that meets the claims processing needs of Medicare, as explained in more detail in this section.

A major goal of an effective code set is to strike a balance between sufficiently identifying and differentiating items and services and producing a manageable system and set of codes for the efficient submission and processing of claims. The HCPCS Level II code set is not intended to be a universal listing of all items and services at a granular, product-specific level. Rather, the HCPCS Level II code set currently contains almost 8,000 separate categories of like items or services that encompass products from different manufacturers. Thus, a code category is generally intended to describe the item or service provided in a way that is general enough so as not to be manufacturer specific. Categorizing items and services in this manner simplifies the submission and processing of claims with a manageable number of codes and thus promotes the goals of administrative simplification and burden reduction as previously discussed.

In striking a balance between sufficiently identifying and differentiating items and services and producing a manageable system and set of codes for the efficient submission and processing of claims, throughout the proposed evaluation process for code applications, we consider CMS' objective of maintaining a code set that allows for the efficient and timely processing of Medicare claims in accordance with the Medicare statute and regulations that are specific to the items and services for which a code is being requested. As explained in section IV.A.1. of this proposed rule, prior to its adoption under HIPAA as the standard medical data code set for reporting certain items and services not identified by CPT® codes in HIPAA standard transactions, HCPCS Level II codes were developed by CMS, then known as HCFA, to standardize the coding systems used to facilitate claims processing and payment for items and services primarily for Medicare. The HCPCS Level II coding system was selected as a standard medical data code set for use in HIPAA standard transactions in part because of its wide acceptance among both public and private payers. We maintain the HCPCS Level II code set primarily to support the claims processing needs of Medicare, recognizing that other payers use HCPCS Level II codes as well.

When we use the term ''claims processing need'' we are referring to evaluating HCPCS applications in a manner that sufficiently identifies and differentiates items and services but produces a manageable system and set of codes for the efficient submission and processing of Medicare claims in accordance with the Medicare statute and regulations that are specific to the items and services for which a code is being requested. The granularity of what falls within code categories in the HCPCS Level II code set is deeply tied to Medicare's ''claims processing need.'' Similarly, reaching a judgment about whether any two items that fall within the code set are sufficiently different so as to require distinct codes is also always tied to ''claims processing need.'' Several of the more specific proposed criteria for evaluating HCPCS Level II code applications, as described later in this proposed rule, can be understood to encompass an assessment of Medicare ''claims processing need.'' Sometimes a Medicare ''claims processing need'' is driven by Medicare program integrity concerns. A Medicare program integrity need may drive a need to add a HCPCS Level II code to identify an item or service that would otherwise fall outside the scope of the HCPCS Level II code set or may drive a need for a more specific code in order to make it efficient for CMS to distinguish and deny corresponding claims. In general, CMS has a ''claims processing need'' for each code within the HCPCS Level II taxonomy to adequately describe a corresponding item or service, such that when a related claims form is filed, CMS can understand what the Medicare beneficiary actually received from the provider or supplier, but without the code being overly specific and thereby causing undue administrative burden

for CMS (or for other users of the code set, for that matter). In other words, when we review applications for HCPCS Level II coding requests, we evaluate the information offered by the applicant that articulates the reasons why the applicant believes a specific code is warranted, against the information CMS believes is needed to process a claim effectively for a specific item or service, including the information needed to describe that item or service in order to apply Medicare coverage and payment policies, and to minimize program integrity risks. We invite the public to comment on the term ''claims processing need'' as we use it here and throughout this proposed rule, including in the context of specific provisions of this rule describing the proposed evaluation standards for the review of HCPCS Level II code applications.

a. Proposed Evaluation Process for Applications To Add a Code

In this section, we propose the processes by which we would evaluate code applications to add a code.

(1) Proposed Evaluation Process for Non-Drug, Non-Biological Applications To Add a Code

(a) Proposed Threshold Factors for Evaluating Non-Drug, Non-Biological Applications To Add a Code

As a threshold matter, when an applicant requests to add a code for a non-drug, non-biological item or service, as defined in section IV.B of this proposed rule, we believe it is important to first consider whether the item or service that is the subject of the application is appropriate for inclusion in the HCPCS Level II code set and whether there is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set. Consistent with our current practice, we propose at § 414.10(d)(1)(i)–(iii) that we would first determine whether, as a threshold matter, the subject item or service is appropriate for inclusion in the HCPCS Level II code set by assessing whether: (1) The item or service is not appropriate for inclusion in or already coded in a different HIPAA standard medical data code set, such as CPT®, ICD, or CDT®; (2) the item or service is primarily medical in nature; and (3) if applicable, the item has the appropriate marketing authorization from FDA, or is exempt from premarket notification requirements. Consistent with our current practice, we propose at § 414.10(d)(1)(iv) that we would also determine whether, as a threshold matter, there is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set.

As discussed in section IV.A. of this proposed rule, not all items and services are appropriate for inclusion in the HCPCS Level II code set maintained by CMS. This is because HIPAA mandated the adoption of certain medical data code sets to standardize the way various types of data are reported during routine transmission of electronic claims, with the HCPCS Level II code set specifically adopted to identify particular items and services, such as healthcare equipment and supplies not described by CPT® codes (45 CFR 162.1002). The adoption of standard national medical data code sets helps to avoid duplication and burden (65 FR 50361). Therefore, as a threshold matter, we believe it is important to determine whether the subject item or service is not appropriate for inclusion in or already coded in a HIPAA standard medical data code set other than the HCPCS Level II code set maintained by CMS, such as CPT®, ICD, or CDT®. For example, although technically part of the HCPCS Level II code set, the CDT® code set was adopted under HIPAA as the standard national medical data code set to be maintained by the American Dental Association, for reporting dental items and services supplied to or used by dentists, oral and maxillo-facial surgeons, prosthodontists, and periodontists. Therefore, these items and services are not appropriate for inclusion in the HCPCS Level II code set maintained by CMS.

When we evaluate whether an item or service is appropriate for inclusion in the HCPCS Level II code set, we also take into account the type of item or service, the setting in which it is furnished or used, by whom it is used, and how it is used. For example, an item or service exclusively used or administered in the inpatient hospital setting would not be appropriate for inclusion in the HCPCS Level II code set. Procedures performed during an inpatient stay are identified by ICD–10–PCS codes. In addition, the setting in which the item or service is used or administered and by whom it is used or administered may be considered together when considering whether the item or service is appropriate for inclusion in the HCPCS Level II code set. For example, we consider whether an item or service is typically physician-administered in a physician's office versus self-administered by the patient in the home. Procedures performed by physicians or other health care professionals when performed in a physician's office are typically described by CPT® codes. We also note that an item or service that is the subject of a HCPCS Level II code application could already be captured by a specific code or a comprehensive code used to identify a group of related items and services in another code set such as supplies that are used during an already coded procedure. As part of this assessment, we consider whether a particular item or service, or a component of an item or service, is included in a bundled payment [35] and coded in a different HIPAA standard medical data code set because separate reporting and billing of a bundled item or service could be duplicative.

Consistent with our current practice, we also propose to assess, as a threshold consideration, whether the subject item or service is primarily medical in nature. The HCPCS Level II code set is a standard medical data code set adopted under HIPAA for describing and identifying healthcare equipment and supplies in electronic healthcare transactions (45 CFR 162.1002). The HCPCS Level II code set is not intended to be a universal or exhaustive listing of all items and services on the market, and is generally reserved for medical items and services, since HCPCS Level II codes generally represent categories of like healthcare items and services for health insurer claims processing purposes. As such, we believe it is important to evaluate whether the item or service for which an applicant is requesting coding action is primarily medical in nature. For purposes of this proposed threshold factor, an item or service would be considered ''primarily medical in nature'' when it is primarily and customarily used to serve a medical (diagnostic or therapeutic) purpose, and is generally not useful in the absence of an illness or injury. If the primary or customary use of an item or service is not for a medical (diagnostic or therapeutic) purpose, then it would not be considered primarily medical in nature, even if the item or service could be used in a healthcare setting or in a way that assists a patient. For example,

[35] A bundled payment methodology involves the combining or ''bundling'' items and services together for single rate or payment amount (an all-inclusive payment amount), such that individual items and services are not billed and paid for individually. This is common in many Medicare prospective payment systems, though the constellation of bundled items and services and underlying payment methodologies vary (for example, a bundled payment may be based on expected costs of the items and services furnished to a beneficiary during an episode of care). When bundled payment methodologies apply, we must ensure that duplicate payment is not made by Medicare (that is, that items and services are not ''unbundled'' and billed and paid for separately).

while an air conditioner may have a remote medical (therapeutic) use of lowering room temperature to reduce fluid loss in a cardiac patient and to maintain the proper fluid balance, the primary and customary use of the air conditioner is for a non-medical purpose—that is, the item is generally used by anyone, regardless of an existing medical condition, to stay cool in a way that is not for the diagnosis or treatment of an illness or injury. Furthermore, an air conditioner is useful in the absence of an illness or injury, and thus, an air conditioner would not be considered ''primarily medical in nature'' for purposes of this proposed threshold factor. Other examples of items that may be used by a person with a medical disease or condition, but that we would not consider primarily medical in nature for purposes of this proposed threshold factor due to their common usage for non-medical purposes include: Mirrors used for self-examination; drinking straws (including elongated straws) used to assist with reach; and wearable garments, such as shirts, pants, headbands and belts, even if the styling of the garment permits easier access to IV insertion sites or dialysis shunts, or keeps a body part dry when worn in the shower or swimming pool. The information that applicants include in the code application facilitates our assessment of this proposed threshold factor; applicants describe how the item or service is primarily and customarily used to serve a medical purpose and explain whether the item or service is useful in the absence of an illness or injury.

Consistent with our current practice, we also propose to assess, as a threshold consideration, whether the item that is the subject of the code application has the appropriate marketing authorization from FDA, or is exempt from premarket notification requirements, if applicable. We believe it would be inappropriate and premature to consider potential coding action for an item that does not yet have the appropriate marketing authorization from FDA or a claimed exemption from such requirements. We require applicants to provide documentation of marketing authorization by FDA at the time the application is submitted, and also request information regarding the date the item was granted such marketing authorization, at the time the application is submitted. We also require applicants to explain the basis for any claimed exemptions from FDA premarket notification requirements, with specific citations to the regulation number under 21 CFR parts 862 through 892 as appropriate. Our assessment of this proposed threshold factor involves verifying that the documentation and information provided by the applicant matches the item or service that is the subject of the code application. We seek input from FDA should we have any questions about the documentation and information provided by the applicant.

Consistent with our current practice, we also propose to assess, as a threshold matter, whether there is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set. Given our objective, as explained earlier in section IV.B.2. of this proposed rule, of maintaining a code set that meets the claims processing needs of Medicare, we believe it is important to first ensure that Medicare has a claims processing need to identify the subject item or service with a HCPCS Level II code.

The determination of whether a HCPCS Level II code to identify the subject item or service is needed for claims processing purposes would depend on the individual facts and circumstances presented by each application. As we stated previously, we propose at § 414.10(c) that our evaluation of a code application would be based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made or the evidence produced by the applicant. Consistent with current practice, this includes information obtained from and evaluations conducted by federal employees comprising a team generally known as the CMS HCPCS Workgroup. This is an internal workgroup composed of federal government officials representing the major components of CMS, as well as other employees from pertinent Federal agencies, including the Department of Veterans Affairs and the Defense Health Agency, which includes policy, product, and claims processing experts. The Workgroup discusses whether coding requests warrant a change to the HCPCS Level II code set, and informs CMS' decisions relative to the claims processing needs of Medicare. We also take into consideration any pertinent information that may have been received from code applicants and their representatives and other stakeholders, including government insurers and the general public, through HCPCS public meetings.

Consistent with our current practice, we propose at § 414.10(d)(1) that if we determine that the subject item or service satisfies all the factors at proposed § 414.10(d)(1)(i) through (iv), discussed previously, we would further evaluate the applicant's coding request under the process proposed in § 414.10(d)(4) and discussed later in section IV.B.2.a.(1)(b) of this proposed rule, to determine whether it would be appropriate to add a code for the item or service.

Furthermore, given our objective of maintaining a code set that meets the claims processing needs of Medicare, we propose at § 414.10(d)(2) that if one or more of the proposed factors under § 414.10(d)(1)(i)–(iii) are not met but the proposed factor in § 414.10(d)(1)(iv) is met, we would further evaluate the applicant's coding request under the process proposed in § 414.10(d)(4). We believe it would be premature to deny the application when a Medicare claims processing need exists. For instance, Medicare may need to separately identify a non-covered, previously non-coded item or service that has been frequently miscoded using an existing specific or miscellaneous HCPCS Level II code, which could result in inappropriate payment. As an example, we created code A4467 (''Belt, strap, sleeve, garment, or covering, any type'') to identify certain items that were not found to be primarily medical in nature and thus not appropriate for inclusion in the HCPCS Level II code set, but that had been miscoded under miscellaneous or other existing HCPCS Level II codes for DME, resulting in erroneous payment. To ensure the accuracy of Medicare claims, code A4467 was established to separately identify these particular items in order to prevent them from being inappropriately reported through the use of other existing HCPCS Level II codes. In this way, separately identifying these items clarifies to coders that the particular item is not described by a different existing HCPCS Level II code. As another example, we may need a code to distinguish items statutorily excluded under Medicare, such as certain contact lenses, similarly to avoid miscoding and ensure more accurate claims processing. Thus, consistent with our current practice, we believe it is appropriate to propose the exception at proposed § 414.10(d)(2).

We propose at § 414.10(d)(3) that if the application satisfies neither proposed § 414.10(d)(1) nor § 414.10(d)(2), we would not further evaluate the applicant's coding request under the process proposed in § 414.10(d)(4) and thus would not

modify the HCPCS Level II code set in response to the coding request. If we determine that the subject item or service is only appropriately coded in a code set other than the HCPCS Level II code set, such as CPT®, ICD, or CDT®, we would, where appropriate, redirect the applicant to the other code set.

(b) Proposed Process for Further Evaluating Non-Drug, Non-Biological Applications To Add a Code

If the application satisfies proposed § 414.10(d)(1) or (d)(2), the focus of our evaluation then shifts from whether the subject item or service is appropriate for inclusion in the HCPCS Level II code set to the appropriate placement within the HCPCS Level II code set. Under this proposed evaluation process, we would further evaluate an applicant's coding request by assessing the functional and clinical differences of the subject item or service compared to other similar items or services already described in the HCPCS Level II code set, and determine based on our assessment of those differences, whether it would be appropriate to take coding action to add a new code to identify the subject item or service or revise the descriptor of an existing code category to clarify that the subject item or service is captured by the existing code category, or to take no coding action due to the availability of an existing code category that adequately describes the subject item or service. As explained in more detail in this section, we assess these differences due to the nature of HCPCS Level II codes, which generally represent categories of like items or services, grouped together at the broadest level, on the basis of performing the same or similar function for a patient. This is because, as previously noted in this section, the HCPCS Level II code set is not intended to be a universal listing of all items and services at a granular, product-specific level. Additionally, the information submitted by the applicant in the code application facilitates our determination of appropriate coding action. In the code application, applicants describe the item or service that is the subject of the code application, such as what the item or service does, how it is used, the patient population for which the item or service is clinically indicated; the medical benefit of the item or service to the patient, such as the clinical outcome resulting from the use of the item or service; and the reason why the applicant believes existing codes do not adequately describe the item or service.

As explained in more detail later in this section, we propose at § 414.10(d)(4) to assess: (1) Whether the subject item or service performs a significantly different clinical function compared to other items or services described by the HCPCS Level II code set; and (2) whether the use of the subject item or service results in a significant therapeutic distinction compared to the use of other similar items or services described by the HCPCS Level II code set. Furthermore, as discussed later in this section, we propose to consider whether a new HCPCS Level II code to separately identify the subject item or service is needed by Medicare to facilitate claims processing. These proposed factors balance our desire to facilitate patient access to innovative items or services with our consideration of CMS' objectives of maintaining a code set that is manageable for users and that meets the claims processing needs of Medicare.

(i) Significantly Different Clinical Function

As previously discussed, codes generally represent categories of like items and services, grouped together at the broadest level, on the basis of performing the same or similar clinical function for a patient. In order to evaluate what code category is appropriate for an item or service, we need to evaluate the clinical function performed for the patient and how the item or service addresses their condition. Therefore, our evaluation of applications to add a code begins with identifying and assessing the clinical function of the item or service that is the subject of the code application. Broadly speaking, the clinical function performed by an item or service refers to what the item or service does for a patient. It can also be understood as the general function of the item or service in the body, or the intended purpose of the item or service in the delivery of care. Clinical function can also refer to the overall treatment provided to a patient through the use of the item or service. For example, the clinical function of positive airway pressure is respiratory ventilation, and the clinical function of an electrode is to conduct electricity. As explained earlier, applicants are requested to provide information to facilitate our assessment of clinical function, such as fully explaining what the subject item or service does, how it is used, and the patient population for which the item or service is clinically indicated.

