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Presidential Documents

Title 3—

The President

Proclamation 10368 of April 11, 2022

Education and Sharing Day, USA, 2022

By the President of the United States of America

A Proclamation

As we work together to build a better America, we must remember that education is the key to achieving greater opportunity, prosperity, stability, and equality both here and around the world. A high-quality education develops the mind, opens the heart, nurtures our talents, and fortifies our character. Through education, we learn to recognize ourselves in our neighbors and cherish the dignity of our shared human experience. No one understood this better than the man whose life and legacy we celebrate on this day: Rabbi Menachem Mendel Schneerson, the Lubavitcher Rebbe and leader of the Chabad-Lubavitch movement.

The Rebbe's devotion to educating people worldwide and his profound respect for diversity, inclusiveness, and equal justice have set a strong example for generations of Americans and people across the globe. Having survived one of history's cruelest chapters, the Rebbe emerged determined to help heal the soul of humanity. He left his mark as a thinker, leader, and teacher who recognized the limitless potential of every human being regardless of their background. His outreach is still felt today in countless houses of worship, centers of education, cultural exchanges, and service communities worldwide.

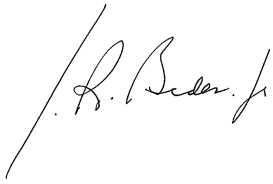
The Rebbe's work reminds us, in the words of the Prophet Amos, to ''hate evil, love good, and establish justice in the gate.'' We each share a responsibility to live up to those words—in and out of the classroom—and to plant the seeds of love, kindness, and empathy in the hearts and minds of every child in America.

To ensure that our children are provided every opportunity to learn and grow, my Administration provided resources through the American Rescue Plan for schools to safely reopen for in-person instruction. Today, thanks to our COVID–19 strategy and the resilience of local communities, more than 99 percent of America's schools are open again. But if we are truly going to build a better America, we must continue to make transformational investments in education—including making high-quality pre-school available to every 3- and 4-year old in America and coming together to address the invisible toll on children's mental health that was exacerbated by the pandemic.

Today—on what would have been the Rebbe's 120th birthday—let us celebrate all the educators, advocates, and pioneers who teach young people the lessons that create caring neighbors and closer communities. Let us commit to learning together, sharing the best we have to offer, and working in unity for the common good.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 12, 2022, as Education and Sharing Day, USA. I call upon all government officials, educators, volunteers, and all the people of the United States to observe this day with appropriate programs, ceremonies, and activities.

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



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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 906

[Doc. No. AMS–SC–21–0065; SC21–906–1 FR]

Increased Assessment Rate for Texas Oranges and Grapefruit

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Texas Valley Citrus Committee to increase the assessment rate established for the 2021–22 and subsequent fiscal periods. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective May 16, 2022.

FOR FURTHER INFORMATION CONTACT: Abigail Campos, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Abigail.Campos@usda.gov* or *Christian.Nissen@usda.gov*.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@usda.gov*.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Agreement No. 121 and Marketing Order No. 906, both as amended (7 CFR part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. Part 906, (referred to as ''the Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Texas Valley Citrus Committee (Committee) locally administers the Order and is comprised of producers and handlers of oranges and grapefruit operating within the area of production.

The Department of Agriculture (USDA) is issuing this rule in conformance with 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, 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. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. USDA has determined this rule is unlikely to 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.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, Texas citrus handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate will be applicable to all assessable oranges and grapefruit for the 2021–22 fiscal year, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule increases the assessment rate from $0.01 per 7/10-bushel carton or equivalent, the rate that was established for the 2018–19 and subsequent fiscal periods, to $0.05 per 7/10-bushel carton or equivalent of oranges and grapefruit handled for the 2021–22 and subsequent fiscal periods.

The Order authorizes the Committee, with the approval of AMS, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. Members are familiar with the Committee's needs and with the costs for goods and services in their local area and are in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2018–19 and subsequent fiscal periods, the Committee recommended, and AMS approved, an assessment rate $.01 per 7/10-bushel carton or equivalent of oranges and grapefruit handled. That assessment rate continues to be in effect unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other information available to AMS.

The Committee met on July 14, 2021, and recommended 2021–22 expenditures of $43,900 and an assessment rate of $0.05 per 7/10-bushel carton or equivalent. In comparison, the previous fiscal period's budgeted expenditures were $155,720. The assessment rate of $0.05 is $0.04 higher than the rate currently in effect. The Committee unanimously voted to increase the assessment rate due to the

extensive tree damage from a freeze experienced in Texas occurring in February 2021. This February freeze decreased the 2020–21 production from an expected 7.5 million 7/10-bushel cartons to 3.1 million 7/10-bushel cartons. The Committee discussed how freeze damages caused a depletion of financial reserves for the 2020–21 fiscal period due to assessment income being lower than expected. Production will be further reduced during the upcoming fiscal period because of freeze damage to trees. Estimated production for 2021–22 fiscal period has been reduced from 7.5 million 7/10-bushel cartons or equivalents to 1 million. At the current assessment rate, assessment income would equal only $10,000, an amount insufficient to cover the Committee's anticipated expenditures of $43,900. By increasing the assessment rate by $0.04, assessment income would be $50,000. This amount should provide sufficient funds to meet 2021–22 anticipated expenses.

Major expenditures recommended by the Committee for the 2021–22 fiscal period include $20,000 for management expenses, $13,900 for administrative expenses, and $10,000 for compliance. Budgeted expenses for these items in the 2020–21 fiscal period were $79,220, $26,500, and $50,000, respectively.

The Committee derived the recommended assessment rate by considering anticipated expenses and expected shipments of Texas oranges and grapefruit. Orange and grapefruit shipments for the 2021–22 year are estimated at 1,000,000 7/10-bushel cartons or equivalents, which should provide $50,000 in assessment income (1,000,000 cartons × $0.05). Income derived from handler assessments at the new rate, along with interest income, should be adequate to cover estimated program expenses of $43,900. Funds in the reserve (currently about $43,000) would be kept within the maximum permitted by § 906.35 of the Order (approximately one fiscal period's expenses).

The assessment rate will continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. Dates and times of Committee meetings are available from the Committee or AMS. Committee meetings are open to the public and interested persons may express their views at these meetings. AMS would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2021–22 budget and those for subsequent fiscal periods would be reviewed and, as appropriate, approved by AMS.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 119 producers of oranges and grapefruit in the production area and 14 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $1,000,000, and small agricultural service firms are defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

According to data from the National Agricultural Statistics Service (NASS), the industry, and the Committee, the weighted average free-on board price for Texas citrus for the 2019–20 season was approximately $16.20 per carton, with total shipments of around 8.2 million cartons. Based on this information, total annual receipts of Texas citrus handlers in the 2019–20 fiscal period were approximately $132,840,000 ($16.20 multiplied by 8.2 million cartons equals $132,840,000). Dividing by the number of citrus handlers infers average annual receipts of less than $30 million ($132,840,000 divided by 14 handlers equals $9.5 million).

In addition, based on NASS data, the weighted average producer price for the 2019–20 fiscal period was around $5.65 per carton of Texas citrus. Based on producer price, shipment data, and the total number of Texas citrus producers, the average annual producer revenue is below $1,000,0000 ($5.65 multiplied by 8.2 million cartons equals $46,330,000 divided by 119 producers equals approximately $389,328). Thus, the majority of Texas citrus handlers and producers are classified as small entities.

This rule increases the assessment rate established and collected from handlers for the 2021–22 and subsequent fiscal periods from $0.01 per 7/10-bushel carton or equivalent to $0.05 per 7/10-bushel carton or equivalent of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. The Committee recommended 2021–22 expenditures of $43,900 and an assessment rate of $0.05 per 7/10-bushel carton. The assessment rate of $0.05 is $0.04 higher than the previous rate. The quantity of assessable Texas Citrus for the 2021–22 season is estimated at 1,000,000 7/10-bushel cartons. Thus, the $0.05 rate should provide $50,000 in assessment income ($0.05 multiplied by 1,000,000 cartons), which should be adequate to cover budgeted expenses for the 2021–22 season.

Major expenditures recommended by the Committee for the 2021–22 fiscal period include $20,000 for management expenses, $13,900 for administrative expenses, and $10,000 for compliance. Budgeted expenses for these items in 2020–21 were $79,220, $26,500, and $50,000, respectively.

The Committee recommended increasing the assessment rate because of the extensive tree damage from the freeze in February 2021. At the current assessment rate of $0.01 and with the 2021–22 crop estimated to be 1,000,000 7/10-bushel cartons, assessment income would equal $10,000 ($0.01 multiplied by 1,000,000 cartons), an amount insufficient to cover the Committee's anticipated expenditures of $43,900. By increasing the assessment rate by $0.04, assessment income would be approximately $50,000 ($0.05 multiplied by 1,000,000 cartons). This amount should provide sufficient funds to meet 2021–22 anticipated expenses.

Prior to arriving at this budget and assessment rate, the Committee considered maintaining the current assessment rate of $0.01. However, leaving the assessment unchanged would not generate sufficient revenue to meet the Committee's expenses for the 2021–22 budget of $43,900 and would diminish reserves. Therefore, the alternative was rejected.

A review of historical information and preliminary information pertaining to the upcoming fiscal period indicates that the producer price for the 2021–22 season should be approximately $5.42 per 7/10-bushel carton or equivalent of oranges and grapefruit. Therefore, the estimated assessment revenue for the 2021–22 fiscal period as a percentage of

total producer revenue would be approximately 0.9 percent ($50,000 divided by ($5.42 × 1,000,000 cartons) × 100%).

This action increases the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, costs are minimal and uniform on all handlers, and some portion of the additional costs may be passed on to producers. However, these costs are expected to be offset by benefits derived by the operation of the Order.

The Committee's meeting was widely publicized throughout the Texas citrus industry. All interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the July 14, 2021, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0189 Fruit Crops. No changes in those requirements are necessary as a result of this rule. Should any changes become necessary, they would be submitted to OMB for approval.

This rule imposes no additional reporting or recordkeeping requirements on either small or large Texas orange and grapefruit handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. As noted in the initial regulatory flexibility analysis, AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

AMS is committed to complying with the E-Government Act, promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

A proposed rule concerning this action was published in the **Federal Register** on November 18, 2021 (86 FR 64408). Copies of the proposed rule were also mailed or sent via email to all Texas citrus handlers. The proposal was made available through the internet by AMS and the Office of the Federal Register. A 30-day comment period ending December 20, 2021, was provided for interested persons to respond to the proposal.

No comments were received. Accordingly, no changes will be made to the rule as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses*. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 906 as follows:

PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

■ 1. The authority citation for 7 CFR part 906 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 906.235 is revised to read as follows:

§ 906.235 Assessment rate.

On and after August 1, 2021, an assessment rate of $0.05 per 7/10-bushel carton or equivalent is established for oranges and grapefruit grown in the Lower Rio Grande Valley in Texas.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–07975 Filed 4–13–22; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 983

[Doc. No. AMS–SC–21–0068; SC21–983–1 FR]

Increased Assessment Rate for Pistachios

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Administrative Committee for Pistachios (Committee) to increase the assessment rate established for the 2021–22 and subsequent production years. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective May 16, 2022.

FOR FURTHER INFORMATION CONTACT:

Peter Sommers, Marketing Specialist, or Gary Olson, Regional Director, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724 or Email: *PeterR.Sommers@usda.gov* or *GaryD.Olson@usda.gov*.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov*.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Agreement and Order No. 983, as amended (7 CFR part 983), regulating the handling of pistachios grown in California, Arizona, and New Mexico. Part 983 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers and handlers of pistachios operating within the production area, and a public member.

The Department of Agriculture (USDA) is issuing this rule in conformance with 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, 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. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. Agricultural Marketing Service (AMS) has determined this rule is unlikely to 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.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, pistachio handlers are subject to assessments. Funds to administer the Order are derived from such assessments. The assessment rate established herein is applicable to all assessable pistachios for the 2021–22 and subsequent production years and will continue until amended, suspended, or terminated. The production year runs from September 1 to August 31. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed no later than 20 days after the date of the entry of the ruling.

This rule increases the assessment rate from $0.00015 per pound of pistachios, the rate established for the 2020–21 and subsequent production years, to $0.0007 per pound of pistachios for the 2021–22 and subsequent production years.

The Order authorizes the Committee, with the approval of AMS, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. Members are familiar with the Committee's needs and with costs of goods and services in their local area and are in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting, and all directly affected persons have an opportunity to participate and provide input.

For the 2020–21 and subsequent production years, the Committee recommended, and AMS approved, an assessment rate of $0.00015 per pound of pistachios. That assessment rate continued in effect from production year to production year until modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other information available to AMS.

The Committee met on July 20, 2021, and unanimously recommended expenditures of $828,000 and an assessment rate of $0.0007 per pound of pistachios handled for the 2021–22 and subsequent production years. In comparison, the prior year's budgeted expenditures were $679,800. The assessment rate of $0.0007 is $0.00055 higher than the rate previously in effect. The Committee recommended increasing the assessment rate to pay for additional Committee staff in preparation for the retirement of key staff positions (manager and administrative assistant) and to provide adequate income to cover all of the Committee's budgeted expenses for the 2021–22 production year.

Major expenditures recommended by the Committee for the 2021–22 production year include $462,500 for personnel expenses, $125,000 for research, $100,000 for a contingency fund, $82,700 for administration, and $57,800 for office expenses. Budgeted expenses for these items in the 2020–21 production year were $336,500, $125,000, $80,000, $80,700, and $57,600, respectively.

The Committee derived the recommended assessment rate by considering anticipated expenses, an estimated crop of 975 million pounds of pistachios, and the amount of funds available in the authorized reserve. Income derived from handler assessments, calculated at $682,500 (975,000,000 pounds multiplied by $0.0007 assessment rate), along with other income ($220,200), will be adequate to cover budgeted expenses of $828,000. Excess assessment revenue would be added to the Committee's reserve fund. Funds in the Committee's financial reserve are expected to be approximately $385,157 at the end of the 2021–22 production year, which would be within the Order's requirement of no more than approximately two production years' budgeted expenses.

The assessment rate established by this rule will continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each production year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. Dates and times of Committee meetings are available from the Committee or AMS. Committee meetings are open to the public and interested persons may express their views at these meetings. AMS will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's 2022–23 production year budget, and those for subsequent production years, will be reviewed and, as appropriate, approved by AMS.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the AMS has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 19 handlers subject to regulation under the Order, and approximately 1,624 producers of pistachios in the production area. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $1,000,000, and small agricultural service firms have been defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service (NASS), the national average producer price for pistachios for the 2019–20 production year was $2.75 per pound. Committee data indicates 2019–20 production year total pistachio production was 582,111,271 pounds. The total 2019–20 production year value of the pistachio crop was calculated as $1,600,805,995

(582,111,271 pounds times $2.75 per pound equals $1,600,805,995). Dividing the crop value by the estimated number of producers (1,624) yields an estimated average receipt per producer of $985,718, which is just below the SBA threshold for small producers.

According to AMS Market News data, the reported terminal price for 2021 for pistachios ranged between $150.00 to $250.00 per 25-pound carton. The average of this range is $200.00 ($150.00 plus $250.00 divided by 2 equals $200.00). Dividing the average value by the 25-pound carton yields an estimated average price per pound of $8.00 ($200.00 average value for 25-pound carton divided by 25). Multiplying the 2019–20 production year total pistachio production of 582,111,271 pounds by the estimated average price per pound of $8.00 equals $4,656,890,168. Dividing this figure by 19 regulated handlers yields estimated average annual handler receipts of $245,099,483, which is well above the SBA threshold for small agriculture service firms.

Therefore, using the above data, and assuming a normal distribution, the majority of pistachio producers may be classified as small entities and the majority of handlers of pistachios may be classified as large entities.

The assessment rate of $0.0007 that the Committee recommended complies with § 983.71(b) of the Order which states that any assessment rate must not exceed one-half of one percent of the average price received by producers in the preceding production year. The average price received by producers in the preceding production year was $2.75 per pound of pistachios. Thus, $2.75 times 0.5 percent equals $0.01375, which is greater than the assessment rate of $0.0007.

This rule increases the assessment rate collected from handlers for the 2021–22 and subsequent production years from $0.00015 to $0.0007 per pound of pistachios. The Committee unanimously recommended 2021–22 production year expenditures of $828,000 and an assessment rate of $0.0007 per pound of pistachios handled. The assessment rate of $0.0007 per pound of pistachios is $0.00055 higher than the current rate. The volume of assessable pistachios for the 2021–22 production year is estimated to be 975 million pounds. Thus, the $0.0007 per pound assessment rate should provide $682,500 in assessment income (975,000,000 multiplied by $0.0007). Income derived from handler assessments, along with an estimated $220,000 of other income, will be adequate to cover budgeted expenses for the 2021–22 production year.

Major expenditures recommended by the Committee for the 2021–22 production year include $462,500 for personnel expenses, $125,000 for research, $100,000 for a contingency fund, $82,700 for administration, and $57,800 for office expenses. Budgeted expenses for these items in the 2020–21 production year were $336,500, $125,000, $80,000, $80,700, and $57,600, respectively.

The Committee recommended increasing the assessment rate to cover the Committee's budgeted expenses for the 2021–22 production year and maintain its financial reserve. Additionally, the Committee has approved a hiring search for both the Manager and Administrative Assistant, as both are expected to retire in the near future. The increased assessment income will accommodate the hiring of additional staff to aid in the transition.

Prior to arriving at this budget and assessment rate recommendation, the Committee discussed an alternative that considered the timing of when the additional staff salaries would be required to assist the management transition. However, the Committee determined that the recommended assessment rate will fully fund budgeted expenses, avoid utilizing reserves, and permit the Committee to hire the needed staff to facilitate the replacement of the key management positions.

This rule increases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, these costs are offset by the benefits derived by the operation of the Order.

The Committee's meeting was widely publicized throughout the pistachio industry. All interested persons were invited to attend the meeting and encouraged to participate in Committee deliberations on all issues. Like all Committee meetings, the July 20, 2021, meeting was a public meeting, and all entities, both large and small, were able to express views on this issue. Interested persons were invited to submit comments on this rule, including regulatory and information collection impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0215, Pistachios Grown in California, Arizona, and New Mexico. No changes in those requirements are necessary as a result of this rule. Should any changes become necessary, they would be submitted to OMB for approval.

This rule imposes no additional reporting or recordkeeping requirements on either small or large pistachio handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A proposed rule concerning this action was published in the **Federal Register** on December 6, 2021 (86 FR 68932). Copies of the proposal were provided by the Committee to members and handlers. Finally, the proposed rule was made available through the internet by AMS and the **Federal Register**. A 30-day comment period ending January 5, 2022, was provided to allow interested persons to respond to the proposal.

No comments were received. Accordingly, no changes were made to the rule as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 983

Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service is amending 7 CFR part 983 as follows:

PART 983—PISTACHIOS GROWN IN CALIFORNIA, ARIZONA, AND NEW MEXICO

■ 1. The authority citation for 7 CFR part 983 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 983.253 is revised to read as follows:

§ 983.253 Assessment rate.

On and after September 1, 2021, an assessment rate of $0.0007 per pound is established for California, Arizona, and New Mexico pistachios.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–08009 Filed 4–13–22; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 986

[Doc. No. AMS–SC–21–0080; SC21–986–2 FR]

Decreased Assessment Rate for Pecans Grown in 15 States

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: This rule decreases the assessment rate established for the 2021–22 fiscal year and subsequent fiscal years. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective May 16, 2022.

FOR FURTHER INFORMATION CONTACT: Abigail Campos, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Abigail.Campos@usda.gov* or *Christian.Nissen@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Agreement and Marketing Order No. 986, as amended (7 CFR part 986), regulating the handling of pecans grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas. Part 986, (referred to as ''the Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Council locally administers the Order and is comprised of growers and handlers of pecans operating within the production area, and one accumulator and one public member.

The Department of Agriculture (USDA) is issuing this rule in conformance with 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, 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. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. USDA has determined this rule is unlikely to 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.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, pecan handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rates will be applicable to all assessable pecans for the 2021–22 fiscal year, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

The Order provides that based on the recommendation of the Council or other available data, the Secretary shall fix three base rates of assessments for inshell pecans handled during each fiscal year. This rule decreases the assessment rates from $0.03 per pound for improved varieties and $0.02 per pound for native and seedling varieties and for substandard pecans, the rates that were established for the 2016–17 and subsequent fiscal years, to $0.01 per pound for improved varieties and $0.00 per pound for native and seedling varieties and for substandard pecans handled for the 2021–22 and subsequent fiscal years.

The Order authorizes the Council, with the approval of Agricultural Marketing Service (AMS), to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Council are familiar with the Council's needs and with the costs of goods and services in their local area and can formulate an appropriate budget and assessment rates. The assessment rates are formulated and discussed in a public meeting, and all directly affected persons have an opportunity to participate and provide input.

For the 2016–17 and subsequent fiscal years, the Council recommended, and AMS approved, assessment rates of $0.03 per pound for improved varieties and $0.02 per pound for native and seedling varieties and for substandard pecans handled. The assessment rates continue in effect from fiscal year to fiscal year unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Council or other information available to AMS.

The Council held a virtual meeting on September 22, 2021, and recommended 2021–22 expenditures of $9,002,508, and a decreased assessment rate of $0.01 per pound of improved varieties, and $0.00 per pound for native and seedling varieties and for substandard pecans. In comparison, the previous fiscal year's budget expenditures were $11,741,400. The assessment rate for improved varieties of $0.01 and the assessment rate of $0.00 for native and seedling varieties and for substandard pecans are

$0.02 lower than the rates currently in effect.

On February 12, 2021, USDA established the Pecan Promotion, Research and Information Order, a new research and promotion program. Under the new program, research and promotion activities for pecans are funded through the collection of assessments from U.S. growers and foreign importers.

With the new program in effect, the Council recommended reducing expenditures for research and promotion under the Order. With these reductions, total budgeted expenditures for 2021–22 are estimated at $9,002,508 which is $2,738,892 less than the $11,741,400 budgeted for 2020–21. The Council unanimously voted to decrease the assessment rates to reflect the reduction in expenditures, and to offset the assessments collected under the new program so the assessment burden on the industry does not increase.

The major expenditures for the Council for the 2021–22 year include $2,510,000 for international relations, $2,180,000 for marketing, and $1,447,066 for general administration. Budgeted expenses for these items in 2020–21 were $1,968,000, $6,715,000, and $1,425,000, respectively.

The Council derived the recommended assessment rates by considering anticipated expenses, expected shipments of pecans, Market Access Program (MAP) funds, and the amount of funds available in the authorized reserve. Assessable shipments for the year are an estimated 315 million pounds of improved varieties, which should provide approximately $3,150,000 in assessment income (315,000,000 pounds multiplied by $0.01). Income derived from handler assessments calculated at the new rate, along with interest income, MAP funds, and funds from the Council's authorized reserve, should be adequate to cover projected budgeted expenses of $9,002,508. Funds in the reserve are estimated to be $2,800,000 at the end of the 2021–22 fiscal year, which is within the maximum permitted by § 986.64 of the Order (approximately three fiscal years' expenses).

The assessment rate will continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Council or other available information.

Although these assessment rates will be in effect for an indefinite period, the Council will continue to meet prior to or during each fiscal year to recommend a budget of expenses and consider recommendations for modification of the assessment rates. The dates and times of Council meetings are available from the Council or AMS. Council meetings are open to the public and interested persons may express their views at these meetings. AMS will evaluate Council recommendations and other available information to determine whether modification of the assessment rates is needed. Further rulemaking would be undertaken as necessary. The Council's 2021–22 budget and those for subsequent fiscal years will be reviewed and, as appropriate, approved by AMS.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 4,500 growers of pecans in the production area and approximately 150 handlers subject to regulation under the Order. Small agricultural growers are defined by the Small Business Administration (SBA) as those having annual receipts less than $1,000,000, and small agricultural service firms are defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service (NASS), the 2020–21 crop value was $435.28 million. With a crop size of 305.36 million pounds, the season average grower price was $1.43 per pound. Dividing the $435.28 million crop value by the estimated number of pecan growers (4,500) yields an annual average receipts per grower estimate of $96,729. This is well below the SBA threshold for small growers.

Evidence presented at the pecan marketing order promulgation hearing indicates an average handler margin of $0.58 per pound. Adding this margin to the average grower price of $1.43 per pound for in-shell pecans yields an estimated annual handler price of $2.01 per pound. With a total 2020–21 utilization of 305.36 million pounds, the total estimated value of production at the handler level for the fiscal year was $613.77 million ($2.01 per pound multiplied by 305.36 million pounds). Dividing this $613.77 million figure by the number of handlers (150) yields an average annual receipts per handler estimate of $4.09 million. This is well below the SBA threshold for small agricultural service firms. Assuming a normal distribution, the majority of pecan growers and handlers may be classified as small entities.

This action decreases the assessment rates collected from handlers for the 2021–22 and subsequent fiscal years from $0.03 to $0.01 per pound of improved varieties and from $0.02 to $0.00 per pound of native and seedling varieties and for substandard pecans handled. The Council recommended 2021–22 fiscal year expenditures of $9,002,508 and assessment rates of $0.01 per pound for improved varieties and $0.00 per pound for native and seedling varieties and for substandard pecans. The assessment rates are $0.02 per pound lower than 2016–17 rates. The quantity of assessable pecans for the 2021–22 fiscal year is estimated at 315 million pounds. Thus, the $0.01 per pound for improved varieties and $0.00 per pound for native and seedling varieties and for substandard pecans rate should provide $3,150,000 in assessment income. Income derived from handler assessments, along with interest income, MAP funds, and funds from the Council's authorized reserve, will be adequate to cover budgeted expenses.

The major expenditures projected by the Council for the 2021–22 year include $2,510,000 for international relations, $2,180,000 for marketing, and $1,447,066 for general administration. Budgeted expenses for these items in 2020–21 were $2,510,000, $6,285,000, and $1,447,066, respectively.

The Council recommended decreasing the assessment rates to reflect a reduction in research and promotion expenditures as these activities will be carried out by the new USDA research and promotion program also funded by the industry. Consequently, the Council recommended a corresponding decrease in the assessment rates to reflect the decrease in research and promotion expenditures.

Prior to arriving at the estimated expenditures and assessment rates, the Council considered information from various sources, such as the Council's Governance Committee. Alternative expenditure levels were discussed by this Committee, based upon the relative value of various activities to the pecan industry and the impact of the new research and promotion program. The Council determined that based on the information currently available,

program activities should be appropriately funded, and no alternate expenditure levels were deemed appropriate.

Using NASS data, a weighted average grower price for the past 3 seasons (2018–19 through 2020–21) is $1.66 per pound. This provides a reasonable forecast of the average grower price for 2021–22 season. The new assessment rate of $0.01 per pound for improved varieties represents 0.6 percent of the $1.66 weighted average price (six tenths of one percent; $0.01 divided by $1.66 × 100).

This action will decrease the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to growers. However, decreasing the assessment rates reduces the burden on handlers and may also reduce the burden on growers.

The September 22, 2021, Council meeting was widely publicized throughout the pecan industry. Meetings are held virtually or in a hybrid style. Participants have a choice whether to attend in person or virtually and can participate in the Council's deliberations on all issues. Like all Council meetings, the September 22, 2021, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by the OMB and assigned OMB No. 0581–0291 Federal Marketing Order for Pecans. No changes in those requirements are necessary as a result of this rule. Should any changes become necessary, they would be submitted to OMB for approval.

This rule imposes no additional reporting or recordkeeping requirements on either small or large pecan handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. As noted in the initial regulatory flexibility analysis, AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

A proposed rule concerning this action was published in the **Federal Register** on December 6, 2021 (86 FR 68934). Copies of the proposed rule were also mailed or sent via email to all pecan handlers. The proposal was made available through the internet by AMS and the Office of the Federal Register. A 30-day comment period ending January 5, 2022, was provided for interested persons to respond to the proposal.

No comments were received. Accordingly, no changes will be made to the rule as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendations submitted by the Council and other available information, AMS has determined that this rule will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 986

Marketing agreements, Nuts, Pecans, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service is amending 7 CFR part 986 as follows:

PART 986—PECANS GROWN IN THE STATES OF ALABAMA, ARKANSAS, ARIZONA, CALIFORNIA, FLORIDA, GEORGIA, KANSAS, LOUISIANA, MISSOURI, MISSISSIPPI, NORTH CAROLINA, NEW MEXICO, OKLAHOMA, SOUTH CAROLINA, AND TEXAS

■ 1. The authority citation for 7 CFR part 986 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 986.161 is revised to read as follows:

§ 986.161 Assessment rate.

On and after October 1, 2021, assessment rates of $0.01 per pound for pecans classified as improved, $0.00 per pound for pecans classified as native and seedling, and $0.00 per pound for pecans classified as substandard pecans are established.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–08001 Filed 4–13–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2022–0127; Special Conditions No. 25–810–SC]

Special Conditions: Dassault Aviation Model Falcon 6X Airplane; Dynamic Test Requirements for Multiple-Occupant Side-Facing Seats With Inflatable Restraints

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Dassault Aviation (Dassault) Model Falcon 6X airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is multiple-occupant side-facing seats with inflatable restraints. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Dassault on April 14, 2022. Send comments on or before May 31, 2022.

ADDRESSES: Send comments identified by Docket No. FAA–2022–0127 using any of the following methods:

- *Federal eRegulations Portal:* Go to *https://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in title 14, Code of Federal Regulations (14 CFR) 11.35, the FAA will post to *https://*

www.regulations.gov/ all comments received without change, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about these special conditions.

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 these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, 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 the indicated comments will not be placed in the public docket of these special conditions. Send submissions containing CBI to Shannon Lennon, Human Machine Interface, AIR–626, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3209; email *shannon.lennon@faa.gov.* Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for these special conditions.

Docket: Background documents or comments received may be read at *https://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Shannon Lennon, Human Machine Interface, AIR–626, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3209; email *shannon.lennon@faa.gov.*

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA finds, pursuant to 14 CFR 11.38(b), that new comments are unlikely, and notice and comment prior to this publication are unnecessary.

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

The FAA will consider all comments received by the closing date for comments. The FAA may change these special conditions based on the comments received.

Background

On July 1, 2012, Dassault Aviation applied for a type certificate for its new Model Falcon 5X airplane. However, Dassault has decided not to release an airplane under the model designation Falcon 5X, instead choosing to change that model designation to Falcon 6X.

In February of 2018, due to engine supplier issues, Dassault extended the type certificate application date for its Model Falcon 5X airplane under new Model Falcon 6X. This airplane is a twin-engine business jet with seating for 19 passengers, and has a maximum takeoff weight of 77,460 pounds.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Dassault must show that the Model Falcon 6X airplane meets the applicable provisions of part 25, as amended by amendments 25–1 through 25–146.

If the Administrator finds that the applicable airworthiness regulations (*e.g.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Dassault Model Falcon 6X airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Dassault Model Falcon 6X airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Dassault Model Falcon 6X airplane will incorporate the following novel or unusual design features:

Multiple-occupant side-facing seats that include an airbag system in the shoulder belt.

Discussion

Side-facing seats are considered a novel design for transport-category airplanes that include §§ 25.562 and 25.785 at amendment 25–64 in their certification basis, and were not considered when those airworthiness standards were issued. The FAA has determined that the existing regulations do not provide adequate or appropriate safety standards for occupants of side-facing seats. To provide a level of safety that is equivalent to that afforded to occupants of forward- and aft-facing seats, additional airworthiness standards in the form of special conditions are necessary.

On June 16, 1988, 14 CFR part 25 was amended by amendment 25–64 to revise the emergency-landing conditions that must be considered in the design of transport-category airplanes. Amendment 25–64 revised the static-load conditions in § 25.561, and added a new § 25.562 that required dynamic testing for all seats approved for occupancy during takeoff and landing. The intent of amendment 25–64 was to provide an improved level of safety for occupants on transport-category airplanes. However, because most seating on transport-category airplanes is forward-facing, the pass/fail criteria developed in amendment 25–64 focused primarily on these seats. For some time, the FAA granted exemptions for the multiple-place side-facing-seat installations because the existing test methods and acceptance criteria did not produce a level of safety equivalent to the level of safety provided for forward- and aft-facing seats. These exemptions were subject to many conditions that reflected the injury-evaluation criteria and mitigation strategies available at the time of the exemption issuance.

The FAA also issued special conditions to address single-place side-facing seats based on the data available at the time the FAA issued those special conditions. Continuing concerns regarding the safety of side-facing seats prompted the FAA to conduct research

to develop an acceptable method of compliance with §§ 25.562 and 25.785(b) for side-facing seat installations. That research has identified injury considerations and evaluation criteria in addition to those previously used to approve side-facing seats (see published report DOT/FAA/AR–09/41, July 2011).

One particular concern that was identified during the FAA's research program, but not addressed in the previous special conditions, was the significant leg injuries that can occur to occupants of both single- and multiple-place side-facing seats. Because this type of injury does not occur on forward- and aft-facing seats, the FAA determined that, to achieve the level of safety envisioned in amendment 25–64, additional requirements would be needed as compared to previously issued special conditions. Nonetheless, the research has now allowed the development of a single set of special conditions that is applicable to all fully side-facing seats.

On November 5, 2012, the FAA released policy statement PS–ANM–25–03–R1, ''Technical Criteria for Approving Side-Facing Seats,'' to update existing FAA certification policy on §§ 25.562 and 25.785(a) at amendment 25–64 for single- and multiple-place side-facing seats. This policy addresses both the technical criteria for approving side-facing seats and the implementation of those criteria. The FAA methodology detailed in PS–ANM–25–03–R1 has been used in establishing a new set of proposed special conditions. Some of the conditions issued for previous exemptions are still relevant and are included in these new special conditions. However, others have been replaced by different criteria that reflect current research findings.

In Policy Statement PS–ANM–25–03–R1, conditions 1 and 2 are applicable to all side-facing seat installations, whereas conditions 3 through 16 represent additional requirements applicable to side-facing seats equipped with an airbag system in the shoulder belt. These special conditions follow those conditions found in Policy Statement PS–ANM–25–03–R1.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Dassault Model Falcon 6X airplane. Should Dassault apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on one model of airplane. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Dassault Model Falcon 6X airplane.

(a) Additional requirements applicable to tests or rational analysis conducted to show compliance with §§ 25.562 and 25.785 for side-facing seats:

(1) The longitudinal test(s) conducted in accordance with § 25.562(b)(2), to show compliance with the seat-strength requirements of § 25.562(c)(7) and (8) and these special conditions, must have an ES–2re anthropomorphic test dummy (ATD) (49 CFR part 572, subpart U) or equivalent, or a Hybrid II ATD (49 CFR part 572, subpart B as specified in § 25.562) or equivalent, occupying each seat position and including all items (*e.g.,* armrest, interior wall, or furnishing) contactable by the occupant if those items are necessary to restrain the occupant. If included, the floor representation and contactable items must be located such that their relative position, with respect to the center of the nearest seat place, is the same at the start of the test as before floor misalignment is applied. For example, if floor misalignment rotates the centerline of the seat place nearest the contactable item 8 degrees clockwise about the airplane x-axis, then the item and floor representations must be rotated by 8 degrees clockwise also, to maintain the same relative position to the seat place, as shown in Figure 1. Each ATD's relative position to the seat after application of floor misalignment must be the same as before misalignment is applied. To ensure proper occupant seat loading, the ATD pelvis must remain supported by the seat pan, and the restraint system must remain on the pelvis and shoulder of the ATD until rebound begins. No injury-criteria evaluation is necessary for tests conducted only to assess seat-strength requirements.

(2) The longitudinal test(s) conducted in accordance with § 25.562(b)(2), to show compliance with the injury assessments required by § 25.562(c) and these special conditions, may be conducted separately from the test(s) to show structural integrity. In this case, structural-assessment tests must be conducted as specified in paragraph (a)(1), above, and the injury-assessment test must be conducted without yaw or floor misalignment. Injury assessments may be accomplished by testing with ES–2re ATD (49 CFR part 572, subpart U) or equivalent at all places. Alternatively, these assessments may be accomplished by multiple tests that use an ES–2re ATD at the seat place being evaluated, and a Hybrid II ATD (49 CFR part 572, subpart B, as specified in § 25.562) or equivalent used in all seat places forward of the one being assessed, to evaluate occupant interaction. In this case, seat places aft of the one being assessed may be unoccupied. If a seat installation includes adjacent items that are contactable by the occupant, the injury potential of that contact must be assessed. To make this assessment, tests may be conducted that include the actual item, located and attached in a representative fashion. Alternatively, the injury potential may be assessed by a combination of tests with items having the same geometry as the actual item, but having stiffness characteristics that would create the worst case for injury (injuries due to both contact with the item and lack of support from the item).

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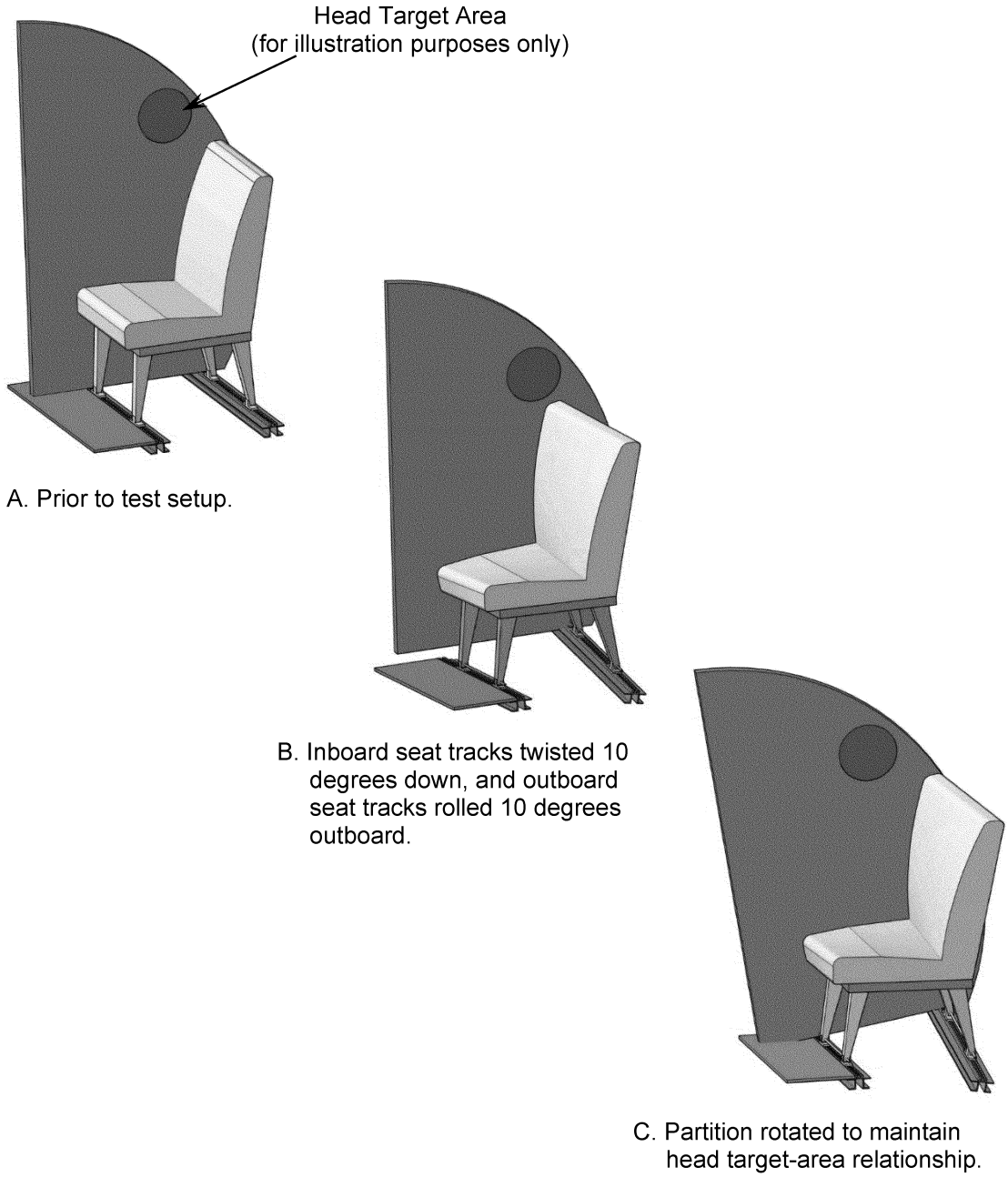

Figure 1

(3) If a seat is installed aft of structure (*e.g.,* an interior wall or furnishing) that does not have a homogeneous surface contactable by the occupant, additional analysis and/or test(s) may be required to demonstrate that the injury criteria are met for the area that an occupant could contact. For example, different yaw angles could result in different injury considerations and may require additional analysis or separate test(s) to evaluate.

(4) To accommodate a range of occupant heights (5th percentile female to 95th percentile male), the surface of items contactable by the occupant must be homogenous 7.3 in. (185 mm) above and 7.9 in. (200 mm) below the point (center of area) that is contacted by the 50th percentile male size ATD's head during the longitudinal test(s) conducted in accordance with paragraphs (a)(1), (2), and (3), above. Otherwise, additional head-injury criteria (HIC) assessment tests may be necessary. Any surface (inflatable or otherwise) that provides support for the occupant of any seat place must provide that support in a consistent manner regardless of occupant stature. For example, if an inflatable shoulder belt is used to mitigate injury risk, then it must be demonstrated by inspection to bear against the range of occupants in a similar manner before and after inflation. Likewise, the means of limiting lower-leg flail must be demonstrated by inspection to provide protection for the range of occupants in a similar manner.

(5) For longitudinal test(s) conducted in accordance with § 25.562(b)(2) and these special conditions, the ATDs must be positioned, clothed, and have lateral instrumentation configured as follows:

(i) ATD positioning: Lower the ATD vertically into the seat while simultaneously (see Figure 2):

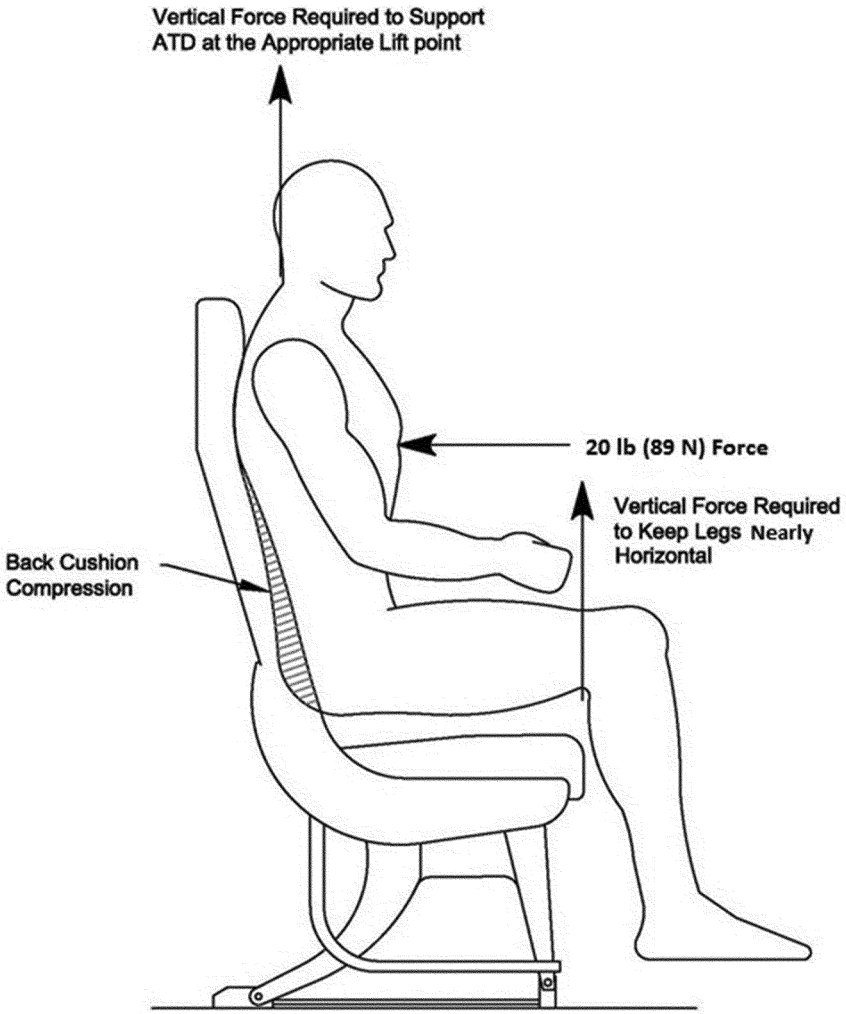

Figure 2

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(A) Aligning the midsagittal plane (a vertical plane through the midline of the body; dividing the body into right and left halves) with approximately the middle of the seat place.

(B) Applying a horizontal x-axis direction (in the ATD coordinate system) force of about 20 lb (89 N) to the torso at approximately the intersection of the midsagittal plane and the bottom rib of the ES–2re or lower sternum of the Hybrid II at the midsagittal plane, to compress the seat back cushion.

(C) Keeping the upper legs nearly horizontal by supporting them just behind the knees.

(D) After all lifting devices have been removed from the ATD:

(1) Rock it slightly to settle it into the seat.

(2) Separate the knees by about 4 in. (100 mm).

(3) Set the ES–2re ATD's head at approximately the midpoint of the available range of z-axis rotation (to align the head and torso midsagittal planes).

(4) Position the ES–2re ATD's arms at the joint's mechanical detent that puts them at approximately a 40-degree angle with respect to the torso. Position the Hybrid II ATD hands on top of its upper legs.

(5) Position the feet such that the centerlines of the lower legs are approximately parallel to a lateral vertical plane (in the airplane coordinate system).

(ii) ATD clothing: Clothe each ATD in form-fitting, mid-calf-length (minimum) pants and shoes (size 11E) weighing about 2.5 lb (1.1 Kg) total. The color of the clothing should be in contrast to the color of the restraint system. The ES–2re jacket is sufficient for torso clothing, although a form-fitting shirt may be used in addition if desired.

(iii) ES–2re ATD lateral instrumentation: The rib-module linear slides are directional, *i.e.,* deflection occurs in either a positive or negative ATD y-axis direction. The modules must be installed such that the moving end of the rib module is toward the front of the airplane. The three abdominal-force sensors must be installed such that they are on the side of the ATD toward the front of the airplane.

(6) The combined horizontal/vertical test, required by § 25.562(b)(1) and these special conditions, must be conducted with a Hybrid II ATD (49 CFR part 572, subpart B, as specified in § 25.562), or equivalent, occupying each seat position.

(7) Restraint systems:

(i) If inflatable restraint systems are used, they must be active during all dynamic tests conducted to show compliance with § 25.562.

(ii) The design and installation of seatbelt buckles must prevent unbuckling due to applied inertial forces, or impact of the hands or arms

of the occupant during an emergency landing.

(b) Additional performance measures applicable to tests and rational analysis conducted to show compliance with §§ 25.562 and 25.785 for side-facing seats:

(1) Body-to-body contact: Contact between the head, pelvis, torso, or shoulder area of one ATD with the adjacent-seated ATD's head, pelvis, torso, or shoulder area is not allowed. Contact during rebound is allowed.

(2) Thoracic: The deflection of any of the ES–2re ATD upper, middle, and lower ribs must not exceed 1.73 in. (44 mm). Data must be processed as defined in Federal Motor Vehicle Safety Standards (FMVSS) 571.214.

(3) Abdominal: The sum of the measured ES–2re ATD front, middle, and rear abdominal forces must not exceed 562 lb (2,500 N). Data must be processed as defined in FMVSS 571.214.

(4) Pelvic: The pubic symphysis force measured by the ES–2re ATD must not exceed 1,350 lb (6,000 N). Data must be processed as defined in FMVSS 571.214.

(5) Leg: Axial rotation of the upper-leg (femur) must be limited to 35 degrees in either direction from the nominal seated position.

(6) Neck: As measured by the ES–2re ATD and filtered at Channel Frequency Class 600 as defined in SAE J211, ''Instrumentation for Impact Test—Part 1—Electronic Instrumentation.''

(i) The upper-neck tension force at the occipital condyle (O.C.) location must be less than 405 lb (1,800 N).

(ii) The upper-neck compression force at the O.C. location must be less than 405 lb (1,800 N).

(iii) The upper-neck bending torque about the ATD x-axis at the O.C. location must be less than 1,018 in-lb (115 Nm).

(iv) The upper-neck resultant shear force at the O.C. location must be less than 186 lb (825 N).

(2) Occupant (ES–2re ATD) retention: The pelvic restraint must remain on the ES–2re ATD's pelvis during the impact and rebound phases of the test. The upper-torso restraint straps (if present) must remain on the ATD's shoulder during the impact.

(3) Occupant (ES–2re ATD) support:

(i) Pelvis excursion: The load-bearing portion of the bottom of the ATD pelvis must not translate beyond the edges of its seat's bottom seat-cushion supporting structure.

(ii) Upper-torso support: The lateral flexion of the ATD torso must not exceed 40 degrees from the normal upright position during the impact.

(c) For seats with an airbag system in the shoulder belts:

(1) Show that the airbag system in the shoulder belt will deploy and provide protection under crash conditions where it is necessary to prevent serious injury. The means of protection must take into consideration a range of stature from a 2-year-old child to a 95th percentile male. The airbag system in the shoulder belt must provide a consistent approach to energy absorption throughout that range of occupants. When the seat system includes an airbag system, that system must be included in each of the certification tests as it would be installed in the airplane. In addition, the following situations must be considered:

(i) The seat occupant is holding an infant.

(ii) The seat occupant is a pregnant woman.

(2) The airbag system in the shoulder belt must provide adequate protection for each occupant regardless of the number of occupants of the seat assembly, considering that unoccupied seats may have an active airbag system in the shoulder belt.

(3) The design must prevent the airbag system in the shoulder belt from being either incorrectly buckled or incorrectly installed, such that the airbag system in the shoulder belt would not properly deploy. Alternatively, it must be shown that such deployment is not hazardous to the occupant, and will provide the required injury protection.

(4) It must be shown that the airbag system in the shoulder belt is not susceptible to inadvertent deployment as a result of wear and tear, or inertial loads resulting from in-flight or ground maneuvers (including gusts and hard landings), and other operating and environmental conditions (vibrations, moisture, etc.) likely to occur in service.

(5) Deployment of the airbag system in the shoulder belt must not introduce injury mechanisms to the seated occupant, or result in injuries that could impede rapid egress. This assessment should include an occupant whose belt is loosely fastened.

(6) It must be shown that inadvertent deployment of the airbag system in the shoulder belt, during the most critical part of the flight, will either meet the requirement of § 25.1309(b) or not cause a hazard to the airplane or its occupants.

(7) It must be shown that the airbag system in the shoulder belt will not impede rapid egress of occupants 10 seconds after airbag deployment.

(8) The airbag system must be protected from lightning and high-intensity radiated fields (HIRF). The threats to the airplane specified in existing regulations regarding lighting, § 25.1316, and HIRF, § 25.1317, are incorporated by reference for the purpose of measuring lightning and HIRF protection.

(9) The airbag system in the shoulder belt must function properly after loss of normal aircraft electrical power, and after a transverse separation of the fuselage at the most critical location. A separation at the location of the airbag system in the shoulder belt does not have to be considered.

(10) It must be shown that the airbag system in the shoulder belt will not release hazardous quantities of gas or particulate matter into the cabin.

(11) The airbag system in the shoulder-belt installation must be protected from the effects of fire such that no hazard to occupants will result.

(12) A means must be available for a crewmember to verify the integrity of the airbag system in the shoulder-belt activation system prior to each flight, or it must be demonstrated to reliably operate between inspection intervals. The FAA considers that the loss of the airbag-system deployment function alone (*i.e.,* independent of the conditional event that requires the airbag-system deployment) is a major-failure condition.

(13) The inflatable material may not have an average burn rate of greater than 2.5 inches/minute when tested using the horizontal flammability test defined in part 25, appendix F, part I, paragraph (b)(5).

(14) The airbag system in the shoulder belt, once deployed, must not adversely affect the emergency-lighting system (*i.e.,* block floor proximity lights to the extent that the lights no longer meet their intended function).

Issued in Kansas City, Missouri, on April 8, 2022.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2022–07933 Filed 4–13–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2022–0125; Special Conditions No. 25–808–SC]

Special Conditions: Dassault Aviation Model Falcon 6X Airplane; Flight Envelope Protection: Pitch and Roll Limiting Functions

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Dassault Aviation (Dassault) Model Falcon 6X airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is an Electronic Flight Control System (EFCS) that limits pitch and roll functions to prevent the airplane from attaining certain pitch attitudes and roll angles. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Dassault on April 14, 2022. Send comments on or before May 31, 2022.

ADDRESSES: Send comments identified by Docket No. FAA–2022–0125 using any of the following methods:

- *Federal eRegulations Portal:* Go to *https://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

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

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 these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, 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 the indicated comments will not be placed in the public docket of these special conditions. Send submissions containing CBI to Troy Brown, Performance and Environment Section, AIR–625, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 1801 S Airport Rd., Wichita, KS 67209–2190; telephone and fax 405–666–1050; email *troy.a.brown@faa.gov.* Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for these special conditions.

Docket: Background documents or comments received may be read at *https://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Troy Brown, Performance and Environment Section, AIR–625, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 1801 S Airport Rd., Wichita, KS 67209–2190; telephone and fax 405–666–1050; email *troy.a.brown@faa.gov.*

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA finds, pursuant to 14 CFR 11.38(b), that new comments are unlikely, and notice and comment prior to this publication are unnecessary.

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

The FAA will consider all comments received by the closing date for comments. The FAA may change these special conditions based on the comments received.

Background

On July 1, 2012, Dassault Aviation applied for a type certificate for its new Model Falcon 5X airplane. However, Dassault has decided not to release an airplane under the model designation Falcon 5X, instead choosing to change that model designation to Falcon 6X.

In February of 2018, due to engine supplier issues, Dassault extended the type certificate application date for its Model Falcon 5X airplane under new Model Falcon 6X. This airplane is a twin-engine business jet with seating for 19 passengers, and has a maximum takeoff weight of 77,460 pounds.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Dassault must show that the Model Falcon 6X airplane meets the applicable provisions of 14 CFR part 25, as amended by amendments 25–1 through 25–146.

If the Administrator finds that the applicable airworthiness regulations (*e.g.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Dassault Model Falcon 6X airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Dassault Model Falcon 6X airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-

certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Dassault Aviation Model Falcon 6X airplane will incorporate the following novel or unusual design features:

An Electronic Flight Control System (EFCS) that limits pitch and roll functions to prevent the airplane from attaining certain pitch attitudes and roll angles.

Discussion

Part 25 of 14 CFR does not specifically relate to flight characteristics associated with fixed-attitude limits. The Dassault Aviation Model Falcon 6X airplane will incorporate pitch and roll attitude-limiting functions, via the Electronic Flight Control System (EFCS) normal modes, to prevent airplane pitch attitudes greater than +30 degrees and less than −15 degrees, and roll angles greater than plus or minus 67 degrees. In addition, positive spiral stability is introduced for roll angles greater than 35 degrees at speeds below V_{MO}/M_{MO}. At speeds greater than V_{MO} and up to V_{DF}, maximum aileron control force is limited to only 45 degrees maximum bank angle.

The installed attitude-limiting functions are designed such that, at V_{MO} + 6 knots or M_{MO} + 0.012, an automatic nose-up pitch is applied with phase advance in case of high acceleration. The speed stabilizes at V_D/M_D if the stick is full forward, or the speed will return to V_{MO}/M_{MO} if the stick is released.

The basic envelope-protection requirement, historically applied, is to not unduly limit the maneuver capability of the airplane, nor interfere with its ability to perform maneuvers required for normal and emergency operations. The design details for the Dassault Model Falcon 6X support the objective of not unduly limiting the maneuver capability, while also protecting the airplane from adverse attitudes.

These special conditions are in addition to the requirements of 14 CFR 25.143. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Dassault Model Falcon 6X airplane. Should Dassault apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on one model of airplane. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Dassault Aviation Model Falcon 6X airplanes.

In addition to § 25.143, the following requirements apply:

1. The pitch-limiting function must not impede normal maneuvering for pitch angles up to the maximum required for normal maneuvering, including a normal all-engines-operating takeoff, plus a suitable margin to allow for satisfactory speed control.

2. The pitch- and roll-limiting functions must not restrict, or prevent attaining pitch attitudes necessary for, emergency maneuvering, or roll angles up to 66 degrees with flaps up, or 60 degrees with flaps down. Spiral stability, which is introduced above 35 degrees roll angle, must not require excessive pilot strength to achieve these roll angles. Other protections, which further limit the roll capability under certain extreme angle-of-attack, attitude, or high-speed conditions, are acceptable, if they allow at least 45 degrees of roll capability.

Issued in Kansas City, Missouri, on April 8, 2022.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2022–07932 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0663; Project Identifier MCAI–2020–01618–T; Amendment 39–21996; AD 2022–07–08]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2016–17–12, which applied to all Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2016–17–12 required inspecting certain trimmable horizontal stabilizer actuators (THSAs) to determine the number of total flight cycles the THSA has accumulated, and replacing the THSA if necessary. Since the FAA issued AD 2016–17–12, the FAA has determined that a more restrictive airworthiness limitations is necessary for carbon friction disks on the no-back brake (NBB) of the THSA. This AD continues to require the inspections of the THSAs and replacement if necessary. This AD also requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations; as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also limits the installation of affected parts under certain conditions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 19, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 19, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of September 30, 2016 (81 FR 58823, August 26, 2016).

ADDRESSES: For EASA material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email

ADs@easa.europa.eu; internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* For Airbus service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *https://www.airbus.com.* 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. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0663. For the UTC Aerospace Systems material identified in this AD that will not be incorporated by reference, contact Collins Aerospace, Product Support Department 13, Avenue de L'Eguillette—Saint-Ouen L'Aumone, Boite Postale 7186 95056 Cergy Pontoise Cedex, France; telephone 1–877–808–7575; email *crc@collins.com;* internet *https://www.collinsaerospace.com/support.*

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0663; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

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

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0270, dated December 7, 2020 (EASA AD 2020–0270) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes; Model A320–211, –212, –214, –215, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2016–17–12, Amendment 39–18625 (81 FR 58823, August 26, 2016) (AD 2016–17–12). AD 2016–17–12 applied to all Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, 231, and –232 airplanes. The NPRM published in the **Federal Register** on August 13, 2021 (86 FR 44663). Since the FAA issued AD 2016–17–12, new investigations determined that the compliance time for removal from service and replacement of certain carbon friction disks on the NBB of the THSA must be reduced. This replacement was required by AD 2016–17–12. This replacement, and newly reduced compliance time, have now been incorporated into Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS) Part 4 Variation 7.1, dated October 5, 2020, as ALS limitation task 274000–00004–1–E.

The NPRM was prompted by a determination that a more restrictive airworthiness limitations is necessary for the carbon friction disks on the NBB of the THSA. The NPRM proposed to retain the requirements of AD 2016–17–12; and also require revising the existing maintenance or inspection program, as applicable, to incorporate a more restrictive airworthiness limitations, as specified in EASA AD 2020–0270. The NPRM also proposed to limit the installation of affected parts under certain conditions.

The NPRM also specified that revising the existing maintenance or inspection program, as applicable, to incorporate the more restrictive airworthiness limitation would terminate the ALS limitation task 274000–00004–1–E for the THSA, as required by paragraph (i) of AD 2020–21–10, Amendment 39–21283 (85 FR 65190, October 15, 2020) (AD 2020–21–10). The new airworthiness limitation for ALS limitation task 274000–00004–1–E specified in the NPRM reduces the compliance times and expands the applicability for the task.

The FAA is issuing this AD to address premature wear of the carbon friction disks on the no-back brake (NBB) of the THSA, which could lead to reduced braking efficiency in certain load conditions, and, in conjunction with the inability of the power gear train to keep the ball screw in its last commanded position, could result in uncommanded movements of the trimmable horizontal stabilizer and loss of control of the airplane. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from two commenters, including Air Line Pilots Association, International (ALPA) and United Airlines, who supported the NPRM without change.

The FAA received additional comments from two commenters, including Alaska Airlines (Alaska) and Delta Air Lines (Delta). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Remove Paragraph (m)(7) of the Proposed AD

Alaska and Delta requested removal of paragraph (m)(7) of the proposed AD. Alaska stated that removing paragraph (m)(7) of the proposed AD would alleviate any confusion that would result from the FAA's exception to the EASA AD, and would also address any burden on U.S. operators having leased airplanes that have a return condition that those airplanes are in compliance with both the FAA and EASA's AD. Alaska noted that the vendor service bulletin, UTC Service Bulletin 47145–27–17, must be used for the NBB carbon disk replacement on a THSA assembly and referred to the Accomplishment Instructions of Airbus Service Bulletin A320–27–1242, which states to ''send to the supplier the THSA (FIN 9CE) for modification in accordance with'' the vendor service bulletin. Delta added that the airworthiness limitations section (ALS) variation references the UTC service information. Delta noted that a similar exception was not included in AD 2020–21–10, Amendment 39–21283 (85 FR 65190, October 15, 2020) (AD 2020–21–10), so it should not be added now. Delta also stated that paragraph (l)(2) of the proposed AD could be affected if

paragraph (m)(7) of the proposed AD is removed.

The FAA disagrees. ALS limitation task 274000–00004–1–E specifies that the replacement can be done using ''SB A320–27–1242 or VSB [vendor service bulletin] 47145–27–17.'' The exception stated in paragraph (m)(7) of this AD removes the allowance in ALS limitation task 274000–00004–1–E to use only the UTC service information (''VSB 47145–27–17'') as a means to show compliance with the requirements of this AD. The UTC service information referred to certain information on testing and fault isolation as a source of information, but did not require doing those tests, which would have led to compliance being voluntary for those actions. The Airbus service information (''SB A320–27–1242'') contains more complete instructions for operators to comply with as previously required in AD 2016–17–12. Although a similar exception was not included in AD 2020–21–10 for ALS limitation task 274000–00004–1–E, the FAA has determined that this exception is necessary and must be included for the purposes of enforcing the AD requirements for U.S.-registered operators. As part of the rulemaking process for FAA ADs that correspond to ADs issued by other States of Design, the FAA determines if the MCAI ADs adequately address the identified unsafe condition or if exceptions are needed in order to address the unsafe condition. The FAA has not changed this AD in this regard.

Request To Revise Paragraph (b) of the Proposed AD

Delta requested that paragraph (b) of the proposed AD be revised from replacing AD 2016–17–12 to affecting AD 2016–17–12, and subsequently remove paragraphs (g) through (k) of the proposed AD that would retain AD 2016–17–12 requirements and then revise the terminating action paragraph to state that doing the actions of the proposed AD would terminate all requirements of AD 2016–17–12. Delta believed the changes would simplify the AD and clarify how to comply with the proposed requirements.

The FAA disagrees. In this case, the FAA determined that the supersedure method used in this AD would be the most effective for AD 2016–17–12 because the existing actions and the new changes related to those actions are within the same AD. The FAA has not changed this AD in this regard.

Request To Revise the Applicability

Delta requested that the applicability specified in paragraph (c) of the proposed AD be revised to affect only airplanes that have an original airworthiness certificate or original export airworthiness certificate issued on or before the date of the airworthiness limitations publication required. Delta pointed out that the FAA has published ADs with the requested language because airplanes with a later date are delivered with the required publication. Delta stated that for compliance with AD 2016–17–12, it needed to request an alternative method of compliance (AMOC) to use later revisions of the referenced airworthiness limitation documents because that AD did not have a cut-off date. Delta also stated that if its request for paragraph (c) of the proposed AD is granted, then the wording for paragraph (l) of the proposed AD would also be affected.

The FAA agrees that in most ADs that affect airworthiness limitations and reference airworthiness publications, the publication's date is used as a means of defining or limiting the group of airplanes based on its latest type design requirements. However, in this case, changing paragraph (c) of this AD would conflict with the requirements of AD 2016–17–12, which applied to all airplanes. Paragraph (c) of this AD has not been changed in this regard. However, the FAA has added paragraph (p)(1)(ii) to this AD to clarify the previously approved AMOCs for AD 2016–17–12 are approved as AMOCs to the corresponding retained requirements of this AD.

Request To Revise Paragraph (o) of the Proposed AD

Delta stated that the terminating action statement in paragraph (o) of the proposed AD should be deleted because paragraph (k) of the affected AD, AD 2020–21–10, contains a provision to allow alternative actions and intervals if approved by certain provisions in EASA AD 2020–0034, dated February 25, 2020. Delta also pointed out that the task specified in paragraph (o) of the proposed AD is only for certain airplanes, so those airplanes should be listed in paragraph (o) of the proposed AD.

The FAA disagrees with the statement that paragraph (o) of this AD should be deleted. The terminating action statement in paragraph (o) of this AD provides relief to operators, and avoids duplication and possible conflicting requirements. If paragraph (o) of this AD is removed, there would be two FAA ADs in effect that would require the same task and operators would be required to show compliance with both ADs for the same task with variable requirements. Paragraph (k) of AD 2020–21–10 provides provisions for alternative actions and intervals for paragraph (i) of AD 2020–21–10, but does not mandate the alternative method. The FAA has changed paragraph (o) of this AD to remove reference to the models and to the issuance date of original airworthiness certificate or original export certificate of airworthiness as not all models referenced in paragraph (o) of the proposed AD are in AD 2020–21–10. The models and the issuance date of the original airworthiness certificate or original export certificate of airworthiness specified in AD 2020–21–10 do not need to be referenced in paragraph (o) of this AD.

Request To Revise Process for Requiring Airworthiness Limitations

Delta suggested that the FAA consider revising FAA regulations to incorporate a requirement for commercial operators to incorporate and use new revisions of airworthiness limitation (AWL) or ALS documents within a certain time after those revisions are published. Delta believed that this change to the regulations would eliminate the need to issue ADs, simplify airworthiness limitations requirements for operators, and reduce operator taskloads in determining if they are in compliance with ADs or need to request an AMOC. Delta stated that there are usually two or three ADs a year that are published on ALS tasks for Model A320 airplanes.

While the FAA understands the commenter's concern, current FAA regulations require incorporating the latest ALS included in the type design of the airplane, such as 14 CFR 91.403(c) and 91.409(e). ADs are the only viable method to mitigate risk identified in a product when its type design did not require incorporation of the latest ALS document, as applicable, by mandating subsequent ALS revisions or variations at the applicable thresholds. The FAA's regulatory requirements are promulgated via notice-and-comment rulemaking as required by the Administrative Procedure Act (APA), and the public can petition for rulemaking pursuant to 14 CFR part 11.

Explanation of Change to Paragraph (m)(7) of the Proposed AD

The FAA has revised paragraph (m)(7) of this AD to clarify the location of the Note and to revise the format.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires

adopting this AD as proposed. Except for minor editorial changes and any other change described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products.

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0270 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD also requires Airbus Service Bulletin A320–27–1242, Revision 01, dated February 4, 2016, which the Director of the Federal Register approved for incorporation by reference as of September 30, 2016 (81 FR 58823, August 26, 2016).

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.

Costs of Compliance

The FAA estimates that this AD affects 1,630 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2016–17–12 (959 airplanes).	1 work-hour × $85 per hour = $85	$0	$85	$81,515

* Table does not include estimated costs for reporting/revising the existing maintenance or inspection program.

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
21 work-hours × $85 per hour = $1,785	$26,500	$28,285

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2016–17–12, Amendment 39–18625 (81 FR 58823, August 26, 2016); and

■ b. Adding the following new AD:

2022–07–08 Airbus SAS: Amendment 39–21996; Docket No. FAA–2021–0663; Project Identifier MCAI–2020–01618–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 19, 2022.

(b) Affected ADs

(1) This AD replaces AD 2016–17–12, Amendment 39–18625 (81 FR 58823, August 26, 2016) (AD 2016–17–12).

(2) This AD affects AD 2020–21–10, Amendment 39–21283 (85 FR 65190, October 15, 2020) (AD 2020–21–10).

(c) Applicability

This AD applies to all Airbus SAS airplanes, certificated in any category, identified in paragraphs (c)(1) through (7) of this AD.

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

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

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

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(5) Model A319–151N, –153N, and –171N airplanes.

(6) Model A320–251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(7) Model A321–251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks; 27, Flight Controls.

(e) Reason

This AD was prompted by a determination that a more restrictive airworthiness limitation is necessary for the carbon friction disks on the no-back brake (NBB) of the trimmable horizontal stabilizer actuator (THSA). The FAA is issuing this AD to address premature wear of the carbon friction disks on the NBB of the THSA, which could lead to reduced braking efficiency in certain load conditions, and, in conjunction with the inability of the power gear train to keep the ball screw in its last commanded position, could result in uncommanded movements of the trimmable horizontal stabilizer and loss of control of the airplane.

(f) Compliance

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

(g) Retained Inspection To Determine THSA Part Number and Accumulated Total Flight Cycles, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: No later than each date specified in paragraphs (g)(1) through (5) of this AD, inspect the THSA to determine if it has a part number (P/N) 47145–(XXX), and, if any THSA P/N 47145–(XXX) is found, determine the total number of flight cycles accumulated since the THSA's first installation on an airplane, or since the most recent NBB replacement, whichever is later. A review of airplane delivery or maintenance records is acceptable in lieu of this inspection if the part number of the THSA can be conclusively determined from that review. In case maintenance records concerning the most recent NBB disk replacement are unavailable or incomplete, the total flight cycles accumulated since first installation of the THSA on an airplane apply. Accomplishing the maintenance or inspection program revision required by paragraph (l) of this AD terminates the requirements of this paragraph.

(1) *As of September 30, 2016 (the effective date of AD 2016–17–12):* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 40,000 total flight cycles.

(2) *As of December 31, 2016:* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 36,000 total flight cycles.

(3) *As of December 31, 2017:* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 33,600 total flight cycles.

(4) *As of December 31, 2018:* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 31,600 total flight cycles.

(5) *As of December 31, 2019:* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 30,000 total flight cycles.

(h) Retained Replacements, With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: For airplanes with any THSA P/N 47145–(XXX), do the replacements required by paragraphs (h)(1) and (2) of this AD. Accomplishing the maintenance or inspection program revision required by paragraph (l) of this AD terminates the requirements of this paragraph.

(1) No later than each date specified in paragraphs (g)(1) through (5) of this AD, replace all THSA that have reached or exceeded on each date the corresponding number of flight cycles specified in paragraphs (g)(1) through (5) of this AD. Do the replacement in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1242, Revision 01, dated February 4, 2016. Affected THSAs must be replaced with serviceable THSAs.

(2) As of each date specified in paragraphs (g)(1) through (5) of this AD, and before exceeding the flight cycle limit corresponding to each date, as applicable: Replace each THSA with a serviceable THSA, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1242, Revision 01, dated February 4, 2016.

(i) Retained Definition of Serviceable THSA, With No Changes

This paragraph restates the definition of paragraph (i) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: For the purposes of this AD, a serviceable THSA is a THSA that has not exceeded the applicable flight-cycle limits, as specified paragraphs (g)(1) through (5) of this AD, since first installation of the THSA on an airplane or since last NBB replacement, whichever is later.

Note 1 to paragraph (i): Guidance for NBB disk replacement can be found in UTC Aerospace Systems Service Bulletin 47145–27–17, Revision 1, dated July 21, 2015.

(j) Retained Parts Installation Limitation, With No Changes

This paragraph restates the provisions of paragraph (j) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: As of each date specified in paragraphs (g)(1) through (5) of this AD, as applicable, only installation of a serviceable THSA P/N 47145–(XXX) is allowed on an airplane. Accomplishing the maintenance or inspection program revision required by paragraph (l) of this AD terminates the requirements of this paragraph.

(k) Retained Credit for Previous Actions, With No Changes

This paragraph restates the requirements of paragraph (k) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: This paragraph provides credit for actions required by paragraph (h) of this AD, if those actions were performed before September 30, 2016 (the effective date of AD 2016–17–12), using Airbus Service Bulletin A320–27–1242, dated February 9, 2015.

(l) New Maintenance or Inspection Program Revision

(1) For the airplanes identified in paragraph (c) of this AD with an original airworthiness certificate or original export certificate of airworthiness issued on or before October 5, 2020, except as specified in paragraph (m) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0270, dated December 7, 2020 (EASA AD 2020–0270). Accomplishing the maintenance or inspection program revision required by this paragraph terminates the requirements of paragraphs (g), (h), and (j) of this AD.

(2) For the airplanes identified in paragraph (c) of this AD with an original airworthiness certificate or original export certificate of airworthiness issued after October 5, 2020, revise the existing maintenance or inspection program, as applicable, to incorporate the provision specified in paragraph (m)(7) of this AD.

(m) Exceptions to EASA AD 2020–0270

(1) Where EASA AD 2020–0270 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2020–0270 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2020–0270 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2020–0270 is at the applicable ''limitations'' as incorporated by the requirements of paragraph (3) of EASA AD

2020–0270, or within 90 days after the effective date of this AD, whichever occurs later.

(5) The provisions specified in paragraph (4) of EASA AD 2020–0270 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2020–0270 does not apply to this AD.

(7) For all airplanes identified in paragraph (c) of this AD: Where the Note for Item 274000–00004–1–E of Section 4–1 in the service information referenced in EASA AD 2020–0270 specifies ''NBB carbon disc replacement'' instructions, for this AD, replace the text ''NBB carbon disc replacement can be accomplished in accordance with SB A320–27–1242 or VSB 47145–27–17,'' with ''NBB carbon disk replacement must be accomplished in accordance with SB A320–27–1242.''

(n) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (l) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2020–0270.

(o) Terminating Action for Certain Requirements of AD 2020–21–10

Accomplishing the actions required by this AD terminates the airworthiness limitations section (ALS) limitation task 274000–00004–1–E for the THSA, as required by paragraph (i) of AD 2020–21–10.

(p) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (q)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs approved previously for AD 2016–17–12 are approved as AMOCs for the corresponding provisions of paragraphs (g) through (j) of this AD

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

(3) *Required for Compliance (RC):* Except as required by paragraph (p)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those 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.

(q) Related Information

(1) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *sanjay.ralhan@faa.gov.*

(2) For UTC Aerospace Systems service information identified in this AD that is not incorporated by reference, contact Collins Aerospace, Product Support Department 13, Avenue de L'Eguillette—Saint-Ouen L'Aumone, Boite Postale 7186 95056 Cergy Pontoise Cedex, France; telephone 1–877–808–7575; email *crc@collins.com;* internet *https://www.collinsaerospace.com/support.*

(r) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on May 19, 2022.

(i) European Union Aviation Safety Agency (EASA) AD 2020–0270, dated December 7, 2020.

(ii) [Reserved]

(4) The following service information was approved for IBR on September 30, 2016 (81 FR 58823, August 26, 2016).

(i) Airbus Service Bulletin A320–27–1242, Revision 01, dated February 4, 2016.

(ii) [Reserved]

(5) For EASA AD 2020–0270, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(6) For Airbus service information, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *https://www.airbus.com.*

(7) 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.

(8) 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 *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on March 18, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07859 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0400; Project Identifier AD–2022–00179–E; Amendment 39–22009; AD 2022–08–06]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain General Electric Company (GE) CF34–8C and CF34–8E model turbofan engines. This AD was prompted by an ''Engine Degraded'' message received in-flight from the Engine Indicating and Crew Alerting System (EICAS), and a subsequent investigation by the manufacturer that revealed corrosion of the variable geometry (VG) system actuator, which can cause the full authority digital engine control (FADEC) software to command and lock the engine at idle until it is restarted. This AD requires performing a rotational torque check on the actuating linkage assembly and, depending on the results of the rotational torque check, replacement of the compressor inlet guide vane (IGV) outer shroud bushing and vane spindle bushing with parts eligible for installation. This AD also requires reporting the results of the rotational torque check to GE. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: AD is effective April 29, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 29, 2022.

The FAA must receive comments on this AD by May 31, 2022.

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

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

For service information identified in this final rule, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ge.com;* website: *https://www.ge.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0400.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0400; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

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

SUPPLEMENTARY INFORMATION:

Background

On August 11, 2021, a Bombardier CRJ1000 airplane, powered by GE CF34–8C5 model turbofan engines, experienced an in-flight engine shutdown that resulted in a diversion. The manufacturer's investigation found that this airplane was parked outdoors for extended lengths of time within 10 miles (16 km) from a saltwater coastline, causing corrosion to develop on the CF34–8C5 engines' compressor VG actuator rod, seizure of the rod end bearing, and fracture of the rod end. Based on the manufacturer's investigation, on November 4, 2021, the FAA issued Emergency AD 2021–23–51 (followed by publication in the **Federal Register** on December 14, 2021, as a Final Rule, Request for Comments (86 FR 70969)), which requires performing an inspection of the master compressor VG actuator and slave compressor VG actuator on certain GE CF34–8C and CF34–8E model turbofan engines and, depending on the results of the inspection, replacement of the part with a part eligible for installation.

Since the FAA issued AD 2021–23–51, the manufacturer determined that two additional in-flight events occurred that were related to this unsafe condition. On September 7, 2021 and October 26, 2021, two Bombardier CRJ–900 airplanes powered by GE CF34–8C5 model turbofan engines received ''Engine Degraded'' messages from the EICAS during flight. A subsequent investigation by the manufacturer found that these engines were operated infrequently over the past 2 years, with one engine showing corrosion findings after being stored approximately 45 miles (72 km) from a saltwater coastline, and another engine showing corrosion findings after being installed on an airplane parked for over 250 days. The manufacturer's investigation concluded that engines stored outdoors for 250 or more days are at risk of the excessive corrosion build up, with the risk increasing if the engines were stored outdoors in close proximity to a saltwater coastline. These conditions caused corrosion to develop between the high-pressure compressor case and vane bushings, increasing the VG actuation loads and slowing the VG response. As a result, the VG command and actual positions exceeded acceptable disagreement parameters, triggering an EICAS ''Engine Degraded'' message. In response to the ''Engine Degraded'' message, all versions of the full authority digital engine control (FADEC) software on GE CF34–8E engines, and FADEC software earlier than Version 6.60 on GE CF34–8C engines automatically reduces the engine to idle and locks the throttle until the engine is shut down and restarted. This condition, if not addressed, could result in failure of one or more engines, loss of engine thrust control, and reduced control of the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed GE CF34–8C Service Bulletin (SB) 72–0356 R00 and GE CF34–8E SB 72–0244 R00, both dated February 15, 2022. These SBs specify procedures for performing a one-time rotational torque check of the actuating linkage assembly, differentiated by engine model, to identify possible interface corrosion or seizure on the compressor case, compressor IGV outer shroud bushing, vane spindle bushing, compressor stator IGV variable vane, compressor stator stage 1 variable vane, compressor stator stage 2 variable vane, compressor stator stage 3 variable vane, and compressor stator stage 4 variable vane. These SBs also specify instructions for operators to report the rotational torque check results to GE. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

AD Requirements

This AD requires performing a rotational torque check on the actuating linkage assembly and, depending on the results of the rotational torque check, replacement of the compressor IGV outer shroud bushing and vane spindle bushing with parts eligible for installation. This AD also requires reporting the results of the rotational torque check to GE.