In most cases, items and services are developed in a way that is evolutionary or iterative—that is, they are developed in a way that results in new items or services that still retain similar features or functionalities as those performed by previous iterations or versions, such that they may not be so different from those already described by the code set. When evaluating whether a new code is appropriate for the subject item or service, we look to see if an existing code adequately captures the clinical function of the item or service, or whether the clinical function of the item or service is so distinct or dissimilar from the clinical functions performed by other items or services currently described by the HCPCS Level II code set that it cannot be categorized in an existing code category with other items or services. We believe a new code may be warranted if we determine that the subject item or service performs a clinical function that is not performed by any other items and services currently categorized in the HCPCS Level II code set—that is, a clinical function that is considered first-of-kind for purposes of HCPCS Level II coding. Because the clinical function would not be performed by other items or services already categorized in the code set, there would be no existing HCPCS Level II code to describe such an item or service. Thus, consistent with our current practice, we propose at § 414.10(d)(4)(i) that we would evaluate whether the item or service that is the subject of the code application performs a significantly different clinical function as compared to other items and services described by the HCPCS Level II code set, and that an item or service is considered to perform a significantly different clinical function if it performs a clinical function that is not performed by any other item or service currently described by the code set. If we determine that an item or service performs a significantly different clinical function, we further assess whether there is a claims processing need on the part of Medicare to identify that particular item or service based on its clinical function with a new code on a HIPAA standard claim. Thus, we propose at § 414.10(d)(5)(i) that a new code would be warranted if we determine that the item or service that is the subject of the code application performs a significantly different clinical function as compared to other items and services described by the HCPCS Level II code set, and we find there is a claims processing need to separately identify the item or service with a new code to facilitate payment under Medicare.

An example of this can be shown by code Q0480, ''Driver for use with pneumatic ventricular assist device, replacement only,'' which at the time a

code was requested, was an item performing a first-of-kind clinical function not previously captured by the code set and for which there was a demonstrated claims processing need. This device was the first mechanical heart pump with replaceable external components authorized by FDA as a destination therapy so the patient would not have to remain in the hospital while awaiting a transplant, and we issued a new code to identify this device.

(ii) Significant Therapeutic Distinction

Codes represent categories of similar items or services, grouped together at the broadest level, on the basis of performing the same or similar clinical function. Items or services identified in the same code may differ in some respects, for example in the mechanism of operation. We recognize that differences between items or services that perform the same or similar clinical function, such as a difference in mechanism of operation, may result in a significantly improved medical benefit or significantly different medical benefit for patients. We believe it is important for insurers to be able to differentiate and separately identify such items and services to facilitate claims adjudication. As such, and subject to CMS finding there is a claims processing need under proposed § 414.10(d)(5)(i), we believe that when the item or service that is the subject of the code application operates differently than other similar items or services described in existing codes, and that difference in operation results in a significantly improved or significantly different medical benefit for patients (as defined later in the section), the difference between the subject item or service and other similar items or services would be meaningful enough to warrant a differential coding based on significant therapeutic distinction. Differential coding on the basis of significant therapeutic distinction also reflects our desire to facilitate patient access to the advantages and benefits of innovative items or services by ensuring codes are available to providers and suppliers to use.

Under current guidance,[36] a significant therapeutic distinction is shown when the subject item or service results in an improved medical benefit (for example, a significantly improved medical outcome or a significantly superior clinical outcome) when compared with the use of other similar items or services that would otherwise share an existing code category. Requests for modifications to the HCPCS Level II code set based on claims of significant therapeutic distinction are reviewed on a case-by-case basis, taking into consideration clinical information provided by the applicant and others that may support or refute the claim(s) made by the applicant. An applicant should provide the best available information in support of the claim(s). Greater weight is given to more methodologically rigorous and scientifically reliable evidence. Process indicators, such as improved compliance, convenience, and personal preference are considered significant therapeutic distinctions only to the extent that they result in demonstrably improved clinical outcomes.

The application seeks information from the applicant to enable us to assess whether the subject item or service results in a significant therapeutic distinction. Applicants are requested to identify currently coded items or services that perform the same or similar medical function as the subject item or service. Applicants are then requested to identify the differences between the subject item or service or its operation and the currently coded items or services, which would result in a significantly improved medical outcome or significantly superior clinical outcome.

In this proposed rule, we are proposing to broaden opportunities to identify a significant therapeutic distinction by also considering whether the use of the subject item or service results in a significantly different medical benefit, when compared with the use of other similar items or services described in the HCPCS Level II code set. Thus, we propose at § 414.10(d)(4)(ii) that a significant therapeutic distinction is shown when the use of that item or service results in a significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set.

We propose at § 414.10(d)(4)(ii)(A) that we would determine that the use of an item or service results in a significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set if we find that it meets any of the criteria at proposed § 414.10(d)(4)(ii)(A), as further described later in the section. We note that proposed § 414.10(d)(4)(ii)(A) sets forth a framework that is based on the same general criteria that CMS currently uses for determining substantial clinical improvement for purposes of the Inpatient Prospective Payment System (IPPS) New Technology Add-On Payment (NTAP) (42 CFR 412.87(b)(1)), subject to modifications that we are proposing for purposes of evaluating a significant therapeutic distinction claim for a HCPCS Level II code application. We believe that the same general framework used to evaluate whether a service or technology represents a substantial clinical improvement for purposes of the NTAP, as modified here, may also reasonably be used to evaluate whether the use of an item or service results in a significantly improved or significantly different medical benefit for the purpose of evaluating HCPCS Level II code applications. In both the HCPCS Level II context and the NTAP context, the framework allows for reaching a comparative determination about the therapeutic effect of a designated item or service, and whether this represents an advance over other items and services.

While we believe the same framework used for determining substantial clinical improvement for purposes of the IPPS NTAP would be generally appropriate for determining significant therapeutic distinction (significantly improved or significantly different medical benefit) in the context of evaluating a HCPCS Level II code application, we are seeking comment, as indicated in the bullet points later in the section, regarding whether certain factors would appropriately apply in the context of evaluating HCPCS Level II code applications, or whether they should be modified or eliminated for the purpose of determining significant therapeutic distinction. As reflected in proposed § 414.10(d)(4)(ii)(A), CMS would determine that the use of an item or service results in a significantly improved or significantly different medical benefit, when compared with the use of other similar items or services described in the HCPCS Level II code set, if it finds any of the following:

- The item or service that is the subject of the code application offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments (for purposes of determining significant therapeutic distinction, this may include, for example, persons for whom currently available treatments may be contraindicated, such as persons who may be allergic to those treatments or for whom those treatments may be toxic or harmful based on compromised renal or liver function or other co-morbid condition; or for specific populations for whom a currently

[36] See ''HCPCS Decision Tree For External Requests to Add or Revise Codes,'' available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS_Decision_Tree_and_Definitions.pdf.*

available treatment or dosage is contraindicated, based on FDA-approved labeling, related to age, comorbid condition or concurrent treatment that could impact the results of the treatment; or for whom other treatments must be first tried and failed, as per FDA-approved labeling).

• The item or service that is the subject of the code application offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the item or service to make a diagnosis affects the management of the patient. We are seeking public comment regarding whether and under what circumstances this factor might be appropriately applied to HCPCS Level II code applications. We note that diagnostic tests and lab tests are generally not coded in the HCPCS Level II code set. Diagnostic tests and lab tests are not typically administered in patients' homes; and when administered in a physician's office, they are included in the procedure, and would not be separately payable using HCPCS Level II codes, and therefore a HCPCS Level II code would not be needed for Medicare claims adjudication.

• A demonstration of one or more of the following outcomes.

++ A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

++ A decreased rate of at least one subsequent diagnostic or therapeutic intervention.

++ A decreased number of future hospitalizations or physician visits.

++ A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time.

++ An improvement in one or more activities of daily living.

++ An improved quality of life.

++ A demonstrated greater medication adherence or compliance. With regard to this factor in particular, we are seeking comment regarding whether it is useful or appropriate to include improved medication adherence or compliance as a factor in evaluating HCPCS Level II code applications for non-drug, non-biological items and services for the purposes of determining significant therapeutic distinction. We note that medication adherence or compliance, by itself, is an interim measure, and not a clinical end point. While greater adherence or compliance might potentially lead to a clinical end point, those end points are already identified earlier in the list of outcomes. If CMS decides to adopt this factor as proposed, it would substantially modify the current standard CMS uses to evaluate whether the use of a non-drug, non-biological item or service demonstrates a significant therapeutic distinction. Generally, process indicators (such as improved compliance) have been considered significant therapeutic distinctions only to the extent that they result in demonstrably improved clinical outcomes (for example, improved mortality or morbidity).

• The totality of the information otherwise demonstrates that the use of the item or service results in a significantly improved or a significantly different medical benefit, when compared with the use of other similar items or services described in the HCPCS Level II code set.

When determining whether the use of the item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set, we propose at § 414.10(d)(4)(ii)(B) that we may consider instances where the use of the item or service may substantially improve or substantially change the medical benefit realized by a specific subpopulation of patients with the medical condition for whom the item or service is used, based on a common characteristic shared by the subpopulation (for example, allergic sensitivity to a currently available alternative treatment item) that impacts the medical benefit of the subject item or service. To offer another example, a significantly improved or significantly different medical benefit may be demonstrated where the use of an item or service, when compared to a currently available alternative item or service that is currently described in the HCPCS code set, provides a differential benefit to a subset of patients, based on patient characteristics typically needed to use the item or service (such as strength, functionality, and cognitive ability) and the manner in which the item or service is typically used. For example, certain prosthetics or orthotics, such as a heavy prosthetic leg with features that enable quicker gait, use on rough terrain, or on steep inclines might potentially be suitable for a strong patient, but may be more than a frail elderly patient could use or might need. A finding of significantly different medical benefit for such a prosthetic or orthotic item might be supported on the basis that the item provides a differential benefit for strong patients.

In determining whether the use of item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set, we propose at § 414.10(d)(4)(ii)(C) that we would make this determination without regard to the prevalence among Medicare beneficiaries of the underlying medical condition treated or diagnosed by the item or service that is the subject of the code application. In particular, we would not consider a low prevalence rate for the underlying medical condition as a factor weighing against an item or service that is the subject of the code application, for the purpose of our evaluating whether there is a significantly improved or significantly different medical benefit associated with use of the item or service.

Additionally, when determining whether the item or service would meet the criterion of conferring a significant therapeutic distinction, we propose at § 414.10(d)(4)(ii)(D) that an item's designation under the FDA Breakthrough Devices Program and marketing authorization for the indication that received such designation will be given substantial weight in the consideration. Under this voluntary program, FDA evaluates certain devices and device-led combination products that ''provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.'' [37] [38] When FDA grants a designation under the Breakthrough Devices Program, FDA has considered whether or not the underlying device (or device-led combination) meets one of several additional criteria, including the criterion of offering ''significant advantages over existing approved or cleared alternatives,'' as by ''reduc[ing] or eliminat[ing] the need for hospitalization, improv[ing] patient quality of life, facilitat[ing] patients' ability to manage their own care (such as through self-directed personal assistance), or establish[ing] long-term clinical efficiencies.'' [39] In sum, we believe that when an FDA Breakthrough Devices designation has been granted, this strongly suggests that use of the device results in a significantly

[37] 21 U.S.C. 360e–3.

[38] FDA, Final Guidance, Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff (December 18, 2018). Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program.*

[39] Ibid.

improved medical benefit as compared to the use of other items and services for the purpose of meeting the significant therapeutic distinction factor under the HCPCS Level II code evaluation process. Therefore, proof that a device has received an FDA Breakthrough Devices designation will be given substantial weight as CMS considers whether the device meets the significant therapeutic distinction factor under the HCPCS Level II code evaluation process. As such, we propose at § 414.10(d)(4)(ii)(D) that when an application to add a code relates to a device that has already received an FDA Breakthrough Device designation and marketing authorization for the indication for which the device was granted FDA Breakthrough Device designation, then proof of that FDA designation and authorization will be given substantial weight as CMS considers whether the device meets the significant therapeutic distinction factor proposed at § 414.10(d)(4)(ii). The aim of this proposal is to recognize that an FDA Breakthrough Device designation offers supporting evidence that can help to strengthen a claim of significant therapeutic distinction.

We propose at § 414.10(d)(4)(ii)(E) that if an applicant seeks a new code on the basis that the use of the item or service results in a significant therapeutic distinction, the application must contain sufficient information and supporting documentation to support a claim of significant therapeutic distinction. We further propose at § 414.10(d)(4)(ii)(E) that CMS would consider the totality of the circumstances when making a determination that the use of an item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set. It is important that applicants provide sufficient information and documentation so that we can understand the scientific basis for the applicant's claim of significant therapeutic distinction and perform an adequate, evidence-based assessment regarding whether this factor is met. Applicants should provide the best available information to support their claim of significant therapeutic distinction, including copies of all articles that result from systematic analysis of the available literature, as well as any unfavorable articles with appropriate rebuttal or explanation.

Published or unpublished information from sources from within the United States or elsewhere may be submitted by the applicant to help substantiate their claim that the use of an item or service results in a significantly improved or a significantly different medical benefit, when compared with the use of other similar items or services described in the HCPCS Level II code set. Although we are not proposing to require specific types of support, greater weight will be given to more methodologically rigorous and scientifically reliable evidence. Information sources may include the following: Clinical trials, peer reviewed journal articles, study results, meta-analyses, consensus statements, white papers, patient surveys, case studies, reports, systematic literature reviews, letters from major healthcare associations, editorials and letters to the editor, public comments, and other appropriate information sources.

Some examples of past findings that a claim of significant therapeutic distinction is not substantiated include where the applicant specified a clinical indication for, or associated a clinical indication with, the item or service that was not cleared, approved, or otherwise given marketing authorization by FDA, or that is not scientifically supported. Other examples of unsubstantiated claims of significant therapeutic distinction include claims for which the evidence provided is inconclusive or weak (anecdotal, or not methodologically rigorous or reliable); the supporting information provided does not include the actual product or service that is the subject of the code application; the supporting documentation or the applicant's claim is not specifically addressed in or conflicts with other information found in the information packet submitted for review; or the supporting information addresses interim measures and not clinical end points.

We propose at § 414.10(c), our evaluation of an application to add a code would be based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made or the evidence provided by the applicant.

We propose at § 414.10(d)(5)(i) that if we determine that (1) the item or service that is the subject of the application performs a significantly different clinical function when compared to other items or services described in the HCPCS Level II code set (as specified under § 414.10(d)(4)(i)), or the use of the item or service results in a significant therapeutic distinction when compared to the use of other similar items or services described by the HCPCS Level II code set (as specified under § 414.10(d)(4)(ii)), and (2) there is a claims processing need to separately identify the item or service with a new code to facilitate payment under Medicare, we would create a new code to identify the item or service.

We also propose at § 414.10(d)(5)(ii) that if the conditions in § 414.10(d)(5)(i) are not met, we would not create a new code. Further, we propose at § 414.10(d)(6) that if we find that revisions to the descriptor of an existing code category are appropriate to account for minor distinctions between the subject item or service and other items or services described by the existing code category and to clarify that the subject item or service is included in the existing code category, then we would revise the descriptor rather than add a new code.

As proposed in § 414.10(h), our evaluation of the applicant's code application may result in a coding decision that reflects the applicant's coding request in whole, in part, or with modification; or a denial of the coding request. Any coding action taken on an applicant's request would be set forth in the final coding decision.

(2) Proposed Evaluation Process for Drug or Biological Product Applications To Add a Code

There is no HIPAA standard medical data code set designated for reporting drug or biological products for non-retail pharmacy transactions—that is, as described previously, products that are paid separately as drugs or biologicals. In non-retail pharmacy transactions, the choice of code set for drugs or biologicals is governed by specific payer needs. Drug or biological products for which providers or suppliers seek payment that is separate from payments for procedures or other bundled services might be reported on claims in non-retail pharmacy transactions using the National Drug Code (NDC) set, HCPCS Level II code set, or both, however the Medicare Part B claims payment system utilizes HCPCS level II codes to pay these claims. As stated in section IV.B. of this proposed rule, for the purposes of section IV of this proposed rule, the term ''products paid separately as drugs or biologicals'' refers to products that are separately payable under Medicare Part B (and potentially by other payers) as drugs or biologicals as that term is defined in section 1861(t) of the Act. These products typically fall into one or more of the following three categories: (1) Products furnished incident to a physician's services under sections

1861(s)(2)(A) and (B) of the Act, excluding products that are usually self-administered (for example, tablets, capsules, oral solutions, disposable inhalers); (2) products administered via a covered item of DME; and (3) other categories of products for which there is another Part B benefit category as specified by statute or regulations (for example, drug or biological products described elsewhere in section 1861(s) of the Act, such as immunosuppressive drugs (at section 1861(s)(2)(J)); hemophilia blood clotting factors (at section 1861(s)(2)(I)); certain oral anticancer drugs (at section 1861(s)(2)(Q) of the Act); certain oral antiemetic drugs (at section 1861(s)(2)(T) of the Act); pneumococcal pneumonia, influenza and hepatitis B vaccines (at section 1861(s)(10) of the Act). As described previously, for ease of reference, when discussing products paid separately as drugs or biologicals in this rule, we will generally refer to these as ''drug or biological products.''