Interim Action

The FAA considers this AD to be an interim action. The inspection reports that are required by this AD will enable the manufacturer to obtain better insight into the nature, cause, and extent of the corrosion, and eventually to develop final action to address the unsafe condition. Once final action has been identified, the FAA might consider further rulemaking.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance.

Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule. The FAA considers corrosion of the VG system actuator to be an urgent safety issue. Performance of a rotational torque check of the actuating linkage assembly will detect excessive corrosion build up on the VG system actuator. This rotational torque check is necessary to prevent failure of one or more engines, loss of engine thrust control, and reduced control of the airplane. Engines installed on airplanes parked outdoors for 250 or more days are at risk of excessive corrosion build up. The risk of the excessive corrosion build up increases if the engines are stored outdoors in close proximity to a saltwater coastline. For affected engines installed on airplanes that were parked outdoors within 10 miles of a saltwater coastline, a rotational torque check on the actuating linkage assembly must be accomplished within 30 flight hours or 5 calendar days after the effective date of this AD. For affected engines installed on airplanes that were parked outdoors within 50 miles of a saltwater coastline, a rotational torque check of the actuating linkage assembly must be accomplished within 200 FHs or 35 calendar days after the effective date of this AD. Additionally, for all other affected engines installed on airplanes that were parked outdoors, the rotational torque check on the actuating linkage assembly must be accomplished before exceeding 880 FHs. According to fleet data, 880 FHs is approximately 100 calendar days. For affected engines with an actuating linkage assembly that does not pass the rotational torque check, this AD requires replacement of the compressor IGV outer shroud bushing and vane spindle bushing before further flight. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0400 and Project Identifier AD–2022–00179–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

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

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects 617 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Rotation torque check of actuating linkage assembly	2 work-hours × $85 per hour = $170	$0	$170	$104,890
Report results of rotational torque check	1 work-hour × $85 per hour = $85	0	85	52,445

The FAA estimates the following costs to do any necessary replacement that would be required based on the results of the rotational torque check. The agency has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace compressor IGV outer shroud bushing and vane spindle bushing.	2 work-hours × $85 per hour = $170	$25,622	$25,792

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–08–06 General Electric Company: Amendment 39–22009; Docket No. FAA–2022–0400; Project Identifier AD–2022–00179–E.

(a) Effective Date

This airworthiness directive (AD) is effective April 29, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) CF34–8C1, CF34–8C5, CF34–8C5A1, CF34–8C5A2, CF34–8C5A3, CF34–8C5B1, CF34–8E2, CF34–8E2A1, CF34–8E5, CF34–8E5A1, CF34–8E5A2, CF34–8E6, and CF34–8E6A1 model turbofan engines installed on an airplane that has accumulated 250 or more parked days outdoors within the 24 months prior to the effective date of this AD.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by an ''Engine Degraded'' message received in-flight from the Engine Indicating and Crew Alerting System (EICAS), and a subsequent investigation by the manufacturer that revealed corrosion of the variable geometry (VG) system actuator. The FAA is issuing this AD to detect corrosion of the VG system actuator. The unsafe condition, if not addressed, could result in failure of one or more engines, loss of engine thrust control, and reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

(1) Torque Check: CF34–8C Model Turbofan Engines With Full Authority Digital Engine Control (FADEC) Software (SW) Below Version 6.60, and All Affected CF34–8E Model Turbofan Engines

(i) If the affected engine is installed on an airplane that was parked less than or equal to 10 miles from a saltwater coastline for 250 or more parked days, within 30 flight hours (FHs) or 5 calendar days, whichever occurs first after the effective date of this AD, perform a rotational torque check of the actuating linkage assembly. If an airplane has two affected engines installed while parked less than or equal to 10 miles from a saltwater coastline for 250 or more parked days, operators may perform the rotational torque check of the actuating linkage assembly on the second engine before the second engine exceeds 440 FHs after the effective date of this AD.

(ii) For affected engines not requiring the performance of a rotational torque check by paragraph (g)(1)(i) of this AD, if the affected engine is installed on an airplane that was parked less than or equal to 50 miles from a saltwater coastline for 250 or more parked days, within 200 FHs or 35 calendar days, whichever occurs first after the effective date of this AD, perform a rotational torque check of the actuating linkage assembly. If an airplane has two affected engines installed while parked less than or equal to 50 miles from a saltwater coastline for 250 or more parked days, operators may perform the rotational torque check of the actuating linkage assembly on the second engine before the second engine exceeds 880 FHs after the effective date of this AD.

(iii) For affected engines not requiring the performance of a rotational torque check by paragraphs (g)(1)(i) or (g)(1)(ii) of this AD, before exceeding 880 FHs after the effective date of this AD, perform a rotational torque check of the actuating linkage assembly. If an airplane has two affected engines installed, operators may perform the rotational torque check of the actuating linkage assembly on the second engine before the second engine exceeds 1,680 FHs after the effective date of this AD.

(2) Torque Check: CF34–8C Model Turbofan Engines With FADEC SW Version 6.60 or Above Installed on an Airplane That Is in Service as of the Effective Date of This AD

(i) If the affected engine is installed on an airplane that was parked less than or equal to 10 miles from a saltwater coastline for 250 or more parked days, within 200 FHs or 35 calendar days, whichever occurs first after the effective date of this AD, perform a rotational torque check of the actuating linkage assembly. If an airplane has two affected engines installed while parked less than or equal to 10 miles from a saltwater coastline for 250 or more parked days, operators may perform the rotational torque check of the actuating linkage assembly on the second engine before the second engine

exceeds 880 FHs after the effective date of this AD.

(ii) For affected engines not requiring the performance of a rotational torque check by paragraph (g)(2)(i) of this AD, if the affected engine is installed on an airplane that was parked less than or equal to 50 miles from a saltwater coastline for 250 or more parked days, before exceeding 440 FHs after the effective date of this AD, perform a rotational torque check of the actuating linkage assembly. If an airplane has two affected engines installed while parked less than or equal to 50 miles from a saltwater coastline for 250 or more parked days, operators may perform the rotational torque check of the actuating linkage assembly on the second engine before the second engine exceeds 880 FHs after the effective date of this AD.

(iii) For affected engines not requiring the performance of a rotational torque check by paragraphs (g)(2)(i) or (g)(2)(ii) of this AD, before exceeding 880 FHs after the effective date of this AD, perform a rotational torque check of the actuating linkage assembly. If an airplane has two affected engines installed, operators may perform the rotational torque check of the actuating linkage assembly on the second engine before the second engine exceeds 1,680 FHs after the effective date of this AD.

(3) Torque Check: All Affected Engines That Are Not currently in Service

If the affected engine is installed on an airplane that was parked outdoors for 250 or more parked days within the 24 months prior to re-entering service, or if the engine was off-wing and stored outdoors for 250 or more days within the 24 months prior to reentering service, before further flight, perform a rotational torque check of the actuating linkage assembly.

(4) Replacement of the Compressor Inlet Guide Vane (IGV) Outer Shroud Bushing and Vane Spindle Bushing

If the actuating linkage assembly does not pass any rotational torque check required by paragraphs (g)(1) through (3) of this AD, before further flight, remove the compressor IGV outer shroud bushing and vane spindle bushing and replace with a zero cycles since new compressor IGV outer shroud bushing and vane spindle bushing.

(5) Service Information for Performance of the Rotational Torque Check and Replacement of the Compressor IGV Outer Shroud Bushing and Vane Spindle Bushing

Use the Accomplishment Instructions, paragraph 3.A.(1)(c), of GE CF34–8C Service Bulletin (SB) 72–0356 R00 or GE CF34–8E SB 72–0244 R00, both dated February 15, 2022, as applicable to the engine model, to perform the actions required by paragraphs (g)(1) through (4) of this AD.

(h) Reporting Requirements

Within 10 days after performing the rotational torque check required by paragraphs (g)(1) through (3) of this AD, in accordance with paragraph 3.A.(1)(c), of GE CF34–8C SB 72–0356 or GE CF34–8E SB 72–0244, send your inspection report form, pictures, or report findings to GE at *aviation.fleetsupport@ge.com.*

(i) Definition

(1) For the purpose of this AD, a ''parked day'' is 24 consecutive hours without engine operation.

(2) For the purpose of this AD, ''outdoors'' is any location that is not environmentally controlled, including any non-environmentally controlled facility.

(j) Special Flight Permit

Special flight permits are prohibited.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Related Information

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

(m) Material Incorporated by Reference

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

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

(i) GE CF34–8C Service Bulletin (SB) 72–0356 R00, dated February 15, 2022.

(ii) GE CF34–8E SB 72–0244 R00, dated February 15, 2022.

(3) For GE service information identified in this AD, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ge.com;* website: *https://www.ge.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on April 4, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–08037 Filed 4–11–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1013; Project Identifier MCAI–2020–01530–T; Amendment 39–21980; AD 2022–06–14]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2017–12–08, which applied to all BAE Systems (Operations) Limited Model BAe 146–100A, –200A, and –300A airplanes; and Model Avro 146–RJ70A, 146–RJ85A, and 146–RJ100A airplanes. AD 2017–12–08 required revising the maintenance or inspection program, as applicable, to incorporate new or revised structural inspection requirements. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 19, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 19, 2022.

ADDRESSES: For service information identified in this final rule, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.* You may view this referenced service information 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 on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1013.

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–2021–1013; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Todd Thompson, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3228; email *todd.thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The Civil Aviation Authority (CAA), which is the aviation authority for the United Kingdom, has issued CAA AD G–2021–0011, dated October 8, 2021 (CAA AD G–2021–0011) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all BAe 146 and AVRO 146–RJ airplanes. You may examine the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1013.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2017–12–08, Amendment 39–18923 (82 FR 27414, June 15, 2017) (AD 2017–12–08). AD 2017–12–08 applied to all BAE Systems (Operations) Limited Model BAe 146–100A, –200A, and –300A airplanes; and Model Avro 146–RJ70A, 146–RJ85A, and 146–RJ100A airplanes. The NPRM published in the **Federal Register** on November 23, 2021 (86 FR 66471). The NPRM was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA is issuing this AD to address fatigue cracking of certain structural elements, which could adversely affect the structural integrity of the airplane. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA has considered the comment received. An individual indicated their support for the NPRM.

Conclusion

The FAA reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

BAE Systems has issued Chapter 05, Time Limits/Maintenance Checks, of the BAe 146 Series/AVRO 146–RJ Series Aircraft Maintenance Manual, Revision 132, dated June 15, 2021. This service information describes airworthiness limitations, including life limits, maintenance tasks, and critical design configuration control limitations (CDCCLs).

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

Costs of Compliance

The FAA estimates that this AD affects 30 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA estimates the total cost per operator for the retained actions from AD 2017–12–08 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

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,

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:
■ a. Removing Airworthiness Directive (AD) 2017–12–08, Amendment 39–18923 (82 FR 27414, June 15, 2017); and
■ b. Adding the following new AD:

2022–06–14 BAE Systems (Operations) Limited: Amendment 39–21980; Docket No. FAA–2021–1013; Project Identifier MCAI–2020–01530–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 19, 2022.

(b) Affected ADs

This AD replaces AD 2017–12–08, Amendment 39–18923 (82 FR 27414, June 15, 2017) (AD 2017–12–08).

(c) Applicability

This AD applies to all BAE Systems (Operations) Limited airplanes, certificated in any category, identified in paragraphs (c)(1) and (2) of this AD.

(1) Model BAe 146–100A, –200A, and –300A airplanes.

(2) Model Avro 146–RJ70A, 146–RJ85A, and 146–RJ100A airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking of certain structural elements, which could adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision to the Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2017–12–08, with no changes. Within 90 days after July 20, 2017 (the effective date of AD 2017–12–08): Revise the maintenance or inspection program, as applicable, to incorporate new and revised limitations, tasks, thresholds, and intervals using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA.

Note 1 to paragraph (g): An additional source of guidance for the actions specified in paragraph (g) of this AD can be found in BAe 146/AVRO 146–RJ Airplane Maintenance Manual, Revision 112, dated October 15, 2013.

Note 2 to paragraph (g): An additional source of guidance for the actions specified in paragraph (g) of this AD can be found in Corrosion Prevention Control Program (CPCP) Document No. CPCP–146–01, Revision 4, dated September 15, 2010.

Note 3 to paragraph (g): An additional source of guidance for the actions specified in paragraph (g) of this AD can be found in Supplemental Structural Inspections Document (SSID) Document No. SSID–146–01, Revision 2, dated August 15, 2012.

Note 4 to paragraph (g): An additional source of guidance for the actions specified in paragraph (g) of this AD can be found in Maintenance Review Board Report Document No. MRB 146–01, Issue 2, Revision 19, dated August 2012.

Note 5 to paragraph (g): An additional source of guidance for the actions specified in paragraph (g) of this AD can be found in BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–237, Revision 1, dated April 2, 2013.

(h) Retained No Alternative Actions, Intervals, and/or Critical Design Configuration Control Limitations (CDCCLs), With No Changes

This paragraph restates the requirements of paragraph (j) of AD 2017–12–08, with no changes. Except as specified in paragraph (i) of this AD: After accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections), intervals, and/or CDCCLs may be used, unless the actions, intervals, and/or CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (k)(1) of this AD.

(i) New Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 05, Time Limits/Maintenance Checks, of the BAE Systems BAe 146 Series/AVRO 146–RJ Series Aircraft Maintenance Manual, Revision 132, dated June 15, 2021. The initial compliance time for doing the tasks is at the time specified in Chapter 05, Time Limits/Maintenance Checks, of the BAE Systems BAe 146 Series/AVRO 146–RJ Series Aircraft Maintenance Manual, Revision 132, dated June 15, 2021, or within 90 days after the effective date of this AD, whichever occurs later. Accomplishing the revision of the existing maintenance or inspections program required by this paragraph terminates the actions required by paragraph (g) of this AD.

(j) New No Alternative Actions, Intervals, or CDCCLs

After the existing maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections), intervals, or CDCCLs may be used unless the actions, intervals, and/or CDCCLs are approved as an AMOC in accordance with the procedures specified in paragraph (k)(1) of this AD.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs approved for AD 2017–12–08 are approved as AMOCs for the corresponding provisions of this AD.

(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 the Civil Aviation Authority (CAA); or BAE Systems (Operations) Limited's CAA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) CAA AD G–2021–0011, dated October 8, 2021, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1013.

(2) For more information about this AD, contact Todd Thompson, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3228; email *todd.thompson@faa.gov.*

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(3) and (4) of this AD.

(m) 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) Chapter 05, Time Limits/Maintenance Checks, of the BAE Systems BAe 146 Series/AVRO 146–RJ Series Aircraft Maintenance Manual, Revision 132, dated June 15, 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.*

(4) You may view this service information 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.

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

Issued on March 10, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07935 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0028; Airspace Docket No. 21–ASO–41]

RIN 2120–AA66

Amendment of Class E Airspace; Dyersburg, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E surface airspace in Dyersburg, TN, as the Nally Dunston non-directional beacon (NDB) has been decommissioned, and associated approaches cancelled for Dyersburg Regional Airport. This action updates the airport's name and geographic coordinates. In addition, this action makes an editorial change replacing the term Airport/Facility Directory with the term Chart Supplement in the legal description of associated Class E airspace. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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

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 amends the Class E surface airspace in Dyersburg, TN, to support IFR operations in the area.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 6439, February 4, 2022) for Docket No. FAA–2021–0028 to amend Class E surface airspace at Dyersburg Regional Airport, Dyersburg, TN.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment supporting this action was received.

Class E airspace designations are published in Paragraph 6002 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by amending the Class E surface airspace at Dyersburg Regional Airport, Dyersburg, TN, due the decommissioning of the Nally Dunston NDB and cancellation of associated approaches. This action increases the radius to 4.7-miles (previously 4.1-miles), and updates the airport's name (formerly Dyersburg Municipal Airport), and geographic coordinates to coincide with the FAA's database.

This action also replaces the outdated term Airport/Facility Directory with the term Chart Supplement in the airport description.

Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Class E airspace designations are published in Paragraph 6002 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in FAA Order JO 7400.11.

FAA Order JO 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. 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 minimal. Since this is a routine matter that only affects air traffic procedures an air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and

no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6002 Class E Surface Airspace.

* * * * *

ASO TN E2 Dyersburg, TN [Amended]

Dyersburg Regional Airport, TN
(Lat. 35°59′53″ N, long. 89°24′24″ W)

That airspace upward from the surface within a 4.7-mile radius of the Dyersburg Regional Airport. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in College Park, Georgia, on April 7, 2022.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–07970 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 734, 738, and 746

[Docket No. 220408–0089]

RIN 0694–AI83

Expansion of Sanctions Against Russia and Belarus Under the Export Administration Regulations (EAR)

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: In response to the Russian Federation's (Russia) ongoing aggression in Ukraine following its further invasion of the country, as substantially enabled by Belarus, this rule expands license requirements for Russia and Belarus under the Export Administration Regulations (EAR) to all items on the Commerce Control List (CCL). It also removes license exception eligibility for aircraft registered in, owned or controlled by, or under charter or lease by Belarus or a national of Belarus.

DATES: This rule is effective on April 8, 2022.

FOR FURTHER INFORMATION CONTACT: For questions on this final rule, contact Eileen Albanese, Director, Office of National Security and Technology Transfer Controls, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–0092, Fax: (202) 482–482–3355, Email: *rpd2@bis.doc.gov.* For emails, include ''Russia and Belarus'' in the subject line.

SUPPLEMENTARY INFORMATION:

Background

In response to Russia's February 2022 further invasion of Ukraine and Belarus's substantial enabling of this invasion by allowing it to proceed from Belarusian territory, the Bureau of Industry and Security (BIS) imposed extensive sanctions on Russia and Belarus by amending the Export Administration Regulations (15 CFR parts 730–774) (EAR). These sanctions reflected the U.S. Government's position that Russia's invasion of Ukraine, as substantially enabled by Belarus, flagrantly violated international law, was contrary to U.S. national security and foreign policy interests, and undermined global order, peace, and security, and therefore necessitated stringent and expansive sanctions. Since February 2022, BIS, in coordination with its allies and partners, has issued several rules that subject both countries to restrictions under the EAR. BIS has primarily targeted the Russian and Belarusian defense, aerospace, and maritime sectors with expanded export controls, including controls on the export from abroad of certain foreign-produced items that are subject to the EAR.

Stringent licensing restrictions under the EAR were initially imposed on Russia as part of the final rule, *Implementation of Sanctions Against Russia Under the Export Administration Regulations (EAR),* effective on February 24, 2022, and published March 3, 2022 (87 FR 12226). Among other restrictions, BIS implemented a new license requirement for Russia on items subject to the EAR and classified under any Export Control Classification Number (ECCN) in Categories 3 through 9 of the Commerce Control List, supp. no. 1 to part 774 of the EAR (CCL) as part of new § 746.8(a)(1) (Russia sanctions) in part 746 of the EAR (Embargoes and Other Special Controls). BIS extended this new license requirement to Belarus (see § 746.8 (Russia and Belarus sanctions)) as part of the final rule, *Implementation of Sanctions Against Belarus Under the Export Administration Regulations (EAR),* effective on March 2, 2022, and published March 8, 2022 (87 FR 13048) (Belarus rule).

This rule expands the license requirement that was previously imposed on Russia and Belarus to include items classified under any ECCN in Categories 0 through 2 of the CCL. Accordingly, the license requirement under § 746.8(a)(1) (Russia and Belarus sanctions) now applies to all items on the CCL. Additionally, consistent with this expanded license requirement, this rule revises the foreign ''direct product'' rule (FDP rule) in § 734.9(f) of the EAR that relates to both Russia and Belarus (the ''Russia/Belarus FDP rule'') to apply to all items on the CCL. Therefore, foreign-produced items derived from ECCNs in Categories 0 through 9 of the CCL will now be subject to the EAR under the Russia/Belarus FDP rule as well as to the license requirement described in § 746.8(a)(2).

Additionally, as part of the U.S. Government's response to Belarus's actions in support of Russia's aggressive conduct in Ukraine, this rule limits the availability of two paragraphs of License Exception Aircraft, vessels and spacecraft (AVS) (§ 740.15(a) and (b)) for certain Belarus-related aircraft. Specifically, paragraph (c) (License Exceptions) specifies certain license exceptions that apply to § 746.8(a)(1) and (2) for transactions involving Russia or Belarus, and this rule revises paragraph (c)(5) to preclude the availability of paragraphs (a) and (b) of License Exception AVS for any aircraft registered in, owned or controlled by, or under charter or lease by Belarus or a national of Belarus. Thus, as revised by this rule, paragraphs (a) and (b) of License Exception AVS are not available for aircraft registered in, owned, or controlled by, or under charter or lease by, Belarus or Russia, or by a Belarusian or Russian national. As a conforming change, this rule revises footnote 6 to the Commerce Country Chart (supplement no. 1 to part 738) to reflect

the revised license requirements in § 746.8(a)(1).

Savings Clause

For the expanded controls on Russia and Belarus under § 746.8(a)(2), shipments of items removed from eligibility for a License Exception or reexport or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on May 9, 2022, pursuant to actual orders for reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or reexport or transfer (in-country) without a license (NLR).

For all other changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on April 8, 2022, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR).

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (codified, as amended, at 50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. To the extent it applies to certain activities that are the subject of this rule, the Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA) (codified, as amended, at 22 U.S.C. 7201–7211) also serves as authority for this rule.

Rulemaking Requirements

1. This final rule is not a ''significant regulatory action'' because it ''pertain[s]'' to a ''military or foreign affairs function of the United States'' under sec. 3(d)(2) of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves three collections of information. BIS believes there will be minimal burden changes to two of these collections—Five-Year Records Retention Requirement for Export Transactions and Boycott Actions (OMB control number 0694–0096) and Automated Export System (AES) Program (OMB control number 0607–0152).

However, ''Multi-Purpose Application (OMB control number 0694–0088) will exceed existing estimates currently associated with this collection as the respondent burden will increase the estimated number of submissions by 150 for license applications submitted annually to BIS. BIS estimates the burden hours associated with this collection would increase by 77 (*i.e.,* 150 applications × 30.6 minutes per response) for a total estimated cost increase of $2,310 (*i.e.,* 77 hours × $30 per hour). The $30 per hour cost estimate for OMB control number 0694–0088 is consistent with the salary data for export compliance specialists currently available through *glassdoor.com* (*glassdoor.com* estimates that an export compliance specialist makes $55,280 annually, which computes to roughly $26.58 per hour). Consistent with 5 CFR 1320.13, BIS requested, and OMB has approved, emergency clearance for an increase in the burden estimate due to the additional license requirements imposed by this rule.

3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to section 1762 of the Export Control Reform Act of 2018 (50 U.S.C. 4821) (ECRA), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. While section 1762 of ECRA provides sufficient authority for such an exemption, this action is also independently exempt from these APA requirements because it involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)).

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 738

Exports.

15 CFR Part 746

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 734, 738, and 746 of the Export Administration Regulations (15 CFR parts 730 through 774) are amended as follows:

PART 734—SCOPE OF THE EXPORT ADMINISTRATION REGULATIONS

■ 1. The authority citation for 15 CFR part 734 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of November 10, 2021, 86 FR 62891 (November 12, 2021).

■ 2. Section 734.9 is amended by revising paragraph (f) to read as follows:

§ 734.9 Foreign-Direct Product (FDP) Rules.

* * * * *

(f) *Russia/Belarus FDP rule.* A foreign-produced item is subject to the EAR if it meets both the product scope in paragraph (f)(1) of this section and the destination scope in paragraph (f)(2) of this section. See § 746.8 of the EAR for license requirements, license review policy, and license exceptions applicable to foreign-produced items that are subject to the EAR pursuant to this paragraph (f).

(1) *Product scope of Russia/Belarus FDP rule.* The product scope applies if a foreign-produced item meets the conditions of either paragraph (f)(1)(i) or (ii) of this section.

(i) ''*Direct product*'' *of* ''*technology*'' *or* ''*software.*'' A foreign-produced item meets the product scope of this paragraph (f)(1)(i) if the foreign-produced item is not designated EAR99 and is a ''direct product'' of U.S.-origin ''technology'' or ''software'' subject to the EAR that is specified in any ECCN in product groups D or E of the CCL; or

(ii) ''*Direct product*'' *of a complete plant or 'major component' of a plant.* A foreign-produced item meets the product scope of this paragraph (f)(1)(ii) if the foreign-produced item is not designated EAR99 and is produced by any plant or 'major component' of a plant that is located outside the United States, when the plant or 'major component' of a plant, whether made in the United States or a foreign country, itself is a ''direct product'' of U.S.-origin ''technology'' or ''software'' subject to the EAR that is specified in any ECCN in product groups D or E of the CCL.

(2) *Destination scope of the Russia/Belarus FDP rule.* A foreign-produced item meets the destination scope of this paragraph (f)(2) if there is ''knowledge'' that the foreign-produced item is destined to Russia or Belarus or will be incorporated into or used in the ''production'' or ''development'' of any ''part,'' ''component,'' or ''equipment'' not designated EAR99 and produced in or destined to Russia or Belarus.

* * * * *

PART 738—COMMERCE CONTROL LIST OVERVIEW AND THE COUNTRY CHART

■ 3. The authority citation for 15 CFR part 738 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 4. Supplement no. 1 to part 738 is amended by revising the entries for ''Belarus'' and ''Russia'' and footnote 6 to read as follows:

SUPPLEMENT NO. 1 TO PART 738—COMMERCE COUNTRY CHART

[Reason for control]

Countries	Chemical and biological weapons			Nuclear nonproliferation		National security		Missile tech	Regional stability		Firearms convention	Crime control			Anti-terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
*			*		*			*		*		*		*		
Belarus [6]	X	X	X	X	X	X	X	X	X	X		X	X			
*			*		*			*		*		*		*		
Russia [6]	X	X	X	X	X	X	X	X	X	X		X	X			
*			*		*			*		*		*		*		

* * * * * * * * * * * *

[6] See § 746.5 of the EAR for additional license requirements under the Russian Industry Sector Sanctions for ECCNs 0A998, 1C992, 3A229, 3A231, 3A232, 6A991, 8A992, and 8D999 and items identified in supplement no. 2 to part 746 of the EAR. See § 746.8 of the EAR for Sanctions against Russia and Belarus, including additional license requirements for items listed in any ECCN on the CCL.

* * * * *

PART 746—EMBARGOES AND OTHER SPECIAL CONTROLS

■ 5. The authority citation for 15 CFR part 746 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 2151 note; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Presidential Determination 2007–7, 72 FR 1899, 3 CFR, 2006 Comp., p. 325; Notice of May 6, 2021, 86 FR 26793 (May 10, 2021).

■ 6. Section 746.8 is amended by revising paragraphs (a)(1) and (c)(5) to read as follows:

§ 746.8 Sanctions against Russia and Belarus.

(a) * * *

(1) *Items classified in any ECCN on the CCL.* In addition to license requirements specified on the Commerce Control List (CCL) in supplement no. 1 to part 774 of the EAR and in other provisions of the EAR, including part 744 and § 746.5, a license is required, excluding deemed exports and deemed reexports, to export, reexport, or transfer (in-country) to or within Russia or Belarus any item subject to the EAR and specified in any Export Control Classification Number (ECCN) on the CCL.

* * * * *

(c) * * *

(5) License Exception AVS, excluding any aircraft registered in, owned or controlled by, or under charter or lease by Russia or Belarus or a national of Russia or Belarus (§ 740.15(a) and (b) of the EAR).

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2022–07937 Filed 4–8–22; 4:15 pm]

BILLING CODE 3510–33–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0819; FRL–9266–02–R9]

Air Plan Approval; Arizona; Bullhead City; Second 10-Year PM_{10} Limited Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the Bullhead City portion of the Arizona State Implementation Plan (SIP). These revisions concern the second 10-year maintenance plan for the Bullhead City area for the 1987 national ambient air quality standards (NAAQS or ''standards'') for particulate matter less than 10 micrometers in diameter (PM_{10}).

DATES: This rule will be effective on May 16, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2021–0819. All documents in the docket are listed on the *https://www.regulations.gov*

website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Panah Stauffer, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3247 or by email at *stauffer.panah@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Background

The EPA has established health-based standards for PM_{10}. On July 1, 1987, the EPA promulgated two standards for PM_{10}: A 24-hour standard of 150 micrograms per cubic meter (μg/m^3) and an annual PM_{10} standard of 50 μg/m^3.[1] Effective December 18, 2006, the EPA revoked the annual PM_{10} standard but retained the 24-hour PM_{10} standard.[2] In this document, references to the PM_{10} NAAQS or PM_{10} standard refer to the 24-hour average standard of 150 μg/m^3, unless otherwise noted.

Under section 107(d) of the Clean Air Act (CAA or ''Act''), the EPA is required to designate areas of the country, based on ambient air quality data, as attainment, unclassifiable, or nonattainment for each NAAQS. Under the CAA Amendments of 1990, the Bullhead City area was designated as part of a large ''unclassifiable'' area in Arizona for the PM_{10} NAAQS.[3] In 1993, in light of PM_{10} NAAQS violations monitored in 1989 and 1990, the EPA redesignated the Bullhead City area as a ''Moderate'' nonattainment area for the PM_{10} standard.[4] To meet the SIP planning requirements for such areas, state and local agencies adopted and implemented a number of control measures to reduce PM_{10} emissions and lower ambient PM_{10} concentrations in the Bullhead City area, including paving of certain unpaved roads. In 2002, the EPA determined that the Bullhead City area had attained the PM_{10} NAAQS by the applicable attainment date of December 31, 2000.[5] The 24-hour standard is attained when the expected number of days with levels above 150 μg/m^3 (averaged over a 3-year period) is less than or equal to one.

Under CAA section 175A, one of the criteria for an area to be redesignated from nonattainment to attainment is the approval of a maintenance plan. The maintenance plan must, among other requirements, ensure control measures are in place such that the area will continue to maintain the standard for the period extending 10 years after redesignation and include contingency provisions to assure that violations of the NAAQS will be promptly remedied.

In 2002, the Arizona Department of Environmental Quality (ADEQ) submitted a maintenance plan, titled ''Bullhead City Moderate Area PM_{10} Maintenance Plan and Request for Redesignation to Attainment'' (February 2002) (''First 10-Year LMP'') to the EPA as a revision to the Arizona SIP, and requested that the EPA redesignate the Bullhead City area to attainment.[6] The First 10-Year LMP provided for maintenance of the PM_{10} NAAQS in the Bullhead City area for 10 years after redesignation. On June 26, 2002, the EPA approved the First 10-Year LMP for the Bullhead City area as providing for maintenance through 2012.[7]

CAA section 175A(b) requires states to submit an additional SIP revision to maintain the NAAQS for 10 years after the expiration of the 10-year period covered by the initial maintenance plan approved in connection with the redesignation of the area from nonattainment to attainment. On May 24, 2012, ADEQ submitted a second 10-year maintenance plan, titled ''Limited Maintenance Plan Update for the Bullhead City PM_{10} Maintenance Area'' (May 2012) (''Second 10-Year LMP''), to meet the requirement for the subsequent maintenance plan under CAA section 175A(b). The Second 10-Year LMP is intended to provide for continued maintenance of the PM_{10} NAAQS for the 10-year period following the end of the first 10-year period, *i.e.,* through June 2022.

Consistent with the requirements at the time, the First 10-year LMP provided for maintenance of both the 24-hour average and annual average PM_{10} NAAQS. However, because the EPA has revoked the annual average PM_{10} NAAQS, the Second 10-Year LMP addresses only maintenance of the 24-hour PM_{10} NAAQS.

On December 9, 2021, the EPA proposed to approve as a revision to the Arizona SIP the Second 10-Year LMP submitted by ADEQ on May 24, 2012, for the Bullhead City area.[8] The EPA proposed to approve this plan based on the conclusion that it adequately provides for continued maintenance of the PM_{10} NAAQS in the Bullhead City area through 2022 and thereby meets the requirements for subsequent maintenance plans under section 175A of the Act. Our proposed action contains more information on the plan and our evaluation.

II. Public Comments

The EPA's proposed action provided a 30-day public comment period. During this period, we received two comments. Both comments were supportive of our proposed action and do not require a response. The comments are available for viewing in the docket for this rulemaking.

III. Final Action

No comments were submitted that change our assessment of the Second 10-Year LMP as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is taking final action to approve as a revision to the Arizona SIP the Second 10-Year LMP for the Bullhead City area for the PM_{10} NAAQS. The EPA is approving this plan based on the conclusion that it adequately provides for continued maintenance of the PM_{10} NAAQS in the Bullhead City area through 2022 and thereby meets the

[1] 52 FR 24634 (July 1, 1987).

[2] 71 FR 61144 (October 17, 2006).

[3] For the definition of the Bullhead City maintenance area, see 40 CFR 81.303. The Bullhead City maintenance area is located in western Arizona. The original nonattainment area was defined by the equivalent of approximately six townships covering more than 200 square miles: T21N, R20–21W, excluding Lake Mead National Recreation area; T20N, R20–22W; and T19N, R21–22W, excluding the Fort Mohave Indian Reservation. On June 26, 2002, the EPA approved the State's request that some areas of undisturbed desert terrain containing no industrial or commercial activity be excluded from the Bullhead City PM_{10} planning area (67 FR 43020, 43022). As a result of the boundary change, the townships comprising the maintenance area include: T21N, R21W, excluding Lake Mead National Recreation Area; T20N, R21–22W; and T19N, R22W, excluding the Fort Mohave Indian Reservation.

[4] 58 FR 67334 (December 21, 1993).

[5] 67 FR 7082 (February 15, 2002).

[6] ADEQ, Bullhead City Moderate Area PM_{10} Maintenance Plan and Request for Redesignation to Attainment, February 2002.

[7] 67 FR 43020.

[8] 86 FR 70071.

requirements for subsequent maintenance plans under section 175A of the Act. The effect of this action is to make the State's continuing commitments federally enforceable for the second 10-year maintenance period with respect to maintenance of the PM_{10} NAAQS in the Bullhead City area. These commitments include continued monitoring; continued implementation of control measures that were responsible for bringing the area into attainment; preparation and submittal of annual reports; consideration and implementation of contingency measures, as necessary; and submittal of a full maintenance plan if contingency measures fail to provide the required remedy.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 13, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: April 7, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C 7401 *et seq.*

Subpart D—Arizona

■ 2. Section 52.120, paragraph (e), Table 1, is amended by adding under the heading ''Part D Elements and Plans (Other than for the Metropolitan Phoenix or Tucson Areas)'' an entry for ''Limited Maintenance Plan Update for the Bullhead City PM_{10} Maintenance Area (May 2012)'' after the entry for ''San Manuel Sulfur Dioxide Maintenance Plan Renewal, 1971 Sulfur Dioxide National Ambient Air Quality Standards (April 2017)'' to read as follows:

§ 52.120 Identification of plan.

* * * * *

(e) * * *

TABLE 1—EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MEASURES

[Excluding certain resolutions and statutes, which are listed in tables 2 and 3, respectively] [1]

Name of SIP provision	Applicable geographic or nonattainment area or title/subject	State submittal date	EPA approval date	Explanation
*	*	*	*	*
Part D Elements and Plans (Other than for the Metropolitan Phoenix or Tucson Areas)				
*	*	*	*	*
Limited Maintenance Plan Update for the Bullhead City PM_{10} Maintenance Area (May 2012).	Bullhead City PM_{10} Air Quality Planning Area.	May 24, 2012 ...	04/14/2022, [Insert **Federal Register** citation].	Enclosure 1 includes Arizona's statutory authority provisions. Enclosure 2 is ADEQ's completeness checklist. Enclosure 4 includes the public process documentation. Submitted by the Arizona Department of Environmental Quality on May 24, 2012. Fulfills requirements for second 10-year maintenance plan.
*	*	*	*	*

[1] Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * * * *

[FR Doc. 2022–07907 Filed 4–13–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0773; FRL–9219–02–R9]

Air Plan Approval; Arizona: Maricopa County Air Quality Department

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Maricopa County Air Quality Department (MCAQD) portion of the Arizona State Implementation Plan (SIP). These revisions concern emissions of particulate matter (PM) from wood burning devices. We are approving local rules that regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: These rules will be effective on May 16, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2021–0773. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4125 or by email at vineyard.christine@*epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. Proposed Action

On December 14, 2021 (86 FR 70994), the EPA proposed to approve the following rules into the Arizona SIP.

Local agency	Rule No. Ordinance No.	Rule title	Revised	Submitted
MCAQD	Ordinance P–26	Residential Woodburning Restriction	10/23/19	11/20/19
MCAQD	Rule 314	Outdoor Fires and Commercial/Institutional Solid Fuel Burning	10/23/19	11/20/19

We proposed to approve these rules because we determined that they comply with the relevant CAA requirements. Our proposed action and Technical Support Document (TSD) contain more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received one comment from a private citizen.

Comment: The commenter raises the concern that the revisions to the Arizona State Implementation Plan (SIP) ''do not go far enough to reduce the risks of wildfires and particulate matter emissions.'' The comment emphasizes the need to ''uphold the highest air quality standards of the Clean Air Act'' and ''strongly regulat[e] fires in Maricopa County'' to reduce the impacts

on environmental and human health from woodburning and seasonal wildfires, including those impacts that are exacerbated by the COVID–19 pandemic.

The commenter ultimately ''oppose[s] the conditional approval'' from the EPA's proposal and requests that Maricopa County ''further revise these provisions within their State Implementation Plan to meet the strongest of air quality standards regarding particulate matter.''

EPA's Response: We note that we proposed to fully approve, not conditionally approve, revisions to MCAQD Ordinance P–26 and Rule 314.

As we explained in our proposed action and TSD, during Maricopa County's implementation of earlier versions of Ordinance P–26 and Rule 314 (*i.e.,* those that were previously approved into the SIP), the MCAQD found that certain sections of Rule 314 were unclear and confusing to the public. Therefore, the MCAQD revised the rules to clarify which types of residential fires are subject to Rule 314 and which types of residential fires are subject to Ordinance P–26. The EPA's finalization of our proposed action to approve the submitted revisions to Ordinance P–26 and Rule 314 will add clarity to the SIP and improve implementation.

Further, Rule 314 was revised to reduce emissions from outdoor fires for cooking by defining cooking, restricting the size of fires used for cooking, and requiring that fires ignited for cooking during a restricted burn period be extinguished once the food is suitable for human consumption. And to reduce total annual emissions from fireplaces, woodstoves, and chimineas at commercial and institutional establishments and outdoor fires, the rules were revised to require the use of seasoned wood, which contains no more than 20 percent moisture. These revisions will directly reduce particulate matter emissions and contribute to the area's compliance with the 2012 National Ambient Air Quality Standard for fine particulate matter.[1]

Under the CAA, EPA is required to approve a SIP submission that complies with the provisions of the CAA and applicable federal regulations.[2] In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Thus, we are approving MCAQD Ordinance P–26 and Rule 314 because they strengthen the SIP and comply with all requirements for SIP revisions under the Clean Air Act.

III. EPA Action

No comments were submitted that change our assessment of the rules as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving these rules into the Arizona SIP. The October 23, 2019 version of Ordinance P–26 and Rule 314 will replace the previously approved versions of these rules in the SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the MCAQD rules described in Section I. of this preamble and set forth below in the amendments to 40 CFR part 52. Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[3] The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a

[1] Rule 314–SIP Revision Package p. 37–38, Docket ID: EPA–R09–OAR–2021–0773–0002.

[2] 42 U.S.C. 7410(k); 40 CFR 52.02(a).

[3] 62 FR 27968 (May 22, 1997).

''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 13, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: April 7, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart D—Arizona

■ 2. Section 52.120, paragraph (c), Table 4, under the heading ''Post-July 1988 Rule Codification'', is amended by:

■ a. Revising the entry for Rule 314 under the table heading ''Regulation III—Control of Air Contaminants''; and

■ b. Adding a heading for ''Maricopa County Ordinances'' and an entry for ''Ordinance P–26'' under the table heading ''Appendices to Maricopa County Air Pollution Control Rules and Regulations'' after the entry for ''Appendix F''.

The revision and addition read as follows.

§ 52.120 Identification of plan.

* * * * *

(c) * * *

TABLE 4 TO PARAGRAPH (C)—EPA-APPROVED MARICOPA COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Post-July 1988 Rule Codification				
*	*	*	*	*
Regulation III—Control of Air Contaminants				
*	*	*	*	*
Rule 314	Outdoor Fires and Commercial/Institutional Solid Fuel Burning.	October 23, 2019	[INSERT **Federal Register** CITATION], April 14, 2022.	Submitted on November 20, 2019.
*	*	*	*	*
Appendices to Maricopa County Air Pollution Control Rules and Regulations				
*	*	*	*	*
Maricopa County Ordinances				
Ordinance P–26	Residential Woodburning Restriction	October 23, 2019	[INSERT **Federal Register** CITATION], April 14, 2022.	Submitted on November 20, 2019.

* * * * *

[FR Doc. 2022–07922 Filed 4–13–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 226

[Docket No. 220408–0090; RTID 0648–XR119]

Endangered and Threatened Wildlife and Plants; Removal of Johnson's Seagrass From the Federal List of Threatened and Endangered Species Including the Corresponding Designated Critical Habitat

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

ACTION: Final rule.

SUMMARY: We, NMFS, are issuing a final rule to remove Johnson's seagrass (*Halophila johnsonii*) from the Federal List of Threatened and Endangered Species. To correspond with this action, we are also removing the critical habitat designation for Johnson's seagrass. These actions are based on newly obtained genetic data that demonstrate that Johnson's seagrass is not a unique taxon but rather a clone of an Indo-Pacific species, *Halophila ovalis.* Therefore, Johnson's seagrass does not meet the statutory definition of a species

and does not qualify for listing under the Endangered Species Act (ESA). After considering public comment on the proposed rule, we are implementing this final rule to execute the proposed changes to the listing and critical habitat for Johnson's seagrass.

DATES: This final rule is effective on May 16, 2022.

FOR FURTHER INFORMATION CONTACT: Adam Brame, NMFS Southeast Regional Office, *Adam.Brame@noaa.gov,* (727) 209–5958.

SUPPLEMENTARY INFORMATION:

Background

In 1980, a small-statured seagrass species found within Florida's southeastern coastal lagoon system was identified as Johnson's seagrass (*Halophila johnsonii*) (Eiseman and McMillan 1980). Prior to this designation, this seagrass was often referred to as *H. decipiens,* though it was most similar to the morphologically diverse Indo-Pacific species, *H. ovalis.* Morphological and physiological characteristics were the bases for its later taxonomic identification as *H. johnsonii.* For example, Johnson's seagrass was differentiated from other Atlantic *Halophila* species by its smooth leaf margins, angle of the cross veins extending from the midrib, and the lack of hairs on the blade surface (Eiseman and McMillan 1980).

Given the extremely limited geographical distribution of Johnson's seagrass (about 200 kilometers (km) of Florida's east coast), its limited reproductive potential (only asexual reproduction), and the variety of threats that could affect survival, we conducted a status review in 1993 to consider whether Johnson's seagrass should be added to the Federal List of Threatened and Endangered Species. We published a proposed rule to list the species as threatened on September 15, 1993 (58 FR 48326), and a proposed rule to designate critical habitat on August 4, 1994 (59 FR 39716). Additional research on the ecology of this species subsequently became available and was considered in an updated status review, which was completed in 1997. We published a final rule listing Johnson's seagrass as a threatened species in 1998 (63 FR 49035, September 14, 1998) and a final rule designating critical habitat in 2000 (65 FR 17786, April 5, 2000).

A peer reviewed manuscript published in October 2021 (Waycott et al. 2021), used a variety of genetic analyses to conclude that Johnson's seagrass is not a unique taxon but rather a clone of the Indo-Pacific species *H. ovalis.* In light of this new information, we initiated and completed a status review for *H. johnsonii,* which is documented in the proposed rule published December 23, 2021 (86 FR 72908). Based on the best available scientific information as described in the proposed rule, we determined that Johnson's seagrass no longer meets the statutory definition of a species and therefore proposed to delist it under the ESA.

Basis for the Proposed Rule

Section 3 of the ESA defines the term ''species'' as any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature 16 U.S.C. 1532(16). Pursuant to implementing regulations in 50 CFR 424.11(a), in determining whether a particular taxon or population is a species under the ESA, we rely on standard taxonomic distinctions as well as our biological expertise and that of the scientific community concerning the relevant taxonomic group.

Under section 4(c) of the ESA, the Secretary is required to periodically review and revise the Federal List of Endangered and Threatened Species and consider, among other things, whether a species' listing status should be changed, including whether the species should be removed from the list (16 U.S.C. 1533(c)). Pursuant to implementing regulations for the ESA at 50 CFR 424.11(e), the Secretary shall delist a species if, after conducting a status review based on the best scientific and commercial data available, the Secretary determines: (1) The species is extinct; (2) the species does not meet the definition of an endangered species or threatened species; or (3) the listed entity does not meet the statutory definition of a species. When conducting a status review, if we determine the entity under review does not meet the statutory definition of a species, the status review concludes without further evaluation, because we can only list entities that qualify as species under the ESA.

The entity described as Johnson's seagrass grows in a variety of conditions within Florida's intracoastal waters from Sebastian Inlet to Virginia Key in Biscayne Bay. This is the smallest geographic distribution of any seagrass worldwide. Within this range, it is among the least abundant seagrass. It grows in small, sparse patches and may disappear from areas for months or years before reappearing. It can co-occur with other seagrasses, but its short stature precludes it from occurring within dense stands of taller species because it is outcompeted for light resources. Johnson's seagrass has a broader tolerance range for light, temperature, and salinity than congeners and seems capable of growing in suboptimal conditions where other species cannot survive. Johnson's seagrass grows in the intertidal zone, on dynamic flood deltas inside ocean inlets, at the mouths of freshwater discharge canals, and subtidal waters to depths of approximately 3–4 meters.

Johnson's seagrass is dioecious, meaning each plant only contains the flowers of one sex (male or female). Interestingly, no individual Johnson's seagrass plants have been found with male flowers. Similarly, researchers have not found any seedlings. These observations suggest that Johnson's seagrass reproduces only through vegetative fragmentation (asexual reproduction) and not through the development and dispersal of seeds (sexual reproduction). This strategy likely hinders its ability to expand in range and may slow recolonization following disturbances.

At the time of listing, the best available data indicated Johnson's seagrass: (1) Had perhaps the smallest geographic range of any seagrass species worldwide; (2) had a sparse, patchy distribution throughout its range and an ability to survive in a variety of environmental conditions; (3) lacked male flowers necessary for sexual reproduction and therefore appeared to only reproduce asexually; and (4) was unique from other North American *Halophila* species based on morphology, physiological ecology, and genetic analyses. However, the unique life history and ecology of this seagrass raised questions about its phylogeny (history of the evolution of a species or group, including relatedness within a group). The 1997 status review indicated that more detailed studies were necessary to evaluate the overall genetic structure and diversity of *H. johnsonii.* This need was reiterated in the 2002 Johnson's Seagrass Recovery Plan.

A 1997 genetics study using randomly amplified primer DNA-polymerase chain reactions (RAPD–PCR) indicated that genetic diversity was higher than expected at one location within the range of Johnson's seagrass (Jewitt-Smith *et al.* 1997). Yet this study relied on a limited sample size, and a subsequent study using similar techniques indicated very low genetic diversity within *H. johnsonii* as compared to the co-occurring species, *H. decipiens* (Freshwater 1999). The low genetic diversity was attributed to the lack of sexual reproduction. The

methodology used in assessing these *Halophila* samples did not provide the resolution necessary to make species level conclusions about phylogeny.

A molecular phylogenetic analysis of the genus *Halophila* using internal transcribed spacer (ITS) regions of nuclear ribosomal DNA indicated that *H. johnsonii* could not be distinguished from *H. ovalis* and should be further researched (Waycott *et al.* 2002). Umichura (2008) came to a similar conclusion and suggested that *H. johnsonii* and two other *Halophila* species should be reclassified as the broadly distributed *H. ovalis.* Short *et al.* (2010) used ITS regions of nuclear ribosomal sequences and morphology to demonstrate that *Halophila* samples from Antigua belonged to *H. ovalis* and were genetically identical to *H. johnsonii.* Short *et al.* (2010) also found that *Halophila* samples from both Antigua and the United States (the latter of which were previously identified as *H. johnsonii*) fell within the range of morphological characteristics diagnostic for *H. ovalis,* and particularly for *H. ovalis* from east Africa. The outcomes of these studies raised more questions about the taxonomy of *Halophila* species, particularly *H. johnsonii,* given its unusually restricted geographic range, its limited reproductive strategy, and its morphometric similarities to other Indo-Pacific species of *Halophila.*

NMFS began funding projects to resolve the taxonomic uncertainty of Johnson's seagrass in 2012. Waycott *et al.* (2015) used multiple genetic approaches including microsatellite DNA and next generation sequencing to detect single nucleotide polymorphisms (SNPs). Results of this work indicated a complete lack of genetic diversity across the range of Johnson's seagrass and through time, indicating all samples analyzed were from a singular clone. Samples collected and analyzed from Antigua contained the same genetic markers as samples from Florida, suggesting these too were part of the same clone (Waycott *et al.* 2015) despite the Antigua samples having been previously identified as *H. ovalis* (Short *et al.* 2010). Finally, Waycott *et al.* (2015) genetically compared samples from both Florida and Antigua with *H. ovalis* samples collected throughout that species' range (Indo-Pacific). Results indicated all samples, regardless of location or identification, had allelic overlap (same gene variations) at 6 of 10 microsatellite loci analyzed, suggesting samples from the Atlantic originated from *H. ovalis* of the Indo-Pacific. While this report provided further evidence that *H. johnsonii* was not a unique taxon, SNP locations for *H. ovalis* had yet to be verified for *H. johnsonii* samples and the report did not present a comprehensive population genetic analysis of *H. ovalis.*

NMFS provided support for a follow-up study in 2017, recently published as Waycott *et al.* (2021). This study expanded previous efforts with the intent of solidifying the methods and providing a robust conclusion regarding the taxonomic uncertainty within the *H. ovalis* complex. The study used multiple methodological approaches and created molecular data sets for samples of both *H. johnsonii* and *H. ovalis* collected throughout the range of each species. Phylogenetic analyses of 105 samples of *Halophila spp.* from 19 countries using plastid (17,999 base pairs (bp)) and nuclear (6,449 bp) DNA sequences derived from hybrid capture both resolved *H. johnsonii* within *H. ovalis.* A third phylogenetic analysis using 48 samples from 13 populations identified 990 genome-wide SNPs (generated via double digest restriction-site associated digest sequencing (ddRAD)) and also nested *H. johnsonii* within *H. ovalis.* All three phylogenetic analyses indicated *H. johnsonii* samples were most similar to *H. ovalis* samples from Antigua and east Africa.

Waycott *et al.* (2021) also assessed population-level differences using both the genome-wide SNPs (990) developed in the phylogenetic analysis (47 of the 48 samples from 13 populations) and microsatellites (294 samples at 10 microsatellite loci). Cluster analysis indicated three populations within the *H. ovalis* complex, with *H. johnsonii* being part of the Indo-Pacific/Atlantic clade. Other results demonstrated genetic uniformity of all 132 *H. johnsonii* samples, indicating a complete lack of genetic diversity that is consistent with clonal (asexual) reproduction and a single colonization event. These same 132 samples and the 12 *H. ovalis* samples from Antigua shared a single multilocus genotype at all nine comparable microsatellite loci. Furthermore, all 12 *H. johnsonii* samples and the single *H. ovalis* sample from Antigua genotyped with ddRAD loci shared the same multilocus genotype. In contrast, other *H. ovalis* populations, such as those from Australia, generally had multiple multilocus genotypes and substantial genetic diversity, indicating that the genetic markers would have detected differences if they were present. The population-level analyses indicate that *H. johnsonii* is genetically indistinguishable from *H. ovalis,* clustering with samples from Antigua and east Africa.

Collectively, the Waycott *et al.* (2021) study concluded that the entire range of *H. johnsonii* is a single clone of a morphological variant of the Indo-Pacific species *H. ovalis.* After reviewing the best information available, we agree that *H. johnsonii* should be synonomized with *H. ovalis* and not considered a separate taxonomic species. It cannot qualify as a distinct population segment (DPS) under the statutory definition of a species because DPSs can be identified only for vertebrate fish or wildlife, not plants. Therefore, *H. johnsonii* does not meet the statutory definition of a species under the ESA, and on that basis, we published a proposed rule on December 23, 2021, to remove Johnson's seagrass from the Federal List of Threatened and Endangered Species and to remove its corresponding critical habitat from 50 CFR part 226 (86 FR 72908).

Public Comment

Upon publication of the proposed rule, we solicited comments during a 60-day public comment period from all interested parties. We received nine comments, two of which were nearly identical. Summaries of the comments received and our responses are provided in the following paragraphs.

Comment 1: Four commenters supported the proposed delisting based on the information provided in the proposed rule.

Response: We thank these commenters for their support of the proposed delisting.

Comment 2: Two commenters disagreed with the proposed delisting on the basis of the need to continue to protect all seagrasses and seagrass habitats given the unique ecosystem functions they provide. One of these commenters recognized our finding that *H. johnsonii* is not a species eligible for listing because it is a clone of *H. ovalis,* but suggested that *H. ovalis* found in Florida should be listed given the ongoing threats it faces there.

Response: While we agree with the commenters that seagrasses serve a critical ecosystem function by, for example, stabilizing substrate and providing both forage and habitat for a variety of species, the best scientific information available indicates that this seagrass is not a unique taxon but rather a clone of the Indo-Pacific species *H. ovalis.* Synonymizing *H. johnsonii* with *H. ovalis* means the entity currently listed under the ESA as Johnson's seagrass is not a taxonomic species, and is therefore not eligible for listing under the ESA. *H. ovalis* could be considered for future listing under the ESA. However, that would require a separate

review to consider the status of that species throughout the entirety or a significant portion of its range. At that time, we would be able to evaluate whether the species is eligible for and should be listed because of any of the threats it faces in waters off Florida.

We agree with the importance of seagrasses to the environments in which they are found. Though delisting *H. johnsonii* from the ESA removes the protections of the ESA for this ''species'' and its critical habitat, NMFS will continue to support seagrass conservation under other statutory authorities. For example, the South Atlantic Fishery Management Council has identified seagrass and habitats containing seagrasses as essential fish habitat (EFH) for certain federally-managed fish species in the South Altantic, such as snapper and grouper, under the Magnuson-Stevens Fishery Conservation and Management Act (MSA). EFH is defined as ''those waters and substrate necessary to fish for spawning, breeding, feeding, or growth to maturity.'' 16 U.S.C. 1802(10). As required under the MSA, federal agencies (*e.g.,* U.S. Army Corps of Engineers) consult with NMFS on any action that may adversely affect EFH 16 U.S.C. 1855(b)(2). NMFS provides comments and EFH Conservation Recommendations for those actions that affect EFH and those recommendations can include measures to ensure federal projects avoid, minimize, and, if necessary, mitigate impacts to EFH as a means to conserve and promote sustainable fisheries. 16 U.S.C. 1855(b)(4); 50 CFR 600.905(b), 600.920, and 600.925. The delisting under the ESA does not affect the mechanisms to conserve and protect seagrasses as EFH under the Magnuson-Stevens Fishery Conservation and Management Act.

Comment 3: One commenter agreed with the agency's rationale for delisting this seagrass but recommended further consideration for retaining the critical habitat designation as a means of overall ecosystem conservation.

Response: Critical habitat can only be designated for species on the Federal List of Threatened and Endangered Species (16 U.S.C. 1532(5), 16 U.S.C. 1533(a)(3)). Therefore, the Johnson's seagrass critical habitat designation cannot be retained when the species is removed from the List.

Comment 4: One commenter agreed with the agency's rationale for delisting Johnson's seagrass but expressed concern that removal from the list could adversely affect other seagrasses that co-occupy habitat in that region.

Response: As discussed previously, NMFS agrees with the importance of seagrasses and their habitats and will continue to promote conservation through the MSA (see response to Comment 2).

Summary of Changes From Proposed Rule

We evaluated whether any pertinent scientific or commercial information became available since publication of the proposed rule. We reviewed the best available scientific and commercial information, including all public comments. Based on all available information, we have made no changes from the proposed rule.

Final Determination and Effects of Determination

As proposed on December 23, 2021 (86 FR 72908), and concluded with this final rule, we remove *H. johnsonii* from the Federal List of Threatened and Endangered Species because the best available scientific and commercial data indicate that the listed entity is synonymous with *H. ovalis* and does not meet the statutory definition of a species. Because critical habitat can only be designated for species listed under the ESA, we also remove the designated critical habitat for *H. johnsonii.* As of the effective date, the protections of the ESA will no longer apply to *H. johnsonii.* However, the delisting of *H. johnsonii* and removal of the designated critical habitat are specific to the ESA and will have no effect on other Federal, state, county, or local seagrass protections that may be in place. In addition, because *H. ovalis* is not listed as an endangered species or threatened species under the ESA, our delisting of *H. johnsonii* will have no effect on the status of *H. ovalis.*

Per the joint NMFS–U.S. Fish and Wildlife Service Post-Delisting Monitoring Plan Guidance (2008, updated in 2018), the post-delisting monitoring requirements of section 4(g) of the ESA apply without exception to all species delisted due to biological recovery, but do not pertain to species delisted for other reasons, such as taxonomic revision. Based on this reasoning, there is no need for a post-delisting monitoring plan for *H. johnsonii.*

References Cited

The complete citations for the references used in this document can be obtained by contacting NMFS (See **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**).

Information Quality Act and Peer Review

In December 2004, the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review establishing minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation. The OMB Peer Review Bulletin, implemented under the Information Quality Act (Pub. L. 106–554), is intended to enhance the quality and credibility of the Federal Government's scientific information, and applies to influential or highly influential scientific information disseminated on or after June 16, 2005.

To satisfy the requirements under the OMB Peer Review Bulletin, the Waycott *et al.* (2021) manuscript was subjected to peer review in accordance with the Bulletin. Our proposed action relies upon new information within the manuscript, which we consider ''influential scientific information.'' While the manuscript was published in the peer-reviewed journal Frontiers in Marine Science, and peer reviewed by that journal prior to publication, we also peer reviewed the manuscript. We established a peer review plan that consisted of subjecting the manuscript to review by a panel of four expert reviewers identified by NOAA's Genetics Group. The peer review plan, which included the charge statement to the peer reviewers, and the resulting peer review report are posted on the NOAA peer review agenda at: *https://www.noaa.gov/organization/information-technology/peer-review-plans.* In meeting the OMB Peer Review Bulletin requirements, we have also satisfied the requirements of the 1994 joint U.S. Fish and Wildlife Service and NMFS peer review policy (59 FR 34270, July 1, 1994).

Classification

National Environmental Policy Act (NEPA)

The 1982 amendments to the ESA, in section 4(b)(1)(A), restrict the information that may be considered when assessing species for listing to the best scientific and commercial data available. Based on this limitation of criteria for a listing decision and the opinion in *Pacific Legal Foundation* v. *Andrus,* 657 F. 2d 829 (6th Cir. 1981), we have concluded that NEPA does not apply to ESA listing actions. (See NOAA Administrative Order 216–6A and the Companion Manual for NOAA Administrative Order 216–6A, regarding Policy and Procedures for Compliance

with the National Environmental Policy Act and Related Authorities.)

Executive Order 12866, Regulatory Flexibility Act, and Paperwork Reduction Act

As noted in the Conference Report on the 1982 amendments to the ESA, economic impacts cannot be considered when assessing the status of a species. Therefore, the economic analysis requirements of the Regulatory Flexibility Act are not applicable to the listing process. In addition, this final rule is exempt from review under Executive Order 12866. This final rule does not contain a collection of information requirement for the purposes of the Paperwork Reduction Act.

Executive Order 13132, Federalism

E.O. 13132 requires agencies to take into account any federalism impacts of regulations under development. It includes specific consultation directives for situations where a regulation will preempt state and local law, or impose substantial direct compliance costs on state and local governments (unless required by statute). Neither of these circumstances is applicable to this final rule.

List of Subjects

50 CFR Part 223

Endangered and threatened species.

50 CFR Part 226

Endangered and threatened species.

Dated: April 11, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 223 and 226 are amended as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531 1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

§ 223.102 [Amended]

■ 2. In § 223.102, in the table in paragraph (e), remove the undesiganted heading ''Marine Plants'' and the entry for ''Seagrass, Johnson's''.

PART 226—DESIGNATED CRITICAL HABITAT

■ 3. The authority citation for part 226 continues to read as follows:

Authority: 16 U.S.C. 1533.

§ 226.213 [Removed and Reserved]

■ 4. Remove and reserve § 226.213.

[FR Doc. 2022–08029 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 72
Thursday, April 14, 2022

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 AGRICULTURE

Agricultural Marketing Service

7 CFR Part 932

[Doc. No. AMS–SC–21–0099; SC22–932–1 PR]

Olives Grown in California; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the California Olive Committee (Committee) to decrease the assessment rate established for the 2022 fiscal year and subsequent fiscal years. The proposed assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by June 13, 2022.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk electronically by Email: *MarketingOrderComment@usda.gov* or via the internet at: *https://www.regulations.gov.* All comments should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this proposed rule will be included in the record and will be made available to the public and can be viewed at: *https://www.regulations.gov.* Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Kathie Notoro, Marketing Specialist, or Gary Olson, Regional Director, West Region Marketing Field Office, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 538–1672, or Email: *Kathie.Notoro@usda.gov* or *GaryD.Olson@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This proposed action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Agreement and Order No. 932, as amended (7 CFR part 932), regulating the handling of olives grown in California. Part 932 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers and handlers of olives operating within the area of production, and one public member.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with 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, 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. This proposed action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. Agricultural Marketing Service (AMS) has determined that this proposed rule is unlikely to 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.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have retroactive effect. Under the Order now in effect, California olive handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate would be applicable to all assessable olives beginning on January 1, 2022, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

The Order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members are familiar with the Committee's needs and with the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

This proposed rule would decrease the assessment rate from $30.00 per ton of assessed olives, the rate that was established for the 2021 and subsequent fiscal years, to $16.00 per ton of assessed olives for the 2022 and subsequent fiscal years. The proposed lower rate is the result of the

significantly higher crop size in 2021 (fruit that is marketed over the course of the 2022 fiscal year) and the need to reduce the Committee's financial reserve.

The Committee met on November 10, 2021, and unanimously recommended 2022 expenditures of $1,245,085 and an assessment rate of $16.00 per ton of assessed olives to fund necessary administrative expenses and to maintain a financial reserve within the limits prescribed under the Order. In comparison, last year's budgeted expenditures were $1,151,831. The proposed assessment rate of $16.00 is $14.00 lower than the rate currently in effect. Producer receipts show a yield of 43,336 tons of assessable olives from the 2021 crop year, which is more than double the quantity of olives harvested in 2020.

Olives harvested in 2021 will be marketed over the course of the 2022 fiscal year, which begins on January 1, 2022. The 43,336 tons of assessable olives from the 2021 crop would generate $693,376 in assessment revenue at the proposed assessment rate. The balance of funds needed to cover budgeted expenditures would come from interest income, Federal grants, and the Committee's financial reserve. The 2022 fiscal year assessment rate decrease would be appropriate to ensure the Committee has sufficient revenue to fund the recommended 2022 fiscal year budgeted expenditures while ensuring the funds in the financial reserve would be kept within the maximum permitted by § 932.40.

The Order has a fiscal year and a crop year that are independent of each other. The crop year is a 12-month period that begins on August 1 of each year and ends on July 31 of the following year. The fiscal year is the 12-month period that begins on January 1 and ends on December 31 of each year. Olives are an alternate-bearing crop, with a small crop followed by a large crop. The Committee used the actual 2021 crop year receipts, in part, to determine the proposed assessment rate for the 2022 fiscal year.

The major expenditures recommended by the Committee for the 2022 fiscal year includes $538,700 for program administration, $284,000 for marketing activities, $379,485 for research, and $42,900 for inspection. Budgeted expenses for these items during the 2021 fiscal year were $531,300, $238,000, $334,532, and $48,000, respectively.

The Committee derived the recommended assessment rate by considering anticipated fiscal year expenses, actual olive tonnage received by handlers during the 2021 crop year, and the amount in the Committee's financial reserve. Income derived from handler assessments and other revenue sources is expected to be adequate to cover budgeted expenses. The assessment rate proposed in this rule would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each fiscal year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's budget for subsequent fiscal years would be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 800 producers of olives in the production area and 2 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $1,000,000, and small agricultural service firms are defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

Because of the large year-to-year variation in California olive production it is helpful to use two-year averages of seasonal average grower price when undertaking calculations relating to average grower revenue. The National Agricultural Statistics Service (NASS) reported season average grower prices of olives utilized for canning for 2019 and 2020 of $1,040 and $1,060 per ton, respectively. The two-year average price is $1,050.

The appropriate quantities to consider are the annual assessable olive quantities, which were 20,020 tons in 2020 and 43,336 tons in 2021. The two-year average quantity was 31,678 tons. Multiplying 31,678 tons by the two-year average grower price of $1,050 yields a two-year average crop value of $33.262 million. Dividing the crop value by the number of olive producers (800) yields calculated annual average producer revenue of $41,577, much less than SBA's size standard of $1,000,000. Thus, the majority of olive producers may be classified as small entities.

Dividing the $33.262 million crop value by two equals $16.631 million, which is the annual average producer crop value processed by each of the two handlers over the two-year period. Dividing the $30 million annual sales SBA size threshold for a large handler by the $16.631 crop value per handler yields an estimate of an 80 percent manufacturing margin for the two canners, on average, to be considered large handlers. A key question is whether 80 percent is a reasonable estimate of a manufacturing margin for the olive canning process.

A review of economic literature on canned food manufacturing margins found no recent published estimates. A series of USDA, Economic Research Service reports on cost components of farm to retail price spreads, published in the late 1970s and early 1980s, found that margins above crop value for a canned vegetable product was in the range of 76 to 85 percent. Although the studies are not recent, a key observation is that canning technology has not changed significantly in that time period. Therefore, with the 80 percent margin estimate for the two olive handlers, the data indicates that they are right on the threshold of being large handlers ($30 million in annual sales), using two-year average data, and assuming that the two handlers are about the same size. In a large crop year, one or both handlers would be considered large handlers, depending on the proportion of the crop that each of the handlers processed.

This proposal would decrease the assessment rate collected from handlers for the 2022 and subsequent fiscal years from $30.00 to $16.00 per ton of assessable olives. The Committee unanimously recommended 2022 expenditures of $1,245,085 and an

assessment rate of $16.00 per ton. The recommended assessment rate of $16.00 is $14.00 lower than the 2021 rate. The quantity of assessable olives harvested in the 2021 crop year is 43,336 tons as compared to 20,020 tons in 2020. Olives are an alternate-bearing crop, with a small crop followed by a large crop. Income derived from the $16.00 per ton assessment rate, along with interest income, Federal grants, and funds from the authorized reserve, should be adequate to meet this fiscal year's budgeted expenditures.

The Committee's financial reserve is projected to be $1,990,000. The major expenditures recommended by the Committee for the 2022 fiscal year include $538,700 for program administration, $284,000 for marketing activities, $379,485 for research, and $42,900 for inspection. Budgeted expenses for these items during the 2021 fiscal year were $531,300, $238,000, $334,531, and $48,000, respectively. The Committee deliberated on many of the expenses, weighed the relative value of various programs or projects, and decreased their expenses for marketing and research activities while increasing program administration. Overall, the 2022 budget of $1,245,085 is $93,254 more than the $1,151,831 budgeted for the 2021 fiscal year.

Prior to arriving at this budget and assessment rate, the Committee considered information from various sources including the Committee's Executive, Marketing, Inspection, and Research Subcommittees. Alternate expenditure levels were discussed by these groups, based upon the relative value of various projects to the olive industry and the increased olive production. The assessment rate of $16.00 per ton of assessable olives was derived by considering anticipated expenses, the high volume of assessable olives, the current balance in the monetary reserve, and additional pertinent factors.

A review of NASS information indicates that the average producer price for the 2020 crop year was $1,060 per ton and the quantity of assessable olives harvested in the 2021 crop year is 43,336 tons, which makes total producer revenue $45,936,160 ($1,060 multiplied by 43,336 tons). Therefore, utilizing the assessment rate of $16.00 per ton, the assessment revenue for the 2022 fiscal year as a percentage of total producer revenue would be approximately 1.5 percent ($16.00 multiplied by 43,336 tons divided by $45,936,160 multiplied by 100).

This proposed action would decrease the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate would reduce the burden on handlers and may also reduce the burden on producers.

The Committee's meetings are widely publicized throughout the production area. The olive industry and all interested persons are invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the November 10, 2021 meeting was public meeting and all entities, both large and small, were able to express views on this issue. In addition, interested persons are invited to submit comments on this proposed rule, including the regulatory and information collection impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178 Vegetable and Specialty Crops. No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large California olive handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendations submitted by the Committee and other available information, USDA has determined that this proposed rule is consistent with and will effectuate the purposes of the Act.

A 60-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments timely received will be considered before a final determination is made on this proposed rule.

List of Subjects in 7 CFR Part 932

Marketing agreements, Olives, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service proposes to amend 7 CFR part 932 as follows:

PART 932—OLIVES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 932 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 932.230 is revised to read as follows:

§ 932.230 Assessment rate.

On and after January 1, 2022, an assessment rate of $16.00 per ton is established for California olives.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–07992 Filed 4–13–22; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1017; Product Identifier AD–2021–00495–A]

RIN 2120–AA64

Airworthiness Directives; True Flight Holdings LLC Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed rule; withdrawal.

SUMMARY: The FAA is withdrawing a notice of proposed rulemaking (NPRM) that proposed to adopt a new airworthiness directive (AD) for all True Flight Holdings LLC Model AA–1, AA–1A, AA–1B, AA–1C, AA–5, AA–5A, and AA–5B airplanes. The NPRM was prompted by the report of an accident of an airplane with bondline corrosion and delamination of the horizontal stabilizers. The NPRM proposed to require inspecting the wings, fuselage,

and stabilizers for bondline separation, corrosion, and previous repair. The NPRM also proposed to require repairing or replacing parts and applying corrosion inhibitor as necessary. Since issuance of the NPRM, the FAA has determined that there is not an unsafe condition, but instead incorrectly followed maintenance procedures. Accordingly, the NPRM is withdrawn.

DATES: As of April 14, 2022, the proposed rule, which published in the **Federal Register** on December 1, 2021 (86 FR 68171), is withdrawn.

ADDRESSES:

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1017; 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 action, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Fred Caplan, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5507; email: *frederick.n.caplan@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued AD 2021–14–12, Amendment 39–21639 (86 FR 36491, July 12, 2021) (AD 2021–14–12), for True Flight Holdings LLC Model AA–1, AA–1A, AA–1B, AA–1C, and AA–5 airplanes. AD 2021–14–12 was prompted by an accident involving a Model AA–5 airplane that occurred on January 19, 2021. During flight, the outboard elevator attach bracket on the horizontal stabilizer detached, causing loss of elevator control and significant damage to the airplane. An investigation identified corrosion and delamination of the airplane skin bondlines around the area of the horizontal stabilizer where the elevator attach bracket was attached. Multiple field reports identified additional instances of corrosion and delamination of skin bondlines around the horizontal stabilizer and other primary structures.

AD 2021–14–12 stated that Model AA–1, AA–1A, AA–1B, AA–1C, and AA–5 airplanes have horizontal stabilizers that are similar in design and use the same metal-to-metal bonding process. While the bond adhesive remains structurally sound throughout the aging process, factors such as corrosion and freezing moisture may compromise the structural integrity of some of the bond joints. This can lead to delamination of the skin from the primary structure. The FAA determined that a more thorough inspection was necessary to reliably identify corrosion and delamination of bondlines in these critical areas, including the horizontal stabilizer. As a result, AD 2021–14–12 requires a one-time inspection of the horizontal stabilizers, paying particular attention to the bondlines, for cracks, buckles, corrosion, delamination, rust, or previous repair.

The FAA issued an NPRM that proposed to amend 14 CFR part 39 by adding an AD for all True Flight Holdings LLC Model AA–1, AA–1A, AA–1B, AA–1C, AA–5, AA–5A, and AA–5B airplanes. The NPRM published in the **Federal Register** on December 1, 2021 (86 FR 68171). In the NPRM, the FAA proposed to require a repetitive inspection of the wings, stabilizers, and aft fuselage for bondline separation, corrosion, and previous repair. While AD 2021–14–12 requires only inspecting the bondlines on the horizontal stabilizers, in the NPRM, the FAA proposed to require inspecting all of the bondlines on the airplane, including the bondlines on the wings and aft fuselage. In the NPRM, the FAA also proposed to add Model AA–5A and AA–5B airplanes to the applicability due to the similar bonded construction of all models.

The original decision to pursue corrective action was based upon multiple field reports, including direct observation of two airplanes, of issues related to inspection of bonded structure. The first was the originating accident airplane, and the second was another same model airplane located in the same hangar as the first airplane. Both of these airplanes exhibited damage (bondline delamination) in an area believed to be the source of the accident, at the attachment of the elevator bearing to the horizontal stabilizer. The construction in this area is similar among the applicable models in AD 2021–14–12. The issue specific to this area was addressed in AD 2021–14–12.

The FAA proposed the NPRM to address inspection for bondline delamination on the entire airplane based on an understanding that standard maintenance actions were insufficient to detect an issue. Because more models than those covered by AD 2021–14–12 share a similar bonded construction for the airplane as a whole, the NPRM proposed to also apply to True Flight Holdings LLC Model AA–5A and AA–5B airplanes.

Comments

The FAA received comments from 41 commenters. The commenters were the Aircraft Owners and Pilots Association (AOPA), the Grumman Owners & Pilots Association (GOPA), Fortnight Aviation Maintenance, and many individual airplane owners and pilots.

All commenters opposed the NPRM. Most commenters stated that the actions proposed in the NPRM are already addressed by existing maintenance practices or included in maintenance documents such as the Grumman maintenance manual, the annual inspection checklist, service bulletins, and AD 2021–14–12. The commenters noted that the January 2021 accident resulted from poor maintenance practices and failure to adequately follow these existing procedures, not from any fault with the procedures themselves. For this reason, some commenters requested the FAA withdraw the NPRM due to lack of supporting data and issue a special airworthiness information bulletin (SAIB) instead.

Several commenters requested that the FAA remove Model AA–5, AA–5A, and AA–5B airplanes from the applicability because these models have a different design than the accident airplane. Many commenters noted that the proposed AD is overly broad because the delamination issue is limited to pre-1977 models manufactured with a ''purple glue'' for adhesive. AOPA, GOPA, and a few individuals stated the proposed requirement to tap test all bondlines on the airplane annually would damage the paint and lead to corrosion. Lastly, AOPA, GOPA, and two individuals requested the FAA increase its estimated labor rate of $85 per hour.

The FAA agrees that the instructions in the airplane maintenance manual are sufficient to detect the type of damage that is believed to have led to the originating accident, as well as similar damage on the rest of the airplane. The FAA further agrees that the original findings were not indicative of an unsafe condition, but instead indicative of incorrectly followed maintenance procedures. Based on this assessment, the proposed inspection in the NPRM would exceed what is sufficient to detect the main issue of bondline delamination. The FAA has determined that additional AD action is not warranted and the proposal should be withdrawn.

The FAA acknowledges the comments unrelated to whether there is an unsafe condition. However, because the FAA is withdrawing the NPRM, those commenters' requests are no longer necessary.

Withdrawal of the NPRM constitutes only such action and does not preclude the FAA from further rulemaking on this issue, nor does it commit the FAA to any course of action in the future.

Regulatory Findings

Since this action only withdraws an NPRM, it is neither a proposed AD nor a final rule. This action, therefore, is not covered under Executive Order 12866 or the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Withdrawal

Accordingly, the notice of proposed rulemaking, Docket No. FAA–2021–1017; Project Identifier AD–2021–00495–A, published in the **Federal Register** on December 1, 2021 (86 FR 68171), is withdrawn.

Issued on April 7, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07871 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA 2022–0460; Project Identifier AD–2021–00824–R]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Inc., Helicopters and Various Restricted Category Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters and various restricted category helicopters. This proposed AD was prompted by reports of cracks found on the main transmission support case. This proposed AD would require repetitive inspections of the main transmission housing assembly for cracks, pitting, and corrosion and depending on the results, corrective action. 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 May 31, 2022.

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 Bell Helicopter service information identified in this AD, contact Bell Textron, Inc., P.O. Box 482, Fort Worth, TX, 76101, United States; phone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; email *productsupport@bellflight.com;* or at *https://www.bellflight.com/support/contact-support.* You may purchase the ASTM International standard from ASTM International at *https://www.astm.org/.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA 2022–0460; 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.

FOR FURTHER INFORMATION CONTACT: Hye Yoon Jang, Aerospace Engineer, Delegation Oversight Section, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5190; email *hye.yoon.jang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA 2022–0460; Project Identifier AD–2021–00824–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

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 Hye Yoon Jang, Aerospace Engineer, Delegation Oversight Section, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5190; email *hye.yoon.jang@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA proposes to adopt a new AD for Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters and the following restricted category helicopters:

- Model HH–1K helicopters; current type certificate holders include but are not limited to Rotorcraft Development Corporation;
- Southwest Florida Aviation International, Inc., Model SW205A–1 helicopters;

• Model TH–1F helicopters; current type certificate holders include but are not limited to Robinson Air Crane Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc.;

• Model TH–1L helicopters; current type certificate holders include but are not limited to Bell Textron Inc.; Overseas Aircraft Support, Inc. (type certificate previously held by JTBAM, Inc.); and Rotorcraft Development Corporation;

• Model UH–1A helicopters; current type certificate holders include but are not limited to Richards Heavylift Helo, Inc.;

• Model UH–1B helicopters; current type certificate holders include but are not limited to International Helicopters, Inc.; Overseas Aircraft Support, Inc.; Red Tail Flying Services, LLC; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc. (helicopters with an SW204 or SW204HP designation are Southwest Florida Aviation International, Inc., Model UH–1B helicopters); and WSH, LLC (type certificate previously held by San Joaquin Helicopters);

• Model UH–1E helicopters; current type certificate holders include but are not limited to Bell Textron Inc.; Overseas Aircraft Support, Inc.; Rotorcraft Development Corporation; Smith Helicopters; and West Coast Fabrications;

• Model UH–1F helicopters; current type certificate holders include but are not limited to AST, Inc.; California Department of Forestry; Robinson Air Crane, Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc.;

• Model UH–1H helicopters; current type certificate holders include but are not limited to Arrow Falcon Exporters Inc.; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC; JJASPP Engineering Services, LLC; Northwest Rotorcraft, LLC; Overseas Aircraft Support, Inc.; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc. (helicopters with an SW205 designation are Southwest Florida Aviation International, Inc., Model UH–1H helicopters); and Tamarack Helicopters, Inc.;

• Model UH–1L helicopters; current type certificate holders include but are not limited to Bell Textron Inc.; Overseas Aircraft Support, Inc.; and Rotorcraft Development Corporation; and

• Model UH–1P helicopters; current type certificate holders include but are not limited to Robinson Air Crane, Inc.; and Rotorcraft Development Corporation.