Similar to applications for non-drug, non-biological items or services, we believe it is important for CMS to first consider whether the drug or biological product that is the subject of an application to add a code is appropriate for the HCPCS Level II code set. Consistent with our current practice, we propose at § 414.10(e)(1) that we would first determine whether, as a threshold matter, the subject drug or biological product is appropriate for the HCPCS Level II code set by assessing whether: (1) The product is not appropriate for inclusion or already coded in a different HIPAA code set, such as CPT®; (2) the product is primarily medical in nature; (3) if applicable, the product has the appropriate marketing authorization from FDA; and (4) there is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set.

CPT® codes and codes from other code sets do not frequently describe drug or biological products paid under Medicare Part B. Few CPT® codes are listed in the Medicare payment files, such as the ASP Drug Pricing files, where CPT® codes typically describe vaccines (influenza, pneumococcal pneumonia, and hepatitis B vaccines) that are paid under Part B based on their average wholesale price (AWP) per requirements in section 1842(o) of the Act. When CPT® codes do not adequately describe drug or biological products, HCPCS Level II codes have been developed and are used to bill for them, particularly when there is a Medicare program need for such codes. Also, CPT® codes that may describe drug or biological products may not be sufficiently precise to distinguish between situations where separate payment for a drug or biological product is necessary, such as certain hepatitis B immune globulin products approved under separate BLAs, that require separately calculated payment allowances under section 1847A of the Act (as operationalized by the program instruction that is discussed in the next paragraph). Separate billing and payment codes allow for the products approved under different BLAs to be paid separately, consistent with section 1847A of the Act. Also, in general, the CPT® code set focuses primarily on services, like procedures, rather than separately payable drugs that are used in Medicare Part B settings.

Payment for most drug or biological products under Medicare Part B is described in section 1842(o) of the Act. This provision provides for payments based on the average wholesale price (AWP) for products such as vaccines, as well as payments based on section 1847A of the Act. Section 1847A of the Act includes payments based on the average sales price (ASP), and most Medicare Part B drugs are paid based on the ASP. Section 1847A of the Act defines terms such as multiple source drugs, single source drugs, and biologicals, and specifies how payment for each of them is to be determined, and also authorizes CMS to assign individual drug or biological products (for example products identified at the National Drug Code level) to billing and payment codes so that code-specific payment amounts may be assigned. Section 1847A is implemented by regulation at 42 CFR 414.904. However, section 1847A(c)(5)(C of the Act) also permits the use of program instruction for the implementation of section 1847A of the Act, notwithstanding any other provision of law. In 2007, CMS issued a program instruction explaining how coding and pricing of multiple source drugs, single source drugs, and biologicals has been operationalized (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*).

Section 1847A of the Act and its corresponding regulations and program instructions have driven a claims processing program need for using HCPCS Level II codes to report Part B drug or biological products where CPT® codes do not exist or are insufficiently precise to be used for this purpose. CMS has made payment determinations for Part B drug or biological products identified in external coding applications on a case by case basis in accordance with statutory requirements, such as those in section 1847A(b) of the Act, that specify different payment amounts for single source drugs, multiple source drugs, and biologicals (including biosimilar biological products), and CMS has also made coding determinations to facilitate implementation of separate pricing of drug or biological products, as necessary, as discussed in the 2007 program instruction. For example, in that program instruction, CMS stated that ''the payment limit under Section 1847A for that biological product . . . will be based on the pricing information for products produced or distributed under the applicable FDA approval.'' Thus, a biological product with its own unique BLA that is administered incident to a physician's services and not bundled with payments for other services would typically be priced and paid under its own HCPCS code, meaning that CMS would typically assign NDCs associated with the product to a unique HCPCS code. Because most Part B drugs are paid using the methodologies in section 1847A of the Act, these provisions have driven Part B drug coding since the implementation of the Medicare Modernization Act. However, other statutory provisions, such as the requirement in Section 1842(o)(1)(A)(iv) to base payment for certain vaccines on AWP, also create coding needs, for example the development of new codes or revisions of existing codes when existing CPT® codes are insufficiently precise for Part B payment.

Once we determine that the HCPCS Level II code set is the appropriate code set for the product that is the subject of the application, we then evaluate an application to determine the appropriate HCPCS Level II coding action on the code application—that is, whether it would be appropriate to take coding action to add a new code to identify the subject product, or revise the descriptor of an existing code category to clarify that the subject product is captured by the existing code category, or to take no coding action due to the availability of an existing code category that adequately describes the subject product. We use the evaluation factors described in the bullet points later in this section to determine whether separate payment for the product may be made under Part B, how that payment is made (for example, separate payment under a specific statutory requirement), and the coding action appropriate to implement the payment (including facilitating separate payment, if necessary) based on statutory requirements, such as those in sections 1842(o) or 1847A of the Act, applicable

regulations pertaining to Part B drug payment such as 42 CFR part 414 Subparts J and K, and program instructions pertaining to section 1847A of the Act, such as the 2007 guidance cited in this proposed rule.

Consistent with our current practice, we propose at § 414.10(e)(2) that if CMS determines that the factors set forth in § 414.10(e)(1) are met, then CMS next determines, for purposes of claims processing (and payment), whether an existing code adequately describes a product, or whether a revision to the descriptor of an existing code category is appropriate, or whether a new code is necessary. In making this determination, we would consider applicable Medicare Part B statutory and regulatory payment requirements, program instructions, and information, such as the following: (1) Sections 1842(o) and 1847A of the Act; (2) 42 CFR part 414 subparts J and K; (3) program instructions implementing section 1847A of the Act; and (4) information from the code application and other applicable sources such as FDA, drug compendia, the manufacturer, and scientific literature. As noted previously, consistent with our current practice, we propose at § 414.10(c) that our evaluation of a code application would be based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made by or the evidence provided by the applicant. Consistent with the foregoing and as proposed at § 414.10(e)(2)(iv), such research and information may be drawn from a range of outside sources relevant to the application, such as FDA, drug compendia, the manufacturer, and scientific literature. Based on such information and the statutory and regulatory requirements and payment instructions described in § 414.10(e)(2), we would determine whether an existing code adequately describes a product for the purpose of claims processing (and payment), or whether a revision to the descriptor of an existing code category is appropriate, or whether a new code is necessary. This includes determining whether Medicare Part B billing and payment for the product can be accomplished under existing codes, whether revisions to existing codes are necessary, or whether new codes are necessary.

As a whole, the information in the bullet points described later in this section is used to determine appropriate coding action for the product that is the subject of the code application. This information is obtained from the code applications (and information and documentation that is submitted with the code application) and from other sources such as FDA, drug compendia, the manufacturer (or applicant), and scientific literature. We propose at § 414.10(e)(3) to evaluate each application to determine: (1) Whether the product is separately payable under Medicare Part B as a drug or biological product; and (2) whether the product is a single source drug, multiple source drug, biological, or biosimilar biological product for purposes of section 1847A of the Act, or if other specific payment provisions such as those in sections 1842(o)(1)(A) or (F) of the Act apply.

While there is some overlap between the information used to make these determinations, the following paragraphs briefly describe how certain factors, that is information in the groups of bullet points later in this section, are used to make these determinations and describe the framework for the decision-making process on external code applications. Under this framework, the information in the groups of bullet points is assessed as a whole to determine a coding action, specifically whether to create a new code that would typically result in separate payment for a product provided that the product is covered under Part B, revise the descriptor of an existing code in response to an application, for example to make clear that the product in the application is described by an existing code or to better distinguish existing codes from a new code resulting from an application. Alternatively, we may decide to take no coding action, for example if the product is never or rarely paid separately under Part B.

The following information is used primarily to determine whether the product is separately payable as a drug or biological under Medicare Part B, and is also used to begin the process of determining the appropriate coding action on an application for a drug or biological product:

- The active ingredient(s) and drug name(s) of the product and other potentially similar drug or biological products in existing Level II HCPCS codes.
- The product's labeling and description, including whether there are differences between the product and previously coded products, such as the salt form; whether the product includes any additional ingredients when compared to previously coded products; and the indications for which the product is used.
- Prescribing information, setting-of-use and other information found in FDA-required prescription drug labeling.

The active ingredient(s), drug name(s), product labeling, and description assist CMS in first identifying the product. The active ingredient(s), drug name(s), product labeling and description also help to inform CMS's evaluation under § 414.10 (e)(2), (e)(3) and (e)(4), and this information guides CMS in determining whether there are any comparable products that are described by existing Level II HCPCS codes.

The prescribing information and setting of use information help CMS to understand where the product is used and whether the product is separately payable under Medicare Part B (and therefore whether a HCPCS Level II code is appropriate for the product). Some products are used in settings where drug or biological products generally are not separately payable under Medicare Part B and a HCPCS Level II code is not likely to be necessary. Examples of situations where a HCPCS Level II code would not be necessary include: Products furnished exclusively in an inpatient hospital and paid exclusively under Part A; products furnished in retail pharmacy, such as a self-administered drug, like an orally administered antihypertensive drug, that is not covered under a Part B benefit category. Such products would not require a HCPCS Level II code for separate payment under Medicare Part B. However, in cases where the information provided in response to the bullet points described previously is insufficient to allow CMS to determine whether the product is separately payable as a drug or biological under Medicare Part B, other information discussed later in the section, such as the route and method of administration, dosage, and frequency, may also be used by CMS to assist with a determination about whether the product is separately payable under Medicare Part B. This additional information may also potentially be used to distinguish the product from other potentially similar products that are not paid separately under Part B.

In addition to the information in the previous bullet point list of items, the following information is used to help determine whether the product is a single source drug, multiple source drug, biological product, or biosimilar biological product for purposes of section 1847A or if other specific

payment provisions, such as those in sections 1842 (o)(1)(A) or (F) of the Act apply:

- FDA approval, including the date of approval and how the FDA regulates the product, for example whether it is approved as a drug, biological product, or biosimilar biological product.
- Therapeutic equivalence ratings as provided in section 1847A(c)(6)(C), if applicable.
- Date of first sale in the United States.
- Active ingredient(s) and labeling information.
- Product information such as trade or brand name; nonproprietary drug name(s) and National Drug Code (NDC) or other applicable drug product identifier, if one exists.
- Packaging and labeling that indicates how the drug is supplied, including the How Supplied/storage and handling section in prescribing information.

FDA approval information, therapeutic equivalence rating as provided in section 1847A(c)(6)(C) (if applicable), and date of first sale in the United States help us to determine whether the product may be paid under section 1847A of the Act and whether the product satisfies the definition of multiple source drugs, single source drugs, and biological products as the definitions have been operationalized by program instruction under the authority of section 1847A of the Act. While this information primarily pertains to products paid under section 1847A of the Act, it also helps us evaluate other products, such as flu, pneumococcal, and hepatitis B vaccines, which are paid based on AWP per section 1842(o) of the Act and to identify situations where it would be appropriate to add a new code or revise an existing code for such products to facilitate payment, for example if existing codes (including CPT® codes used for Part B vaccines) are not sufficiently clear or do not sufficiently distinguish between similar products that have significant price or payment differences and thus may be candidates for separate codes and payment determinations.

The active ingredients and labeling information, product information such as trade or brand name(s); nonproprietary drug name(s) and National Drug Code (NDC) or other applicable drug product identifier, if one exists, and packaging and labeling that indicates how the drug is supplied also help us to accurately identify a product for the purpose of making a coding decision for that product. If a new code is necessary, for example when a product is approved under a new BLA, in most cases the active ingredient(s) will play a major role in the development of a code descriptor, and other information, such as packaging and other product information, can be used to refine the descriptor and to help select an amount of drug for the descriptor, as necessary. Also, all of this information can be used to determine if an existing code adequately describes the product without further revision or whether revisions would be necessary to the descriptor of an existing code to accommodate the product. For example, if a product that is the subject of a code application is described by an existing biological drug code, is approved under the same BLA as other products assigned to that code, and uses the same trade name, a new code would probably not be necessary because the existing code could be used without modification. However, at times a revision to the descriptor of one or more existing codes may be made, for example, to include a new trade name in the descriptor, to better distinguish between other similar codes.

The following information is used to help CMS determine whether it is appropriate to add a new code or revise an existing code in situations where the information in the bullet points described previously is not sufficient to allow CMS to make a coding determination on an application. The following information is used to further clarify the similarities and differences between the products that are the subject of a code application and products described in existing codes, to determine whether the product that is the subject of a code application is adequately described by an existing code. The information helps CMS to determine whether it is appropriate to add a new code or revise an existing code(s) consistent with discussion in the previous paragraph, for the purpose of claims processing and facilitating payment under Medicare Part B:

- Indications for use.
- Mechanism of action.
- Dosage, frequency, route, and method of administration.
- Other drugs (including those with different proprietary names) that are marketed with the same active ingredient(s) or use the same drug name(s).
- FDA labeling and compendia information (aspects not already listed in previous bullet points, such as pharmacokinetics, contraindications, warnings, drug interactions, and adverse reactions).
- Billing information, like any third-party payers that pay for the product; any codes that are currently being billed to those payers for the product; and existing policies of third-party payers for reporting the product (if available) to compare how other payers are paying for the product.

Drawing on all of the foregoing information and considerations, and consistent with our current review process, we propose at § 414.10(e)(4) that after reviewing an application to add a HCPCS Level II code for a drug or biological product, and after considering the factors listed in § 414.40(e)(1) through (e)(3), CMS will then make a determination about whether the appropriate action is to add a code, revise a code, or take no coding action, in response to that application.

In addition, we propose at § 414.10(e)(5) to continue to use code descriptors with drug amounts that correspond to quantities of a drug or biological product that are smaller than, for example, the product's package size or usual adult dose, where appropriate. The quantities of drug or biological products described by HCPCS Level II code descriptors often vary. Some are based on the size of typical adult doses of a drug or biological product. Many older HCPCS Level II codes, particularly codes that became effective before the implementation of ASP-based payments, have code descriptors reflecting quantities that correspond to available package amounts, such as 500 mg for cefazolin. Cefazolin is an injectable first generation cephalosporin antibiotic that has been available for decades as an inexpensive generic product and can be billed under HCPCS code J0690, injection, cefazolin sodium, 500 mg. Dosage adjustments for typical adult doses of cefazolin are often made in increments of 500 mg, so the code descriptor quantity for cefazolin corresponds well to its frequently used doses (and their multiples, such as 1 gram, 1.5 grams, and 2 grams). However, many newer and much more expensive drug or biological products, such as those used to treat cancer, require weight-based dosing, and dosage adjustments for individuals are made in much smaller increments, such as a milligram or a fraction of a milligram. Thus, many newer HCPCS Level II codes have code descriptors reflecting quantities that are less than the smallest available package size. Decisions about the code descriptor quantities in these cases generally have been based on the factors discussed in the preceding bullet points, including indications, the active ingredient(s), dosage, and route of administration, packaging, and how the

drug is supplied as indicated in labeling. We propose to continue to use smaller quantities in the code descriptors for drug or biological products, as appropriate and discussed in this paragraph, to facilitate more accurate billing, particularly for products that must be dosed based on the patient's weight, and for products where dosing must be adjusted in small increments, due to factors such as age, a patient's ability to metabolize or excrete a drug, toxicity, or response. Improvements in billing accuracy by the use of smaller quantities in descriptors will also facilitate the accurate tracking of payments for discarded drugs (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf* section 40). In situations where the discarded drug policy does not apply, this approach can help minimize out of pocket costs for drugs that are not administered. For example, if the amount of drug or biological specified in the code descriptor for a single HCPCS billing unit of a drug uses a quantity of 500 mg and the patient is given 550 mg, that patient would be billed for two billing units or 1,000 mg of the drug. The use of a smaller quantity in the descriptor, such as 10 mg, would permit billing for exactly 550 mg.

b. Proposed Evaluation Process for Non-Drug, Non-Biological and Drug or Biological Applications To Revise an Existing Code

An applicant may submit an application to revise an existing code if the applicant believes that the descriptor of an existing HCPCS Level II code does not adequately describe the item or service that is the subject of the code application, and that a modification to the long descriptor language (code text) would provide a better description of the category of items or services represented by the code. Applicants provide the language currently used in the descriptor of an existing HCPCS Level II code and the language that the applicant suggests to use as the descriptor.

When evaluating whether the requested revision provides a better description of the category of items or services represented by a code, we consider whether there is a Medicare claims processing need for the requested revision. For example, a revision may be considered when a claims processing need has been identified to improve the descriptor to clarify that the existing code also describes a newer or different version of an item or service which performs the same clinical function as other items or services included in the existing code category.

When evaluating applications to revise an existing code, we also consider whether the requested revision is appropriate given the nature and purpose of the HCPCS Level II code set. For example, we do not believe that a request to include information in the descriptor for the purposes of tracking or data analysis would be appropriate unless there is a Medicare claims processing need to do so, because the primary purpose of HCPCS Level II code set is to facilitate efficient claims processing. We also consider the nature of the code set, because HCPCS Level II codes generally represent categories of similar items or services, and are generally intended to describe an item or service provided or performed in way that is general enough so as not to be manufacturer specific. Where multiple like items or services are grouped together in a single HCPCS Level II code category, the corresponding descriptor uses language to describe the entire category of items or services at the collective, rather than product-specific, level. Thus, the suggested language should be applicable to the entire category of items or services, rather than only to the item or service that is the subject of the code application.