This proposed AD would require repetitive inspections of the main transmission housing assembly. This proposed AD was prompted by reports of main transmission support cases found cracked at one of the lateral mounts. This condition, if not addressed, could result in cracking at the upper or lower surfaces of the lateral mounts, loss of load carrying capabilities of the main transmission, and subsequent loss of control of the helicopter.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Other Related Service Information

The FAA reviewed Fluorescent Penetrant Inspection Method (ASTM E1417) of Chapter 6—Non-Destructive Inspection, of Bell Helicopter, Standard Practices Manual BHT–ALL–SPM, Revision 8, dated August 30, 2021, and ASTM International Standard Practice for Liquid Penetrant Testing E1417/E1417M–21, dated September 1, 2021 (ASTM E1417). This service information specifies procedures for the fluorescent penetrant inspection.

Proposed AD Requirements in This NPRM

This proposed AD would require, within 3,000 hours time-in-service (TIS) accumulated by the main transmission after the effective date of this proposed AD, and thereafter at intervals not to exceed 3,000 hours TIS accumulated by the main transmission, removing certain screws and washers and visually inspecting the upper and lower transmission support case lateral mount screws for corrosion and thread damage, washers for corrosion and pitting, bushings for corrosion and pitting, and lateral mount surfaces for corrosion and mechanical damage such as any crack or pitting. If there is any corrosion, thread damage, or mechanical damage, this proposed AD would require removing the affected parts from service before further flight.

This proposed AD would also require repetitive fluorescent penetrant inspections (FPIs) of all surfaces of the main transmission support case lateral mounts for a crack. For helicopters with a main transmission that has accumulated 6,000 or more total hours TIS, the initial FPI would be required before further flight after the effective date of this AD. For helicopters with a main transmission that has accumulated less than 6,000 total hours TIS, the initial FPI would be required before the main transmission accumulates 6,000 total hours TIS. For all helicopters, following the initial FPI, this proposed AD would require performing an FPI at intervals not to exceed 6,000 hours TIS accumulated by the main transmission. If there is any crack, this proposed AD would require removing the main transmission support case from service before further flight.

Costs of Compliance

The FAA estimates that this proposed AD would affect up to 621 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Inspecting the main transmission mount assembly would take about 1 work-hour, for an estimated cost of $85 per helicopter and $52,785 for the U.S. fleet, per inspection cycle.

Inspecting the main transmission support case lateral mounts by fluorescent penetrant method would take about 1 work-hour for an estimated cost of $85 per helicopter, and $52,785 for the U.S. fleet, per inspection cycle.

If required, replacing the transmission support case assembly hardware parts including 8 washers, 8 screws, and 4 bushings would take about 1 work-hour and parts would cost up to $100 per part for an estimated cost of up to $2,000 per helicopter.

If required, replacing the main transmission support case assembly would take up to 60 work-hours and parts would cost up to $54,501 for an estimated cost of up to $59,601 per helicopter.

Authority for This Rulemaking

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

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

develop on products identified in this rulemaking action.

Regulatory Findings

The FAA 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) Would not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bell Textron Inc., and Various Restricted Category Helicopters: Docket No. FAA 2022–0460; Project Identifier AD–2021–00824–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 31, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following:

(1) Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters, certificated in any category; and

(2) Various restricted category helicopters:

(i) Model HH–1K helicopters; current type certificate holders include but are not limited to Rotorcraft Development Corporation;

(ii) Southwest Florida Aviation International, Inc. Model SW205A–1 helicopters;

(iii) Model TH–1F helicopters; current type certificate holders include but are not limited to Robinson Air Crane Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc.;

(iv) Model TH–1L helicopters; current type certificate holders include but are not limited to Bell Textron Inc.; Overseas Aircraft Support, Inc. (type certificate previously held by JTBAM, Inc.); and Rotorcraft Development Corporation;

(v) Model UH–1A helicopters; current type certificate holders include but are not limited to Richards Heavylift Helo, Inc.;

(vi) Model UH–1B helicopters; current type certificate holders include but are not limited to International Helicopters, Inc.; Overseas Aircraft Support, Inc.; Red Tail Flying Services, LLC; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc.; and WSH, LLC (type certificate previously held by San Joaquin Helicopters);

Note 1 to paragraph (c)(2)(vi): Helicopters with an SW204 or SW204HP designation are Southwest Florida Aviation International, Inc., Model UH–1B helicopters.

(vii) Model UH–1E helicopters; current type certificate holders include but are not limited to Bell Textron Inc.; Overseas Aircraft Support, Inc.; Rotorcraft Development Corporation; Smith Helicopters; and West Coast Fabrications;

(viii) Model UH–1F helicopters; current type certificate holders include but are not limited to AST, Inc.; California Department of Forestry; Robinson Air Crane, Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc.;

(ix) Model UH–1H helicopters; current type certificate holders include but are not limited to Arrow Falcon Exporters, Inc.; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC; JJASPP Engineering Services LLC; Northwest Rotorcraft, LLC; Overseas Aircraft Support, Inc.; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc.; and Tamarack Helicopters, Inc.;

Note 2 to paragraph (c)(2)(ix): Helicopters with an SW205 designation are Southwest Florida Aviation International, Inc., Model UH–1H helicopters.

(x) Model UH–1L helicopters; current type certificate holders include but are not limited to Bell Textron Inc.; Overseas Aircraft Support, Inc.; and Rotorcraft Development Corporation; and

(xi) Model UH–1P helicopters; current type certificate holders include but are not limited to Robinson Air Crane, Inc.; and Rotorcraft Development Corporation.

(d) Subject

Joint Aircraft System Component (JASC) Code 6320, Main Rotor Gearbox.

(e) Unsafe Condition

This AD was prompted by reports of cracks found in the main transmission support case possibly due to corrosion. The FAA is issuing this AD to detect and address corrosion and other mechanical damage of the main transmission support case assembly. The unsafe condition, if not addressed, could result in cracking at the upper or lower surfaces of the lateral mounts, loss of load carrying capabilities of the main transmission, and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 3,000 hours time-in-service (TIS) accumulated by the main transmission after the effective date of this AD, and thereafter at intervals not to exceed 3,000 hours TIS accumulated by the main transmission, remove the screws and washers from the upper and lower surfaces of the main transmission support case lateral mounts and accomplish the following:

(i) Visually inspect each screw for corrosion and thread damage. If there is any corrosion or thread damage, before further flight, remove the screw from service.

(ii) Visually inspect each upper and lower washer for corrosion and pitting. If there is any corrosion or pitting, before further fight, remove the washer from service.

(iii) Visually inspect each installed bushing for corrosion and pitting. If there is any corrosion or pitting, before further fight, remove the bushing from service.

(iv) Visually inspect each upper and lower main transmission support case lateral mount machined surface adjacent to each washer and each lateral mount threaded screw hole for corrosion and mechanical damage. For the purposes of this AD, mechanical damage may be indicated by a crack or pitting. If there is any corrosion or mechanical damage, before further flight, remove the main transmission support case assembly from service.

(2) Fluorescent penetrant inspect (FPI) all surfaces of the main transmission support case lateral mounts for a crack at the compliance times identified in paragraph (g)(2)(i) or (ii) of this AD.

(i) For helicopters with a main transmission that has accumulated 6,000 or more total hours TIS, before further flight after the effective date of this AD.

(ii) For helicopters with a main transmission that has accumulated less than 6,000 total hours TIS, before accumulating 6,000 total hours TIS on the main transmission after the effective date of this AD.

(iii) If there is any crack, before further flight, remove the main transmission support case assembly from service.

Note 3 to paragraph (g)(2): This note applies to paragraphs (g)(2) and (3) of this AD. ASTM International Standard Practice for Liquid Penetrant Testing E1417/E1417M–21, dated September 1, 2021 (ASTM E1417) provides additional information regarding and is an acceptable method for the fluorescent penetrant inspection.

(3) Thereafter following paragraph (g)(2) of this AD, at intervals not to exceed 6,000 hours TIS accumulated by the main

transmission, FPI all surfaces of the main transmission support case lateral mounts for a crack. If there is any crack, before further flight, remove the main transmission support case assembly from service.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, DSCO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. Information may be emailed to: *9-ASW-190-COS@faa.gov.*

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

(i) Related Information

(1) For more information about this AD, contact Hye Yoon Jang, Aerospace Engineer, Delegation Oversight Section, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5190; email *hye.yoon.jang@faa.gov.*

(2) For ASTM service information identified in this AD, you may purchase the ASTM standard from ASTM International at *https://www.astm.org/.* 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.

Issued on April 7, 2022.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07887 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0459; Project Identifier MCAI–2021–00266–E]

RIN 2120–AA64

Airworthiness Directives; GE Aviation Czech s.r.o. (Type Certificate Previously Held by WALTER Engines a.s., Walter a.s., and MOTORLET a.s.) Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all GE Aviation Czech s.r.o. (GEAC) M601D–11 model turboprop engines. This proposed AD was prompted by the manufacturer revising the airworthiness limitation section (ALS) of the existing engine maintenance manual (EMM) to include a visual inspection of the centrifugal compressor case for cracks. This proposed AD would require revising the ALS of the existing EMM to incorporate a visual inspection of the centrifugal compressor case. 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 May 31, 2022.

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

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

For service information identified in this NPRM, contact GE Aviation Czech, Beranových 65, 199 02 Praha 9—Letňany, Czech Republic; phone: +420 222 538 999; email: *tp.ops@ge.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0459; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0459; Project Identifier MCAI–2021–00266–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

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 Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0060, dated March 3, 2021 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

The airworthiness limitations for certain M601 engine models, which are approved by

EASA, are currently defined and published in the ALS. These instructions have been identified as mandatory for continued airworthiness.

Failure to accomplish these instructions could result in an unsafe condition.

Recently, GEAC published the ALS, as defined in this [EASA] AD, introducing a visual inspection of the Centrifugal Compressor Case.

For the reason described above, this [EASA] AD requires accomplishment of the actions specified in the ALS.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0459.

FAA's Determination

This product has been approved by EASA and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA of the unsafe condition described in the MCAI and service information. The FAA is proposing this AD because the agency evaluated all the relevant information provided by EASA and has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information

The FAA reviewed GE Aviation Czech Airworthiness Limitations R18, Section 5. Mandatory Inspections, of the GE Aviation Czech EMM, Part No. 0982309, Revision No. 18, dated December 18, 2020 (Airworthiness Limitations R18, Section 5. Mandatory Inspections). Airworthiness Limitations R18, Section 5. Mandatory Inspections, of the EMM specifies procedures for performing a visual inspection of the centrifugal compressor case for cracks.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the ALS of the existing EMM to incorporate a visual inspection of the centrifugal compressor case for cracks. An owner/operator (pilot) holding at least at least a private pilot certificate may revise the ALS of the existing EMM, and the owner/operator must enter compliance with the applicable paragraphs of the AD into the aircraft records in accordance with 14 CFR 43.9(a)(1) through (4) and 14 CFR 91.417(a)(2)(v). This is an exception to the FAA's standard maintenance regulations.

Differences Between This Proposed AD and the MCAI or Service Information

The MCAI specifies replacing each component before exceeding the applicable life limit and accomplishing all the applicable maintenance tasks within the thresholds and intervals, as defined in the ALS. This proposed AD would require revising the ALS of the existing EMM to incorporate a visual inspection of the centrifugal compressor case. The MCAI specifies that if discrepancies are found during the accomplishment of the EASA AD, to accomplish corrective actions in accordance with existing GEAC instructions. The MCAI also specifies to contact GEAC for approved instructions if a detected discrepancy cannot be corrected using existing GEAC instruction. This proposed AD would not require performing corrective actions in accordance with existing GEAC instructions or contacting GEAC for approved instructions. The MCAI specifies revising the aircraft maintenance program within 12 months from its effective date. This proposed AD would require revising the ALS of the existing EMM to incorporate a visual inspection of the centrifugal compressor case within 90 days after the effective date of this proposed AD.

The MCAI and GE Aviation Czech Airworthiness Limitations R18, Section 5. Mandatory Inspections, apply to GEAC M601D–1, M601D–2, M601D–11, M601D–11NZ, and M601Z model turboprop engines. This proposed AD would not apply to GEAC M601D–1, M601D–2, M601D–11NZ, and M601Z model turboprop engines because these model turboprop engines do not have an FAA type certificate.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 7 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise the ALS of the EMM	1 work-hour × $85 per hour = $85	$0	$85	$595

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) Would not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

GE Aviation Czech s.r.o (Type Certificate previously held by WALTER Engines a.s., Walter a.s., and MOTORLET a.s.): Docket No. FAA–2022–0459; Project Identifier MCAI–2021–00266–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 31, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to GE Aviation Czech s.r.o. M601D–11 model turboprop engines.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by the manufacturer revising the airworthiness limitation section (ALS) of the existing engine maintenance manual (EMM) to include a visual inspection of the centrifugal compressor case for cracks. The FAA is issuing this AD to prevent failure of the centrifugal compressor case. The unsafe condition, if not addressed, could result in failure of the centrifugal compressor case, engine separation, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

(1) Within 90 days after the effective date of this AD, revise the ALS of the existing EMM by incorporating Figure 1 to paragraph (g)(1) of this AD.

BILLING CODE 4910–13–P

Figure 1 to Paragraph (g)(1) – Visual Inspection of the Centrifugal Compressor Case

5. Mandatory Inspections

5.1 Visual inspection of Centrifugal Compressor Case

Accomplishment Instruction

Do a visual inspection of the compressor case in the specified areas, shown in Figure 1, for every 100±10 Flight Hours. Use magnifying lens 10x for inspection. No visible cracks are allowed.

Equipment:

The following equipment is required and may be obtained as shown:

- A 150-watt standard spotlight or 40-watt high intensity spotlight or alternative (Commercial) to acquire necessary illumination at minimum 1000lux.
- Magnification equipment 10x (Commercial).

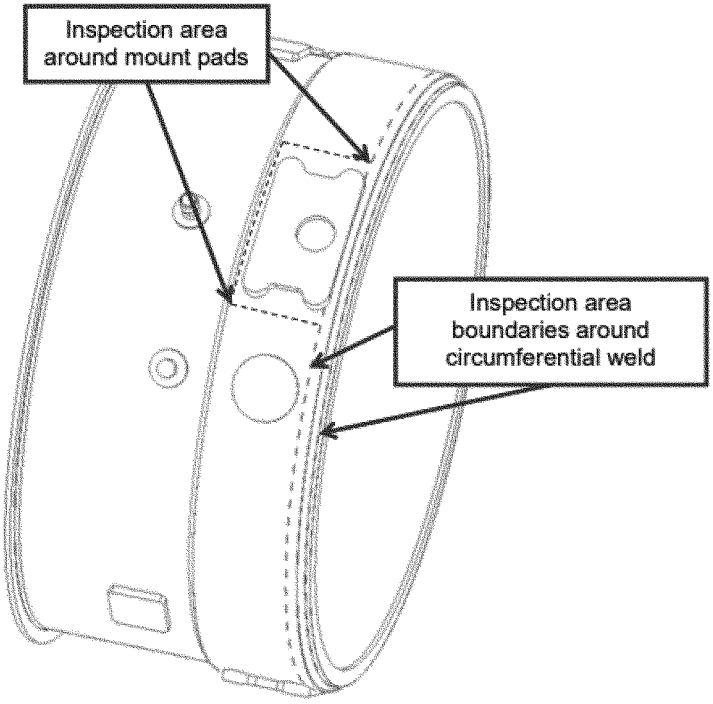

Figure 1. Centrifugal Compressor Case

(2) After revising the ALS of the existing EMM required by paragraph (g)(1) of this AD, no alternative inspection intervals may be used unless they are approved as provided in paragraph (h) of this AD.

(3) The action required by paragraph (g)(1) of this AD may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1) through (4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

(1) For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2021–0060, dated March 3, 2021, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2022–0459.

Issued on April 8, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–08005 Filed 4–13–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0511; Project Identifier AD–2020–01229–E]

RIN 2120–AA64

Airworthiness Directives; Williams International Co., L.L.C. Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: The FAA is revising a notice of proposed rulemaking (NPRM) that applied to certain Williams International Co., L.L.C. (Williams) FJ44–2A, FJ44–2C, FJ44–3A, and FJ44–3A–24 model turbofan engines. This action revises the NPRM by expanding the applicability, updating the estimated costs information, updating the compliance time, and adding an installation prohibition. This action also revises the NPRM by updating the service information references. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions would impose an additional burden over those in the NPRM, the agency is requesting comments on this SNPRM.

DATES: The FAA must receive comments on this SNPRM by May 31, 2022.

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

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

For service information identified in this SNPRM, contact Williams International, Product Support, 2000 Centerpoint Parkway, Pontiac, MI 48341; phone: (800) 859–3544; website: *http://www.williams-int.com/product-support.* You may view this service information at the FAA, Chicago ACO, 2300 East Devon Avenue, Des Plaines, IL 60018. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0511; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this SNPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Kyle Bush, Aviation Safety Engineer, Chicago ACO, FAA, 2300 East Devon Avenue, Des Plaines, IL 60018; phone: (847) 294–7870; email: *kyle.bush@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0511; Project Identifier AD–2020–01229–E'' at the beginning of your comments.

The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may again revise this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed 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 SNPRM 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 SNPRM, 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 SNPRM. Submissions containing CBI should be sent to Kyle Bush, Aviation Safety Engineer, Chicago ACO, FAA, 2300 East Devon Avenue, Des Plaines, IL 60018. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to Williams FJ44–2A, FJ44–2C, FJ44–3A, and FJ44–3A–24 model turbofan engines. The NPRM published in the **Federal Register** on June 25, 2021 (86 FR 33579). The NPRM was prompted by a report of cracks in the high-pressure turbine (HPT) disk posts and failure of an HPT disk post, resulting in the contained fracture of an HPT disk post and blade. Williams initiated an investigation to understand the root cause of the cracks and to determine the necessary corrective action. Metallurgical evaluation showed cracking related to intergranular oxidation related to HPT disk post metal temperatures.

As a result of this investigation, Williams determined the root cause of this cracking was due to higher HPT disk post temperatures and a difference in manufacturing processes. Williams determined that these cracks have only occurred on HPT disks with part number (P/N) 67093 installed on FJ44–2A or FJ44–2C model turbofan engines. Williams subsequently published service information specifying procedures to remove the HPT disk, P/N 67093. In the NPRM, the FAA proposed to require removing the HPT disk, P/N 67093, from service before reaching its new life limit and replacing it with a part eligible for installation.

Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, Williams notified the FAA that revised service information was available. The revised service information, Williams International Service Bulletin (SB) WISB–72–1032, Revision 2, dated June 4, 2020, adds additional serial-numbered FJ44–2A, FJ44–2C, and FJ44–3A model turbofan engines to the effectivity and updates the compliance time for replacing the HPT disk. The FAA determined that the additional

serial-numbered FJ44–2A, FJ44–2C, and FJ44–3A model turbofan engines are susceptible to the same unsafe condition. Therefore, the FAA revised the applicability of this proposed AD to include FJ44–2A, FJ44–2C, FJ44–3A, and FJ44–3A–24 model turbofan engines with an engine serial number identified in paragraph 1.A., Effectivity, of Williams International SB WISB–72–1032, Revision 2, dated June 4, 2020, with an installed HPT disk, P/N 67093. In addition, the FAA revised the estimated number of affected engines installed on airplanes of U.S. registry from 213 engines to 242 engines, updated the compliance time specified in Table 1 to Paragraph (g), and added an installation prohibition paragraph to this proposed AD. Finally, the FAA revised all references to the service information in this AD.

Comments

The FAA received a comment from one commenter on the NPRM, Williams. The following presents the comment received on the NPRM and the FAA's response to the comment.

Request That the NPRM Reflect Current Service Document Revisions

Williams requested that the NPRM be revised to reflect the specified procedures of the current service document revisions, Williams International SB WISB–72–1032, Revision 2, dated June 4, 2020, and Williams International SB WISB–72–1034, Revision 3, dated July 2, 2021.

The FAA agrees. The FAA has revised this proposed AD to include Williams International SB WISB–72–1032, Revision 2, dated June 4, 2020, and Williams International SB WISB–72–1034, Revision 3, dated July 2, 2021.

Other Differences Between This SNPRM and the NPRM

In this SNPRM, the FAA has replaced the term ''life limit'' with ''defined life cycles,'' where appropriate. In this SNPRM, the FAA has replaced all instances of ''resulting in the release of an HPT blade'' to ''resulting in the contained fracture of an HPT disk post and blade.''

FAA's Determination

The FAA is proposing this AD after determining the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of the NPRM. As a result, it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Williams International SB WISB–72–1032, Revision 2, dated June 4, 2020. This service information specifies procedures for removing and replacing the HPT rotor assemblies that include HPT disk, P/N 67093. The service information also provides instructions for incorporating the latest HPT combustor/fuel slinger module on FJ44–2A and FJ44–2C model turbofan engines. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Other Related Service Information

The FAA reviewed Williams International SB WISB–72–1034, Revision 3, dated July 2, 2021. This service information describes procedures for re-identifying the HPT rotor assembly and HPT disk.

Proposed AD Requirements in This SNPRM

This proposed AD would require removing the HPT disk, P/N 67093, from service before reaching defined cycle limits and replacing it with a part eligible for installation.

Differences Between This SNPRM and the Service Information

The Accomplishment Instructions, paragraph 2.D., of Williams International SB WISB–72–1032, Revision 2, dated June 4, 2020, specifies procedures for replacing or reworking the HPT combustor/fuel slinger module on FJ44–2A and FJ44–2C model turbofan engines, while this proposed AD would not mandate that action. The FAA has determined that replacement or rework of the HPT combustor/fuel slinger module is not necessary to resolve the unsafe condition in this proposed AD.

The Accomplishment Instructions, paragraphs 2.C. and E. and 3.C. and D., of Williams International SB WISB–72–1032, Revision 2, dated June 4, 2020, specify procedures for removing and replacing the HP turbine rotor assembly containing HPT disk, P/N 67093, whereas this proposed AD would mandate removing and replacing the HPT disk, P/N 67093. Although removing the HPT rotor assembly is a necessary step in the replacement of the HPT disk, this proposed AD only requires replacement of the HPT disk to resolve the unsafe condition addressed by this proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 242 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Remove and replace the HPT disk.	33 work-hours × $85 per hour = $2,805	$16,694	$19,499	$4,718,758

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

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) Would not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Williams International Co., L.L.C.: Docket No. FAA–2021–0511; Project Identifier AD–2020–01229–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 31, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Williams International Co., L.L.C. (Williams) FJ44–2A, FJ44–2C, FJ44–3A, and FJ44–3A–24 model turbofan engines with an engine serial number identified in paragraph 1.A., Effectivity, of Williams International Service Bulletin WISB–72–1032, Revision 2, dated June 4, 2020 (the SB), with an installed high-pressure turbine (HPT) disk, part number (P/N) 67093.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by a report of cracks in the HPT disk posts and failure of an HPT disk post, resulting in the contained fracture of an HPT disk post and blade. The FAA is issuing this AD to prevent cracking and failure of the HPT disk posts. The unsafe condition, if not addressed, could result in release of the HPT blade, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) For FJ44–2A and FJ44–2C model turbofan engines, within the compliance times specified in Table 1 to Paragraph (g) of this AD, remove the affected HPT disk from service and replace it with a part eligible for installation using paragraphs 2.C. and E., Accomplishment Instructions—FJ44–2A & FJ44–2C, of the SB.

(2) For FJ44–3A and FJ44–3A–24 model turbofan engines, within the compliance times specified in Table 1 to Paragraph (g) of this AD, remove the affected HPT disk from service and replace it with a part eligible for installation using paragraphs 3.C. and D., of the SB.

Table 1 to Paragraph (g) – Compliance Time

HPT disk, P/N 67093, cycles since new (CSN) as of the effective date of this AD	Replace within HPT disk cycles after the effective date of this AD
0 to 999 CSN	620
1,000 to 1,999 CSN	530
2,000 to 2,999 CSN	245
3,000 or higher CSN	130

(h) Installation Prohibition

After the effective date of this AD, do not install onto any engine an HPT disk with P/N 67093.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Chicago ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD.

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

(j) Related Information

(1) For more information about this AD, contact Kyle Bush, Aviation Safety Engineer, Chicago ACO, FAA, 2300 East Devon Avenue, Des Plaines, IL 60018; phone: (847) 294–7870; email: *kyle.bush@faa.gov.*

(2) For service information identified in this AD, contact Williams International, Product Support, 2000 Centerpoint Parkway, Pontiac, MI 48341; phone: (800) 859–3544; website: *http://www.williams-int.com/product-support.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

Issued on April 7, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07822 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0457; Project Identifier MCAI–2022–00263–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus SAS Model A318 series airplanes, Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. This proposed AD was prompted by a report that cracks were found on the web horizontal flange and inner cap on frame (FR) 68, left-hand (LH) and right-hand (RH) side, at stringer (STGR) 22. This proposed AD would require repetitive high frequency eddy current (HFEC) inspections for cracks on the web horizontal flange and inner cap on FR 68, LH and RH side at STGR 22, and applicable corrective actions, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 31, 2022.

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 that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* 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. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0457.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0457; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0457; Project Identifier MCAI–2022–00263–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. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

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 should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0030, dated February 25, 2022 (EASA AD 2022–0030) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus SAS Model A318–111, A318–112, A318–121, A318–122, A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A320–211, A320–212, A320–214, A320–215, A320–216, A320–231, A320–232, A320–233, A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231 and A321–232 airplanes.

Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by a report that during the inspection for the door stop fitting holes at FR 66 and FR 68 required by EASA AD 2016–0238, dated December 2, 2016; corrected January 4, 2017 (which corresponds to FAA AD 2018–03–12, Amendment 39–19185 (83 FR 5906, February 12, 2018), cracks were found on web horizontal flange and inner cap on FR 68, LH and

RH sides, at STGR 22. The FAA is proposing this AD to address the cracks on web horizontal flange and inner cap on FR 68, LH and RH sides, at STGR 22, which could result in reduced structural integrity of the fuselage. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0030 specifies procedures for repetitive HFEC inspections for cracks at the web horizontal flange and inner cap on FR 68, LH and RH sides, at STGR 22, and applicable corrective actions (*e.g.,* repairs). 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

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2022–0030 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2022–0030 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0030 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 EASA AD 2022–0030 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 EASA AD 2022–0030. Service information required by EASA AD 2022–0030 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0457 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD would affect 1,585 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
28 work-hours × $85 per hour = $2,380	$0	$2,380	$3,772,300

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this proposed 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 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) Would not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2022–0457; Project Identifier MCAI–2022–00263–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 31, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS airplanes specified in paragraphs (c)(1) through (4) of

this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2022–0030, dated February 25, 2022 (EASA AD 2022–0030).

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

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

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

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 53, fuselage.

(e) Unsafe Condition

This AD was prompted by a report that cracks were found on web horizontal flange and inner cap on frame (FR) 68, left-hand (LH) and right-hand (RH) sides, at stringer (STGR) 22. The FAA is issuing this AD to address the cracks on web horizontal flange and inner cap on FR 68, LH and RH sides, at STGR 22, which could result in reduced structural integrity of the fuselage.

(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 2022–0030.

(h) Exceptions to EASA AD 2022–0030

(1) Where EASA AD 2022–0030 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2022–0030 does not apply to this AD.

(3) Where paragraph (2) of EASA AD 2022–0030 specifies ''Accomplishment on an aeroplane of (repetitive) maintenance instructions, issued and approved by Airbus,'' for this AD, those instructions must have been approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) Where paragraph (3) of EASA AD 2022–0030 specifies if ''discrepancies and/or cracks are detected, before next flight, contact Airbus for approved corrective action(s) instructions and, within the compliance time specified therein, accomplish those instructions accordingly,'' for this AD, if cracks are detected, the cracks must be repaired before further flight using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(5) Where paragraph (4) of EASA AD 2022–0030 specifies ''the instructions provided by Airbus,'' for this AD, those instructions must be approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch of the certification office, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

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

(j) Related Information

(1) For EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* 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 at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0457.

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

Issued on April 7, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07857 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0290; Project Identifier AD–2021–01266–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. This proposed AD was prompted by a report from Boeing that Rolls-Royce Deutschland Ltd & Co KG (RRD) discovered a design issue in the engine fuel feed system, which could result in fuel flow restrictions to both engines when ice that has accumulated in the airplane fuel feed system suddenly releases into the engines. This proposed AD would require revising the existing airplane flight manual (AFM) to update the limitations on minimum fuel temperatures. 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 May 31, 2022.

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.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No.

FAA–2022–0290; 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.

FOR FURTHER INFORMATION CONTACT: Tak Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3553; email: *Takahisa.Kobayashi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0290; Project Identifier AD–2021–01266–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. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

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 Takahisa Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3553; email: *Takahisa.Kobayashi@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA has received a report from Boeing that affects certain Model 787–8, 787–9, and 787–10 airplanes, with RRD Model Trent 1000 engines installed. RRD discovered and reported to Boeing that a design issue in the engine fuel feed system could result in fuel flow restrictions to both engines when ice that has accumulated in the airplane fuel feed system suddenly releases into the engines. The sudden release of accumulated ice into the engine fuel feed system, in combination with low fuel temperatures, could cause freezing temperatures at the inlet of certain engine fuel feed system components. This condition, if not addressed, could result in fuel flow restrictions to both engines, causing a potential loss of dual engine thrust control and reduced controllability of the airplane.

Explanation of Applicability

The applicability of this proposed AD includes additional designations for RRD Model Trent 1000 engines not explicitly identified on the model list of the FAA Type Certificate Data Sheet (TCDS) Number E00076EN, but are identified on the EASA TCDS EASA.E.036. The parenthetical text included in paragraph (c) of this proposed AD is an additional identifier for RRD Model Trent 1000 engines that specifies certain build standards have been incorporated on the engine. The designation of ''/01'' identifies RRD Model Trent 1000 engines on which Service Bulletin 72–G319 has been incorporated, and ''/01A'' identifies RRD Model Trent 1000 engines on which Service Bulletin 72–G893 has been incorporated.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the existing AFM to update the limitations on minimum fuel temperatures.

Compliance With AFM Revisions

Section 91.9 prohibits any person from operating a civil aircraft without complying with the operating limitations specified in the AFM. FAA regulations also require operators to furnish pilots with any changes to the AFM (14 CFR 121.137) and pilots in command to be familiar with the AFM (14 CFR 91.505).

Interim Action

The FAA considers this proposed AD interim action. Boeing is currently working with RRD to develop updated electronic engine control (EEC) software, which will change the engine oil temperature amber line indicated in the engine indication and crew alerting system (EICAS). This change will ensure that, before takeoff, the engine oil temperature would be warm enough to operate the engine with cold fuel. The updated EEC software combined with the action required by this proposed AD will address the unsafe condition identified in this AD. Once this software is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 14 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revising the existing AFM	1 work-hour × $85 per hour = $85	$0	$85	$1,190

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) Would not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2022–0290; Project Identifier AD–2021–01266–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 31, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8, 787–9, and 787–10 airplanes, certificated in any category, with Rolls-Royce Deutschland Ltd & Co KG Model Trent 1000–A (including –A/01 and –A/01A), Trent 1000–A2, Trent 1000–AE (including –AE/01A), Trent 1000–AE2, Trent 1000–AE3, Trent 1000–C (including –C/01 and –C/01A), Trent 1000–C2, Trent 1000–CE (including –CE/01A), Trent 1000–CE2, Trent 1000–CE3, Trent 1000–D (including –D/01 and –D/01A), Trent 1000–D2, Trent 1000–D3, Trent 1000–E (including –E/01 and –E/01A), Trent 1000–E2, Trent 1000–G (including –G/01 and –G/01A), Trent 1000–G2, Trent 1000–G3, Trent 1000–H (including –H/01 and –H/01A), Trent 1000–H2, Trent 1000–H3, Trent 1000–J2, Trent 1000–J3, Trent 1000–K2, Trent 1000–K3, Trent 1000–L2, Trent 1000–L3, Trent 1000–M3, Trent 1000–N3, Trent 1000–P3, Trent 1000–Q3, or Trent 1000–R3 engines installed.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by a report from Boeing that Rolls-Royce Deutschland Ltd & Co KG discovered a design issue in the engine fuel feed system, which could result in fuel flow restrictions to both engines when ice that has accumulated in the airplane fuel feed system suddenly releases into the engines. The sudden release of accumulated ice into the engine fuel feed system, in combination with low fuel temperatures, could cause freezing temperatures at the inlet of certain engine fuel feed system components. The FAA is issuing this AD to address possible fuel flow restrictions to both engines, which could result in loss of dual engine thrust control and reduced controllability of the airplane.

(f) Compliance

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

(g) Airplane Flight Manual (AFM) Revision

Within 30 days after the effective date of this AD, revise the existing AFM to incorporate the information specified in figure 1 to paragraph (g) of this AD into the ''Certificate Limitations'' chapter of the applicable Engine Appendix of the existing AFM.

Figure 1 to paragraph (g) – *Fuel System – Minimum Tank Fuel Temperature*

FUEL SYSTEM

(REQUIRED BY AD **-**-**)**

The fuel tank temperature limits below must be followed, even when using fuel system icing inhibitor:

- Prior to takeoff, the tank fuel temperature must be at -28 °C or warmer.
- In-flight, the tank fuel temperature must be maintained at -28 °C or warmer, as well as 3 °C above the freezing point of the fuel being used.

(h) Alternative Methods of Compliance (AMOCs)

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

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(i) Related Information

For more information about this AD, contact Tak Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3553; email: *Takahisa.Kobayashi@faa.gov.*

Issued on March 17, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07903 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0403; Airspace Docket No. 22–AEA–6]

Proposed Revocation of Class E Airspace and Proposed Amendment of Class E Airspace; Honesdale, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove Class E airspace in Honesdale, PA, as Spring Hill Airport has been abandoned, and controlled airspace is no longer required. This action would also amend Class E airspace extending upward from 700 feet above the surface for Cherry Ridge Airport, and update the airport's geographic coordinates to coincide with the FAA's database. This action would enhance the safety and management of controlled airspace within the national airspace system.

DATES: Comments must be received on or before May 31, 2022.

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–2022–0403; Airspace Docket No. 22–AEA–6, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, 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.

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 proposed 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 remove Class E airspace extending upward from 700 feet above the surface at Spring Hill Airport, due to the closing of the airport, and amend Class E airspace extending upward from 700 feet above the surface at Cherry Ridge Airport, Honesdale, PA, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this rule 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–2021–0403 and Airspace Docket No. 22–AEA–6) and be submitted in triplicate to the DOT Docket Operations (see **ADDRESSES** section for 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–2021–0403; Airspace Docket No. 22–AEA–6.'' 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. 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 telephone 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F 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 14 CFR 71 to remove Class E airspace extending upward from 700 feet above the surface at Spring Hill Airport, as the airport has closed. Therefore, the airspace is no longer necessary. This action would also amend Class E airspace extending upward from 700 feet above the surface at Cherry Ridge Airport, Honesdale, PA, by removing Wilkes-Barre VORTAC from the description, as it is no longer necessary. This action would also update the geographic coordinates of Cherry Ridge Airport to coincide with the FAA's database. This action would enhance the safety and management of controlled airspace within the national airspace system.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 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 would 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA PA E5 Honesdale, PA [Amended]

Cherry Ridge Airport, PA
(Lat. 41°30′56″ N, long. 75°15′06″ W)
Honesdale Sports Complex Heliport Point in Space Coordinates
(Lat. 41°34′11″ N, long. 75°14′49″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Cherry Ridge Airport, and that airspace within a 6-mile radius of the point in space coordinates serving the Honesdale Sports Complex Heliport.

Issued in College Park, Georgia, on April 7, 2022.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–07969 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–13–P

POSTAL SERVICE

39 CFR Part 20

International Mailing Services: Proposed Price Changes

AGENCY: Postal Service™.

ACTION: Proposed rule; request for comments.

SUMMARY: The Postal Service proposes to revise *Mailing Standards of the United States Postal Service,* International Mail Manual (IMM®), to reflect changes coincident with the recently announced mailing services price adjustments.

DATES: We must receive your comments on or before May 16, 2022.

ADDRESSES: Mail or deliver comments to the manager, Product Classification, U.S. Postal Service®, 475 L'Enfant Plaza SW, RM 4446, Washington, DC 20260–5015. You may inspect and photocopy all written comments at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor N, Washington, DC by appointment only between the hours of 9 a.m. and 4 p.m., Monday through Friday by calling 1–202–268–2906 in advance. Email comments, containing the name and address of the commenter, to: *PCFederalRegister@usps.gov,* with a subject line of ''July 2022 International Mailing Services Proposed Price Changes.'' Faxed comments are not accepted. All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Kathy Frigo at 202–268–4178 or Dale Kennedy at 202–268–6592.

SUPPLEMENTARY INFORMATION:

International Price and Service Adjustments

On April 6, 2022, the Postal Service filed a notice of mailing services price adjustments with the Postal Regulatory Commission (PRC), effective on July 10, 2022. The Postal Service proposes to revise Notice 123, *Price List,* available on Postal Explorer® at *https://pe.usps.com,* to reflect these new price changes. The new prices are or will be available under Docket Number R2022–1 on the Postal Regulatory Commission's website at *www.prc.gov.*

This proposed rule describes the price changes for the following market dominant international services:

- First-Class Mail International (FCMI) service.

• International extra services and fees.

First-Class Mail International

The Postal Service plans to increase prices for single-piece FCMI postcards, letters, and flats by approximately 7.4%. The proposed price for a single-piece postcard will be $1.40 worldwide. The First-Class Mail International letter nonmachinable surcharge will increase to $0.39. The proposed FCMI single-piece letter and flat prices will be as follows:

LETTERS

Weight not over (oz.)	Price groups			
	1	2	3–5	6–9
1	$1.40	$1.40	$1.40	$1.40
2	1.40	2.11	2.62	2.42
3	1.97	2.80	3.82	3.45
3.5	2.54	3.50	5.04	4.46

FLATS

Weight not over (oz.)	Price groups			
	1	2	3–5	6–9
1	$2.75	$2.75	$2.75	$2.75
2	3.03	3.60	3.90	3.85
3	3.29	4.40	5.03	4.91
4	3.52	5.23	6.18	5.98
5	3.78	6.05	7.31	7.05
6	4.03	6.86	8.44	8.13
7	4.29	7.69	9.58	9.19
8	4.54	8.50	10.70	10.26
12	5.80	10.26	12.98	12.48
15.994	7.05	12.03	15.25	14.68

International Extra Services and Fees

The Postal Service plans to increase prices for certain market dominant international extra services including:

- Certificate of Mailing
- Registered Mail™
- Return Receipt
- Customs Clearance and Delivery Fee
- International Business Reply™ Mail Service

CERTIFICATE OF MAILING

Individual pieces:	
Individual article (PS Form 3817)	$1.75
Duplicate copy of PS Form 3817 or PS Form 3665 (per page)	1.75
Firm mailing sheet (PS Form 3665), per piece (minimum 3) First-Class Mail International only	0.50
Bulk quantities:	
For first 1,000 pieces (or fraction thereof)	9.95
Each additional 1,000 pieces (or fraction thereof)	1.30
Duplicate copy of PS Form 3606	1.75

Registered Mail

Fee: $18.25.

Return Receipt

Fee: $5.05.

Customs Clearance and Delivery

Fee: per piece $7.50.

International Business Reply Service

Fee: Cards $1.90; Envelopes up to 2 ounces $2.40.

Following the completion of Docket No. R2022–1, the Postal Service will adjust the prices for products and services covered by the International Mail Manual. These prices will be on Postal Explorer at *pe.usps.com.*

Accordingly, although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites public comment on the proposed changes to *Mailing Standards of the United States Postal Service,* International Mail Manual (IMM®), set out in this **SUPPLEMENTARY INFORMATION**, which is incorporated by reference in the *Code of Federal Regulations* in accordance with 39 CFR 20.1, and to associated changes to Notice 123, *Price List.*

The Postal Service will publish an appropriate update to Notice 123, *Price List* of the IMM, to reflect these changes following the completion of the notice and comment period for this proposed rule. The Postal Service annually publishes an amendment to 39 CFR part 20 to finalize updates to the IMM.

Sarah E. Sullivan,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2022–07706 Filed 4–13–22; 4:15 pm]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0754; FRL–9514–01–R9]

Air Plan Approvals; California; South Coast Air Quality Management District, Imperial and Ventura County Air Pollution Control Districts; Nonattainment New Source Review; 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve three state implementation plan (SIP) revisions submitted by the State of California addressing the nonattainment new source review (NNSR) requirements for the 2015 8-hour ozone National Ambient Air Quality Standards

(NAAQS). These SIP revisions address the South Coast Air Quality Management District (SCAQMD or ''District''), Imperial County Air Pollution Control District (ICAPCD or ''District''), and Ventura County Air Pollution Control District (VCAPCD or ''District'') portions of the California SIP. This action is being taken pursuant to the Clean Air Act (CAA or ''Act'') and its implementing regulations.

DATES: Comments must be received on or before May 16, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2021–0754, at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Amita Muralidharan, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4140 or by email at *muralidharan.amita@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Background and Purpose

On October 26, 2015, the EPA promulgated a revised 8-hour ozone NAAQS of 0.070 parts per million (ppm).[1] Upon promulgation of a new or revised NAAQS, the CAA requires the EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data. This action relates to three California air districts that were designated nonattainment for the 2015 8-hour ozone NAAQS on June 4, 2018.[2]

Within the SCAQMD, the South Coast Air Basin was classified as an Extreme ozone nonattainment area and the Coachella Valley Air Basin was classified as a Severe ozone nonattainment area. Within the ICAPCD, Imperial County was classified as a Marginal ozone nonattainment area. Within the VCAPCD, the part of Ventura County excluding the Channel Islands of Anacapa and San Nicolas Islands was classified as a Serious nonattainment area.

On December 6, 2018, the EPA issued a final rule entitled ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements'' (''2015 SIP Requirements Rule'') that establishes the requirements and deadlines that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where ozone concentrations exceed the 2015 8-hour ozone NAAQS.[3] Based on the initial nonattainment designations for the 2015 8-hour ozone standards, each district was required to make a SIP revision addressing NNSR no later than August 3, 2021.[4] This requirement may be met by submitting a SIP revision consisting of a new or revised NNSR permit program, or an analysis demonstrating that the existing SIP-approved NNSR permit program meets the applicable 2015 ozone requirements and a letter certifying the analysis.

II. The State's Submittal

A. What did the State submit?

Table 1 lists the dates the submitted 2015 Ozone Certification letters addressed by this proposal were adopted by each air district and submitted by the California Air Resources Board (CARB), the agency that serves as the governor's designee for California SIP submittals.

TABLE 1—SUBMITTED CERTIFICATION LETTERS

District	Adoption date	Submittal date	Cover letter date
South Coast AQMD	6/4/2021	8/3/2021	8/3/2021
Imperial County APCD	6/22/2021	8/3/2021	8/3/2021
Ventura County APCD	6/8/2021	8/3/2021	8/3/2021

CARB's August 3, 2021, submittal of the SCAQMD, ICAPCD, and VCAPCD 2015 Certification letters were deemed by operation of law on February 3, 2022, to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

B. What is the purpose of the submitted certification letters?

The submittal from each district is intended to satisfy the 2015 SIP Requirement Rule that requires states to

[1] 80 FR 65292 (October 26, 2015).

[2] 83 FR 25776 (June 4, 2018).

[3] 83 FR 62998 (December 6, 2018). The 2015 SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2015 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP.

[4] 40 CFR 51.1314.

make a SIP revision addressing nonattainment new source review. The SIP for each district currently contains approved NNSR permit programs based on their nonattainment classification for the 2008 8-hour ozone NAAQS. The submitted certification letters provide a mechanism for each district to satisfy the 40 CFR 51.1314 submittal requirements based on their 2015 8-hour ozone nonattainment designations. The EPA's analysis of how these SIP revisions address the NNSR requirements for the 2015 8-hour ozone NAAQS is provided below.

III. Analysis of Nonattainment New Source Review Requirements

NNSR is a preconstruction review permit program that applies to new major stationary sources or major modifications at existing sources within a nonattainment area and is required under CAA sections 172(c)(5) and 173.

As mentioned in Section I of this document, NNSR permit program requirements were adopted for the 2015 ozone NAAQS at 40 CFR 51.1314 by the implementation rule for the 2015 8-hour ozone NAAQS.[5] The minimum SIP requirements for NNSR permitting programs for the 2015 8-hour ozone NAAQS are contained in 40 CFR 51.165. These NNSR program requirements include those promulgated in the 2015 SIP Requirements Rule implementing the 2015 8-hour ozone NAAQS. The SIP for each ozone nonattainment area must contain NNSR provisions that: (1) Set major source thresholds for nitrogen oxides (NO_X) and volatile organic compounds (VOC) pursuant to 40 CFR 51.165(a)(1)(iv)(A)(*1*)(*i*)–(*iv*) and (a)(1)(iv)(A)(*2*); (2) classify physical changes as a major source if the change would constitute a major source by itself pursuant to 40 CFR 51.165(a)(1)(iv)(A)(*3*); (3) consider any significant net emissions increase of NO_X as a significant net emissions increase for ozone pursuant to 40 CFR 51.165(a)(1)(v)(E); (4) consider any increase of VOC emissions in Extreme ozone nonattainment areas as a significant net emissions increase and a major modification for ozone pursuant to 40 CFR 51.165(a)(1)(v)(F); (5) set significant emissions rates for VOC and NO_X as ozone precursors pursuant to 40 CFR 51.165(a)(1)(x)(A)–(C) and (E); (6) contain provisions for emissions reductions credits pursuant to 40 CFR 51.165(a)(3)(ii)(C)(*1*)–(*2*); (7) provide that the requirements applicable to VOC also apply to NO_X pursuant to 40 CFR 51.165(a)(8); (8) set offset ratios for VOC and NO_X pursuant to 40 CFR 51.165(a)(9)(ii)–(iv); and (9) require public participation procedures compliant with 40 CFR 51.165(i).

A. South Coast Air Quality Management District (SCAQMD)

The SCAQMD's longstanding SIP-approved NNSR program,[6] established in Regulation XIII, ''New Source Review,'' of the SCAQMD's Rules and Regulations, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The SCAQMD's submitted SIP revision includes a compliance demonstration, consisting of a table listing each of the 2015 ozone NAAQS NNSR SIP requirements from 40 CFR 51.165 and a citation to the specific provision of the rule satisfying the requirement. The submittal also includes a certification by the SCAQMD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designations. These documents are available in the docket for this action. The EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the SCAQMD's submittal because the current SIP-approved NSR program satisfies all the 2015 SIP Requirements Rule NNSR program requirements applicable to the South Coast Air Basin as an Extreme ozone nonattainment area, and all the requirements applicable to the Coachella Valley Air Basin as a Severe ozone nonattainment area.

B. Imperial County Air Pollution Control District (ICAPCD)

The ICAPCD's SIP-approved NNSR program,[7] established in Rule 207, ''New and Modified Stationary Source Review,'' of the ICAPCD's Rules and Regulations, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The ICAPCD's submitted SIP revision includes a compliance demonstration, consisting of a table listing each of the 2015 ozone NAAQS NNSR SIP requirements from 40 CFR 51.165 and a citation to the specific provision of the rule satisfying that requirement. The submittal also includes a certification by the ICAPCD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designation. These documents are available in the docket for this action. The EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the ICAPCD's submittal because the current SIP-approved NSR program satisfies all the 2015 SIP Requirements Rule NNSR program requirements applicable to Imperial County as a Marginal nonattainment area.

C. Ventura County Air Pollution Control District (VCAPCD)

The VCAPCD's SIP-approved NNSR program,[8] established in Rule 26, ''New Source Review,'' of the VCAPCD's Rules and Regulations, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The VCAPCD's submitted SIP revision includes a compliance demonstration, consisting of a table listing each of the 2015 ozone NAAQS NNSR SIP requirements from 40 CFR 51.165 and a citation to the specific provision of the rule satisfying that requirement. The submittal also includes a certification by the VCAPCD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designation. These documents are available in the docket for this action. The EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the VCAPCD's submittal because the current SIP-approved NSR program satisfies all the 2015 SIP Requirements Rule NNSR program requirements applicable to Ventura County as a Serious nonattainment area.

IV. Proposed Action and Public Comment

The EPA is proposing to approve SIP revisions addressing the NNSR requirements for the 2015 8-hour ozone NAAQS for the SCAQMD, the ICAPCD, and the VCAPCD. In support of this proposed action, we have concluded that our approval of the submitted 2015 ozone certifications for each district would comply with section 110(l) of the Act because the submittals will not interfere with continued attainment of the NAAQS in each district. The EPA has concluded that the State's submission fulfills the 40 CFR 51.1314 revision requirement and meets the requirements of CAA sections 110, 172(c)(5), 173, and 182(a)(2)(C), and the minimum SIP requirements of 40 CFR

[5] 83 FR 62998.

[6] 61 FR 64291 (December 4, 1996); 64 FR 13514, (March 19, 1999); 71 FR 35157 (June 19, 2006); 83 FR 64026 (December 13, 2018).

[7] 84 FR 44545 (August 26, 2019).

[8] 75 FR 1284 (January 11, 2010).

51.165. If we finalize this action as proposed, our action will incorporate these certifications into the federally enforceable SIP and be codified through revisions to 40 CFR 52.220 (Identification of plan—in part).

We will accept comments from the public on this proposal until May 16, 2022.

V. Incorporation by Reference

In this proposed rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the certifications listed in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available electronically through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 7, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2022–07919 Filed 4–13–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 22–146; RM–11925; DA 22–367; FRS 81585]

Television Broadcasting Services Memphis, Tennessee

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Federal Communications Commission (Commission) has before it a petition for rulemaking filed by Gray Television Licensee, LLC (Petitioner), the licensee of WMC–TV, channel 5, Memphis, Tennessee. The Petitioner requests the substitution of channel 30 for channel 5 at Memphis in the Table of Allotments.

DATES: Comments must be filed on or before May 16, 2022 and reply comments on or before May 31, 2022.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Joan Stewart, Esq., Wiley Rein LLP, 2050 M Street NW, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647; or at *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: In support, the Petitioner states the proposed channel substitution serves the public interest because it will resolve significant over-the-air reception problems in WMC–TV's existing service area. The Petitioner further states that the Commission has recognized the deleterious effects manmade noise has on the reception of digital VHF signals, and that the propagation characteristics of these channels allow undesired signals and noise to be receivable at relatively farther distances compared to UHF channels, and nearby electrical devices can cause interference. According to the Petitioner, an analysis using the Commission's *TVStudy* software tool indicates that WMC–TV's move from channel 5 to channel 30 is predicted to create an area where 4,072 persons are predicted to lose service. The loss area, however, is partially overlapped by the noise limited contours of other NBC affiliated stations and most viewers will continue to receive service from five or more stations. As a result, Petitioner asserts that only 64 persons would no longer receive NBC network programming, or service from five or more full power television services. In practice, Gray expects that few if any persons who are currently able to receive WMC–TV's over-the-air signal on channel 5 would no longer be able to receive WMC–TV's over-the-air signal as a result of the transition to channel 30.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 22–146; RM–11925; DA 22–367, adopted April 5, 2022, and released April 5, 2022. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer & Government Affairs

Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a notice of proposed rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in § 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a). *See* §§ 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(j), amend the Table of Allotments under Tennessee by revising the entry for Memphis to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
Tennessee	
* * * * *	
Memphis	13, 23, 25, 28, *29, 30, 31, 33
* * * * *	

[FR Doc. 2022–07959 Filed 4–13–22; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 87, No. 72

Thursday, April 14, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity 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 appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by May 16, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Request for Special Priorities Assistance (Agriculture Priorities and Allocations System (APAS)).

OMB Control Number: 0560–0280.

Summary of Collection: The Request for Special Priorities Assistance (Agriculture Priorities and Allocations System (APAS)) regulation is promulgated in 7 CFR 789. This information is used to support the APAS managed by the United States Department of Agriculture, Farm Service Agency (FSA). The APAS program supports not only national defense needs (such as food for combat rations), but also emergency preparedness initiatives by addressing essential civilian needs (food and food resources) through the placing of priorities on contracts for items and services or allocating resources, as necessary. Priorities contracts are required to be given preference over other respective contracts to ensure timely delivery of an item that has been deemed necessary only in times of emergency or to promote the U.S. national defense.

Need and Use of the Information: Information collected on the form AD–2102, Request for Special Priorities Assistance for Emergency Preparedness form is used to grant a priority rating request on contract(s) between the government and private parties or between private parties for the production or delivery of food, food resources (including livestock, feed, and agriculture seed), fertilizer, and farm equipment. The information collected on the Request for Special Priorities Assistance is limited to: (1) Name, address, and contact information of the person making the request for priority rating of a contract, (2) Name, address, and contact information of the vendor supplying the item, (3) Items the person is requesting for a priority rating on a contract, including 'required by shipping dates' and (4) Explanatory section for the person to include circumstances requiring this request.

Failure to collect and maintain the data collected on the form will limit or eliminate USDA's ability to prepare for, respond to, and conduct emergency recovery actions because of an actual or impending hazard.

Description of Respondents: Business or other for-profit.

Number of Respondents: 50.

Frequency of Responses: Recordkeeping; Reporting: Annually.

Total Burden Hours: 25.

Dated: April 11, 2022.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–08017 Filed 4–13–22; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2022–0005]

Concurrence With World Organization for Animal Health's Risk Designation for Bovine Spongiform Encephalopathy for Ireland

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our preliminary concurrence with the World Organization for Animal Health's (OIE) bovine spongiform encephalopathy (BSE) risk designation for Ireland. The OIE recognizes Ireland as being of negligible risk for BSE. We are taking this action based on our review of information supporting the OIE's risk designation for Ireland.

DATES: We will consider all comments that we receive on or before June 13, 2022.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2022–0005 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2022–0005, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Any comments we receive on this docket may be viewed at *regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal

reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Gordon, Senior Staff Officer, Regionalization Evaluation Services, Veterinary Services, APHIS, 920 Main Campus Drive, Raleigh, NC 27606; (919) 855–7741; email: *AskRegionalization@usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 92 subpart B, ''Importation of Animals and Animal Products; Procedures for Requesting BSE Risk Status Classification With Regard To Bovines'' (referred to below as the regulations), set forth the process by which the Animal and Plant Health Inspection Service (APHIS) classifies regions for bovine spongiform encephalopathy (BSE) risk. Section 92.5 of the regulations provides that all countries of the world are considered by APHIS to be in one of three BSE risk categories: Negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. The list of those regions classified by APHIS as having either negligible risk or controlled risk can be accessed on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.* The list can also be obtained by writing to APHIS at Regionalization Evaluation Services, Veterinary Services, APHIS, 4700 River Road, Unit 38, Riverdale, MD 20737–1238.

Under the regulations, APHIS may classify a region for BSE in one of two ways. One way is for regions that have not received a risk classification from the World Organization for Animal Health (OIE) to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country or region by the OIE.

If the OIE has classified a region as either BSE negligible risk or BSE controlled risk, APHIS will seek information to support concurrence with the OIE classification. This information may be publicly available information, or APHIS may request that regions supply the same information given to the OIE. APHIS will announce in the **Federal Register**, subject to public comment, its intent to concur with an OIE classification.

In accordance with this process, we are giving notice in this document that APHIS intends to concur with the OIE risk classification of the country of Ireland as a region of negligible risk for BSE.

The OIE recommendation regarding Ireland can be viewed at *https://www.oie.int/en/disease/bovine-spongiform-encephalopathy/.* The conclusions of the OIE Scientific Commission for Animal Diseases, with regard to Ireland, can be viewed in the ''Report of the Meeting of the OIE Scientific Commission for Animal Diseases, February 1–11, 2021'' at *https://www.oie.int/app/uploads/2021/05/a-scad-feb2021.pdf* (page 41).

After reviewing any comments that we receive, we will announce our final determination regarding the BSE classification of Ireland in the **Federal Register**, along with a discussion of and response to pertinent issues raised by commenters. If APHIS recognizes Ireland as negligible risk for BSE, the Agency will include this country on the list of regions of negligible risk for BSE that is available to the public on the Agency's website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.*

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 8th day of April 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2022–08027 Filed 4–13–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Rapid Cycle Evaluation of Operational Improvements in Supplemental Nutrition Assistance Program (SNAP) Employment & Training (E&T) Programs

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

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on the proposed information collection. This is a new collection for the contract Rapid Cycle Evaluation of Operational Improvements in Supplemental Nutrition Assistance Program (SNAP) Employment & Training Programs (SNAP E&T RCE). The purpose of SNAP E&T RCE is to test small-scale interventions in SNAP E&T operations or service delivery using rapid cycle evaluation (RCE).

DATES: Written comments must be received on or before June 13, 2022.

ADDRESSES: Comments may be sent to: Mehreen Ismail, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314. Comments may also be submitted via email to *Mehreen.Ismail@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *https://www.regulations.gov,* and follow the online instructions for submitting comments electronically. All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Mehreen Ismail at 703–305–2960.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Rapid Cycle Evaluation of Operational Improvements in Supplemental Nutrition Assistance Program Employment & Training Programs (SNAP E&T RCE).

Form Number: N/A.

OMB Number: 0584–NEW.

Expiration Date: Not Yet Determined.

Type of Request: New Collection.

Abstract: In addition to providing nutrition assistance benefits to millions of low-income individuals experiencing economic hardship, the Supplemental Nutrition Assistance Program (SNAP) provides work supports through Employment and Training (E&T)

programs that help SNAP participants gain skills and find work. State agencies are required to operate an E&T program and have considerable flexibility to determine the services they offer and populations they serve. The U.S. Department of Agriculture's Food and Nutrition Service (FNS) seeks to ensure the quality of the services and activities offered through SNAP E&T programs by investing resources and providing technical assistance to help States build capacity, create more robust services, and increase engagement in their programs.

The Rapid Cycle Evaluation of Operational Improvements in SNAP E&T Programs (SNAP E&T RCE) evaluation will use rapid cycle evaluation (RCE) to test small-scale interventions in SNAP E&T operations or service delivery to determine their effectiveness in improving program engagement and service take-up. RCE is an approach that involves cycles of identifying, testing, and refining small-scale, low-cost operational interventions to determine their effectiveness. SNAP E&T RCE has partnered with eight sites to identify the main challenges their SNAP E&T programs face: (1) Colorado Department of Human Services, (2) Connecticut: Community Colleges, (3) District of Columbia Department of Human Services, (4) Kansas Division of Children and Families, (5) Minnesota Department of Human Services, (6) Minnesota: Hennepin County Department of Human Services, (7) Massachusetts Department of Transitional Assistance, and (8) Rhode Island Department of Human Services. Objectives for this study include: (a) Describing how RCE can be used to improve SNAP E&T operations, service delivery and program outcomes; (b) designing and implementing RCEs to obtain impact estimates of small-scale interventions on SNAP E&T outcomes; (c) conducting an implementation evaluation; (d) assessing the scalability of small-scale interventions to SNAP E&T operations and services delivery to other SNAP E&T programs; and (e) determining and documenting the costs associated with implementing and maintaining small-scale interventions.

The SNAP E&T RCE team is using the *Learn, Innovate, and Improve* (LI^2) framework to collaborate with sites, identify the challenges they want to address, and eventually design and test the interventions. The Learn phase focuses on assessing sites' needs and readiness to make changes, which informs development of solutions or strategies—the focus of the Innovate phase. The challenges the eight sites identified through the Learn phase generally involve recruitment and outreach or participant engagement and receipt of services. The SNAP E&T RCE team worked with each site to co-create an intervention addressing one of these challenges through the Innovate phase. Examples of interventions the sites plan to test include sending text messages and emails to participants to encourage enrollment in SNAP E&T or attendance at appointments or activities, using assessments of work readiness to improve participant referrals, or enhancing case management.

After identifying challenges in each site and designing interventions for addressing them, the SNAP E&T RCE team will work with each site to define operational plans for implementing the interventions and testing, refining, and retesting selected strategies in the Improve phase. Most interventions will be evaluated using randomized control trials in which individuals eligible for the intervention will be randomly assigned to a treatment group that receives the intervention or a control group that does not. The control group will be offered the existing approach to recruiting, outreach, and engagement, depending on the focus of intervention. Once interventions have been successfully piloted to ensure they operate smoothly for the site, the SNAP E&T RCE team will provide technical assistance to sites while they implement the intervention for a period of about three to four months.

The study will gather data from administrative records, State and local SNAP administrators, and SNAP participants to evaluate the interventions' effectiveness in improving recruitment and program engagement. Where appropriate, the study will create a system for enrollment into the evaluation and random assignment. Data collected in this system may include demographic and socioeconomic characteristics, contact information, and the collection of service use data. The study will conduct a 10-minute participant survey among a total of 4,000 participants in four of the eight sites. The participant survey will be used to collect information on barriers to engaging with services and seeking employment, program satisfaction, and reasons for engagement decisions for both individuals who engaged in the E&T program and those who either never engaged or disengaged.

The study will also collect data for the implementation evaluation across all eight sites using a combination of semi-structured interviews with administrators, focus groups with participants, and staff characteristics questionnaires with frontline intervention staff. In addition, the study will conduct in-depth interviews with participants in four of the eight sites. Data collected from administrators and staff will be used to describe how the interventions were implemented, assess the fidelity of the implementation and costs of the intervention, and identify implications for future application of similar types of changes. Additional data collected from participants will provide context to the administrative data and survey responses related to participant decisions, satisfaction, and barriers, as well as give a voice to participant backgrounds and experiences.

Affected Public: Members of the public affected by the data collection include Individuals and Households and State, Local, and Tribal Governments from eight sites. Respondent groups identified include: (1) Individuals eligible for SNAP E&T participation; (2) directors and managers from State and local government agencies supporting the SNAP E&T programs; and (3) staff from State and local government agencies providing direct services to SNAP E&T participants.

Estimated Number of Respondents: The estimated total number of respondents and nonrespondents is 91,910, including 73,566 respondents and 18,344 non-respondents. The sample includes 91,528 individuals, 135 State program staff, and 247 local program staff. As part of the site interventions, FNS will contact 91,528 SNAP participants across all eight sites, out of whom 18,306 will be non-respondents.

As part of data collection activities for the evaluation, FNS will contact approximately 4,000 SNAP participants to conduct the participant survey, 2,000 of whom will have also received the intervention offered to the treatment group and 2,000 in the control group who did not receive the intervention. We expect that 80 percent of the 4,000 individuals contacted will complete the participant survey (800 will be non-respondents). Among individuals participating in the site interventions, FNS will recontact a total of 800 individuals to participate in focus groups (160 will be focus group respondents and 640 will be considered non-respondents). Among individuals participating in the site interventions, 240 individuals will also be recontacted for in-depth-interviews (including 60 respondents and 180 non-respondents). FNS will also contact 382 SNAP program staff for administrative data requests, semi-structured interviews,

and a staff characteristics survey; of the 382 contacted, 135 will be State staff and 247 will be local staff.

Estimated Number of Responses per Respondent: SNAP participants will be asked to participate in an intervention (which includes several possible notifications), as well as a possible in-depth interview, survey (which includes several possible notifications), and focus group for an average total of 3.40 responses across all instruments or activities. State and local program staff will respond to a semi-structured interview, administrate data request, or a brief questionnaire for a total of 1.63 responses each.

Estimated Total Annual Responses: 249,401.

Estimated Time per Response: The estimated time of response for respondents varies from 1 minute to 8 hours depending on the respondent group, with an average estimated time of 0.062 hours (3.72 minutes).

Estimated Total Annual Burden on Respondents: The total estimated burden on respondents and non-respondents is 17,254 hours (1,035,235 minutes). The total burden on respondents, excluding nonrespondents, is 15,458 hours (927,458 minutes).

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–08011 Filed 4–13–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket #RBS–22–CO–OP–0008]

Notice of Solicitation of Applications for the Socially Disadvantaged Groups Grant

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice of Solicitation of Applications.

SUMMARY: This notice announces that the Rural Business-Cooperative Service (Agency) is inviting fiscal year (FY) 2022 applications for the Socially Disadvantaged Groups Grant (SDGG) program, subject to the availability of funding. This notice is being issued in order to allow applicants sufficient time to leverage financing, prepare and submit their applications, and give the Agency time to process applications within FY 2022. The purpose of this program is to provide technical assistance to socially disadvantaged groups in rural areas. Eligible applicants include cooperatives, groups of cooperatives, and cooperative development centers. This program supports Rural Development's (RD) mission of improving the quality of life for rural Americans and commitment to directing resources to those who most need them. Detailed information can be found on the SDGG website located at *https://www.rd.usda.gov/programs-services/socially-disadvantaged-groups-grant.* Expenses incurred in developing applications are the responsibility of the applicant. An announcement on the website at *https://www.rd.usda.gov/newsroom/federal-funding-opportunities* will identify the amount available in FY 2022 for SDGG applications. All applicants are responsible for any expenses incurred in developing their applications.

DATES: Completed applications for grants must be submitted electronically by no later than 11:59 p.m. Eastern Time June 13, 2022, through *https://www.grants.gov to be eligible for grant funding.* Please review the *Grants.gov* website at *https://www.grants.gov/web/grants/applicants/organization-registration.html* for instructions on the process of registering your organization as soon as possible to ensure that you are able to meet the electronic application deadline. Applications received after the deadline are not eligible for funding under this notice and will not be evaluated.

ADDRESSES: You are encouraged to contact your USDA Rural Development State Office well in advance of the application deadline to discuss your project and ask any questions about the application process. Contact information for State Offices can be found at: *https://www.rd.usda.gov/contact-us/state-offices.*

Program guidance as well as application templates may be obtained at *https://www.rd.usda.gov/programs-services/socially-disadvantaged-groups-grant* or by contacting your State Office. To submit an electronic application, follow the instructions for the SDGG funding announcement located at *https://www.grants.gov.* You are strongly encouraged to file your application early and allow sufficient time to manage any technical issues that may arise.

FOR FURTHER INFORMATION CONTACT: Arti Kshirsagar, Program Management Division, Rural Business-Cooperative Service, United States Department of Agriculture, 1400 Independence Avenue SW, Mail Stop-3226, Washington, DC 20250–3226, (202) 720–1400 or by email at: *arti.kshirsagar@usda.gov.*

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency Name: USDA Rural Business-Cooperative Service.

Funding Opportunity Title: Socially Disadvantaged Groups Grant.

Announcement Type: Notice of Solicitation of Applications (NOSA).

Assistance Listing Number: 10.871.

Funding Opportunity Number: RBCS–SDGG–2022.

Dates: Application Deadline. Your electronic application must be received by *https://www.grants.gov* no later than 11:59 p.m. Eastern Time, by June 13, 2022, or it will not be considered for funding.

Administrative: The following apply to this NOSA:

(i) *Key Priorities.* The Agency encourages applicants to consider projects that will advance the following:

- Assisting Rural communities recover economically from the impacts of the COVID–19 pandemic, particularly disadvantaged communities;
- Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects; and
- Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.

(ii) *Technical Assistance.* The Application Template provides specific, detailed instructions for each item of a complete application. The Agency emphasizes the importance of including every item and strongly encourages applicants to follow the instructions carefully, using the examples and illustrations in the Application Template. Prior to official submission of applications, applicants may request technical assistance or other application guidance from the Agency, as long as such requests are made prior to May 16, 2022. Agency contact information can be found in section D (Application and Submission Information) of this Notice.

(iii) *Hemp Related Projects.* Please note that no assistance or funding from this grant can be provided to a hemp producer unless they have a valid license issued from an approved State, Tribal or Federal plan in accordance with Subtitle G of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*). Verification of valid hemp licenses will occur at the time of award. The purpose of this program is to provide technical assistance, so funding for the production of hemp or marketing hemp production is not eligible.

(iv) *Persistent Poverty Counties.* Section 736 of the Consolidated Appropriations Act, 2021, Public Law 116–260, designates funding for projects

in persistent poverty counties. Availability of funding in Persistent Poverty Counties (PPC) is contingent on inclusion of such a provision in the Appropriations Act for Fiscal Year 2022 (the ''2022 Appropriations Act''), once enacted. Persistent poverty counties as defined in Section 736 is ''any county that has had 20 percent or more of its population living in poverty over the past 30 years, as measured by the 1990 and 2000 decennial censuses, and 2007–2011 American Community Survey 5-year average, or any territory or possession of the United States''. Another provision in Section 736 expands the eligible population in persistent poverty counties to include any county seat of such a persistent poverty county that has a population that does not exceed the authorized population limit by more than 10 percent. This provision expands the current 50,000 population limit to 55,000 for only county seats located in persistent poverty counties. Therefore, applicants and/or beneficiaries of technical assistance services located in persistent poverty county seats with populations up to 55,000 (per the 2010 Census) are eligible contingent on inclusion in the 2022 Appropriations Act, once enacted.

(v) *Other.* The Agency will not solicit or consider new scoring or eligibility information that is submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification on materials contained in the submitted application. See the Application Guide for a full discussion of each item. For requirements of completed grant applications, refer to Section D (Application and Submission Information) of this notice.

A. Program Description

1. Purpose of the Program. The primary objective of the SDGG program is to provide technical assistance to socially disadvantaged groups. Eligible applicants are cooperative development centers, individual cooperatives, or groups of cooperatives (i) that serve socially disadvantaged groups and (ii) of which a majority of the board of directors or governing board is comprised of individuals who are members of socially disadvantaged groups.

2. Statutory Authority. The SDGG program is authorized by the Consolidated Farm and Rural Development Act (7 U.S.C. 1932(e)(11)).

3. Definitions. The definitions applicable to this notice are as follows:

Agency—Rural Business-Cooperative Service, an agency of the United States Department of Agriculture (USDA) Rural Development or a successor agency.

Conflict of interest—A situation in which a person or entity has competing personal, professional, or financial interests that make it difficult for the person or business to act impartially. Federal procurement standards prohibit transactions that involve a real or apparent conflict of interest for owners, employees, officers, agents or their immediate family members having a financial or other interest in the outcome of the project or that restrict open and free competition for unrestrained trade. Specifically, project funds may not be used for services or goods going to, or coming from, a person or entity with a real or apparent conflict of interest, including, but not limited to, owner(s) and their immediate family members. Examples of conflicts of interest include using grant funds to pay a member of the applicant's board of directors to provide proposed technical assistance to socially disadvantaged groups, paying a cooperative member to provide proposed technical assistance to other members of the same cooperative, and paying an immediate family member of the applicant to provide proposed technical assistance to socially-disadvantaged groups.

Cooperative—A business or organization that is owned and operated for the benefit of its members, with returns of residual earnings paid to such members on the basis of patronage. Eligible cooperatives for the SDGG program are those where a majority of the board of directors or governing board is comprised of individuals who are members of socially disadvantaged groups.

Cooperative development center—A nonprofit corporation or institution of higher education operated by the grantee for cooperative or business development. An eligible cooperative development center for the SDGG program is one where a majority of the board of directors or governing board is comprised of individuals who are members of socially disadvantaged groups. It may or may not be an independent legal entity separate from the grantee.

Feasibility study—An analysis of the economic, market, technical, financial, and management feasibility of a proposed project.

Group of cooperatives—A group of cooperatives whose primary focus is to provide assistance to socially disadvantaged groups; each cooperative must meet the eligibility requirements set forth in the definition of ''cooperative'' herein. One of the cooperatives must be designated as the lead entity and have legal authority to contract with the federal government.

Immediate family(ies)—A group of individuals who live in the same household or who are closely related by blood, marriage, or adoption, such as a spouse, domestic partner, parent, child, sibling, aunt, uncle, grandparent, grandchild, niece, nephew, or first cousin.

Operating cost—The day-to-day expenses of running a business; for example: Utilities, rent on the office space a business occupies, salaries, depreciation, marketing and advertising, and other basic overhead items.

Participant support costs—Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences or training projects.

Project—Any activities to be funded by the Socially Disadvantaged Groups Grant (SDGG).

Rural and rural area—Any area of a state other than (a) a city or town that has a population of more than 50,000 inhabitants, according to the latest decennial census of the United States and (b) any urbanized area contiguous and adjacent to a city or town described in clause (a), and urbanized areas that are rural in character as defined by 7 U.S.C. 1991(a)(13)(D). For the purposes of this definition, cities and towns are incorporated population centers with definite boundaries, local self-government, and legal powers set forth in a charter granted by the state. Notwithstanding any other provision of this paragraph, within the areas of the County of Honolulu, Hawaii, and the Commonwealth of Puerto Rico, the Secretary may designate any part of the areas as a rural area if the Secretary determines that the part is not urban in character, other than any area included in the Honolulu Census Designated Place or the San Juan Census Designated Place.

Rural Development—A mission area within USDA consisting of the Office of Under Secretary for Rural Development, Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service and any successors.

Socially disadvantaged group—A group whose members have been subjected to racial, ethnic, or gender prejudice because of their identity as members of a group without regard to their individual qualities.

State—Includes each of the 50 states, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, the

Commonwealth of the Northern Mariana Islands.

Technical assistance—An advisory service performed for the purpose of assisting cooperatives or groups that want to form cooperatives such as market research, product and/or service improvement, legal advice and assistance, feasibility study, business planning, marketing plan development, and training.

B. Federal Award Information

Type of Award: Competitive Grant.

Fiscal Year Funds: FY 2022.

Total Funding: Funding is contingent on the passing of the 2022 Appropriations Act.

Maximum Award: $175,000.

Project Period: 1 year.

Anticipated Award Date: September 30, 2022.

C. Eligibility Information

Applicants must meet all the following eligibility requirements. Applications which fail to meet any of these requirements by the application deadline will be deemed ineligible and will not be evaluated further.

1. *Eligible applicants.* Grants may be made to individual cooperatives, groups of cooperatives, or cooperative development centers that serve socially disadvantaged groups and of which a majority of the board of directors or governing board of the applicant is comprised of individuals who are members of socially disadvantaged groups. You must be able to verify your legal structure in the state or the tribe under which you are legally organized or incorporated. Grants may not be made to public bodies or to individuals. Your application must demonstrate that you meet all definition requirements for one of the three eligible applicant types as defined above. Federally recognized tribes have a government-to-government relationship with the United States. Therefore, tribes may consider using a separate entity, such as a tribally owned business, tribal authority, tribal non-profit, tribal college or university to apply for SDGG funding that would provide technical assistance to members of the tribe. This separate tribal entity must also demonstrate that it meets all definition requirements for one of the three eligible applicant types as defined above.

(i) At the time of application, each applicant must have an active registration in the System for Award (SAM) before submitting its application in accordance with 2 CFR part 25. In order to register in SAM, entities will be required to create a Unique Entity Identifier (UEI). Instructions for obtaining the UEI are available at *https://sam.gov/content/entity-registration.* Further information regarding SAM registration and the UEI can be found in section D 2 of this notice.

(ii) An applicant is ineligible if it has been debarred or suspended or otherwise excluded from or ineligible for participation in Federal assistance programs under Executive Order 12549, ''Debarment and Suspension.'' The Agency will check the Do Not Pay (DNP) system to determine if the applicant has been debarred or suspended at the time of application and also prior to funding any grant award. In addition, an applicant will be considered ineligible for a grant due to an outstanding judgment obtained by the U.S. in a Federal Court (other than U.S. Tax Court), is delinquent on the payment of Federal income taxes, or is delinquent on Federal debt. The applicant must certify as part of the application that they do not have an outstanding judgment against them. Applicants are responsible for resolving any issues that are reported in the 'Do Not Pay' System and if issues are not resolved by deadlines found in this Notice, the Agency may proceed to award funds to other eligible applicants.

(iii) Any corporation or cooperative (a) that has been convicted of a felony criminal violation under any Federal law within the past 24 months or (b) that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, is not eligible for financial assistance provided with funds appropriated by the 2022 Appropriations Act, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government. Certification of compliance with this provision is now completed during registration or annual recertification in the System for Awards Management (SAM) at *SAM.gov* via the Financial Assistance General Certifications and Representations.

2. *Cost sharing or matching.* No matching funds are required.

3. *Other eligibility requirements.*

(i) *Use of funds:* Your application must propose technical assistance that will benefit socially disadvantaged groups. Any recipient of technical assistance must have a membership that consists of a majority of members from socially disadvantaged groups. Please review section D(6) (Funding Restrictions) of this notice carefully.

(ii) *Project eligibility:* The proposed project must only serve members of socially disadvantaged groups located in rural areas.

(iii) *Grant period eligibility:* Your application must include a grant period of one-year or less or it will not be considered for funding. The proposed time frame should begin no earlier than October 1, 2022 and end no later than December 31, 2023. Applications that request funds for a time period ending after December 31, 2023, will not be considered for funding. You should note that the anticipated award date is September 30, 2022. Projects must be completed by December 31, 2023 or within the 12-months of award funding, whichever is earlier.

The Agency may approve requests to extend the grant period for up to an additional 12 months at its discretion. However, you may not have more than one SDGG award during the same grant period. If you extend the period of performance for your current award, you may be deemed ineligible to receive a SDGG in the next grant cycle. Further guidance on grant period extensions will be provided in the award document.

(iv) *Satisfactory performance eligibility:* If you have an existing SDGG award, you must be performing satisfactorily to be considered eligible for a new SDGG award. Satisfactory performance includes being up to date on all financial and performance reports as prescribed in the grant award and being current on tasks and timeframes for utilizing grant and matching funds as approved in the work plan and budget. If you have any unspent grant funds on SDGG awards from projects prior to September 30, 2020, your application will not be considered for funding. If your FY 2021 award has unspent funds of 50 percent or more than what your approved work plan and budget projected at the time of evaluation of your FY 2021 application, your FY 2022 application may not be considered for funding. The Agency will verify the performance status of any FY 2021 awards and make a determination after the FY 2022 application period closes.

(v) *Completeness eligibility:* Your application must provide all the information requested in section D(2) (Content and form of application submission) of this notice. Applications lacking sufficient information to determine eligibility and scoring criteria will be considered ineligible.

(vi) *Duplication of current services.* Your application must demonstrate that you are providing services to new customers or new services to current customers. If your work plan and budget is duplicative of your existing award, your application will not be considered for funding. If your work plan and budget is duplicative of a previous or existing Rural Cooperative Development Grant (RCDG) and/or SDGG award, your application will not be considered for funding.

(vii) *Multiple grant eligibility:* You may only submit one SDGG grant application each funding cycle. If two applications are submitted (regardless of the applicant name) that include the same Executive Director and/or advisory boards or committees of an existing cooperative or cooperative development center, both applications will be determined ineligible for funding.

D. Application and Submission Information

1. *Application template.* The application template to assist you in applying for this funding opportunity is located at *https://www.rd.usda.gov/programs-services/socially-disadvantaged-groups-grant.* Use of the application template is strongly recommended to assist you with the application process. You may also contact your USDA RD State Office for more information. Contact information for State Offices is located at *https://www.rd.usda.gov/contact-us/state-offices.*

2. *Content and form of application submission.* You must submit your application electronically through *Grants.gov*. Your application must contain all required information. To apply electronically, you must follow the instructions for this funding announcement at *https://www.grants.gov.* Please note that we cannot accept applications through mail or courier delivery, in-person delivery, email, or fax.