We propose at § 414.10(c) that our evaluation of an application to revise an existing code would be based on information contained in the code application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made by or the evidence provided by the applicant. Consistent with our current practice, we propose at § 414.10(f) that if we determine that the revised descriptor language suggested by the applicant would provide a more appropriate description of the category of items or services, as discussed earlier in this section, we would revise the descriptor accordingly. As proposed in § 414.10(h), our evaluation of the applicant's code application may result in a coding decision that reflects the applicant's coding request in whole, in part, or with modification; or a denial of the coding request. Any coding action taken on an applicant's request would be set forth in the final coding decision.

c. Proposed Evaluation Process for Non-Drug, Non-Biological and Drug or Biological Applications To Discontinue an Existing Code

To maintain a manageable and efficient coding system, HCPCS Level II codes that are no longer needed may be removed from the code set. An application to discontinue an existing code may be submitted when the applicant believes that an existing HCPCS Level II code is duplicative of another code or has become obsolete and should be removed from the HCPCS Level II code set.

When evaluating applications to discontinue an existing code, we determine whether the code is duplicative of another code in the code set, or has become obsolete, and we have no further expectation that the same or similar item or service will be marketed at a later date, such that there is no longer a claims processing need to retain the existing code. A code that is duplicative of another code because it is superseded by a more specific code, for example, would no longer be utilized to process claims. The presence of a duplicative code could potentially result in erroneous billing.

We also consider whether a code has become obsolete by evaluating the availability of the item or service, or category of items or services, described by the code. In order to avoid removing a code prematurely, we would first determine that each item or service described by the code is no longer marketed, and that there does not appear to be an intent to market. For example, before discontinuing a code for a product that has been discontinued, we would first determine that there is no remaining stock available—in other words, we would determine that the stock has been depleted, with no expectation of the stock being refilled, and thus there would be no need to retain the code for future claims processing. We would make this determination based on information provided by the applicant, as well as through information we gather from our own market surveillance and claims examination. Before making this determination or taking action on a particular application to discontinue a code, we also consider the possibility of the same or similar item or service reappearing on the market at a later date by the same or different manufacturer, and we may retain the code for a period of time for this reason.

We propose at § 414.10(c) that our evaluation of an application to discontinue an existing code would be

based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made by or the evidence provided by the applicant. Consistent with our current practice, we propose at § 414.10(g) to discontinue an existing code when we find that the code is duplicative of another code or has become obsolete and we have no further expectation that the same or similar item or service will be marketed at a later date. As proposed in § 414.10(h), our evaluation of the applicant's code application may result in a coding decision that reflects the applicant's coding request in whole, in part, or with modification; or a denial of the coding request. Any coding action taken on an applicant's request would be set forth in the final coding decision.

We seek comment on the proposed processes described in this section for evaluating applications to add a code, to revise an existing code, and to discontinue an existing code.

V. Benefit Category and Payment Determinations for Durable Medical Equipment, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

A. Background

1. Benefit Category Determinations

Medicare generally covers an item or service that—(1) falls within a statutory benefit category; (2) is not statutorily excluded from coverage; and (3) is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member as described in section 1862(a)(1)(A) of the Act. We make benefit category determinations (BCDs) based on the scope of Part B benefits identified in section 1832 of the Act, as well as certain statutory and regulatory definitions for specific items and services. Section 1832(a)(1) of the Act defines the benefits under Part B to include ''medical and other health services,'' including items and services described in section 1861(s) of the Act such as surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations under paragraph (5), prosthetic devices under paragraph (8), leg, arm, back, and neck braces, artificial legs, arms, and eyes under paragraph (9), therapeutic shoes under paragraph (12), and durable medical equipment (DME) under paragraph (6) and as defined in section 1861(n) of the Act. The words ''orthotic(s)'' or ''orthosis(es)'' are used in various parts of the statute and regulations instead of the word brace(s) but have the same meaning as brace(s). For example, section 1847(a)(2)(C) of the Act refers to ''orthotics described in section 1861(s)(9)'' of the Act; however, section 1861(s)(9) of the Act describes ''leg, arm, neck, and back braces'' and does not use the word ''orthotics.'' Likewise, section 1834(h)(4)(C) of the Act specifies that ''the term 'orthotics and prosthetics' has the meaning given such term in section 1861(s)(9)'' of the Act; however, section 1861(s)(9) of the Act describes ''leg, arm, neck, and back braces'' and does not use the word ''orthotics.'' Also, the word ''prosthetic(s)'' is used in various parts of the statute and regulations to describe artificial legs, arms, and eyes referenced in section 1861(s)(9) of the Act, but it is important to note that these items are not the same items as the prosthetic devices referenced in section 1861(s)(8) of the Act. While the statutory definition of DME in section 1861(n) of this Act sets forth some items with particularity, such as iron lungs, oxygen tents, hospital beds, wheelchairs, and blood glucose monitors, whether other items and services are covered under the Medicare Part B DME benefit is based on our interpretation of the statute, which does not, for example, elaborate on the meaning of the word ''durable'' within the context of ''durable medical equipment.'' Therefore, we further defined DME in the regulation at 42 CFR 414.202 as equipment that: (1) Can withstand repeated use; (2) effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; (3) is primarily and customarily used to serve a medical purpose; (4) generally is not useful to a person in the absence of an illness or injury; and (5) is appropriate for use in the home. In conducting an analysis of whether an item falls within the DME benefit category, we review the functions and features of the item, as well as other supporting material, where applicable. For example, research and clinical studies may help to demonstrate that the item meets the prongs of the definition of DME at § 414.202. For items to be considered DME, all requirements of the regulatory definition must be met. Additional details on the Medicare definition of DME are located in section 110.1 of the Medicare Benefit Policy Manual (CMS 100–02). The Medicare definitions for surgical dressings, splints, casts, and other devices used for reductions of fractures and dislocations, prosthetic devices, orthotics and prosthetics, and therapeutic shoes and inserts are located in sections 100, 120, 130, and 140, respectively, of the Medicare Benefit Policy Manual (CMS 100–02).

In situations where CMS has not established a BCD for an item or service, the BCD is made by the MACs on a case-by-case basis as they adjudicate claims. The MACs may have also addressed the benefit category status of an item or service locally in a written policy article. This proposed rule would apply to BCDs for all items and services described in section 1861(s) of the Act such as surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations under paragraph (5), prosthetic devices under paragraph (8), leg, arm, back, and neck braces, artificial legs, arms, and eyes under paragraph (9), therapeutic shoes under paragraph (12), and DME under paragraph (6) and as defined in section 1861(n) of the Act.

2. Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554)

Section 531(b) of BIPA mandated the establishment of procedures that permit public consultation on coding and payment determinations for new DME under Medicare Part B of title XVIII of the Act in a manner consistent with the procedures established for implementing coding modifications to ICD–9–CM. Accordingly, we host public meetings that provide a forum for interested parties to make oral presentations and to submit written comments in response to preliminary HCPCS coding and Medicare payment determinations for new DME items and services. A payment determination for DME items and services would include a determination regarding which of the paragraphs (2) through (7) of subsection (a) of section 1834 of the Act the items and services are classified under as well as how the fee schedule amounts for the items and services are established so that they are in compliance with the exclusive payment rules under sections 1834(a) and 1847(a) and (b) of the Act. The preliminary HCPCS coding and Medicare payment determinations for new DME items and services are made available to the public via our website prior to the public meetings. In addition, although this type of forum and opportunity for obtaining public consultation on preliminary HCPCS

coding and Medicare payment determinations for items and services other than new DME items is not mandated by the statute, we expanded this process for obtaining public consultation on preliminary coding and payment determinations to all HCPCS code requests for items and services in 2005, and since January 2005, we have been holding public meetings to obtain public consultation on preliminary coding and payment determinations for non-drug, non-biological items and services. As discussed in section IV., we propose to continue holding these public meetings for non-drug, non-biological items and services and, in limited circumstances, for drug or biological products (as defined and discussed in section IV of this proposed rule) that are associated with external requests for HCPCS codes. External requests for HCPCS codes are made by submitting a HCPCS application available on the CMS.gov website at the following address: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Application_Form_and_Instructions.*

HCPCS Level II codes are used by Medicare, Medicaid, and other public health insurance programs and private insurers for the purpose of identifying items and services on health insurance claims. A code identifies and describes a category of items and services and the HCPCS Level II coding system and process is not used to make coverage or payment determinations on behalf of any insurer. Once a code describing a category of items and services is established, separate processes and procedures are used by insurers to determine whether payments for the item or service can be made, what method of payment, for example, purchase or rental, will be used to make payment for the item or service, and what amount(s) will be paid for the item or service. Whether or not an item falls under one of the Medicare benefit categories such as DME is a decision made by CMS or the MACs based on statutory and regulatory definitions, separate from the HCPCS Level II coding system and process for identifying items and services.

In order to make a Medicare payment determination for an item or service, that is, to determine the statutory and regulatory payment rules that apply to the item or service and how to establish allowed payment amounts for the item or service, CMS must first determine whether the item or service falls under a benefit category, for example DME, and if so, which benefit category in particular. Therefore, since 2001, the procedures established by CMS to obtain public consultation on national payment determinations for new DME items as mandated by section 531(b) of BIPA have also in effect been procedures for obtaining public consultation on national DME BCDs, or determinations about whether an item or service meets the Medicare definition of DME. Then in 2005, when these procedures were expanded to include requests for HCPCS codes for all items and services, they became in effect procedures for obtaining public consultation on BCDs and payment determinations for all items and services.

B. Current Issues

In order to increase transparency and structure around the process for obtaining public consultation on benefit category and payment determinations for these items and services, we believe it would be beneficial to set forth in our regulations the process and procedures that have been used since 2001 for obtaining public consultation on BCDs and payment determinations for new DME and since 2005 for requests for HCPCS codes for items and services other than DME. As further discussed in section IV.A.2. of this proposed rule, we recently revised our coding cycle for requests for HCPCS Level II codes to implement shorter and more frequent coding application cycles.[40] Beginning January 2020, for non-drug, non-biological items and services, we shortened the existing annual coding cycle to conduct more frequent coding cycles on a bi-annual basis and include public meetings to obtain consultation on preliminary coding determinations twice a year under these new bi-annual coding cycles. We believe that continuing to establish payment determinations, which, as a condition precedent, include BCDs, for new DME items and services and the other items and services described previously at these same bi-annual public meetings would be an efficient and effective way to address coding, benefit category, and payment issues for these new items and services and would prevent delays in coverage of new items and services.

C. Provisions of the Proposed Regulation

We are proposing to set forth in regulations BCD and payment determination procedures for new DME items and services described in sections 1861(n) and (s)(6) of the Act, as well as the items and services described in sections 1861(s)(5), (8), (9), and (12) of the Act, that permit public consultation at public meetings. The payment rules for these items and services are located in 42 CFR part 414, subparts C and D, so we propose to include these procedures under both subparts C and D. We are proposing that the public consultation on BCDs and payment determinations would be heard at the same public meetings where consultation is provided on preliminary coding determinations for new items and services the requestor of the code believes are: DME as described in sections 1861(n) and (s)(6) of the Act; surgical dressings, splints, casts, and other devices as described in section 1861(s)(5) of the Act; prosthetic devices as described in section 1861(s)(8) of the Act; leg, arm, back, and neck braces (orthotics), and artificial legs, arms, and eyes (prosthetics) as described in section 1861(s)(9) of the Act; or therapeutic shoes and inserts as described in section 1861(s)(12) of the Act. This proposal generally reflects the procedures that have been used by CMS since 2005, however, we are proposing to specifically solicit or invite consultation on preliminary BCDs for each item or service in addition to the consultation on preliminary payment and coding determinations for new items and services.

Accordingly, we are proposing procedures under new § 414.114 for determining whether new items and services meet the Medicare definition of items and services subject to the payment rules at 42 CFR part 414 subpart C. This would include determinations regarding whether the items and services are parenteral and enteral nutrition (PEN), which are nutrients, equipment, and supplies that are categorized under the prosthetic device benefit, as defined at section 1861(s)(8) of the Act and covered in accordance with section 180.2 of Chapter 1, Part 3 of the Medicare National Coverage Determinations Manual (Pub. 100–03). This would also include determinations regarding whether items and services are intraocular lenses (IOLs) inserted in a physician's office, which are also categorized under the prosthetic device benefit at section 1861(s)(8) of the Act. We would also use the proposed procedures to determine whether items and services are splints, casts, and other devices used for reduction of fractures and dislocations at section 1861(s)(5) of the Act. For the purpose of these proposed procedures and § 414.114, we are proposing to establish the following definition:

[40] CMS, Announcement of Shorter Coding Cycle Procedures, Applications, and Deadlines for 2020, HCPCS—General Information. Available at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.*

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of a prosthetic device at section 1861(s)(8) of the Act or is a splint, cast, or device used for reduction of fractures or dislocations subject to section 1842(s) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

We are also proposing procedures under new § 414.240 for determining whether new items and services meet the Medicare definition of items and services subject to the payment rules at 42 CFR part 414 subpart D. This would include determinations regarding whether the items and services are in the DME benefit category as defined at section 1861(n) of the Act and under 42 CFR 414.202. This would also include determinations regarding whether the items and services are in the benefit category for prosthetic devices that fall under section 1861(s)(8) of the Act other than PEN nutrients, equipment and supplies or IOLs inserted in a physician's office. This would also include determinations regarding whether the items and services are in the benefit category for leg, arm, neck, and back braces (orthotics), and artificial legs, arms, and eyes (prosthetics) under section 1861(s)(9) of the Act. This would also include determinations regarding whether the items and services are in the benefit category for surgical dressings under section 1861(s)(5) of the Act or custom molded shoes or extra-depth shoes with inserts for an individual with diabetes under section 1861(s)(12) of the Act. For the purpose of these proposed procedures and § 414.240, we are proposing to establish the following definition:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of durable medical equipment at section 1861(n) of the Social Security Act, a prosthetic device at section 1861(s)(8) of the Social Security Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Social Security Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

We are proposing that if a preliminary determination is made that a new item or service falls under one of the benefit categories for items and services paid in accordance with subparts C or D of 42 CFR part 414, then CMS will make a preliminary payment determination regarding how the fee schedule amounts for the item or services would be established in accordance with these subparts, and, for items and services identified as DME, under which of the payment classes under sections 1834(a)(2) through (7) of the Act the item or service falls. We are proposing that the procedures for making BCDs and payment determinations for new items and services subject to the payment rules under subparts C or D of 42 CFR part 414 would be made by CMS during each bi-annual coding cycle and the proposed procedures under new §§ 414.114 and 414.240 would include the following steps.

First, at the start of the coding cycle, an analysis is performed by CMS to determine if the item or service is statutorily excluded from coverage under Medicare under any of the provisions at section 1862 of the Act, and, if not excluded by statute, the analysis looks to see if the item or service falls under a Medicare benefit category defined in the statute and regulations for any of the items or services subject to the payment rules under subparts C or D of 42 CFR part 414. Information about the item or service from several sources is considered as part of this analysis such as the description of the item or service in the HCPCS application, HCPCS codes used to bill for the item or service in the past, product brochures and literature, information on the manufacturer's website, information related to the FDA clearance or approval of the item or service for marketing or related to items that are exempted from the 510(k) requirements or otherwise granted marketing authorization by the FDA. This step could take anywhere from 1-week to 1 or 2 months. For more complex items or services, the process may take several months, in which case public consultation on the benefit category and payment determinations would slip to a subsequent coding cycle.

Second, if a preliminary determination is made by CMS that the item or service is an item or service falling under a benefit category for items and services paid for in accordance with subpart C or D of 42 CFR part 414, a preliminary payment determination is made by CMS regarding how the fee schedule amounts will be established for the item or service and what payment class the item falls under if the item meets the definition of DME. This step could take anywhere from 1-week to 1 or 2 months. For more complex items or services, the process may take several months, in which case public consultation on the benefit category and payment determinations would slip to a subsequent coding cycle.

Third, approximately 4-months into the coding cycle, the preliminary benefit category and payment determinations are posted on *CMS.gov* 2-weeks prior to the public meeting described under § 414.8(d) in which CMS receives consultation from the public on the preliminary benefit category and payment determinations made for the item or service. After consideration of public consultation on any preliminary benefit category or payment determinations made for the item or service, the benefit category or payment determinations are established through program instructions issued to the Medicare Administrative Contractors.

It is important to note that even though a determination may be made that an item or service meets the Medicare definition of a benefit category, and fee schedule amounts may be established for the item or service, this does not mean that the item or service would be covered for a particular beneficiary. After a BCD and payment determination has been made for an item or service, a determination must still be made by CMS or the relevant local MAC that the item or service is reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member, as required by section 1862(a)(1)(A) of the Act.

We seek public comment on our proposed process and procedures for making BCDs and payment determinations for new items and services paid for in accordance with subpart C or D of 42 CFR part 414. We note that our proposed approach does not affect or change our existing process for developing National Coverage Determinations (NCDs), which we can continue to use to develop NCDs both in response to external requests and internally-generated reviews. We further note that we are not limited to only addressing benefit categories in response to external HCPCS code applications and could decide to use the proposed process to address benefit categories in response to internally generated HCPCS coding changes as well.