You can locate the *Grants.gov* downloadable application package for this program by using a keyword, the program name, Assistance Listing number, or the Funding Opportunity Number for this program.

When you enter the *Grants.gov* website, you will find information about applying electronically through the site, as well as the hours of operation. Users of *Grants.gov* must already have a Unique Entity Identifier (UEI) number and you must also be registered and maintain registration in SAM. The UEI is assigned by SAM and replaces the formerly known Dun & Bradstreet D–U–N–S Number. The UEI number must be associated with the correct tax identification number of the RCDG applicant. 2 CFR part 25 requires registration in SAM. We strongly recommend that you do not wait until the application deadline date to begin the application process through *Grants.gov*.

You must submit all application documents electronically through *Grants.gov*. Applications must include electronic signatures. Original signatures may be required if funds are awarded.

After applying electronically through *Grants.gov*, you will receive an automated acknowledgement from *Grants.gov* that contains a *Grants.gov* tracking number.

Your application must also contain the following required forms and proposal elements:

(i) Standard Form SF–424, ''Application for Federal Assistance,'' to include your UEI number. You must also provide your SAM Commercial and Government Entity (CAGE) Code and expiration date under the applicant eligibility discussion in your proposal narrative. If you do not include the CAGE code and expiration date and the UEI number in your application, it will not be considered for funding.

(ii) Form SF–424A, ''Budget Information-Non-Construction Programs.'' This form must be completed and submitted as part of the application package. You no longer must complete the Form SF 424B, ''Assurances—Non-Construction Programs'' as a part of your application. This information is now collected through your registration or annual recertification in *SAM.gov* through the Financial Assistance General Certifications and Representation.

(iii) Federal Debt and Judgement Certification. You must certify that there are no current outstanding Federal judgments against your property and that you will not use grant funds to pay for any judgment obtained by the United States. You must also certify that you are not delinquent on the payment of Federal income taxes, or any Federal debt. There is no standard form to complete, but to satisfy the certification requirement, you should include this statement in your application: ''[INSERT NAME OF APPLICANT] certifies that the United States has not obtained an unsatisfied judgment against its property, is not delinquent on the payment of Federal income taxes, or any Federal debt, and will not use grant funds to pay any judgments obtained by the United States.'' A separate signature is not required.

(iv) Table of Contents. Your application must contain a detailed Table of Contents (TOC). The TOC must include page numbers for each part of the application. Page numbers should begin immediately following the TOC.

(v) Executive Summary. A summary of the proposal, not to exceed one page, must briefly describe the project, tasks to be completed, and other relevant information that provides a general overview of the project.

(vi) Eligibility Discussion. A detailed discussion, not to exceed four pages, must describe how you meet the following requirements:

(a) Applicant Eligibility. You must describe how you meet the definition of a cooperative, group of cooperatives, or cooperative development center. Your application must also show that your individual cooperative, group of cooperatives or cooperative development center has a majority of its board of directors or governing board comprised of individuals who are members of socially disadvantaged groups and that the applicant serves socially disadvantaged groups. Your application must include a list of your board of directors/governing board and the percentage of board of directors/governing board that are members of socially disadvantaged groups. *Note:* Your application will not be considered for funding if you fail to show that a majority of your board of directors/governing board is comprised of individuals who are members of socially disadvantaged groups.

You must verify your incorporation and status in the state that you have applied by providing the state's or Tribe's Certificate of Good Standing and your Articles of Incorporation. You may also submit your Bylaws if they provide additional information not included in your Articles of Incorporation that will help verify your legal status. If applying as an institution of higher education, documentation verifying your legal status is not required; however, you must demonstrate that you qualify as an Institution of Higher Education as defined at 20 U.S.C. 1001. You must apply as only one type of applicant. The requested verification documents should be included in Appendix A of your application. If they are not included, your application will not be considered for funding.

(b) Use of Funds. You must provide a brief discussion on how the proposed project activities meet the definition of technical assistance and identify the socially disadvantaged groups that will be assisted.

(c) Project Area. You must provide specific information that details the

location of the Project area and explain how the area meets the definition of ''rural area.''

(d) Grant Period. You must provide a time frame for the proposed project and discuss how the project will be completed within that time frame. Your project must have a time frame of one year or less.

(e) Indirect Costs. Please indicate if you have a negotiated indirect cost rate agreement (NICRA), and if so, the rate. Your negotiated indirect cost rate approval does not need to be included in your application, but you will be required to provide it if a grant is awarded. Approval for indirect costs that are requested in an application without an approved indirect cost rate agreement is at the discretion of the Agency.

(vii) Scoring Criteria. Each of the scoring criteria in this notice must be addressed in narrative form, with a maximum of three pages for each individual scoring criterion, unless otherwise specified. Failure to address each scoring criteria will result in the application being determined ineligible.

(viii) The Agency has established annual performance evaluation measures to evaluate the SDGG program. You must provide estimates on the following performance evaluation measures as part of your narrative:

(a) Number of cooperatives assisted; and

(b) Number of socially disadvantaged groups assisted.

3. *System for Awards Management (SAM) and assigned Unique Entity Identifier (UEI).* Each applicant applying for grant funds must be registered in SAM before submitting its application and provide a valid UEI, unless determined exempt under 2 CFR 25.110(b), (c) or (d).

(i) Applicants register in SAM at no cost at: *https://sam.gov/SAM/.* You must provide your SAM CAGE Code and expiration date in the application materials. When registering in SAM, you must indicate you are applying for a Federal financial assistance project or program or are currently the recipient of funding under any Federal financial assistance project or program; and

(ii) The SAM registration must remain active with current information at all times while the Agency is considering an application or while a Federal grant award or loan is active. To maintain the registration in the SAM database, the applicant must review and update the information in the SAM database annually from date of initial registration or from the date of the last update. The applicant must ensure that the information in the database is current, accurate, and complete. Applicants must ensure they complete the Financial Assistance General Certifications and Representations in SAM.

(iii) The Agency will not make an award until the applicant has complied with all applicable SAM and UEI requirements. If an applicant has not fully complied with the requirements by the time the Agency is ready to make an award, the Agency may determine that the applicant is not qualified to receive a Federal award and the Agency may use that determination as a basis for making an award to another applicant. Please refer to section F(2) (Administrative and national policy requirements) for additional submission requirements that apply to grantees selected for this program.

4. *Submission Dates and Times.* Electronic applications must be *received* and accepted by *https://www.grants.gov* by 11:59 p.m. Eastern Time June 13, 2022, to be eligible for funding. Please review the *Grants.gov* website at *https://www.grants.gov/web/grants/applicants/organization-registration.html* for instructions on the process of registering your organization as soon as possible to ensure you can meet the electronic application deadline. *Grants.gov* will not accept applications submitted after the deadline.

5. *Intergovernmental Review.* Executive Order (E.O.) 12372, ''Intergovernmental Review of Federal Programs,'' applies to this program. This E.O. requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many states have established a Single Point of Contact (SPOC) to facilitate this consultation. The Rural Development State Office where the project is located will provide compliance guidance to applicants.

6. *Funding Restrictions.* Grant funds must be used for technical assistance as defined.

(i) No funds made available under this notice shall be used to:

(a) Plan, repair, rehabilitate, acquire, or construct a building or facility, including a processing facility;

(b) Purchase, rent, or install fixed equipment, including processing equipment;

(c) Purchase vehicles, including boats;

(d) Pay for the preparation of the grant application;

(e) Pay expenses not directly related to the funded Project;

(f) Fund political or lobbying activities;

(g) Fund any activities considered unallowable by the applicable grant cost principles, including 2 CFR part 200, subpart E and the Federal Acquisition Regulation (48 CFR part 1);

(h) Fund architectural or engineering design work for a specific physical facility;

(i) Fund any direct expenses for the production of any commodity or product to which value will be added, including seed, rootstock, labor for harvesting the crop, and delivery of the commodity to a processing facility;

(j) Fund research and development;

(k) Purchase land;

(l) Duplicate current activities or activities paid for by other Federal grant programs;

(m) Pay costs of the project incurred prior to the date of grant approval;

(n) Pay for assistance to any private business enterprise that does not have at least 51 percent ownership by those who are either citizens of the United States or reside in the United States after being legally admitted for permanent residence;

(o) Pay any judgment or debt owed to the United States;

(p) Pay any operating costs of the cooperative, group of cooperatives, or cooperative development center not directly related to the project;

(q) Pay expenses for applicant employee training or professional development not directly related to the project;

(r) Pay for any goods or services from a person or entity who has a conflict of interest with the grantee; or

(s) Pay for technical assistance provided to a cooperative that does not have a membership that consists of a majority of members from socially disadvantaged groups.

(ii) Your application will not be considered for funding if it does any of the following:

(a) Requests more than the maximum grant amount;

(b) Proposes ineligible costs that equal more than 10 percent of total grant funds requested; or

(c) Proposes participant support costs that equal more than 10 percent of total grant funds requested.

(iii) We will consider your application for funding if it includes ineligible costs of 10 percent or less of total grant funds requested if it is determined eligible otherwise. However, if your application is successful, those ineligible costs must be removed and replaced with eligible costs before the Agency will make the grant award or the amount of the grant award will be reduced accordingly. If we cannot determine the percentage of ineligible costs, your application will not be considered for funding.

7. *Other Submission Requirements.* Applications will not be accepted if the

text is less than an 11-point font. You must submit your application electronically, through *Grants.gov*. You must follow the instructions for this funding announcement at *https://www.grants.gov.* A password is not required to access the website.

E. Application Review Information

The State Offices will review applications to determine if they are eligible for assistance based on requirements in this notice, and other applicable Federal regulations. If determined eligible, your application will be scored by a panel of USDA employees in accordance with the point allocation specified in this notice. A recommendation will be submitted to the Administrator to fund applications from highest ranking order. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion.

1. *Scoring Criteria.* All eligible and complete applications will be evaluated based on the following criteria. Evaluators will base scores only on the information provided or cross-referenced by page number in each individual evaluation criterion. SDGG is a competitive program, so you will receive scores based on the quality of your responses. Simply addressing the criteria will not guarantee higher scores. The total points possible for the criteria are 105.

(i) *Technical Assistance (maximum score of 25 points).* Three-page limit. A panel of USDA employees will evaluate your application to determine your ability to assess the needs of and provide effective technical assistance to socially disadvantaged groups. You must discuss the:

(a) Needs of the socially disadvantaged groups to be assisted and explain how those needs were determined,

(b) Proposed technical assistance to be provided to the socially disadvantaged groups; and

(c) Expected outcomes of the proposed technical assistance, including how socially disadvantaged groups will benefit from participating in the project. You will score higher on this criterion if you provide examples of past projects that demonstrate successful outcomes in identifying specific needs and providing technical assistance to socially disadvantaged groups.

(ii) *Work Plan/Budget (maximum of 25 points).* Six-page limit. Your work plan must provide specific and detailed descriptions of the tasks and the key project personnel that will accomplish the project's goals. The budget will be reviewed for completeness. You must list what tasks are to be done, when it will be done, who will do it, and how much it will cost. Reviewers must be able to understand what is being proposed and how the grant funds will be spent. The budget must provide a detailed breakdown of estimated costs. These costs should be allocated to each of the tasks to be undertaken.

A panel of USDA employees will evaluate your work plan for detailed actions and an accompanying timetable for implementing the proposal. Clear, logical, realistic, and efficient plans that allocate costs to specific tasks using applicable budget object class categories provided on the Form SF–424A will result in a higher score. You must discuss at a minimum:

(a) Specific tasks to be completed using grant funds;

(b) How customers will be identified;

(c) Key personnel and what tasks they are undertaking; and

(d) The evaluation methods to be used to determine the success of specific tasks and overall project objectives.

Please provide qualitative methods of evaluation. For example, evaluation methods should go beyond quantitative measurements of completing surveys or number of evaluations, such as discussion of evaluation methods per task.

(iii) *Experience (maximum score of 25 points).* Three-page limit. A panel of USDA employees will evaluate your experience, commitment, and availability for identified staff or consultants in providing technical assistance, as defined in this notice. You must describe the technical assistance experience for each identified staff member or consultant, as well as years of experience in providing that assistance. You must also discuss the commitment and the availability of identified staff, consultants, or other professionals to be hired for the project—especially those who may be consulting on multiple SDGG/RCDG projects. If staff or consultants have not been selected at the time of application, you must provide specific descriptions of the qualifications required for the positions to be filled. In addition, resumes for each individual staff member or consultant must be included as an attachment in Appendix B. The attachments will not count toward the maximum page total. We will compare the described experience in this section and in the resumes to the work plan to determine relevance of the experience. Applications that do not include the attached resumes will not be considered for funding. Applications that demonstrate strong credentials, education, capabilities, experience, and availability of project personnel that will contribute to a high likelihood of project success will receive more points than those that demonstrate less potential for success in these areas.

Points will be awarded as follows:

(a) 0 points will be awarded if you do not substantively address the criterion.

(b) 1–9 points will be awarded if qualifications and experience of some, but not all, staff is addressed and, if necessary, qualifications of unfilled positions are not provided.

(c) 10–14 points will be awarded if (b) is met, plus all project personnel are identified but do not demonstrate qualifications or experience relevant to the project.

(d) 15–19 will be awarded if (b) and (c) are met, plus most, but not all, key personnel demonstrate strong credentials and/or experience, and availability indicating a reasonable likelihood of success.

(e) 20–25 points will be awarded if (b)–(d) are met, plus all personnel demonstrate strong, relevant credentials or experience and availability indicating a high likelihood of project success.

(iv) *Commitment (maximum of 10 points).* Three-page limit. A panel of USDA employees will evaluate your commitment to providing technical assistance to socially disadvantaged groups in rural areas. You must list the number and location of socially disadvantaged groups that will directly benefit from the assistance provided. You must also define and describe the underserved and economically distressed areas within your service area and provide current and relevant statistics that support your description of the service area. Projects located in Persistent Poverty Counties as defined in 2022 Appropriations Act, if included, will score higher on this factor.

(v) *Local support (maximum of 10 points).* Three-page limit. A panel of USDA employees will evaluate your application for local support of the technical assistance activities. Your discussion on local support should include previous and/or expected local support and plans for coordinating with other developmental organizations in the proposed service area or with tribal, State, and local government institutions. You will score higher if you demonstrate strong support from potential beneficiaries and other developmental organizations. You may submit a maximum of 10 letters of support with the application.

Points will be awarded as follows:

(a) 0 points are awarded if you do not adequately address this criterion.

(b) A range of 1–5 points are awarded if you demonstrate support from

potential beneficiaries and other developmental organizations in your discussion but do not provide letters of support.

(c) Additional 1 point is awarded if you provide 2–3 support letters that show support from potential beneficiaries and/or support from local organizations.

(d) Additional 2 points are awarded if you provide 4–5 support letters that show support from potential beneficiaries and/or support from local organizations.

(e) Additional 3 points are awarded if you provide 6–7 support letters that show support from potential beneficiaries and/or support from local organizations.

(f) Additional 4 points are awarded if you provide 8–9 support letters that show support from potential beneficiaries and/or support from local organizations.

(g) Additional 5 points are awarded if you provide 10 support letters that show support from potential beneficiaries and/or support from local organizations.

You may submit a maximum of 10 letters of support. Support letters should be signed and dated after the publication date of this notice and should come from potential beneficiaries and other local organizations. Letters received from Congressional members and technical assistance providers will not be included in the count of support letters received. Additionally, identical form letters signed by multiple potential beneficiaries and/or local organizations will not be included in the count of support letters received. Support letters should be included as an attachment to the application in Appendix C and will not count against the maximum page total. Additional letters from industry groups, commodity groups, Congressional members, and similar organizations should be referenced, but not included in the application package. When referencing these letters, provide the name of the organization, date of the letter, the nature of the support, and the name and title of the person signing the letter.

(vi) *Administrator Discretionary Points (maximum of 10 points).* In the event two projects have the same score, the Administrator may award points to the applicant that has not received SDGG funds in the past. In addition, the Administrator may choose to award points to applications that:

(a) Increase the geographic diversity of socially disadvantaged groups served by approved projects.

(b) Advance the key priorities addressed in the Supplemental Section of this notice. Data sources for the key priorities are found at: *https://www.rd.usda.gov/priority-points.*

2. *Review and Selection Process.* Applications will be reviewed in the State Offices to determine if they are eligible for assistance based on requirements in this notice, and other applicable Federal regulations. If determined eligible, your application will be scored by a panel of USDA employees in accordance with the point allocation specified in this notice. The review panel will convene to reach a consensus on the scores for each of the eligible applications. The Administrator may choose to award up to 10 Administrator priority points based on criterion (vi) in section E(1) (Scoring Criteria) of this notice. These points will be added to the cumulative score for a total possible score of 105. Applications will be funded from highest ranking order until the funding limitation has been reached. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion. If your application is ranked and not funded, it will not be carried forward into the next competition.

F. Federal Award Administration Information

1. *Federal award notices.* If you are selected for funding, you will receive a signed notice of Federal award by postal or electronic mail, containing instructions on requirements necessary to proceed with execution and performance of the award.

If you are not selected for funding, you will be notified in writing via postal or electronic mail and informed of any review and appeal rights. Funding of successfully appealed applications will be limited to available FY 2022 funding.

2. *Administrative and national policy requirements.* Additional requirements that apply to grantees selected for this program can be found in 2 CFR parts 200, 215, 400, 415, 417, 418, and 421. All recipients of Federal financial assistance are required to report information about first tier subawards and executive compensation (See 2 CFR part 170). You will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act reporting requirements (See 2 CFR 170.200(b), unless you are exempt under 2 CFR 170.110(b)).

The following additional requirements apply to grantees selected for this program:

(i) Execution of an Agency approved Grant Agreement.

(ii) Acceptance of a written Letter of Conditions.

(iii) Submission of Form RD 1940–1, ''Request for Obligation of Funds.''

(iv) Submission of Form RD 1942–46, ''Letter of Intent to Meet Conditions.''

(v) Assurance Agreement. By signing the Financial Assistance General Certifications and Representations in SAM, grant recipients affirm that they will operate the program free from discrimination. The grant recipients will maintain the race and ethnic data on their board members and the beneficiaries of the program. The grant recipient will provide alternative forms of communication to persons with limited English proficiency. The Agency will conduct civil rights compliance reviews on grant recipients to identify the collection of racial and ethnic data on program beneficiaries. In addition, the compliance review will ensure that equal access to the program benefits and activities are provided for persons with disabilities and language barriers.

3. *Reporting.* After grant approval and through grant completion, you will be required to provide the following:

(i) An SF–425, ''Federal Financial Report,'' and a project performance report will be required on a semiannual basis (due 30 calendar days after the end of the semiannual period). The project performance reports shall include a comparison of actual accomplishments to the objectives established for that period;

(ii) A statement providing reasons why established objectives were not met, if applicable;

(iii) A statement providing reasons for any problems, delays, or adverse conditions, if any, which have affected or will affect attainment of overall project objectives, prevent meeting time schedules or objectives, or preclude the attainment of particular objectives during established time periods (This disclosure shall be accompanied by a statement of the action taken or planned to resolve the situation);

(iv) Objectives and timetable established for the next reporting period;

(v) A final project and financial status report within 90 days after the expiration or termination of the grant in accordance to 2 CFR 200.344; and

(vi) Outcome project performance reports and final deliverables.

G. Agency Contacts

For general questions about this announcement and for program technical assistance, please contact the appropriate State Office at *https://www.rd.usda.gov/contact-us/state-offices.* You may also contact Arti

Kshirsagar, Program Management Division, Rural Business-Cooperative Service, USDA at (202) 720–1400 or by email at *arti.kshirsagar@usda.gov.*

H. Other Information

(1) *Paperwork Reduction Act.* In accordance with the Paperwork Reduction Act, the paperwork burden associated with this notice has been approved by the Office of Management and Budget (OMB) under OMB Control Number 0570–0052.

(2) *National Environmental Policy Act.* All funding activities under this notice must comply with the National Environmental Policy Act (NEPA), and its implementing regulations as outlined in 7 CFR part 1970. This notice has been reviewed in accordance with 7 CFR part 1970, ''Environmental Policies and Procedures.'' We have determined that an Environmental Impact Statement is not required because the issuance of regulations and instructions, as well as amendments to them, describing administrative and financial procedures for processing, approving, and implementing the Agency's financial programs is categorically excluded in the Agency's National Environmental Policy Act regulation found at 7 CFR 1970.53(f). We have determined that this notice does not constitute a major Federal action significantly affecting the quality of the human environment. The Agency will review each grant application to determine its compliance with 7 CFR part 1970. The applicant may be asked to provide additional information or documentation to assist the Agency with this determination. A review for NEPA compliance is required prior to the award of grant funds.

(3) *Civil Rights Compliance Requirements.* All grants made under this notice are subject to Title VI of the Civil Rights Act of 1964, USDA's nondiscrimination regulation (7 CFR part 15, subpart A), and Section 504 of the Rehabilitation Act of 1973.

(4) *Non-Discrimination Statement.* In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices, 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.

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

To file a program discrimination complaint, a complainant should complete a Form AD 3027, *USDA Program Discrimination Complaint Form,* which can be obtained online at *https://www.ocio.usda.gov/document/ad-3027,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of the alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(i) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or

(ii) *Fax:* (833) 256–1665 or (202) 690–7442; or

(iii) *Email: program.intake@usda.gov.*

Karama Neal,

Administrator, Rural Business-Cooperative Service, Rural Development.

[FR Doc. 2022–07999 Filed 4–13–22; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

Census Bureau

National Advisory Committee

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of public virtual meeting; correction.

SUMMARY: The Census Bureau published a notice in the **Federal Register** of April 7, 2022 giving notice of a virtual meeting of the National Advisory Committee (NAC). The document contained incorrect URL meeting links in the ''Addresses'' section.

FOR FURTHER INFORMATION CONTACT: Shana Banks, Advisory Committee Branch Chief, Office of Program, Performance and Stakeholder Integration (PPSI), *shana.j.banks@census.gov,* Department of Commerce, Census Bureau, telephone 301–763–3815. For TTY callers, please use the Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of April 7, 2022, in FR Document Number 2022–07356, on Page 20389, in the first column, correct the **ADDRESSES** caption to read:

ADDRESSES: The meeting will be held via the WebEx platform at the following presentation links:

- May 5, 2022—*https://uscensus.webex.com/uscensus/onstage/g.php?MTID=e28f8d12408207d3c951d7c7b345a1dd2*
- May 6, 2022—*https://uscensus.webex.com/uscensus/onstage/g.php?MTID=e7dfde37dd4b6aa4f376a2758ee48da9c*

For audio, please call the following number: 1–888–603–9745. When prompted, please use the following Password: Census#1 and Passcode: 8154908#.

Robert L. Santos, Director, Census Bureau, approved the publication of this Notice in the **Federal Register**.

Dated: April 8, 2022.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–07980 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Bureau of Economic Analysis Advisory Committee Meeting

AGENCY: Bureau of Economic Analysis, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Bureau of Economic Analysis (BEA) announces a meeting of the Bureau of Economic Analysis Advisory Committee. The meeting will address proposed improvements, extensions, and research related to BEA's economic accounts. In addition, the meeting will include an update on recent statistical developments.

DATES: Friday, May 13, 2022. The meeting begins at 10:00 a.m. and adjourns at 2:30 p.m. (ET).

ADDRESSES: This meeting will be held virtually. Anyone planning to attend the meeting must contact Gianna Marrone at BEA (301) 278–9282 or *gianna.marrone@bea.gov.* contact Gianna Marrone at BEA (301) 278–9282 or *gianna.marrone@bea.gov.* The call-in number, access code, and presentation link will be posted 24 hours prior to the meeting on *https://www.bea.gov/about/bea-advisory-committee.*

FOR FURTHER INFORMATION CONTACT: Gianna Marrone, Program Analyst, U.S. Department of Commerce, Bureau of Economic Analysis, Suitland, MD 20746; phone (301) 278–9282.

SUPPLEMENTARY INFORMATION: The Committee was established September 2, 1999. The Committee advises the Director of BEA on matters related to the development and improvement of BEA's national, regional, industry, and international economic accounts, with a focus on new and rapidly growing areas of the U.S. economy. The committee provides recommendations from the perspectives of the economics profession, business, and government.

This meeting is open to the public. The meeting is accessible to people with disabilities. Requests for foreign language interpretation or other auxiliary aids should be directed to Gianna Marrone at (301) 278–9282 or *gianna.marrone@bea.gov* by May 6, 2022.

Persons with extensive questions or statements must submit them in writing by May 6, 2022, to Gianna Marrone, *gianna.marrone@bea.gov.*

Dated: April 6, 2022.

Ryan Noonan,

Designated Federal Officer, Bureau of Economic Analysis.

[FR Doc. 2022–07988 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Federal Economic Statistics Advisory Committee Meeting

AGENCY: Bureau of Economic Analysis, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Bureau of Economic Analysis (BEA) is giving notice of a meeting of the Federal Economic Statistics Advisory Committee (FESAC). The Committee advises the Under Secretary for Economic Affairs, the Directors of the Bureau of Economic Analysis and the Census Bureau, and the Commissioner of the U.S. Department of Labor's Bureau of Labor Statistics (BLS) on statistical methodology and other technical matters related to the collection, tabulation, and analysis of federal economic statistics. An agenda will be accessible prior to the meeting at *https://apps.bea.gov/fesac/.*

DATES: June 10, 2022. The meeting begins at 9 a.m. and adjourns at 2:10 p.m. (ET).

ADDRESSES: This meeting will be held virtually. Anyone planning to attend the meeting may contact Gianna Marrone at BEA (301) 278–9282 or *gianna.marrone@bea.gov* by June 3, 2022. The call-in number, access code, and presentation link will be posted 24 hours prior to the meeting on *https://apps.bea.gov/fesac/.*

FOR FURTHER INFORMATION CONTACT: Gianna Marrone, Program Analyst, U.S. Department of Commerce, Bureau of Economic Analysis, 4600 Silver Hill Road (BE–64), Suitland, MD 20746; phone (301) 278–9282; email *gianna.marrone@bea.gov.*

SUPPLEMENTARY INFORMATION: FESAC members are appointed by the Secretary of Commerce. The Committee advises the Under Secretary for Economic Affairs, BEA and Census Bureau Directors, and the Commissioner of the Department of Labor's BLS on statistical methodology and other technical matters related to the collection, tabulation, and analysis of federal economic statistics. The Committee is established in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2).

This meeting is open to the public. The meeting is accessible to people with disabilities. Requests for foreign language interpretation or other auxiliary aids should be directed to Gianna Marrone at *gianna.marrone@bea.gov* by June 3, 2022.

Persons with extensive questions or statements must submit them in writing by June 3, 2022, to Gianna Marrone, *gianna.marrone@bea.gov.*

Dated: April 4, 2022.

Sabrina Montes,

Designated Federal Officer, Bureau of Economic Analysis.

[FR Doc. 2022–07989 Filed 4–13–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–82–2021]

Foreign-Trade Zone (FTZ) 75—Phoenix, Arizona Authorization of Production Activity; LCY Electronic Materials Inc. (Specialty Chemicals for Microchip Production), Casa Grande, Arizona

On December 10, 2021, LCY Electronic Materials Inc., submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 75, in Casa Grande, Arizona.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (86 FR 72576, December 22, 2021). On April 11, 2022, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: April 11, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–08000 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–823]

Raw Honey From Argentina: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of raw honey from Argentina are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation, April 1, 2020, through March 31, 2021.

DATES: Applicable April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas Martin or Eva Kim, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3936 or (202) 482–8283, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 23, 2021, Commerce published its preliminary determination in the LTFV investigation of raw honey from Argentina, and also postponed the final determination until April 7, 2022.[1] Commerce invited interested parties to comment on the *Preliminary Determination.* For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[2]

Scope of the Investigation

The product covered by this investigation is raw honey from Argentina. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

No interested party commented on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, no changes were made to the scope of the investigation.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice.

The Issues and Decision Memorandum is a public document and is made available to the public 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 *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of an on-site verification to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act).[3]

Final Affirmative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily determined that critical circumstances existed with respect to imports of raw honey from Argentina produced and exported by Asociación de Cooperativas Argentinas Cooperativa Limitada (ACA), Industrias Haedo S.A. (Haedo), and Compañía Inversora Platense S.A. (CIPSA) and all other producers and exporters.[4] Commerce did not receive any comments in response to its preliminary determination with respect to critical circumstances. Accordingly, for the final determination and based on our preliminary analysis, we continue to find that critical circumstances exist in the final determination.[5] For a further discussion of our critical circumstances analysis, *see* Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on the comments received from interested parties and record information, we made certain changes to our calculations of the dumping margins for ACA and NEXCO S.A. (NEXCO). For a discussion of these changes, *see* the Issues and Decision Memorandum.

Use of Adverse Facts Available

Both mandatory respondents, Haedo and CIPSA, notified Commerce that it would not participate in this investigation.[6] Therefore, in the *Preliminary Determination,* pursuant to sections 776(a) and (b) of the Act, we assigned to Haedo and CIPSA the highest Petition margin based on adverse facts available (AFA).[7] No party filed comments concerning the *Preliminary Determination* with respect to Haedo and CIPSA, and there is no new information on the record that would cause us to revisit the *Preliminary Determination.* Accordingly, we continue to find that the application of AFA pursuant to sections 776(a) and (b) of the Act is warranted with respect to these companies. Consistent with the *Preliminary Determination,* Commerce has continued to assign to Haedo and CIPSA the highest Petition margin, which is 49.44 percent. We also are applying partial AFA in calculating the weighted-average dumping margin for ACA, under sections 776(a) and (b) of the Act. For a full description of Commerce's partial AFA analysis, *see* the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act. Pursuant to section 735(c)(5)(B) of the Act, if the estimated weighted-average dumping margins established for all of the exporters and producers individually examined are zero, *de minimis* or determined based entirely on facts available, Commerce may use any reasonable method to establish the estimated weighted-average dumping margin for all other producers or exporters not individually investigated. Commerce calculated individual estimated weighted-average dumping margins for ACA and NEXCO, two of the mandatory respondents which were examined as exporters/producers in this investigation. Because ACA and NEXCO's calculated dumping margins are not zero, *de minimis,* or based entirely on facts otherwise available, Commerce calculated the all-others rate using a simple average of the

[1] *See Raw Honey from Argentina: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures,* 86 FR 66531 (November 23, 2021) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Raw Honey from Argentina,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Commerce's Letters, ''Remote Verification Questionnaire,'' dated December 6, 2021; and ''Remote Verification Questionnaire,'' dated December 13, 2021; *see also* NEXCO's Letter, ''Raw Honey from Argentina. Case No. 4–357–823: Remote Verification Questionnaire Response for NEXCO S.A. and * * *,'' dated December 15, 2021; and ACA's Letter, ''Raw Honey from Argentina, Case No. A–357–823: Remote Verification Questionnaire Response for Asociación de Cooperativas Argentinas C.L. and * * *,'' dated December 22, 2021.

[4] For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* Preliminary Determination Memorandum at 12–17 and Memorandum, ''Antidumping Duty Investigation of Raw Honey from Argentina: Preliminary Critical Circumstances Surge Analysis,'' dated November 17, 2021 (Preliminary Critical Circumstances Analysis).

[5] *See* Preliminary Critical Circumstances Analysis; and ''Antidumping Duty Investigation of Raw Honey from Argentina: Final Critical Circumstances Surge Analysis,'' dated April 7, 2022.

[6] *See* Haedo's Letter, ''Raw Honey from Argentina: Explanation of Unique Circumstances,'' dated June 10, 2021; and CIPSA's Letter, ''Raw Honey from Argentina, Case No. A–357–823: Compañia Inversora Platense S.A. Notification of Non-Participation,'' dated June 21, 2021.

[7] *See Preliminary Determination* PDM at 8–11.

estimated weighted-average dumping margins calculated for ACA and NEXCO,[8] pursuant to section 735(c)(5)(A) of the Act.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Asociación De Cooperativas Argentinas Cooperativa Limitada	24.67
NEXCO S.A	9.17
Industrias Haedo S.A	49.44
Compañía Inversora Platense S.A	49.44
All Others	16.92

Disclosure

We intend to disclose the calculations performed in this final determination within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of raw honey from Argentina, as described in Appendix I of this notice, which are entered, or withdrawn from warehouse, for consumption on or after November 23, 2021, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Section 735(c)(4) of the Act provides that if there is an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the later of: (a) The date which is 90 days before the date on which the suspension of liquidation was first ordered; or (b) the date on which notice of initiation of the investigation was published. As noted above, Commerce finds that critical circumstances exist for imports of subject merchandise produced and/or exported by ACA, Haedo, CIPSA, and all other producers and exporters. Therefore, in accordance with section 735(c)(4) of the Act, suspension of liquidation shall continue to apply to unliquidated entries of subject merchandise produced and/or exported by ACA, Haedo, CIPSA, and by all other producers and exporters that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the date of publication of the *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin as follows: (1) The cash deposit rate for the respondent listed above will be equal to the respondent-specific estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not a respondent identified above but the producer is, then the cash deposit rate will be equal to the respondent-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension-of-liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of this final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits posted will be refunded. If the ITC determines that material injury or threat of material injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Orders

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination and notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: April 7, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is raw honey. Raw honey is honey as it exists in the beehive or as obtained by extraction, settling and skimming, or coarse straining. Raw honey has not been filtered to a level that results in the removal of most or all of the pollen, *e.g.,* a level that removes pollen to below 25 microns. The subject products include all grades, floral sources and colors of raw honey and also include organic raw honey.

Excluded from the scope is any honey that is packaged for retail sale (*e.g.,* in bottles or other retail containers of five (5) lbs. or less).

The merchandise subject to this investigation is currently classifiable under statistical subheading 0409.00.0005, 0409.00.0035, 0409.00.0045, 0409.00.0056, and 0409.00.0065 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Final Affirmative Determination of

[8] With more than one respondent under examination, Commerce normally calculates: (A) A weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the examined respondents; and (C) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's publicly-ranged U.S. sale values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). As complete publicly-ranged sales data were available, Commerce based the all-others rate on the publicly-ranged sales data of the mandatory respondents. For a complete analysis of the data, *see* Memorandum, ''Less Than Fair Value Investigation of Raw Honey from Argentina: Preliminary Determination Calculation for the All-Others,'' dated November 19, 2021.

Critical Circumstances
IV. Changes Since the *Preliminary Determination*
V. Discussion of the Issues
Comment 1: Use of Exporters' Acquisition Price as a Reasonable Proxy for the Beekeepers' Cost of Production
Comment 2: Whether To Use Quarterly or Monthly Cost Averaging Periods
Comment 3: Whether Commerce's Inflation Methodology Requires the Use of Monthly Sales Comparisons in Investigations When Sales Prices in Both Markets Are Denominated in U.S. Dollars and Where the Only Difference in Merchandise Adjustment (Homogenization) Has Been Weight Averaged Over the Period
Comment 4: When Using Acquisition Costs, Whether Commerce Should Lag Acquisition Costs by Two Months
Comment 5: Adjustments to Commerce's Alternative Cost Averaging Methodology
Comment 6: Whether Commerce's Use of the Differential Pricing Analysis or the Cohen's *d* Test Comports With the Federal Circuit's Recent Decision in Stupp
Comment 7: Whether Commerce Should Treat ACA's and NEXCO's SENASA-Related Expenses as a U.S. Price Deduction Instead of as Circumstance of Sale Adjustment
Comment 8: Cost of Production Calculation for ACA's Middleman Supplier
Comment 9: Whether To Continue To Apply Facts Available (AFA) for ACA's Non-Responsive Direct Beekeeper Supplier and ACA's Middleman Beekeeper Supplier
Comment 10: ACA's Financial Expenses
Comment 11: Whether Commerce Should Incorporate Bad Debt Expenses Within ACA's Financial Expenses
Comment 12: ACA's General and Administrative Expenses
Comment 13: Whether Commerce Should Correct Ministerial Errors in the Calculation of ACA's Margin for the Final Determination
Comment 14: Errors in NEXCO's Reported Direct Material Costs
Comment 15: Errors in Commerce's Direct Material Cost Calculations for NEXCO
Comment 16: Whether Commerce Should Revise NEXCO's Indirect Selling Expenses
Comment 17: Whether Commerce Should Treat NEXCO's Export Taxes as a U.S. Price Deduction Instead of as a Circumstance of Sale Adjustment
Comment 18: Whether Commerce Should Add a Price Deduction Variable to NEXCO's U.S. Sales Database
Comment 19: Whether To Apply Partial AFA to NEXCO Due to the Unusable Cost Responses Submitted by Its Beekeeper Suppliers
VI. Recommendation

[FR Doc. 2022–07995 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–857]

Raw Honey From Brazil: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of raw honey from Brazil are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation April 1, 2020, through March 31, 2021.

DATES: Applicable April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Genevieve Coen, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3251.

SUPPLEMENTARY INFORMATION:

Background

On November 23, 2021, Commerce published its preliminary determination in the LTFV investigation of raw honey from Brazil, in which we also postponed the final determination until April 7, 2022.[1] For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[2]

Scope of the Investigation

The product covered by this investigation is raw honey from Brazil. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

No interested party commented on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, no changes were made to the scope of the investigation.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice. The Issues and Decision Memorandum is a public document and is made available to the public 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 *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of an on-site verification to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act).[3]

Changes Since the Preliminary Determination

Based on the comments received from interested parties and record information, we have relied on facts otherwise available with an adverse inference (AFA) for one of the mandatory respondents in this investigation, Supermel.[4] For a discussion of these changes, *see* the Issues and Decision Memorandum.

[1] *See Raw Honey from Brazil: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures,* 86 FR 66533 (November 23, 2021) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Raw Honey from Brazil,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Commerce's Letters, ''In Lieu of On-Site Verification Questionnaire,'' dated December 9, 2021, and December 10, 2021; *see also* Melbras' Letter, ''Melbras' In Lieu of Verification Questionnaire Response,'' dated December 17, 2021; and Supermel's Letter, ''Supermel's In Lieu of Verification Questionnaire Response,'' dated December 20, 2021.

[4] As discussed in the *Preliminary Determination,* Supermel is a trade name and consists of mandatory respondent Apiário Diamante Comercial Exportadora Ltda (Apiário Export) and its affiliate Apiário Diamante Produção e Comercial de Mel Ltda (Apiário Produção) (collectively, Supermel). For the final determination, we find that Apiário Export and Apiário Produção are affiliated within the meaning of section 771(33) of the Act and should be treated as a single entity, collectively referred to as Supermel, pursuant to 19 CFR 351.401(f). No parties commented on this treatment. Accordingly, we have continued to treat these companies as a single entity for this final determination. *See* Memorandum, ''Less-Than-Fair-Value Investigation of Raw Honey from Brazil: Preliminary Affiliation and Single Entity Memorandum for Apiário Diamante Comercial Exportadora Ltda and Apiário Diamante Produção e Comercial de Mel Ltda,'' dated November 17, 2021.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

In this investigation, Commerce has determined a rate for Supermel based entirely on section 776 of the Act. Commerce calculated an individual estimated weighted-average dumping margin for Melbras that is not zero, *de minimis,* or based entirely on facts otherwise available. Because the estimated weighted-average dumping margin for Melbras is the only individually-calculated dumping margin that is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for Melbras is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Melbras Importadora E Exportadora Agroindustrial Ltda	7.89
Apiário Diamante Comercial Exportadora Ltda/Apiário Diamante Produção e Comercial de Mel Ltda (Supermel) [5]	* 83.72
All Others	7.89

* Margin is based on AFA.