VI. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

This section addresses classification and payment for CGMs under the Medicare Part B benefit for DME. We are proposing to replace a Ruling issued in January of 2017 (CMS–1682–R) with this new rule.

A. General Background

DME is a benefit category under Medicare Part B, section 1861(n) of the Act defines ''durable medical equipment'' as including ''iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)) of the Act, whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories; except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.''

In addition to this provision, in order to be covered, an item must meet the requirements of section 1862(a)(1)(A) of the Act, which precludes payment for any items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and section 1862(a)(6) of the Act, which precludes payment for personal comfort items.

The Medicare program was created as part of the Social Security Amendments of 1965 (Pub. L. 89–97), and the Part B benefit payments for DME were initially limited to ''rental of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home (including an institution used as his home)'' in accordance with the definition of DME at section 1861(s)(6) of the Act. The Social Security Amendments of 1967 (Pub. L. 90–248) amended the statute to allow for payment on a purchase basis for DME in lieu of rental for items furnished on or after January 1, 1968. Section 144(d) of the Social Security Amendments of 1967 changed the language under section 1861(s) of the Act to ''durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient' home (including an institution used as his home), whether furnished on a rental basis or purchased.'' Payments for purchase of expensive items of DME were limited to monthly installments equivalent to what would have otherwise been made on a rental basis, limited to the period of medical need and not to exceed the purchase price of the equipment.

In 1975, Medicare program instructions in section 2100 of chapter 2 of part 3 of the Medicare Carrier's Manual (HCFA Pub. 14–3) indicated that expenses incurred by a beneficiary for the rental or purchase of DME are reimbursable if the following three requirements are met: The equipment meets the definition of DME in this section; and the equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his malformed body member; and the equipment is used in the patient's home. The instructions also indicated that payment may also be made under the DME benefit category for repairs and maintenance of equipment owned by the beneficiary as well as expendable and non-reusable supplies and accessories essential to the effective use of the equipment. DME was defined under these program instructions from 1975 as equipment meeting four requirements (quoted later in the section verbatim and with text underscored as in the original instructions):

Durable medical equipment is equipment which (a) can withstand repeated use, *and* (b) is primarily and customarily used to serve a medical purpose, *and* (c) generally is not useful to a person in the absence of an illness or injury; and (d) is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be durable medical equipment.

Additional detailed instructions were provided in 1975 describing the underlying policies for determining whether an item meets the definition of DME and specifically addressed what the terms ''durable'' and ''medical equipment'' mean. The instructions indicated that an item is considered durable if it can withstand repeated use, that is, it is the type of item that could normally be rented, and that medical supplies of an expendable nature are not considered ''durable'' within the meaning of the definition. In order to be considered DME, the item must be able to be rented out to multiple patients and thus withstand repeated use. The instructions indicated that medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. The instructions indicated that in some cases information from medical specialists and the manufacturer or supplier of products new to the market may be necessary to determine whether equipment is medical in nature. Additional instructions provide examples of equipment which presumptively constitutes medical equipment, such as canes, crutches, and walkers, and equipment that is primarily and customarily used for a nonmedical purpose and cannot be considered DME even when the item has some remote medically related use, such as air conditioners. Equipment that basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness equipment, first-aid or precautionary-type equipment, self-help equipment, and training equipment are considered nonmedical in nature. These program instructions from 1975 are still in effect and are now located in section 110 of chapter 15 of the Medicare Benefits Policy Manual (CMS Pub. 100–02).

The Social Security Amendments of 1977 (Pub. L. 95–142) amended the statute to mandate a ''rent/purchase'' program or payment methodology for DME; CMS would pay for each item furnished to each beneficiary on either a rental or purchase basis depending on which method was considered more economical. The decision regarding whether payment for DME was made on a rental or purchase basis was made by the Medicare Part B carrier (Medicare contractor) processing the claim. The rent/purchase program was implemented from February 1985 through December 1988.

Section 2321 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) moved the definition of DME from section 1861(s)(6) of the Act to section 1861(n) of the Act and included a more detailed definition of DME.

Section 4062(b) of the Omnibus Budget Reconciliation Act (OBRA) of

1987 (Pub. L. 100–203) amended the statute to terminate the rent/purchase program and add section 1834(a) to the Act with special payment rules for DME furnished on or after January 1, 1989. DME items were to be classified into different classes under paragraphs (2) through (7) of section 1834(a) of the Act, with specific payment rules for each class of DME. Section 1834(a) of the Act still governs payment for items and services furnished in areas that are not included in the competitive bidding program mandated by section 1847(a) of the Act. Section 1834(a)(2) of Act indicates that payment is made on a rental basis or in a lump sum amount for the purchase of an item the purchase price of which does not exceed $150 (inexpensive equipment) or which the Secretary determines is acquired at least 75 percent of the time by purchase (routinely purchased equipment) or which is an item specified under sections 1834(a)(2)(A)(iii) and (iv) of the Act. The term ''routinely purchased equipment'' is defined in regulations at 42 CFR 414.220(a)(2) as equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

Medicare began covering blood glucose monitors under the DME benefit in the early 1980s and the test strips and other supplies essential for the effective use of the glucose monitor were also covered. Blood glucose monitors were expensive equipment within the meaning of section 1834(a)(2) of the Act but were routinely purchased (more than 75 percent of the time on a national basis) during the period July 1986 through June 1987. Therefore, payment was made on a fee schedule basis for blood glucose monitors based on the lower of the supplier's actual charge for the item or a state-wide fee schedule amount calculated for the item based on the average rental or purchase payment for the item in the state for the 12-month period ending on June 30, 1987. The rental and purchase fee schedule amounts are increased on an annual basis based on the provisions set forth in section 1834(a)(14) of the Act.

The special payment rules for DME mandated by section 1834(a) of the Act were implemented via program instructions for all DME items other than oxygen and oxygen equipment on January 1, 1989. CMS established and implemented fee schedule amounts for inexpensive or routinely purchased items, for payment on a rental basis, payment on a lump sum purchase basis when the item is new, and payment on a lump sum purchase basis when the item is used. We also promulgated rules implementing the special payment rules for DME mandated by section 1834(a) of the Act. For more information, see the October 9, 1991 and December 7, 1992 **Federal Registers** (56 FR 50821 and 57 FR 57675, respectively), and a July 10, 1995 final rule (60 FR 35492).

We established a definition for DME items and services during this time at 42 CFR 414.202, which simply mirrored the general definition of DME established in 1975 via program instructions.

Section 1861(n) of the Act was revised by section 4105(b)(1) of the Balanced Budget Act of 1997 (Pub. L. 105–33) to expand coverage of blood glucose monitors and test strips to patients with type II diabetes. As noted, these items had already been covered as DME (glucose monitoring equipment) and disposable supplies (test strips) since the early 1980s, but coverage was limited to patients with type I diabetes.

We added to the definition of DME at 42 CFR 414.202 effective for items furnished after January 1, 2012, to require that the item have a minimum lifetime of 3 years in order to be considered DME. This 3 year minimum lifetime requirement was established in a final rule published in the November 10, 2011 **Federal Register** entitled: Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (76 FR 70228 and 70314). This final rule included a discussion of how the 3-year minimum lifetime requirement (MLR) is applied to multicomponent devices or systems consisting of durable and nondurable components (76 FR 70291). In this rule, we noted that a device may be a system consisting of durable and nondurable components that together serve a medical purpose, and that we consider a multicomponent device consisting of durable and nondurable components nondurable if the component that performs the medically necessary function of the device is nondurable, even if other components that are part of the device are durable. In regards to the 3-year MLR, the component(s) of a multicomponent device that performs the medically necessary function of the device must meet the 3-year MLR (76 FR 70291).

In summary, DME is covered under Medicare Part B. DME is defined under section 1861(n) of the Act and Medicare claims for DME are paid in accordance with the special payment rules under section 1834(a) of the Act or under the competitive bidding program mandated by sections 1847(a) and (b) of the Act. Rules related to the scope and conditions of the benefit are addressed at 42 CFR 410.38. Under § 414.202, durable medical equipment means equipment which—

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be DME.

B. Continuous Glucose Monitors

On January 12, 2017, CMS issued CMS–1682–R articulating the CMS policy concerning the classification of continuous glucose monitoring systems as DME under Part B of the Medicare program. CMS–1682–R is available on the *CMS.gov* website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/CMS-Rulings*.

CMS–1682–R classified continuous glucose monitoring systems as ''therapeutic continuous glucose monitors (CGMs)'' that meet the definition of DME if the equipment—

- Is approved by FDA for use in place of a blood glucose monitor for making diabetes treatment decisions (for example, changes in diet and insulin dosage);
- Generally is not useful to the individual in the absence of an illness or injury;
- Is appropriate for use in the home; and
- Includes a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements.

Under CMS–1682–R, in all other cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM is not considered DME. CMS–1682–R also addressed the calculation of the fee schedule amounts for therapeutic CGMs in accordance with the rules at section 1834(a) of the Act and under regulations at 42 CFR, part 414, subpart D.

CGMs are systems that use disposable glucose sensors attached to the patient to monitor a patient's glucose level on a continuous basis by either automatically transmitting the glucose readings from the sensor via a

transmitter to a device that displays the readings (''automatic'' CGMs), or by displaying the glucose readings from the sensor on a device that the patient manually holds over the sensor (''manual'' CGMs). Some CGMs are class III devices and require premarket approval by FDA, while some newer CGM models are class II devices that do not require premarket approval by FDA. The glucose sensor continuously measures glucose values in the interstitial fluid, the fluid around the cells (in contrast to blood glucose monitors which measure glucose values using fingertip blood samples). The sensor is a small flexible metal probe or wire that is inserted in the skin and has a coating that prevents the body's immune system from detecting and attacking the foreign probe. Once the coating wears off, which in current models takes place in 7 to 14 days, the sensor must be replaced for safety reasons. The glucose sensor generates a small electrical signal in response to the amount of sugar that is present (interstitial glucose). This electrical signal is converted into a glucose reading that is then displayed on a dedicated receiver (or type of monitor), an insulin infusion pump, or a compatible mobile device (smart phone, smart watch, tablet, etc.). The receiver displays the glucose measurements in the form of a graph so that the patient can visualize how their glucose measurements are trending.

CMS–1682–R classifies CGM display devices as DME if they have been approved by FDA for use in making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, that is, without verifying the CGM readings with readings from a blood glucose monitor. These CGMs are referred to as ''non-adjunctive'' or ''therapeutic'' CGMs in CMS–1682–R. In contrast, CGMs that a patient uses to check their glucose levels and trends that must be verified by use of a blood glucose monitor in order to make diabetes treatment decisions are not currently classified as DME. These CGMs are referred to as ''adjunctive'' or ''non-therapeutic'' CGMs in CMS–1682–R.

C. Current Issues

Beneficiaries are continuing to use adjunctive or ''non-therapeutic'' CGMs to help manage their diabetes, and claims submitted for this equipment and its related supplies and accessories are being denied in accordance with CMS–1682–R. We believe classification of CGMs in general is an important issue to address again in notice and comment rulemaking. In this proposed rule we revisit the question of whether CGMs (both adjunctive and non-adjunctive), and their accessories and supplies meet the five requirements or prongs of the definition of DME at 42 CFR 414.202.

1. Requirements of DME Definition

(a) Ability To Withstand Repeated Use

As discussed in CMS–1682–R, we view the receiver that converts the glucose readings from the disposable sensors and displays the readings in a graph showing the continuous change in the trend of glucose levels as the CGM component that performs the primary medical function of self-monitoring of glucose levels and that therefore, the receiver is the component that must be durable or withstand repeated use in order for the CGM as a whole to be classified as DME. The receiver for all CGM systems (both adjunctive and non-adjunctive) can be rented and used by successive patients to monitor the trending of glucose levels that are either transmitted to the device using disposable sensors or are read or received by the device when the patient holds the device near the sensor. Therefore, we believe this equipment meets the requirement to withstand repeated use; that is, equipment that could normally be rented and used by successive patients.

(b) Expected Life of at Least 3 Years

This criterion under 42 CFR 414.202 further addresses the issue of ''durability'' and provides a clear minimum timeframe for how long an item must last in order to meet the definition of DME. As noted previously, for multicomponent equipment (that is, a system of durable and nondurable components), the component that performs the medically necessary function of the equipment must be durable in order for the device to be considered DME. The blood glucose monitor reads the glucose level on the test strip and displays the reading for the patient. CGM receivers operate in a similar fashion and, unlike the glucose sensor component, which must be replaced every 7 to 14 days, we believe the receiver does meet the 3-year minimum lifetime requirement. In the case of one manufacturer, reliability analysis data from an engineering firm that evaluated the receiver component of the CGM system predicted a lifetime of greater than 3 years for the receiver. Therefore, we believe that the receiver, both for adjunctive and non-adjunctive CGMs, has an expected life of at least 3 years.

(c) Primarily and Customarily Used To Serve a Medical Purpose

As noted previously, in CMS–1682–R, we concluded that adjunctive CGMs are not primarily and customarily used to serve a medical purpose. We are proposing to change our determination with regard to whether adjunctive CGMs are primarily and customarily used to serve a medical purpose. The agency's determination that devices like these are not primarily and customarily used to serve a medical purpose has been rejected by several district courts. The district courts hearing these cases have rejected the determination that adjunctive CGMs are not primarily and customarily used to serve a medical purpose. *See, e.g., Finigan* v. *Burwell,* 189 F. Supp. 3d 201 (D. Mass. 2016); *Whitcomb* v. *Hargan,* Case No. 17–cv–14, 2017 U.S. Dist. LEXIS 216571 (E.D. Wis. Oct. 26, 2017); *Lewis* v. *Azar,* 308 F. Supp. 3d 574 (D. Mass. 2018).

CGMs are used by patients to monitor their glucose levels, which can help them to manage their diabetes and make diabetes treatment decisions such as determining what and when to eat and changes in insulin dosage. We are proposing that CGM systems that have not been approved by FDA for use in making these diabetes treatment decisions without the use of a blood glucose monitor but can be used to alert the patient about potentially dangerous glucose levels while they sleep, are primarily and customarily used to serve a medical purpose. We now believe that because adjunctive CGMs can provide information about potential changes in glucose levels while a beneficiary is sleeping and is not using a blood glucose monitor, these CGMs are primarily and customarily used to serve a medical purpose. Specifically, these CGMs serve a medical purpose by helping patients to avoid potential episodes of hypoglycemia or hyperglycemia, despite the fact that fingerstick blood glucose verification is still required for use in making diabetes treatment decisions. Currently, Medicare does not cover adjunctive CGMs because such CGMs are not DME, per CMS–1682–R. CMS is proposing to change this policy issued under CMS–1682–R; all CGMs (adjunctive and non-adjunctive) would be considered DME, effective April 1, 2021.

(d) Generally Not Useful to a Person in the Absence of an Illness or Injury

CMS has determined that both adjunctive and non-adjunctive/therapeutic CGM systems are generally not useful to a person in the absence of an illness or injury because people who do not have diabetes generally would

not find a monitor that tracks their glucose levels to be useful. Thus far, Medicare's coverage policy for CGMs has supported the use of therapeutic CGMs in conjunction with a smartphone (with the durable receiver as backup), including the important data sharing function they provide for patients and their families.[41] CMS previously concluded that therapeutic CGMs, when used in conjunction with a smartphone, still satisfied the definition of DME because the durable receiver, used as a backup, was generally not useful to a person in the absence of an illness or injury, even if the smartphone might be. CMS is now proposing that both therapeutic and non-therapeutic CGMs, when used in conjunction with a smartphone, satisfy the definition of DME because the durable receiver, used as a backup, is not generally useful to a person in the absence of an illness or injury. Medicare does not cover or provide payment for smartphones under the DME benefit. In order for Medicare to cover disposable glucose sensors, transmitters and other non-durable components of a CGM system, these disposable items must be used with durable CGM equipment that meets the Medicare definition of DME. If a Medicare beneficiary is using durable CGM equipment that meets the Medicare definition of DME, but also uses a smartphone or other non-DME device to display their glucose readings in conjunction with the covered DME item as described previously, Medicare will cover the disposable items since the beneficiary is primarily using their covered DME item to display their glucose readings. However, if the beneficiary is exclusively using a non-DME item like a smartphone to display glucose readings from disposable sensors, transmitters or other disposable CGM supplies, these disposable supplies cannot be covered since there is no covered item of DME in this scenario.

(e) Appropriate for Use in the Home

FDA has cleared or approved CGM systems as safe and effective for use by the patient in their homes similar to how blood glucose monitoring systems have been used in the home for many years. Both adjunctive and non-adjunctive CGMs are appropriate for use in the home for the same purpose that a blood glucose monitor is used in the home.

[41] *https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.*

2. Fee Schedule Amounts for CGM Receivers/Monitors and Related Accessories

Medicare payment for DME was made on a reasonable charge basis prior to 1989. The regulations related to implementation of the reasonable charge payment methodology are found at 42 CFR part 405, subpart E. The current Medicare payment rules for glucose monitors and other DME are located at section 1834(a) of the Act and mandate payment on the basis of fee schedule amounts beginning in 1989. Blood glucose monitors are classified as routinely purchased items subject to the payment rules for inexpensive and routinely purchased DME at section 1834(a)(2) of the Act, which mandate payment for routinely purchased items on a purchase or rental basis using fee schedule amounts based on average reasonable charges for the purchase or rental of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987. These base fee schedule amounts are increased on an annual basis based on the update factors located in section 1834(a)(14) of the Act, which includes specific update factors for 2004 through 2008 for class III devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act. Routinely purchased equipment is defined in the regulations at 42 CFR 414.220(a)(2) as ''equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.'' Section 1834(a)(1)(C) of the Act states that ''subject to subparagraph (F)(ii), this subsection must constitute the exclusive provision of this title [Title XVIII of the Act] for payment for covered items under this part [Medicare Part B] or under Part A to a home health agency.'' The fee schedule amounts for blood glucose monitors were revised in 1995 using special payment limits established in accordance with the ''inherent reasonableness'' authority at section 1842(s)(8) of the Act. The final notice (BPD–778–FN) establishing special payment limits for blood glucose monitors was published in the January 17, 1995 **Federal Register** (60 FR 3405), with the payment limits updated on an annual basis using the DME fee schedule update factors in section 1834(a)(14) of the Act.

Because certain CGMs have been granted marketing authorization by FDA to replace blood glucose monitors for use in making diabetes treatment decisions, we believe that CGMs represent a newer technology version of glucose monitors paid for by Medicare in 1986 and 1987. In addition, the CGM systems function similar to the blood glucose monitors in using disposable supplies or accessories, such as test strips or sensors, to measure glucose levels in a patient's body, either from the patient's blood or interstitial fluid, and using durable equipment to convert these glucose measurements in a way that they can be displayed on a screen on the equipment. Therefore, we believe that the CGM receivers/monitors must be classified as routinely purchased DME since they are a technological refinement of glucose monitors routinely purchased from July 1986 through June 1987. The alternative would be to classify CGM receivers/monitors as other items of DME under section 1834(a)(7) of the Act and pay for the equipment on a capped rental basis. We also believe the average reasonable charge data for blood glucose monitors from 1986 and 1987 can be used to establish the fee schedule amounts for CGM receivers/monitors in accordance with our regulations 42 CFR 414.238(b) since CGM receivers/monitors are comparable to blood glucose monitors. We do not believe that the special payment limits established in 1995 for blood glucose monitors must apply to CGM receivers/monitors because these special payment limits were based on specific pricing information on the cost of blood glucose monitors. We therefore propose to continue using the fee schedule amounts established in CMS–1682–R based on the updated 1986/87 average reasonable charges for blood glucose monitors as the fee schedule amounts for CGM receivers/monitors. As noted, section 1834(a)(14) of the Act provides different annual update factors for class III DME versus other DME items and so the fee schedule amounts for class III CGM receivers are slightly higher (from $231.77 to $272.63 in 2020) than the fee schedule amounts for class II CGM receivers (from $208.76 to $245.59 in 2020).

With regard to the fee schedule amounts for supplies and accessories for CGMs, we do not believe these supplies and accessories are comparable to the supplies and accessories for blood glucose monitors, and there is a significant difference in the cost, lifetimes, and types of supplies and accessories used with the various types of CGMs. Namely, some sensors last for 7 days while others last for 14 days, some CGM systems require certain additional accessories such as transmitters or additional supplies such

as calibration supplies while others do not. We believe all CGM receivers essentially serve the same purpose as a blood glucose monitor in interpreting and displaying glucose levels from disposable supplies. However, the disposable supplies for CGMs are very different from the disposable supplies used with a blood glucose monitor, so we do not believe that the 1986/87 average reasonable charges for supplies used with a blood glucose monitor should be used to establish the fee schedule amounts for supplies used with a CGM. In addition, the supplies used with the three types of CGMs currently on the market are also very different. For this reason, we are proposing to separate payment for CGM supplies and accessories into three separate categories of supplies and accessories with different fee schedule amounts for each category. The current 2020 monthly fee schedule amounts of $222.77 and $259.20 for supplies and accessories for CGM systems apply to all types of class II or class III CGMs, respectively, but were established based on supplier price lists for only one type of CGM system approved by FDA for use in making diabetes treatment decisions without the need to use a blood glucose monitor to verify the results (non-adjunctive CGMs). The supplier prices used to establish these fee schedule amounts were for non-adjunctive CGM systems that use a combination of sensors and transmitters to automatically send glucose measurements to the CGM receiver without manual intervention by the patient. We refer to this type of CGM system as a non-adjunctive system, or a system that both replaces a blood glucose monitor for use in making diabetes treatment decisions, and can alert the patient about dangerous glucose levels while they sleep based on the automatic transmission of the glucose readings to the receiver on a 24-hour basis. The fee schedule amounts of $222.77 and $259.20 for supplies and accessories for class II and class III CGMs, respectively, increased by the fee schedule update factor for 2021, would continue to apply to the supplies and accessories for automatic, non-adjunctive CGMs effective April 1, 2021.

As aforementioned, adjunctive and ''non-therapeutic'' CGMs also work with disposable batteries, sensors, and transmitters to automatically send glucose readings to the receiver on a 24-hour basis, but have not been granted marketing authorization for use in place of a blood glucose monitor. As such, if a beneficiary uses one of these CGMs, the beneficiary and program would still incur expenses associated with use of blood glucose monitors and supplies. To avoid a situation where the beneficiary and program would pay twice for glucose monitoring supplies needed to accurately assess glucose levels, we propose to establish the fee schedule amounts for supplies and accessories for adjunctive CGMs based on supplier prices for the sensors and transmitters minus the fee schedule amounts for the average quantity and types of blood glucose monitoring supplies used by insulin-treated beneficiaries who would be more likely to qualify for coverage of a CGM system based on a need to more closely monitor changes in their glucose levels. The adjunctive CGM system is not replacing the function of the blood glucose monitor and related supplies and therefore only provides an adjunctive or added benefit of alerting the beneficiary when their glucose levels might be dangerously high or low. Since the adjunctive CGM system cannot function alone as a glucose monitor for use in making diabetes treatment decisions, we are proposing to reduce the payment for the adjunctive CGM system by the amount that is paid separately for the blood glucose monitor and supplies that are needed in addition to the adjunctive CGM system and are not needed in addition to the non-adjunctive CGM systems. Currently, Medicare is allowing coverage and payment for 135 test strips and lancets per month for insulin-treated beneficiaries using blood glucose monitors. Using the 2020 mail order fee schedule amounts for 50 test strips, divided by 50 and multiplied by 135, plus the 2020 mail order fee schedule amounts for 100 lancets, divided by 100 and multiplied by 135, plus the 2020 mail order fee schedule amounts for a monthly supply of batteries, calibration solution, and lancet device, plus the 2020 fee schedule amount for the blood glucose monitor divided by 60 months (5-year lifetime) results in a 2020 monthly allowance of $34.35, which reflects what Medicare currently pays per month for an insulin-treated diabetic beneficiary. Based on supplier invoices and other prices, a 2020 monthly price for supplies and accessories used with class II or class III adjunctive CGMs would be calculated to be $209.97 and $233.12 respectively. Subtracting the monthly cost of the blood glucose monitor and supplies of $34.35 from the monthly cost of the supplies and accessories for class II adjunctive CGMs results in a net price of $175.62 ($209.97 − $34.35 = $175.62) for the monthly supplies and accessories used with a class II adjunctive CGM after backing out the cost of the separately paid blood glucose supplies. Subtracting the monthly cost of the blood glucose monitor and supplies of $34.35 from the monthly cost of the supplies and accessories for class III adjunctive CGMs results in a net price of $198.77 ($233.12 − $34.35 = $198.77) for the monthly supplies and accessories used with a class III adjunctive CGM after backing out the cost of the separately paid blood glucose supplies. Thus we are proposing 2020 fee schedule amounts of $175.62 and $198.77 (to be increased by the 2021 fee schedule update factor yet to be determined) for use in paying claims in 2021 for the monthly supplies and accessories for use with class II and class III adjunctive CGMs respectively. Reducing the payment amount for supplies and accessories used with adjunctive CGMs by the average monthly payment for the blood glucose monitor and supplies that Medicare and the beneficiary will still have to pay for avoids a situation where the beneficiary and the program pay twice for glucose testing supplies and equipment.

Finally, a third type of CGM system currently on the market is non-adjunctive but does not automatically transmit glucose readings to the CGM receiver and therefore does not alert the patient about dangerous glucose levels while they sleep. We refer to this as a manual, non-adjunctive CGM system. We propose to establish 2020 fee schedule amounts of $46.86 (for class II devices) and $52.01 (for class III devices) for the monthly supplies and accessories for this third category, which only uses disposable batteries and sensors, based on supplier prices for the supplies and accessories for this category of CGMs.

Again, we believe that the types of CGM supplies and accessories used with the three different types of CGM systems currently on the market warrants three separate fee schedule amounts for the different monthly supplies and accessories for these three types of systems.

C. Provisions of the Proposed Rule

We are proposing to classify all CGM systems that use a receiver that meets the definition of DME as DME. We are proposing that a CGM system would need to be granted marketing authorization by FDA, but its FDA-required labeling would not need to indicate that the CGM is appropriate or indicated for use in place of a blood glucose monitor for making diabetes treatment decisions in order to be classified as DME. Therefore, we are now proposing to classify CGM systems

that are adjunctive and non-adjunctive as DME. We are also proposing to establish Medicare fee schedule amounts for CGM receivers/monitors using 1986/87 average reasonable charges for comparable blood glucose monitors updated in accordance with section 1834(a)(14) of the Act. Finally, we propose to establish separate monthly fee schedule amounts for calendar year 2021 for the supplies and accessories used with the three different types of class II and class III CGMs on the market as of the date of publication of this proposed rule based on the following amounts with the addition of the applicable update factors for 2021 to be determined later this year: $222.77 (class II) and $259.20 (class III) for supplies and accessories necessary for the effective use of automatic, non-adjunctive CGMs; $175.62 (class II) and $198.77 (class III) for supplies and accessories necessary for the effective use of automatic, adjunctive CGMs; and $46.86 (class II) and $52.01 (class III) for supplies and accessories necessary for the effective use of manual, non-adjunctive CGMs.

VII. Expanded Classification of External Infusion Pumps as DME

In section 5012 of the 21st Century Cures Act, Congress amended section 1861(s)(2) of the Act, and added subsections 1834(u) and 1861(iii) of the Act, to establish a new Medicare home infusion therapy services benefit to cover certain professional services associated with the provision of home infusion therapy. Congress defined ''home infusion drug[s]'' at section 1861(iii)(3)(C) of the Act as ''a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)),'' excluding insulin pump systems and self-administered drugs or biologicals on a self-administered drug exclusion list. See 42 U.S.C. 1395x(iii)(3)(C).

In light of the new Medicare home infusion therapy services benefit to cover certain professional services associated with the provision of home infusion therapy, we propose to expand the scope of the Medicare Part B benefit for durable medical equipment (DME) by revising the interpretation of the ''appropriate for use in the home'' requirement within the definition of DME at 42 CFR 414.202 specifically for certain drugs or biologicals infused in the home using an external infusion pump. It is important to note that the home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump.

In order for an external infusion pump and associated supplies to be covered under the Part B DME benefit, the pump must, among other statutory and regulatory requirements, be ''appropriate for use in the home.'' See 42 CFR 414.202. In practice, CMS has interpreted this requirement within the definition of DME at 42 CFR 414.202 as limiting coverable DME items to those items which can be used by a patient or caregiver in the home without the assistance of a healthcare professional. We propose to interpret this requirement to be met for an external infusion pump if: (1) The Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both; (2) a qualified home infusion therapy supplier (as defined at § 486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at § 486.505); and (3) the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug. We will use the first requirement in our proposed standard to identify the drugs or biologicals that a beneficiary or caregiver or both is unable to safely and effectively administer in the home, per the FDA-required labeling. The second requirement addresses the necessary services furnished by a qualified home infusion therapy supplier, which are covered by Medicare under the home infusion therapy benefit, and which would provide for the safe and effective administration of the drug or biological in the home. Our justification for the third requirement in our proposed standard is based on our belief that the FDA-required labeling must specify that a drug may be infused via an external infusion pump on a regular basis or over a set period of time at prescribed intervals because DME is a rental benefit. Medicare payment for an external infusion pump classified as DME is typically made over the course of 13 months under a capped rental payment; title for the pump transfers to the beneficiary after 13 months of continuous use. Medicare payment for drugs or biologicals infused through an item of DME is typically made consistent with section 1847A of the Act. Therefore, we propose that in a situation in which a beneficiary or caregiver or both is unable to safely and effectively administer certain drugs or biologicals, the external infusion pump through which such drugs or biologicals are administered could satisfy the definition of DME if all three of the requirements described previously are met. The drug or biological could then be covered as a supply under the DME benefit.

Related to the third requirement in our proposed standard, we are seeking comment on our proposed plan to take into account whether the FDA required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug; we welcome input on alternative standards or factors DME MACs could use when making this determination.

If finalized, the proposed change would result in a greater number of drugs or biologicals being covered as supplies under the DME benefit. The proposed change could also affect home infusion therapy services. We solicit comments on our proposal to reinterpret the ''appropriate for use in home'' requirement at 42 CFR 414.202, which would expand beneficiary access to drugs or biologicals infused in the home using and external infusion pump.

In particular, we solicit comment on whether our proposal would be adequate to expand access to medically appropriate home infusion drugs administered through external infusion pumps and home infusion therapy furnished by qualified home infusion therapy suppliers. We note that in order to receive services under the Medicare home infusion therapy benefit, section 1861(iii)(2)(B) of the Act requires the individual to be under a plan of care that describes the type, amount, and duration of home infusion therapy services and such plan must be established and reviewed by a physician in coordination with the furnishing of home infusion drugs. Therefore, the patient's physician must coordinate, as needed, with the DME supplier and a qualified home infusion therapy supplier (if different from the DME supplier) when establishing and reviewing the home infusion therapy plan of care. Additionally, we solicit public comment with regard to whether there are any additional issues that CMS should consider to ensure effective and safe delivery of home infusion drugs

administered through an external infusion pump to beneficiaries in their homes. We note that the DME and home infusion therapy benefit categories are separate Medicare benefit categories defined by statute, which may be quite different from how home infusion drugs administered through external infusion pumps are covered, delivered, and paid for under private insurance arrangements and private networks of providers. We further note that Medicare beneficiaries generally have choices regarding their site of care treatment options. If drug infusion therapy in the home setting is an available option to a beneficiary, coordination among physicians, home infusion therapy suppliers, and DME suppliers is important to achieving positive health outcomes.

Increased access and choice for beneficiaries in need of home infusion drugs is an important component of moving towards increased value-based care. We request comment on whether the proposed change would be adequate to further this objective.

We note that this proposal, if finalized, would necessitate updates to the local coverage determinations for external infusion pumps by the DME MACs. The DME MACs update local coverage determinations upon receipt and review of an LCD reconsideration request. The DME MACs have instructions about LCD reconsideration requests on their websites, and we anticipate that manufacturers, suppliers, and others would approach the DME MACs in this manner requesting that drugs or biologicals be included in the LCDs for external infusion pumps. This proposal, if finalized, should not be construed as CMS staff and Medical Officers taking on the responsibility for evaluating requests and making determinations on which drugs or biologicals satisfy the ''appropriate for use in the home'' criteria in addition to or in lieu of DME MAC process for updates to LCDs. Consistent with long standing practice, the DME MACs are responsible for maintaining the list of eligible drugs that can be infused using an external infusion pump. In summary, we welcome comments on these issues and in particular—

- On our proposal to interpret the ''appropriate for use in home'' requirement at 42 CFR 414.202, which would expand beneficiary access to drugs or biologicals infused in the home using an external infusion pump;
- On whether our proposal would be adequate to expand access to medically appropriate home infusion drugs administered through external infusion pumps and home infusion therapy furnished by qualified home infusion therapy suppliers;
- With regard to whether there are any additional issues that CMS should consider to ensure effective and safe delivery of home infusion drugs administered through an external infusion pump to beneficiaries in their homes;
- On whether the proposed change would further the objective of moving towards increased value-based care; and
- On our proposed plan to take into account whether the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug; we welcome input on alternative standards or factors DME MACs could use when making this determination.

VIII. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs From the DMEPOS CBP

The Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) was signed into law on December 20, 2019. Section 106(a) of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) amends section 1847(a)(2)(A) of the Act to exclude complex rehabilitative manual wheelchairs, certain manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor codes, and related accessories from the DMEPOS CBP. We are therefore proposing to make conforming changes to the definition of ''item'' under § 414.402 to reflect that these wheelchairs and related accessories are excluded from the DMEPOS CBP. We are proposing to edit the definition of item in § 414.402 to exclude ''power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs''.

In addition, section 106(b) of the Further Consolidated Appropriations Act, 2020 mandates that, during the period beginning on January 1, 2020 and ending June 30, 2021, the adjustments to the Medicare fee schedule amounts for certain DME based on information from competitive bidding programs not be applied to wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs (HCPCS codes E1161, E1231, E1232, E1233, E1234 and K0005) and certain manual wheelchairs currently described by HCPCS codes E1235, E1236, E1237, E1238, and K0008. We are implementing the changes to the fee schedule amounts for these items through program instructions based on the discretion provided by the Further Consolidated Appropriations Act, 2020.

IX. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

As stated earlier, this rule proposes to continue certain existing code application policies and processes and proposes several new coding policies and procedures. However, the new policies and procedures will not have any effect on existing requirements and burden estimates. Specifically, proposed § 414.8, § 414.9, § 414.10, § 414.114, and § 414.240 all make reference to the Level II HCPCS code application process. The information collection requirements associated with the aforementioned proposed regulations are currently approved under OMB control number 0938–1042 as part of the information collection request ''Healthcare Common Procedure Coding System (HCPCS)—Level II Code Modification Request Process (CMS–10224).

X. 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.

XI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 801–808), 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 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). These proposed regulations are not economically significant within the meaning of section 3(f)(1) of the Executive Order.

However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed this proposed rule, and the Departments have provided the following assessment of their impact.

A. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Thus, using the 2019 wage information from the Bureau of Labor Statistics (BLS) *https://www.bls.gov/oes/current/oes119111.htm* for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $111.00 per hour, including overhead and fringe benefits. For manufacturers of DMEPOS products, DMEPOS suppliers, and other DMEPOS industry representatives, we assume the same cost of reviewing this rule. Assuming an average reading speed for those very familiar with the topic matter, we estimate that it would take approximately 5 hours for the medical and health service managers or industry representatives to review this proposed rule. For each entity that reviews this proposed rule, the estimated cost is $555.00 (5 hours' × $111.00 per hour.) Therefore, we estimate that the total cost of closely reviewing this proposed rule is $360,750 ($550.00 × 650 reviewers).[42] Due to the uncertainty involved with accurately quantifying the administrative costs of reviewing this rule, we solicit comments on this assumption.

We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters or DME suppliers will review this proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons, we anticipate that a little more than 2 percent of the 2018 DME suppliers (650) may review the proposed rule. We further assume that some DME entities will read summaries from trade newsletters, trade associations, and trade law firms within the normal course of staying up with current news, incurring no additional cost. We solicit comments on this assumption.

B. Detailed Discussion of Impacts by Major Provisions

1. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

The Office of the Actuary has determined that the proposed regulations would neither increase nor decrease spending from what is assumed in the FY 2021 President's Budget. In November 2019 when the budget baseline was estimated based on historic trends the same level of spending in CBAs and also non-CBAs from 2021 onwards. In other words, no explicit assumption for changing this provision was made in the President's budget baseline.

In addition, we seek comments on three alternatives to our proposal that would have fiscal impacts. The first alternative is to pay fully adjusted fee schedule rates in all areas except super rural areas or non-contiguous areas and pay 120 percent of the fully adjusted rates in super rural areas and non-contiguous areas. The Office of the Actuary estimates that this alternative would generate $2.4 billion in Medicare savings and $0.2 billion in Medicaid savings over 5 years against the FY 2021 President's Budget baseline assuming that the PHE ends by January 2021. second alternative is to adjust fee schedule amounts for items and services furnished in non-CBAs between 2021 and 2023 based on a 75/25 blend of adjusted and unadjusted rates and phase in the full fee schedule adjustments beginning January 1, 2024. The Office of the Actuary estimates that this alternative would generate $1.8 billion in Medicare savings and $0.1 billion in Medicaid savings over 5 years against the FY 2021 President's Budget baseline assuming the PHE ends by January 2021. The third alternative addresses a possible payment methodology for certain product categories that were essentially removed from Round 2021 of the CBP. Under this alternative, we would continue the fee schedule adjustment transition rules at § 414.210(g)(9) and fee schedule adjustment rules at § 414.210(g)(10) for items and services furnished in non-CBAs and CBAs or former CBAs, respectively, for items and services that are essentially removed from Round 2021 of the CBP. Under this alternative, the current fee schedule adjustment methodologies would continue until the next time these items and services are recompeted under the CBP. OACT has estimated that the changes made to the CBP under previous rulemaking (83 FR 57020) would have a minimal impact against the FY 2021 President's Budget baseline; therefore, continuing to use rates set under previous rounds of the CBP to adjust fee schedule amounts would likewise have a minimal impact against the FY 2021 President's Budget baseline since those rates are in line with what OACT assumed would be spent as a result of Round 2021 of the CBP.

The first two alternatives were not proposed primarily due to the assumption that maintaining the current fee schedule adjustment methodology will provide for better access to DMEPOS items. The third alternative addresses a possible payment methodology for certain product categories that are essentially removed from Round 2021 of the CBP and the fee schedule amounts for such items and services furnished in CBAs, former CBAs, and non-CBAs.

2. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

No fiscal impact has been identified by the Office of the Actuary in the

[42] 650 represents a little more than 2 percent of the 2018 number of DME suppliers.

baseline of the FY 2021 President's Budget for these provisions promulgated in 2018.

3. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

This rule proposes to continue certain existing code application policies and processes and proposes certain new coding policies and procedures that are assumed to have no determinable fiscal impact when measured against the FY 2021 President's Budget baseline.

4. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

This rule proposes to use the existing HCPCS public meeting process for BCDs for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations with no additional administrative costs to CMS and no fiscal impact when measured against the FY 2021 President's Budget baseline. BCDs are necessary in order to make payment determinations for these new items and services. As an aside, the proposal to incorporate public consultation on BCDs and payment determinations for these new items and services into the HCPCS public meetings will not affect the ability of manufacturers to make these new items and services. We are proposing to use an already established process (HCPCS public meetings) that has been in use since 2001 for DME and 2005 for other items and services.

5. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

This rule proposes to classify all CGMs as DME and addresses the payment for different types of CGMs. Because we do not anticipate changes in CGM utilization, this proposal is assumed to have no overall fiscal impact when measured against the FY 2021 President's Budget baseline.

6. Expanded Classification of External Infusion Pumps as DME

This proposed rule would expand the scope of the Medicare Part B benefit for DME by revising the interpretation of the ''appropriate for use in the home'' requirement in the definition of DME at 42 CFR 414.202 specifically for certain drugs or biologicals infused in the home using an external infusion pump if: (1) The Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both; (2) a qualified home infusion therapy supplier (as defined at § 486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at § 486.505); and (3) the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug. It is important to note that the home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump. The fiscal impact of this proposal against the FY 2021 President's Budget is estimated to be a small savings to Medicare in CY 2021.

Beneficiaries have continued access in the outpatient setting to the drugs or biologicals that would be covered as supplies under the DME benefit if this proposal is finalized. Medicare pays for the drugs or biologicals using the same methodology regardless of the setting in which they are administered. However, Medicare would be responsible for a smaller portion of the total costs of administration if this proposal is finalized and a beneficiary chooses to receive home infusion rather than infusion in an outpatient setting because the beneficiary would be responsible for a larger portion of the total costs in the home setting, since there is no cap on the beneficiary cost-sharing for DME as there is in the hospital outpatient setting. The Medicare payments for the external infusion pump, supplies, and professional services (labor) in the home setting is higher than in the outpatient setting, however, the overall impact on Medicare costs is a small savings if the beneficiary chooses the home setting over the hospital outpatient setting. In the outpatient setting, Medicare pays for the supplies, including the costs associated with the use of an external infusion pump, and the professional service in a single payment to the facility. The pump is owned by the facility and not paid for separately by Medicare. Under this proposal, our reinterpretation of the ''appropriate for use in the home'' requirement would result in more external infusion pumps and supplies, including the drugs or biologicals, being paid for under the DME benefit, while the professional service component of home infusion would be paid under the home infusion therapy services benefit. Medicare payment for an external infusion pump classified as DME is typically made over the course of 13 months under a capped rental payment; title for the pump transfers to the beneficiary after 13 months of continuous use. Medicare would continue to make a monthly payment for supplies (such as tubing, catheters, and the infusion drugs) for the appropriate use of the external infusion pump for as long as the beneficiary has a medical need for such supplies.

The estimated impact of this proposed policy is based on current utilization, by reviewing Medicare hospital outpatient claims, of the only product known by CMS at this time that is available in the outpatient setting through the use of an external infusion pump and could also be prescribed by a physician for use in the home setting: Patisiran. In 2019, 128 beneficiaries utilized this drug and total Medicare payments to facilities for furnishing patisiran was roughly $26 million. The number of beneficiaries that would shift settings, if this proposal is ultimately finalized, is unknown but a reasonable assumption is that 50 percent—or 64 beneficiaries—would shift settings. CMS estimates that approximately $235,000 per year in Medicare payment would be paid under the home infusion therapy benefit, as CMS estimates home infusion therapy supplier claims would be paid at the category 3 level for those drugs as described in the CY 2020 Home Health Prospectve Payment System (HH PPS) final rule (84 FR 60618) for the home visit. More specifically, CMS estimates that in 2021, a home infusion therapy supplier would come to the home of each of the 64 beneficiaries for one initial visit at a category 3 level of $320 in payment and 16 subsequent visits at a category 3 level of $266 in payment per visit, in the first year, if this proposal is finalized. CMS also estimates that $18 million would be paid to DME suppliers, predominantly based on the costs of the drug and payment for the external infusion pumps. The net impact to Medicare, accounting for enrollment growth and projected payment updates, is estimated to be a savings of roughly $3 million in CY 2021 if this proposal is finalized. This savings is largely attributable to the differential in cost sharing between the hospital outpatient setting and the home, as described below. Please note

that this estimate reflects no assumption for induced utilization of this product or for other products that could meet the definition of DME currently or that may come to market in the future. CMS asks for public comment on other products that could qualify under this proposed revised interpretation of the definition of DME to further inform our estimates.

We further note the impact on the beneficiary. The beneficiary, in consultation with the physician that develops the plan of care, would have the opportunity to select the home or outpatient setting for infusion, if this proposal is finalized. A fiscal impact on a beneficiary is that the Medicare payments for external infusion pump rental occur in the first 13 months of treatment in the home setting, which may increase up front outlays in cost-sharing for beneficiaries. In addition, hospital outpatient cost sharing is capped at the inpatient deductible, which is currently $1,408 per service line (which in this case is for each administration of patisiran every 3 weeks). DME, including DME supplies like the drug, and the home infusion therapy benefit have a 20 percent cost sharing, which does not have a cap (or maximum amount). We estimate that patisiran, for example, would have cost sharing of more than $70,000 per year per beneficiary in the home setting compared to approximately $24,000 in the hospital outpatient setting. We note that many beneficiaries may have supplemental coverage, like Medigap insurance, from a third-party payer that may mitigate this cost sharing. Infusion of patisiran would also continue to be available in an outpatient setting subject to the per service cap at the inpatient deductible. CMS is also aware that premedication drugs may be necessary to safely and effectively administer certain infusion drugs, and that intravenous forms of the premedication drugs are covered in the hospital outpatient payment. CMS notes that premedication drugs would not be covered as supplies necessary for the use of the external infusion pump under the DME benefit, and therefore, if administered intravenously in the home, are estimated to cost a beneficiary a total of $3–19 out of pocket per treatment session. We note that some premedication drugs may also have an oral form and could be covered under Part D or be over-the-counter and non-covered by Medicare.

We seek public comment on the proposed policy, particularly in regard to information about other infusion drugs or biologicals that may be covered as supplies under the DME benefit if this proposal is finalized. We also seek comment on the out-of-pocket costs for beneficiaries who would elect to receive infusion drugs or biologicals in the home rather than the outpatient setting.

7. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs From the DMEPOS CBP

This rule proposes conforming changes to the regulations at 42 CFR 414.402 to revise the definition of ''item'' at 42 CFR 414.402 under the CBP to exclude complex rehabilitative manual wheelchairs and certain other wheelchairs from the CBP and is estimated to have no fiscal impact and is considered in the baseline of the FY 2021 President's Budget.

C. Regulatory Flexibility Act (RFA)

This proposed rule does not impose a significant impact on small entities or DMEPOS suppliers. As a result, the RFA does not apply to this proposed rule. Nevertheless, the discussion later in this section aims to describe why the proposed rule does not impose a significant impact on small entities. The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all DMEPOS suppliers are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year).

According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards*, DME suppliers may fall into either the North American Industrial Classification System (NAICS) code 532291 and Home Health Equipment Rental code 44610, Pharmacies and Drug Stores. The SBA defines Pharmacies and Drug Stores as businesses having less than $30 million and Home Health Equipment Rental as businesses having less than $35 million in annual receipts.

TABLE 5—DMEPOS SUPPLIERS SIZE STANDARDS

NAICS (6-digit)	Industry subsector description	SBA size standard/small entity threshold (million)	Total small businesses
446110 ...	Pharmacies and Drug Stores	$30	18,526
532291 ...	Home Health Equipment Rental	35	673

Source: 2012 Economic Census.

Since we are uncertain of the DMEPOS suppliers' composition, we are seeking comments from the public to aid in understanding the various industries that supply DMEPOS products. So far, we have identified only the two industries mentioned in Table 5.

TABLE 6—DMEPOS SUPPLIERS CONCENTRATION RATIOS

[Pharmacies and drug stores and home healh equipment rental]

Firm size (by receipts)	Firm count	% of small firms	Total Avg. Rev.
SMALL FIRMS	19,199	100.0	159,052,305
<100,000	808	4.2	93,936
100,000–499,999	2,267	11.8	570,733
500,000–999,999	2,056	10.7	1,463,023

TABLE 6—DMEPOS SUPPLIERS CONCENTRATION RATIOS—Continued

[Pharmacies and drug stores and home healh equipment rental]

Firm size (by receipts)	Firm count	% of small firms	Total Avg. Rev.
1,000,000–2,499,999	5,915	30.8	3,341,895
2,500,000–4,999,999	5,158	26.9	6,986,859
5,000,000–7,499,999	1,654	8.6	11,667,724
7,500,000–9,999,999	598	3.1	17,453,816
10,000,000–14,999,999	444	2.3	22,420,998
15,000,000–19,999,999	157	0.8	27,573,076
20,000,000–24,999,999	71	0.4	20,211,074
25,000,000–29,999,999	46	0.2	20,377,955
30,000,000–34,999,999	25	0.1	26,891,217
LARGE FIRMS:			
Receipts >$35 Million	326	NA	2,962,532

SOURCE: 2012 County Business Patterns and 2012 Economic Census.

*Total average revenue data are not included for the Home Health Equipment Rentals (NAICS 532291) for firms greater than 20,000,000 in receipts). Moreover, no revenue data are available for large firms in Home Heath Equipment Rentals Industry.

As can be seen in Table 6, almost all DMEPOS suppliers are small entities as that term is used in the RFA.[43] Additionally, Table 6 shows the disproportionate impacts among firms, and between small and large firms. In Table 6, both industries, Pharmacies and Drug Stores and Home Health Equipment, Rental firm size (by receipts), firm count, % of small firms, and total average revenue were aggregated to determine the DMEPOS concentration ratios. Keep in mind, there are missing data. See footnotes. Nevertheless, the great majority of DMEPOS suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $35 million (see *the Small Business Administration's website at http://www.sba.gov/content/small-business-size-standards*).

For purposes of the RFA, approximately 98 percent of pharmacies and drugs stores and home health equipment rental industries are considered small businesses according to the Small Business Administration's size standards with total revenues of $35 million or less in any 1 year. Individuals and states are not included in the definition of a small entity.

This rule does not affect health care enterprises operated by small government entities such as counties or towns with populations 50,000 or less. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. The RFA threshold analysis, therefore, indicates that there is not a significant economic impact on a substantial number of small entities. We do not believe that this threshold will be reached by the requirements in this rule. Recall, the only cost presented is the regulation review cost of $555 per reviewing firm, which is considered to be a very insignificant cost for the firms.

Since we are uncertain if we have accounted for all the DMEPOS suppliers, we are asking for public comments. We anticipate that additional DMEPOS suppliers not accounted for in this rule are minimal; hence, we do not believe that this regulation will result in a significant impact on a substantial number of small entities. Therefore, the Secretary certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 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's designation under Executive Order 13771 will be informed by comments received.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by OMB.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as follows:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER SERVICES

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

[43] Note, the entire population of DMEPOS suppliers is not known at this time. However, based on our experience, the majority of DMEPOS suppliers are covered in the two industries identified.

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

■ 2. Section 414.8 is added to subpart A to read as follows:

§ 414.8 Healthcare Common Procedure Coding System (HCPCS) Level II code application cycles and procedures.

(a) *Scope.* This section sets forth coding cycles and procedures for external code applications requesting revisions to the HCPCS Level II code set maintained by CMS for the following:

(1) *Non-drug, non-biological items and services.* For purposes of §§ 414.8, 414.9, and 414.10, non-drug, non-biological items and services are items and services that Medicare (and potentially other payers) typically pay separately, as well as certain items and services that are not covered under Medicare, and that are described as the following:

(i) Medical and surgical supplies, such as splints and casts described in section 1861(s)(5) of the Act and therapeutic shoes described in section 1861(s)(12) of the Act.

(ii) Dialysis supplies and equipment such as those described in section 1861(s)(2)(F) of the Act.

(iii) Ostomy and urological supplies such as those described in section 1861(s)(8) of the Act.

(iv) Surgical dressings, such as those described in section 1861(s)(5) of the Act.

(v) Prosthetics (artificial legs, arms, and eyes) such as those described in section 1861(s)(9) of the Act and prosthetic devices such as those described in section 1861(s)(8) of the Act.

(vi) Orthotics (leg, arm, back, and neck braces) such as those described in section 1861(s)(9) of the Act.

(vii) Enteral/parenteral nutrition such as those described in section 1842(s)(2) of the Act.

(viii) Durable Medical Equipment (and related accessories and supplies other than drugs), such as oxygen and oxygen equipment, wheelchairs, infusion pumps, and nebulizers such as described in sections 1861(s)(6) and 1861(n) of the Act.

(ix) Vision items and services, such as prosthetic lenses described in 1861(s)(8) of the Act.

(x) Other items and services that are statutorily excluded from Medicare coverage for which CMS or other government or private insurers have identified a claims processing need for a HCPCS Level II code, such as hearing aids which are excluded from coverage by section 1862(a)(7) of the Act.

(2) *Drug or biological products.* For purposes of §§ 414.8, 414.9, and 414.10, these are products that are separately payable by Medicare under Part B as drugs or biologicals as that term is defined in section 1861(t) of the Act.

(b) *Coding cycles.* HCPCS Level II coding cycles begin with the submission deadlines for code applications described in paragraph (c) of this section, followed by a preliminary recommendation and public meeting as specified in paragraphs (d) and (e) of this section, and the issuance of a final decision described in paragraph (e) of this section. Coding cycles begin no less frequently than—

(1) Bi-annually for non-drug, non-biological items and services; and

(2) Quarterly for drug or biological products.

(c) *Code application deadlines.* HCPCS Level II code application submission deadlines are established on the CMS website or in another manner and are —

(1) In or around January and June of each year for non-drug, non-biological items and services; and

(2) In or around January, April, June, and September each year, for drug or biological products.

(d) *Public meetings.* (1) Public meetings are held to provide the public with notice of, and the opportunity for public input on code applications and preliminary recommendations described in paragraph (e)(1) of this section under consideration by CMS; and for CMS to gather public input regarding these applications and preliminary recommendations.

(2) Public meetings are held during each bi-annual coding cycle.

(3) Subject to paragraph (e)(3) of this section, public meetings are held for all code applications for non-drug, non-biological items and services.

(4) Subject to paragraph (e)(3) of this section, public meetings are held for drug or biological product code applications only under the following circumstances:

(i) The code application is one that was resubmitted for reevaluation as provided in § 414.9(b).

(ii) A decision on the code application is delayed under paragraph (e)(3) of this section, and CMS determines it presents program, policy, or implementation concerns or complexities, or otherwise raises questions that public input could help to address.

(e) *Preliminary recommendations, final decisions, and effective dates.*

(1) *Preliminary recommendations.* CMS issues preliminary recommendations, which may include questions or requests for additional information that could help in reaching a final decision, on code applications for items and services included in the public meeting agenda. Except as provided in paragraph (e)(3) of this section and § 414.9(b)(3)(i), preliminary recommendations are posted on the CMS website or issued in another manner, prior to the public meetings described in paragraph (d) of this section.

(2) *Final decisions.* Except as provided in paragraph (e)(3) of this section, final decisions are posted on the CMS website or issued in another manner within approximately—

(i) Six months of the application deadline for non-drug, non-biological items and services; and

(ii) Three months of the application deadline for drug or biological products.

(3) *Delays in making preliminary recommendations or final decisions.* (i) CMS may delay a preliminary recommendation and therefore a final decision, or delay a final decision alone, one or more times into a subsequent coding cycle where a code application raises complex or significant issues or considerations and CMS determines that additional time is needed to evaluate the code application. Such circumstances may include, but are not limited to, situations where the code application involves a significant policy or claims processing consideration, or requires in-depth clinical or other research.

(ii) For code applications (including code applications for drug or biological products) that are resubmitted for reevaluation and placed on a public meeting agenda in accordance with § 414.9(b)(3), CMS may also delay issuing a preliminary recommendation, a final decision, or both into a subsequent quarterly coding cycle.

(iii) Decisions to delay a preliminary recommendation or final decision are issued by CMS, either on the CMS website or in another manner, at the same time that CMS issues the preliminary recommendations or final decisions, as applicable, for other applications during a coding cycle.

(4) Coding changes are effective approximately 3 months after the issuance of the final coding decision.

■ 3. Section 414.9 is added to subpart A to read as follows:

§ 414.9 HCPCS Level II code application requirements.

(a) *Timely and complete applications.* To be considered in a given HCPCS Level II coding cycle specified in § 414.8(b), a code application must be timely and complete. Code applications that are not timely and complete are declined by CMS but may be submitted

by the applicant in a subsequent coding cycle.

(1) Applications are timely if submitted to CMS by the applicable code application submission deadline specified by CMS on its website or in another manner, for a given application cycle identified in § 414.8(c), or as provided in paragraph (a)(3) of this section.

(2) To be complete, an application must contain the following by the applicable code application submission deadline:

(i) All applicable information and documentation specified in this section, and meet all administrative elements specified by the application instructions issued by CMS and posted on the CMS website.

(ii) FDA documentation of the item's current classification, as applicable, as well as FDA marketing authorization documentation, or the regulation number under 21 CFR parts 862 through 892 for a device exempted from the premarket notification requirement. If a device exceeds the limitations to the exemptions under 21 CFR parts 862 through 892 of the device classification regulations, the appropriate marketing authorization documentation must be submitted as part of the application.

(iii) For applications for non-drug, non-biological items or services that are not subject to marketing authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) or Public Health Service Act (PHSA) to be considered complete, evidence that the item or service is available in the United States market for use and purchase at the time of the relevant HCPCS Level II code application submission deadline specified by CMS.

(3) For biosimilar biological products, CMS allows a 10-business day extension past the code application deadline to provide a complete application as specified in paragraph (a)(2) of this section. This extension applies only if the following criteria are met:

(i) The marketing authorization documentation is dated between the first day of the extension period and no later than the last day of the extension period.

(ii) The applicant submits a complete application to CMS by the last day of the extension period.

(b) *Application resubmission and reevaluation.* (1) An applicant who is dissatisfied with a final coding decision on an initial code application may resubmit their application for reevaluation by CMS no more than two times. Any application resubmitted for reevaluation by CMS must be timely and complete in accordance with paragraph (a) of this section and must include the following:

(i) A description of the previous application submission(s).

(ii) A copy of the prior final code decision(s) with respect to the application.

(iii) An explanation of the reason for disagreement with the prior final coding decision(s).

(2) For applications resubmitted a second time for reevaluation by CMS, in addition to the information and documentation required in paragraph (b)(1) of this section, the application must include any significant new information as described in paragraphs (b)(1)(i) and (ii) of this section.

(i) Any significant new information which would include information that was not previously submitted to CMS with respect to the application that directly relates to the reason for the prior final coding decision(s) and could potentially change the final coding decision.

(ii) An explanation of how the significant new information addresses and directly relates to the reason(s) for the prior final coding decision(s) and supports the request for a different coding decision.

(3) An application that is resubmitted for reevaluation under this paragraph (b) is included on an agenda for a public meeting as described in § 414.8(d) and receives a preliminary recommendation as described in § 414.8(e)(1).

(i) An application for a drug or biological product that is resubmitted for reevaluation will not be included in a public meeting or receive a final decision in the quarterly cycle in which the application is submitted.

(ii) Preliminary recommendations and final decisions for applications that are resubmitted for reevaluation may be delayed as described in § 414.8(e)(3).

■ 4. Section 414.10 is added to subpart A to read as follows:

§ 414.10 HCPCS Level II Processes for evaluating code applications.

(a) *Scope.* This section sets forth the processes for evaluating external HCPCS Level II code applications for drug or biological products and non-drug, non-biological items and services, as described in § 414.8.

(b) *Coding request.* An applicant may submit an external HCPCS Level II code application to request the addition of a code, revision of an existing code, or discontinuation of an existing code.

(c) *Sources of information.* CMS' evaluation of a code application is based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information obtained independently by CMS that may support or refute the claims made or the evidence produced by the applicant.

(d) *Evaluation of non-drug, non-biological applications to add a code.*

(1) Except as provided in paragraph (d)(2) of this section, a request to add a code is further evaluated under paragraph (d)(4) of this section if CMS determines the following—

(i) The item or service is not appropriate for inclusion in or already coded in a different HIPAA standard medical data code set, such as CPT®, ICD, or CDT®;

(ii) The item or service is primarily medical in nature;

(iii) If applicable, the item has the appropriate marketing authorization from FDA, or is exempt from premarket notification requirements; and

(iv) There is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set.

(2) If paragraphs (d)(1)(i), (ii), or (iii) of this section are not met, but paragraph (d)(1)(iv) of this section is met, a request to add a code is further evaluated under paragraph (d)(4).

(3) If neither paragraph (d)(1) nor (2) of this section is met, CMS does not further evaluate the application under paragraph (d)(4) and does not modify the HCPCS Level II code set.

(4) If paragraph (d)(1) or (d)(2) of this section is met, CMS determines if the item or service that is the subject of the code application—

(i) Performs a significantly different clinical function compared to other items or services described in the HCPCS Level II code set. An item or service is considered to perform a significantly different clinical function if it performs a clinical function that is not performed by any other item or service currently described in the HCPCS Level II code set; or

(ii) Results in a significant therapeutic distinction compared to the use of other similar items or services described in the HCPCS Level II code set. An item or service is considered to show a significant therapeutic distinction when the use of that item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set.

(A) CMS determines that the use of the item or service confers a

significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set, if it finds any of the following:

(*1*) The item or service offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(*2*) The item or service offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the item or service to make a diagnosis affects the management of the patient.

(*3*) A demonstration of one or more of the following outcomes:

(*i*) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

(*ii*) A decreased rate of at least one subsequent diagnostic or therapeutic intervention.

(*iii*) A decreased number of future hospitalizations or physician visits.

(*iv*) A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time.

(*v*) An improvement in one or more activities of daily living.

(*vi*) An improved quality of life.

(*vii*) A demonstrated greater medication adherence or compliance.

(*4*) The totality of the information otherwise demonstrates that the use of the item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set.

(B) In determining whether the use of the item or service results in a significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set, CMS may consider instances where the use of the item or service may substantially improve or substantially change the medical benefit realized by a specific subpopulation of patients with the medical condition for whom the item or service is used, based on a common characteristic within the subpopulation that impacts the medical benefit of the subject item or service.

(C) In determining whether the use of the item or service results in a significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set, CMS makes this determination without regard to the prevalence among Medicare beneficiaries of the underlying medical condition treated or diagnosed by the item or service that is the subject of the code application.

(D) An item's designation under the FDA Breakthrough Devices Program and marketing authorization for the indication covered by the FDA Breakthrough Devices designation are given substantial weight in determining whether the item meets the significant therapeutic distinction factor at paragraph (d)(4)(ii) of this section.

(E) An application must contain sufficient information and supporting documentation to support a claim of significant therapeutic distinction. The totality of the circumstances is considered when making a determination that the use of an item or service confers a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set.

(5)(i) If the item or service that is the subject of the code application meets either of the two factors set forth in paragraph (d)(4)(i) or (ii) of this section, and CMS determines there is a claims processing need to separately identify the item or service with a new code to facilitate payment under Medicare, then CMS creates a new code.

(ii) If the conditions in paragraph (d)(5)(i) of this section are not met, CMS does not create a new code.

(6) If CMS finds that revisions to the descriptor of an existing code category are appropriate to account for minor distinctions between the subject item or service and other items or services described by the existing code category and to clarify that the item or service is included in the existing code category, then CMS revises the descriptor rather than add a new code.

(e) *Evaluation of drug or biological applications to add a code.* (1) When evaluating a request to add a code for a drug or biological product, CMS first determines if—

(i) The product is not appropriate for inclusion or already coded in a different HIPAA code set, such as CPT®;

(ii) The product is primarily medical in nature;

(iii) If applicable, the product has the appropriate marketing authorization from FDA; and

(iv) There is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set

(2) If CMS determines that the factors set forth in paragraph (e)(1) of this section are met, then CMS next determines, for the purpose of claims processing (and payment), whether an existing code adequately describes a product, or whether a revision to the descriptor of an existing code category is appropriate, or whether a new code is necessary. In making the determination in this paragraph, CMS considers applicable Medicare Part B statutory and regulatory payment requirements, program instructions, and information such as the following:

(i) Sections 1842(o) and 1847A of the Act.

(ii) 42 CFR part 414 Subparts J and K.

(iii) Program instructions implementing section 1847A of the Act.

(iv) Information from the code application and other applicable sources such as FDA, drug compendia, the manufacturer, and scientific literature.

(3) When evaluating a request to add a code for a drug or biological product, CMS determines if the product that is the subject of the code application —

(i) Is separately payable under Medicare Part B as a drug or biological product; and

(ii) Is a single source drug, multiple source drug, biological, or biosimilar biological product under section 1847A of the Act, or if other specific payment provisions such as those in sections 1842(o)(1)(A) or (F) of the Act apply.

(4) After reviewing an application to add a code for a drug or biological product, and after considering the factors listed in paragraphs (e)(1) through (3) of this section previously, CMS will then make a determination about whether the appropriate action is to add a code, revise a code, or take no coding action, in response to the application for that product.

(5) CMS may assign code descriptors with drug amounts that correspond to smaller quantities of the product to facilitate more accurate billing.

(f) *Evaluation of non-drug, non-biological and drug or biological applications to revise an existing code.* If CMS determines that the revised descriptor suggested by the applicant would provide a more appropriate description of the category of items or services, CMS revises the descriptor accordingly.

(g) *Evaluation of non-drug, non-biological and drug or biological applications to discontinue an existing code.* If CMS determines that an existing code is duplicative of another code, or has become obsolete and CMS has no further expectation that the same or

similar item or service will be marketed at a later date, CMS discontinues the code.

(h) *Coding decision.* CMS's evaluation of a code application may result in a coding decision that reflects an applicant's coding request in whole, in part, or with modification; or a denial of the coding request. Any coding action taken on an applicant's coding request is set forth in the final coding decision.

■ 5. Section 414.114 is added to subpart C to read as follows:

§ 414.114 Procedures for making benefit category determinations and payment determinations for new PEN items and services covered under the prosthetic device benefit; splints and casts; and IOLs inserted in a physician's office covered under the prosthetic device benefit.

(a) *Definitions.* For the purpose of this subpart:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of a prosthetic device at section 1861(s)(8) of the Act or is a splint, cast, or device used for reduction of fractures or dislocations subject to section 1842(s) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services that may be covered and paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit.

(2) If a preliminary determination is made that the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting described under § 414.8(d).

(4) After consideration of public consultation provided at a public meeting described under § 414.8(d) on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

■ 6. Section 414.210 is amended by—

■ a. Revising paragraphs (g)(1)(v) and (g)(2); and

■ b. Adding paragraph (g)(9)(vi).

The revisions and addition read as follows:

§ 414.210 General payment rules.

* * * * *

(g) * * *

(1) * * *

(v) For items and services furnished before April 1, 2021, the fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) Payment adjustments for areas outside the contiguous United States and for items furnished on or after April 1, 2021 in rural areas within the contiguous United States using information from competitive bidding programs.

(i) For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States (Alaska, Hawaii, and U.S. territories) for items and services furnished from January 1, 2016 through December 31, 2020 are reduced to the greater of—

(A) The average of the single payment amounts for the item or service for CBAs outside the contiguous United States.

(B) 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section.

(ii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for areas outside the contiguous United States for items and services furnished on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of the greater of the average of the single payment amounts for the item or service for CBAs outside the contiguous United States or 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

(iii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for rural areas within the contiguous United States for items and services furnished on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

* * * * *

(9) * * *

(vi) For items and services furnished in all areas with dates of service on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, based on the fee schedule amount for the area is equal to the adjusted payment amount established under paragraph (g) of this section.

* * * * *

■ 7. Section 414.240 is added to subpart D to read as follows:

§ 414.240 Procedures for making benefit category determinations and payment determinations for new durable medical equipment, prosthetic devices, orthotics and prosthetics, surgical dressings, and therapeutic shoes and inserts.

(a) *Definitions.* For the purpose of this subpart—

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of durable medical equipment at section 1861(n) of the Act,

a prosthetic device at section 1861(s)(8) of the Act and further defined under section 1834(h)(4) of the Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is durable medical equipment, a prosthetic device as further defined under section 1834(h)(4) of the Act, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert.

(2) If a preliminary determination is made that the item or service is durable medical equipment, a prosthetic device, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting described under § 414.8(d).

(4) After consideration of public consultation provided at a public meeting described under § 414.8(d) on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

■ 8. In § 414.402, amend the definition ''Item'' by revising paragraph (1) introductory text to read as follows:

§ 414.402 Definitions.

* * * * *

Item * * *

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202, group 3 complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs, and further classified into the following categories:

* * * * *

Dated: July 23, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 19, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–24194 Filed 10–29–20; 4:15 pm]

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