Disclosure

Normally, Commerce discloses to the parties in a proceeding the calculations that it performed in connection with the final determination in accordance with 19 CFR 351.224(b). However, because we made no changes to our preliminary weighted-average dumping margin calculations for Melbras, there are no calculations to disclose for this final determination.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of raw honey from Brazil, as described in Appendix I of this notice, which are entered, or withdrawn from warehouse, for consumption on or after November 23, 2021, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin as follows: (1) The cash deposit rate for the respondents listed above will be equal to the respondent-specific estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the respondent-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension-of-liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of this final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of raw honey from Brazil no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits posted will be refunded and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Order

This notice will serve as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: April 7, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is raw honey. Raw honey is honey as it exists in the beehive or as obtained by extraction, settling and skimming, or coarse straining. Raw honey has not been filtered to a level that results in the removal of most or all of the pollen, *e.g.,* a level that removes pollen to below 25 microns. The subject products include all grades, floral sources and colors of raw honey and also include organic raw honey.

Excluded from the scope is any honey that is packaged for retail sale (*e.g.,* in bottles or other retail containers of five (5) lbs. or less).

The merchandise subject to this investigation is currently classifiable under statistical subheading 0409.00.0005, 0409.00.0035, 0409.00.0045, 0409.00.0056, and 0409.00.0065 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[5] As noted above, we find that Apiário Export and Apiário Produção constitute a single entity in this proceeding.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Changes Since the *Preliminary Determination*
IV. Discussion of the Issues
Comment 1: Whether to Base Supermel's Final Dumping Margin on Total Adverse Facts Available (AFA)
Comment 2: Whether Beekeeper 2 Inappropriately Submitted New Factual Information
Comment 3: Moot Arguments for Supermel
Comment 4: Date of Sale
Comment 5: Whether Commerce Should Apply AFA to Melbras' Acquisition Costs
Comment 6: Whether Commerce Should Revise Melbras' Inland Freight Expenses Using Partial AFA or Neutral Facts Available
V. Recommendation

[FR Doc. 2022–07996 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–833]

Raw Honey From the Socialist Republic of Vietnam: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of raw honey from the Socialist Republic of Vietnam (Vietnam) are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation (POI) October 1, 2020, through March 31, 2021.

DATES: Applicable April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Jonathan Hill or Paola Aleman Ordaz, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3518 or (202) 482–4031, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 23, 2021, Commerce published the *Preliminary Determination* in the LTFV investigation of raw honey from Vietnam, in which it also postponed the final determination until April 7, 2022.[1] Additionally, on January 13, 2021, Commerce published the *Preliminary Determination of Critical Circumstances* in the LTFV investigation of raw honey from Vietnam.[2] The petitioners in this investigation are the American Honey Producers Association and Sioux Honey Association (collectively, the petitioners). The two mandatory respondents in this investigation are Ban Me Thuot Honeybee Joint Stock Company (Ban Me Thuot) and Daklak Honeybee Joint Stock Company (DakHoney).[3] We invited interested parties to comment on the *Preliminary Determination.*[4] For a complete summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, *see* Issues and Decision Memorandum.[5]

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 *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is raw honey from Vietnam. For a full description of the scope of this investigation, *see* Appendix I.

Scope Comments

Commerce received no comments from interested parties regarding the scope of this investigation. Accordingly, Commerce has not modified the scope language from the *Preliminary Determination.*

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice at Appendix II.

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of an on-site verification to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act).[6]

Methodology

Commerce conducted this investigation in accordance with section 731 of the Act. Export price was calculated in accordance with section 772(a) of the Act. Because Vietnam is a non-market economy within the meaning of section 771(18) of the Act, normal value was calculated in accordance with section 773(c) of the Act. For a full description of the methodology underlying Commerce's determination, *see* the Preliminary Decision Memorandum; *see also* the Issues and Decision Memorandum.

Vietnam-Wide Entity

For the reasons explained in our *Preliminary Determination,* we continue to find that neither the Vietnam-wide entity nor any company which is part of the Vietnam-wide entity has failed to cooperate in this investigation. Therefore, in accordance with our practice, to determine the estimated weighted-average dumping margin for the Vietnam-wide entity, Commerce assigns to the Vietnam-wide entity a rate equal to the average of publicly available ranged U.S. sales quantities of the mandatory respondents.

[1] *See Raw Honey from the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures,* 86 FR 66526 (November 23, 2021) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] *See Raw Honey from the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Critical Circumstances in the Less-Than-Fair-Value Investigation,* 87 FR 2127 (January 13, 2022), corrected by *Raw Honey from the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Critical Circumstances in the Less-Than-Fair-Value Investigation; Correction,* 87 FR 7800 (February 10, 2022) (collectively, *Preliminary Critical Circumstances Determination*).

[3] *See* Memorandum, ''Less-Than-Fair-Value Investigation of Raw Honey from the Socialist Republic of Vietnam: Selection of Mandatory Respondents for Individual Examination,'' dated June 15, 2021.

[4] *See Preliminary Determination,* 86 FR at 66526.

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Raw Honey from the Socialist Republic of Vietnam,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[6] *See* Commerce's Letters, ''Supplemental Questionnaire In-Lieu of Onsite Verification,'' dated December 6, 2021.

Changes Since the Preliminary Determination

Based on our analysis of the comments received, we made certain changes to the margin calculations for Ban Me Thuot and DakHoney. In light of these changes to the margin calculations and the resulting revised estimated weighted-average dumping margin for Ban Me Thuot and DakHoney, we have also revised the rates assigned to companies eligible for a separate rate and to the Vietnam-wide entity. For a discussion of these changes, *see* the ''Changes Since the *Preliminary Determination*'' section of the Issues and Decision Memorandum, and the Final Analysis Memoranda.[7]

Final Affirmative Determination of Critical Circumstances

Commerce preliminarily determined that critical circumstances did exist for Ban Me Thuot and DakHoney, the eligible separate rate companies, and the Vietnam-wide entity.[8] Parties submitted comments regarding our affirmative preliminary critical circumstances determination; *see* the Issues and Decision Memorandum. For the final determination, in accordance with section 735(a)(3) of the Act and 19 CFR 351.206, Commerce continues to find that critical circumstances do exist for Ban Me Thuot and DakHoney, the eligible separate rate companies, and the Vietnam-wide entity. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Issues and Decision Memorandum.

Separate Rates

No party commented on our preliminary separate rate determinations with respect to the mandatory respondents and the non-individually examined companies. Thus, there is no basis to reconsider the *Preliminary Determination* with respect to separate rate status for this final determination.

Combination Rates

In the *Initiation Notice,*[9] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation.[10] For the list of respondents that established eligibility for separate rates and exporter-producer combination rates applicable to these respondents, *see* the Final Determination section.

Final Determination

Commerce determines that the final estimated weighted-average dumping margins are as follows:

Producer	Exporter	Estimated weighted-average dumping margin (percent)
Ban Me Thuot Honeybee Joint Stock Company	Ban Me Thuot Honeybee Joint Stock Company	61.27
Daklak Honeybee Joint Stock Company	Daklak Honeybee Joint Stock Company	58.74
Dak Nguyen Hong Exploitation of Honey Company Limited TA, Nguyen Hong Honey Co., LTDTA.	Dak Nguyen Hong Exploitation of Honey Company Limited TA, Nguyen Hong Honey Co., LTDTA.	60.03
Nhieu Loc Company Limited	Nhieu Loc Company Limited	60.03
Hoang Tri Honey Bee Company Limited (a.k.a. Hoang Tri Honey Bee Co., Ltd), H. T Honey Co., Ltd.	Hoang Tri Honey Bee Company Limited (a.k.a. Hoang Tri Honey Bee Co., Ltd), H. T Honey Co., Ltd.	60.03
Viet Thanh Food Technology Development Investment Company Limited, Viet Thanh Food Co., Ltd.	Viet Thanh Food Technology Development Investment Company Limited, Viet Thanh Food Co., Ltd.	60.03
Dongnai HoneyBee Corporation	Dongnai HoneyBee Corporation	60.03
Sai Gon Bees Limited Company, Saigon Bees Co., Ltd., Sai Gon Bees Co., Ltd.	Sai Gon Bees Limited Company, Saigon Bees Co., Ltd., Sai Gon Bees Co., Ltd.	60.03
Huong Rung Trading—Investment and Export Company, Huong Rung Co., Ltd.	Huong Rung Trading—Investment and Export Company, Huong Rung Co., Ltd.	60.03
Hai Phong Honeybee Company Limited	Hai Phong Honeybee Company Limited	60.03
Bao Nguyen Honeybee Co., Ltd	Bao Nguyen Honeybee Co., Ltd	60.03
Southern Honey Bee Company LTD	Southern Honey Bee Company LTD	60.03
Golden Bee Company Limited	Golden Bee Company Limited	60.03
Thanh Hao Bees Company Limited	Thanh Hao Bees Company Limited	60.03
Daisy Honey Bee Joint Stock Company, Daisy Honey Bee JSC, Daisy Honey Bee J.S.C.	Daisy Honey Bee Joint Stock Company, Daisy Honey Bee JSC, Daisy Honey Bee J.S.C.	60.03
Bee Honey Corporation of Ho Chi Minh City, Bee Honey Corp. of Ho Chi Minh City, Behonex Corp.	Bee Honey Corporation of Ho Chi Minh City, Bee Honey Corp. of Ho Chi Minh City, Behonex Corp.	60.03
Phong Son Limited Company, Phong Son Co., Ltd	Phong Son Limited Company, Phong Son Co., Ltd	60.03
Hoa Viet Honeybee One Member Company Limited, Hoa Viet Honey Bee Co., Ltd., Hoa Viet Honeybee Co., Ltd.	Hoa Viet Honeybee One Member Company Limited, Hoa Viet Honey Bee Co., Ltd., Hoa Viet Honeybee Co., Ltd.	60.03
Vietnam-wide Entity	Vietnam-wide Entity	60.03

Disclosure

Commerce intends to disclose to interested parties under Administrative Protective Order (APO), the calculations performed in connection with this final determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b).

[7] *See* Memoranda, ''Less-Than-Fair-Value Investigation of Raw Honey from the Socialist Republic of Vietnam: Final Determination Calculations for Ban Me Thuot Honeybee Joint Stock Company,'' and ''Less-Than-Fair-Value Investigation of Raw Honey from the Socialist Republic of Vietnam: Final Determination Calculations for Ban Me Thuot Honeybee Joint Stock Company,'' dated concurrently with this notice (Final Analysis Memoranda).

[8] *See Preliminary Critical Circumstances Determination.*

[9] *See Raw Honey from Argentina, Brazil, India, Ukraine, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigation,* 86 FR 26897 (May 18, 2021) (*Initiation Notice*).

[10] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' dated April 5, 2005, available at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

Continuation of Suspension of Liquidation

In accordance with section 735(c)(4)(A) of the Act, because we continue to find that critical circumstances exist, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of raw honey from Vietnam, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after August 25, 2021, which is 90 days prior to the date of publication of the affirmative *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), upon publication of this notice, Commerce will instruct CBP to require a cash deposit for estimated antidumping duties for such entries as follows: (1) For the exporter/producer combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Vietnamese exporters/producers not listed in the above table, the cash deposit rate is equal to the estimated weighted-average dumping margin listed in the table for the Vietnam-wide entity; and (3) for all third-country exporters, the cash deposit rate is equal to the cash deposit rate applicable to the Vietnamese exporter/producer combination (or the Vietnam-wide entity) that supplied that third-country exporter. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, Commerce will notify the ITC of the final affirmative determination of sales at LTFV. Because the final determination is affirmative, in accordance with section 735(b)(2)(B) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, no later than 45 days after this final determination. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated, and all cash deposited will be refunded. If the ITC determines that material injury or threat of material injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding APO

This notice serves as a reminder to the parties subject to APO of their responsibility concerning the disposition of propriety information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or, alternatively, conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation that is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: April 7, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is raw honey. Raw honey is honey as it exists in the beehive or as obtained by extraction, settling and skimming, or coarse straining. Raw honey has not been filtered to a level that results in the removal of most or all of the pollen, *e.g.,* a level that removes pollen to below 25 microns. The subject products include all grades, floral sources and colors of raw honey and also include organic raw honey.

Excluded from the scope is any honey that is packaged for retail sale (*e.g.,* in bottles or other retail containers of five (5) lbs. or less).

The merchandise subject to this investigation is currently classifiable under statistical subheading 0409.00.0005, 0409.00.0035, 0409.00.0045, 0409.00.0056, and 0409.00.0065 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Final Affirmative Determination of Critical Circumstances
IV. Changes Since the *Preliminary Determination*
V. Discussion of the Issues
  Comment 1: The Appropriate Surrogate Value (SV) for Raw Honey
  Comment 2: The Appropriate SV for New and Refurbished Drums
  Comment 3: The Appropriate Financial Statements
  Comment 4: Whether to Make Certain Adjustments to the Surrogate Financial Statements
  Comment 5: Whether Commerce Should Establish a Comments Schedule to Submit Factual Information to Rebut the Critical Circumstances Allegation
  Comment 6: Whether Commerce Should Include the Trade Names of the Separate Rate Companies
  Comment 7: Whether Commerce Should Adjust Ban Me Thuot's Gross Unit Price by its Reported Testing Expenses
  Comment 8: Whether Commerce Should Include DakHoney's Consumption of Unpainted Drums in the Calculation of DakHoney's Raw Material Cost
  Comment 9: Whether Commerce Should Treat Certain Claimed Discounts as Warranty Expenses
  Comment 10: Whether to Make an Adjustment to Raw Honey Consumption Factors
VI. Recommendation

[FR Doc. 2022–07993 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–847]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From Mexico: Final Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that the producers/exporters of heavy walled rectangular welded carbon steel pipes and tubes (HWR pipes and tubes) from Mexico subject to this administrative review made sales of subject merchandise at less than normal value (NV) during the period of review (POR) September 1, 2019, through August 31, 2020.

DATES: Applicable April 14, 2022.

FOR FURTHER INFORMATION CONTACT: David Crespo, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3693.

SUPPLEMENTARY INFORMATION:

Background

Commerce selected two companies, Maquilacero S.A. de C.V. (Maquilacero) and Productos Laminados de Monterrey S.A. de C.V. (Prolamsa) (collectively, the

respondents), for individual examination.[1]

On October 12, 2021, Commerce published the *Preliminary Results* and invited interested parties to comment.[2] On November 12, 2021, Maquilacero, Nucor Tubular Products, Incorporated (Nucor), and Prolamsa filed case briefs.[3] On November 24, 2021, Nucor, Maquilacero, and Prolamsa filed rebuttal briefs.[4] For a description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[5]

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the order are heavy walled rectangular welded steel pipes and tubes from Mexico.[6] Products subject to the order are currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) item number 7306.61.1000. Subject merchandise may also be classified under 7306.61.3000. Although the HTSUS numbers and ASTM specification are provided for convenience and for customs purposes, the written product description remains dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are listed in the appendix to this notice and addressed in the Issues and Decision Memorandum. 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.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain changes to the weighted-average dumping margin calculations for Maquilacero and Prolamsa for the final results.[7]

Final Results of the Review

We are assigning the following weighted-average dumping margins to the firms listed below for the period September 1, 2019, through August 31, 2020:

Producers/exporters	Weighted-average dumping margin (percent)
Maquilacero S.A. de C.V	0.52
Productos Laminados de Monterrey S.A. de C.V	1.37

Disclosure

Commerce intends to disclose the calculations performed in connection with these final results to interested parties within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Pursuant to 19 CFR 351.212(b)(1), where Maquilacero and Prolamsa reported the entered value of their U.S. sales, we calculated importer-specific ad valorem duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. Because Prolamsa did not report the actual entered value for its sales, we calculated the entered value in order to calculate the assessment rate. Where either a respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review.[8]

Commerce's ''reseller policy'' will apply to entries of subject merchandise during the POR produced by Maquilacero or Prolamsa for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[9]

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[10]

We intend to issue liquidation instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies listed above will be equal to the weighted-average dumping margin established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be

[1] Commerce initiated this review covering 11 companies. In the *Preliminary Results,* we rescinded the review, in part, for nine of these companies. *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Preliminary Results and Partial Recission of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 56689 (October 12, 2021) (*Preliminary Results*). As a result, these final results cover only Maquilacero and Prolamsa.

[2] *See Preliminary Results.*

[3] *See* Maquilacero's Letter, ''Maquilacero S.A. de C.V.'s Case Brief,'' dated November 12, 2021; *see also* Nucor's Letter, ''Nucor Tubular's Case Brief,'' dated November 12, 2021; and Prolamsa's Letter, ''Case Brief and Request to Participate in Heading, if Held,'' dated November 11, 2021.

[4] *See* Nucor's Letter, ''Nucor Tubular's Rebuttal Brief,'' dated November 24, 2021; *see also* Maquilacero's Letter, ''Maquilacero S.A. de C.V.'s Rebuttal Brief,'' dated November 24, 2021; and Prolamsa's Letter, ''Rebuttal Brief,'' dated November 26, 2021.

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Antidumping Duty Administrative Review: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[6] For a complete description of the scope of the order, *see Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 56689 (October 12, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[7] *See* Issues and Decision Memorandum at 2–3.

[8] *See* section 751(a)(2)(C) of the Act.

[9] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[10] *See* section 751(a)(2)(C) of the Act.

the company-specific cash deposit rate published for the most recently completed segment in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the cash deposit rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 4.91 percent, the all-others rate established in the LTFV investigation.[11] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

[11] *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey: Antidumping Duty Orders,* 81 FR 62865, 62867 (September 13, 2016).

Dated: April 8, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Margin Calculations
IV. Discussion of the Issues
  Comment 1: Whether Non-Prime Merchandise is Within the Scope of the Order
  Comment 2: Treatment of Maquilacero's Further-Processed Downstream Sales
  Comment 3: Treatment of Abinsa S.A. de C.V.'s (Abinsa's) General and Administrative (G&A) Expenses
  Comment 4: Allocation of Maquilacero's Selling, General, and Administrative (SG&A) Expenses
  Comment 5: Treatment of Maquilacero's Non-Prime Products
  Comment 6: Adjustment to Maquilacero's Costs for Purchases From Affiliated Supplier
  Comment 7: Adjustment to Maquilacero's Costs for Variances and Discounts
  Comment 8: Adjustment to Maquilacero's Scrap Offset
  Comment 9: Level of Trade (LOT) for Prolamsa's Home Market Sales
  Comment 10: Inclusion of Non-Prime Costs of U.S. Products
  Comment 11: Treatment of Prolamsa's Home Market Downstream Sales
  Comment 12: Adjustment to Prolamsa's Costs for Purchases From Affiliated Supplier
V. Recommendation

[FR Doc. 2022–08010 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–903]

Raw Honey From India: Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of raw honey from India are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation April 1, 2020, through March 31, 2021.

DATES: Applicable April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Brittany Bauer or Benito Ballesteros, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3860 or (202) 482–7425, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 23, 2021, Commerce published its preliminary determination in the LTFV investigation of raw honey from India, in which we also postponed the final determination until April 7, 2022.[1] For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[2]

Scope of the Investigation

The product covered by this investigation is raw honey from India. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

No interested party commented on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, no changes were made to the scope of the investigation.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice. The Issues and Decision Memorandum is a public document and is made available to the public 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 *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

[1] *See Raw Honey from India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Negative Determination of Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures,* 86 FR 66528 (November 23, 2021) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Raw Honey from India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of an on-site verification to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act).[3]

Final Negative Determination of Critical Circumstances

Commerce preliminarily determined that critical circumstances do not exist for the two mandatory respondents in this investigation, Allied and Ambrosia, or with respect to all other producers/exporters. No parties submitted comments regarding our negative preliminary critical circumstances determination, and the factual basis for the preliminary negative finding remains unchanged for this final determination. Therefore, in accordance with section 735(a)(3) of the Act and 19 CFR 351.206, Commerce finds that critical circumstances do not exist for Allied, Ambrosia, and all other producers/exporters. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on the comments received from interested parties and record information, we made certain changes to the weighted-average dumping margin calculations for Allied and Ambrosia. For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

In this investigation, Commerce calculated estimated weighted-average dumping margins for Allied and Ambrosia that are not zero, *de minimis,* or based entirely on facts otherwise available. Commerce calculated the all-others rate using a weighted average of the estimated weighted-average dumping margins calculated for the examined respondents weighted by each respondent's publicly-ranged total U.S. sale values for the merchandise under consideration.[4]

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Allied Natural Product	6.24
Ambrosia Natural Products (India) Private Limited/Ambrosia Enterprise/Sunlite India Agro Producer Co. Ltd	5.52
All Others	5.87

Disclosure

We intend to disclose the calculations performed in this final determination within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of raw honey from India, as described in Appendix I of this notice, which are entered, or withdrawn from warehouse, for consumption on or after November 23, 2021, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin as follows: (1) The cash deposit rate for the respondents listed above will be equal to the respondent-specific estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the respondent-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension-of-liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of this final affirmative determination of sales at LTFV. Because Commerce's final

[3] For the final determination, we find that Ambrosia Natural Products (India) Private Limited is affiliated with two additional companies, Ambrosia Enterprise, and Sunlite India Agro Producer Co. Ltd., within the meaning of section 771(33) of the Act. We also find that these companies should be treated as a single entity, pursuant to 19 CFR 351.401(f). *See* Memorandum, ''Less-Than-Fair-Value Investigation of Raw Honey from India: Final Determination Affiliation and Single Entity Memorandum for Ambrosia Natural Products (India) Private Limited,'' dated April 7, 2022. We collectively refer to these companies as ''Ambrosia.'' *See also* Commerce's Letters, ''Antidumping Duty Investigation of Raw Honey from India: In-Lieu of Verification Questionnaire,'' both dated January 6, 2022; Allied Natural Product (Allied)'s Letter, ''Raw Honey from India: In-Lieu-of-Verification Questionnaire Response,'' dated January 18, 2022; and Ambrosia's Letter, ''Raw Honey from India: Ambrosia Natural Products ('Ambrosia') Response to In Lieu of On-Site Verification of the Antidumping Duty Investigation of Raw Honey,'' dated January 18, 2022.

[4] With more than one respondent under examination, Commerce normally calculates: (A) A weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the examined respondents; and (C) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's publicly-ranged U.S. sale values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects either the (B) or (C) rate based on the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). As complete publicly-ranged sales data are available, Commerce based the all-others rate on the publicly-ranged sales data of the mandatory respondents. For a complete analysis of the data, *see* Memorandum, ''Less-Than-Fair-Value Investigation of Raw Honey from India: Calculation of All-Others Rate,'' dated April 7, 2021.

determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of raw honey from India no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits posted will be refunded and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Order

This notice will serve as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: April 7, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is raw honey. Raw honey is honey as it exists in the beehive or as obtained by extraction, settling and skimming, or coarse straining. Raw honey has not been filtered to a level that results in the removal of most or all of the pollen, *e.g.,* a level that removes pollen to below 25 microns. The subject products include all grades, floral sources and colors of raw honey and also include organic raw honey.

Excluded from the scope is any honey that is packaged for retail sale (*e.g.,* in bottles or other retail containers of five (5) lbs. or less).

The merchandise subject to this investigation is currently classifiable under statistical subheading 0409.00.0005, 0409.00.0035, 0409.00.0045, 0409.00.0056, and 0409.00.0065 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Final Negative Determination of Critical Circumstances
IV. Changes Since the *Preliminary Determination*
V. Discussion of the Issues
General Issues
Comment 1: Whether to Find a Particular Market Situation in the Indian Raw Honey Market
Comment 2: Whether to Use Acquisition Cost as a Proxy for the Beekeepers' Cost of Production (COP)
Comment 3: Whether to Apply Total Adverse Facts Available (AFA) to Allied and Ambrosia for Alleged Failure to Submit Complete and Audited Financial Statements
Comment 4: Application of AFA to Allied and Ambrosia due to Certain Aspects of the Cost Responses Submitted by Middlemen and Beekeeper-Suppliers
Allied-Specific Issues
Comment 5: Whether to Continue to Rely on Quarterly Average Costs
Comment 6: Whether to Make Certain Adjustments to Credit Expenses
Comment 7: Whether to Make Certain Adjustments for Returned Sales
Ambrosia-Specific Issues
Comment 8: Whether to Make Certain Adjustments for Returned Sales
Comment 9: Whether to Make Certain Adjustments to Credit Expenses
Comment 10: Whether to Make Certain Adjustments for Packing Expenses
VI. Recommendation

[FR Doc. 2022–07994 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–139]

Certain Mobile Access Equipment and Subassemblies Thereof From the People's Republic of China: Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC), Commerce is issuing an antidumping duty (AD) order on certain mobile access equipment and subassemblies thereof (mobile access equipment) from the People's Republic of China (China).

DATES: Applicable April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Andre Gziryan, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2201.

SUPPLEMENTARY INFORMATION:

Background

On February 22, 2022, Commerce published in the **Federal Register** its affirmative final determination in the less-than-fair-value (LTFV) investigation of mobile access equipment from China.[1] On April 8, 2022, the ITC notified Commerce of its final determination, pursuant to section 735(d) of the Tariff Act of 1930, as amended (the Act), that an industry in the United States is threatened with material injury within the meaning of section 735(b)(1)(A)(i) of the Act by reason of LTFV imports of mobile access equipment from China.[2]

Scope of the Order

The products covered by this order are mobile access equipment from China. For a complete description of the scope of this order, *see* the appendix to this notice.

Antidumping Duty Order

On April 8, 2022, in accordance with section 735(d) of the Act, the ITC notified Commerce of its final determination in this investigation, in which it found that an industry in the United States is threatened with material injury by reason of imports of mobile access equipment from China.[3] Therefore, in accordance with section 735(c)(2) of the Act, Commerce is issuing this AD order. Because the ITC determined that imports of mobile access equipment from China are threatening material injury to a U.S. industry, unliquidated entries of such merchandise from China entered or withdrawn from warehouse for consumption, are subject to the assessment of antidumping duties.

Therefore, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instructions by Commerce, antidumping

[1] *See Certain Mobile Access Equipment and Subassemblies Thereof from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value,* 87 FR 9576 (February 22, 2022) (*Final Determination*).

[2] *See* ITC's Letter, ''Notification of ITC Final Determination,'' dated April 8, 2022.

[3] *Id.*

duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of mobile access equipment from China.

Because the ITC's final determination is based on the threat of material injury, other than threat of material injury described in section 736(b)(1) of the Act, duties shall be assessed on subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's notice of final determination, pursuant to section 736(b)(2) of the Act. In addition, section 736(b)(2) of the Act requires CBP to release any bond or other security, and refund any cash deposit made of estimated antidumping duties posted since Commerce's preliminary antidumping duty determination.

Accordingly, Commerce will direct CBP to terminate the suspension of liquidation of entries of mobile access equipment from China entered, or withdrawn from warehouse, for consumption prior to the publication of the ITC final determination in the **Federal Register**. Commerce will also instruct CBP to refund any cash deposits made with respect to entries of mobile access equipment from China entered, or withdrawn from warehouse, for consumption on or after September 30, 2021, the date of publication of the *Preliminary Determination* in the **Federal Register**.[4]

Suspension of Liquidation

Commerce will instruct CBP to reinstitute the suspension of liquidation of mobile access equipment from China, effective the date of publication of the ITC's final determination in the **Federal Register**, and to assess, upon further instruction by Commerce, pursuant to section 736(a)(1) of the Act, antidumping duties for each entry of the subject merchandise equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise. These instructions suspending liquidation will remain in effect until further notice.

Commerce also intends to instruct CBP to require cash deposits equal to the amount as indicated in the tables below. Accordingly, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on subject merchandise, a cash deposit equal to the rates listed below.[5] The rate for the China-wide entity applies to all exporters not specifically listed. For the purpose of determining cash deposit rates, the estimated weighted-average dumping margins for imports of subject merchandise from China have been adjusted, as appropriate, for export-contingent subsidies calculated based on the final determination of the companion countervailing duty investigation of mobile access equipment from China.[6]

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Lingong Group Jinan Heavy Machinery Co., Ltd	Lingong Group Jinan Heavy Machinery Co., Ltd	165.30	165.10
Zhejiang Dingli Machinery Co., Ltd	Zhejiang Dingli Machinery Co., Ltd	31.70	31.54

SEPARATE RATE APPLICABLE TO THE FOLLOWING NON-SELECTED COMPANIES

Non-selected exporter receiving a separate rate	Producer supplying the non-selected exporter receiving a separate rate	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Hunan Sinoboom Intelligent Equipment Co., Ltd	Hunan Sinoboom Intelligent Equipment Co., Ltd	51.83	51.66
Mantall Heavy Industry Co., Ltd	Mantall Heavy Industry Co., Ltd	51.83	51.66
Noblelift Intelligent Equipment Co., Ltd	Noblelift Intelligent Equipment Co., Ltd	51.83	51.66
Oshkosh JLG (Tianjin) Equipment Technology Co., Ltd.	Noblelift Intelligent Equipment Co., Ltd	51.83	51.66
Sany Marine Heavy Industry Co., Ltd	Sany Marine Heavy Industry Co., Ltd	51.83	51.66
Terex (Changzhou) Machinery Co., Ltd	Terex (Changzhou) Machinery Co, Ltd	51.83	51.66
Xuzhou Construction Machinery Group Imp. & Exp. Co., Ltd.	Xuzhou Construction Machinery Group Fire-Fighting Safety Equipment Co., Ltd.	51.83	51.66
China-Wide Entity		165.30	165.14

[4] *See Certain Mobile Access Equipment and Subassemblies Thereof from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures,* 86 FR 54164 (September 30, 2021) (*Preliminary Determination*). However, we note that the extended provisional measures period expired on March 28, 2022, as such, effective March 29, 2022, we discontinued suspension of liquidation in accordance with section 733(d) of the Act.

[5] *See* section 736(a)(3) of the Act.

[6] *See Final Determination,* 87 FR at 9576; *see also See Certain Mobile Access Equipment and Subassemblies Thereof from the People's Republic of China: Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination,* 86 FR 70439 (December 10, 2021).

Establishment of the Annual Inquiry Service Lists

On September 20, 2021, Commerce published the final rule titled ''Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws'' in the **Federal Register**.[7] On September 27, 2021, Commerce also published the notice titled ''Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions'' in the **Federal Register**.[8] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[9]

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** after November 4, 2021, Commerce will create an annual inquiry service list segment in Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available at *https://access.trade.gov,* within five business days of publication of the order. Each annual inquiry service list will be saved in ACCESS, under each case number, and under a specific segment type called ''AISL-Annual Inquiry Service List.'' [10]

Interested parties who wish to be added to the annual inquiry service list for an order must submit an entry of appearance to the annual inquiry service list segment for the order in ACCESS within 30 days after the date of publication of the order. For ease of administration, Commerce requests that law firms with more than one attorney representing interested parties in an order designate a lead attorney to be included on the annual inquiry service list. Commerce will finalize the annual inquiry service list within five business days thereafter. As mentioned in the *Procedural Guidance,* the new annual inquiry service list will be in place until the following year, when the opportunity notice for the anniversary month of the order is published.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov.*

Special Instructions for Petitioner and the Government of China

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [11] Accordingly, as stated above, the petitioner and the Government of China should submit their initial entry of appearance after publication of this notice in order to appear in the first annual inquiry service list. Pursuant to 19 CFR 351.225(n)(3), the petitioner and the Government of China will not need to resubmit their entry of appearance each year to continue to be included on the annual inquiry service list. However, the petitioner and the Government of China are responsible for making amendments to their entry of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice constitutes the AD order with respect to mobile access equipment from China pursuant to section 736(a) of the Act. Interested parties can find a list of AD orders currently in effect at *https://enforcement.trade.gov/stats/iastats1.html.*

This AD order is issued and published in accordance with section 736(a) of the Act and 19 CFR 351.211(b).

Dated: April 8, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Order

The merchandise covered by this order consists of certain mobile access equipment, which consists primarily of boom lifts, scissor lifts, and material telehandlers, and subassemblies thereof. Mobile access equipment combines a mobile (self-propelled or towed) chassis, with a lifting device (*e.g.,* scissor arms, boom assemblies) for mechanically lifting persons, tools and/or materials capable of reaching a working height of ten feet or more, and a coupler that provides an attachment point for the lifting device, in addition to other components. The scope of this order covers mobile access equipment and subassemblies thereof whether finished or unfinished, whether assembled or unassembled, and whether the equipment contains any additional features that provide for functions beyond the primary lifting function.

Subject merchandise includes, but is not limited to, the following subassemblies:

- Scissor arm assemblies, or scissor arm sections, for connection to chassis and platform assemblies. These assemblies include: (1) Pin assemblies that connect sections to form scissor arm assemblies, and (2) actuators that power the arm assemblies to extend and retract. These assemblies may or may not also include blocks that allow sliding of end sections in relation to frame and platform, hydraulic hoses, electrical cables, and/or other components;
- boom assemblies, or boom sections, for connection to the boom turntable, or to the chassis assembly, or to a platform assembly or to a lifting device. Boom assemblies include telescoping sections where the smallest section (or tube) can be nested in the next larger section (or tube) and can slide out for extension and/or articulated sections joined by pins. These assemblies may or may not include pins, hydraulic cylinders, hydraulic hoses, electrical cables, and/or other components;
- chassis assemblies, for connection to scissor arm assemblies, or to boom assemblies, or to boom turntable assemblies. Chassis assemblies include: (1) Chassis frames, and/or (2) frame sections. Chassis assemblies may or may not include axles, wheel end components, steering cylinders, engine assembly, transmission, drive shafts, tires and wheels, crawler tracks and wheels, fuel tank, hydraulic oil tanks, battery assemblies, and/or other components;
- boom turntable assemblies, for connection to chassis assemblies, or to boom assemblies. Boom turntable assemblies include turntable frames. Boom turntable assemblies may or may not include engine assembly, slewing rings, fuel tank, hydraulic oil tank, battery assemblies, counterweights, hoods (enclosures), and/or other components.

Importation of any of these subassemblies, whether assembled or unassembled, constitutes unfinished mobile access equipment for purposes of this order.

[7] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[8] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[9] *Id.*

[10] This segment will be combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[11] *See Final Rule,* 86 FR 52335.

Processing of finished and unfinished mobile access equipment and subassemblies such as trimming, cutting, grinding, notching, punching, slitting, drilling, welding, joining, bolting, bending, beveling, riveting, minor fabrication, galvanizing, painting, coating, finishing, assembly, or any other processing either in the country of manufacture of the in-scope product or in a third country does not remove the product from the scope. Inclusion of other components not identified as comprising the finished or unfinished mobile access equipment does not remove the product from the scope.

The scope excludes forklifts, vertical mast lifts, mobile self-propelled cranes and motor vehicles that incorporate a scissor arm assembly or boom assembly. Forklifts are material handling vehicles with a working attachment, usually a fork, lifted along a vertical guide rail with the operator seated or standing on the chassis behind the vertical mast. Vertical mast lifts are person and material lifting vehicles with a working attachment, usually a platform, lifted along a vertical guide rail with an operator standing on the platform. Mobile self-propelled cranes are material handling vehicles with a boom attachment for lifting loads of tools or materials that are suspended on ropes, cables, and/or chains, and which contain winches mounted on or near the base of the boom with ropes, cables, and/or chains managed along the boom structure. The scope also excludes motor vehicles (defined as a vehicle driven or drawn by mechanical power and manufactured primarily for use on public streets, roads, and highways, but does not include a vehicle operated only on a rail line pursuant to 49 U.S.C. 30102(a)(7)) that incorporate a scissor arm assembly or boom assembly. The scope further excludes vehicles driven or drawn by mechanical power operated only on a rail line that incorporate a scissor arm assembly or boom assembly. The scope also excludes: (1) Rail line vehicles, defined as vehicles with hi-rail gear or track wheels, and a fixed (non-telescopic) main boom, which perform operations on rail lines, such as laying rails, setting ties, or other rail maintenance jobs; and (2) certain rail line vehicle subassemblies, defined as chassis subassemblies and boom turntable subassemblies for rail line vehicles with a fixed (non-telescopic) main boom.

Certain mobile access equipment subject to this order is typically classifiable under subheadings 8427.10.8020, 8427.10.8030, 8427.10.8070, 8427.10.8095, 8427.20.8020, 8427.20.8090, 8427.90.0020 and 8427.90.0090 of the Harmonized Tariff Schedule of the United States (HTSUS). Parts of certain mobile access equipment are typically classifiable under subheading 8431.20.0000 of the HTSUS. While the HTSUS subheadings are provided for convenience and customs purposes only, the written description of the merchandise under order is dispositive.

[FR Doc. 2022–08014 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB949]

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits, permit amendments, and permit modifications.

SUMMARY: Notice is hereby given that permits, permit amendments, and permit modifications have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Erin Markin, Ph.D. (Permit No. 20528–03), Shasta McClenahan, Ph.D. (Permit No. 20523–01), and Amy Hapeman (Permit No. 25498–01); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit, permit amendment, or permit modification had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the activities, go to *www.federalregister.gov* and search on the permit number provided in Table 1 below.

TABLE 1—ISSUED PERMITS, PERMIT AMENDMENTS, AND PERMIT MODIFICATIONS

Permit No.	RTID	Applicant	Previous **Federal Register** notice	Issuance date
20523–01	0648–XF455	National Museum of Natural History, P.O. Box 37012, Washington, DC 20013 (Responsible Party: Kirk Johnson, Ph.D.).	82 FR 39776; August 22, 2017.	March 23, 2022.
20528–03	0648–XB500	South Carolina Department of Natural Resources, 217 Fort Johnson Road, Charleston, SC 29412 (Responsible Party: Bill Post).	86 FR 56692; October 12, 2021.	February 28, 2022.
25498–01	0648–XB629	Titan Productions, Limited, 51–55 Whiteladies Road Bristol, BS8 2LY, United Kingdom (Responsible Party: Lucy Meadows).	86 FR 71624; December 17, 2021.	March 17, 2022.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the MMPA of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: April 11, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–08024 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB934]

Identification of Nations or Entities Engaged in Illegal, Unreported, or Unregulated Fishing, Bycatch of Protected Living Marine Resources, or Shark Fishing on the High Seas

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

ACTION: Notice; request for information.

SUMMARY: NMFS is seeking information regarding nations or entities whose vessels are engaged in illegal, unreported, or unregulated (IUU) fishing; fishing practices that result in the bycatch of protected living marine resources (PLMRs) without a regulatory program comparable in effectiveness to that of the United States; and/or fishing activities in waters beyond any national jurisdiction that target or incidentally catch sharks without a regulatory program comparable to that of the United States. Such information will be reviewed for the purposes of the identification of nations or entities pursuant to the High Seas Driftnet Fishing Moratorium Protection Act (Moratorium Protection Act).

DATES: Information should be received on or before December 31, 2022. However, we encourage submission of information as early as possible.

ADDRESSES: Information may be submitted either by mail to: NMFS Office of International Affairs, Trade, and Commerce, Attn.: Moratorium Protection Act Information, F/IATC 1315 East-West Highway, Silver Spring, MD 20910, or electronically to: *IUU.PLMR.Sharks@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Ellie Bors, phone (240) 429–4461, or email *eleanor.bors@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Moratorium Protection Act requires the Secretary of Commerce (Secretary) to issue a Biennial Report to Congress that identifies nations and entities whose vessels are engaged in IUU fishing, bycatch of PLMRs, and/or fishing activities in waters beyond any national jurisdiction that target or incidentally catch sharks, in specific circumstances elaborated below. NMFS is soliciting information from the public regarding fishing activities by foreign fishing vessels in 2020, 2021, and/or 2022 that may support identification of those nations and entities in the Biennial Report.

The Shark Conservation Act of 2010 (Pub. L. 111–348) amended the Moratorium Protection Act by requiring action by the United States to strengthen shark conservation globally, including the potential identification of nations and entities with vessels fishing for sharks on the high seas (16 U.S.C. 1826k(a)(2)). In November 2015, the Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015 (Pub. L. 114–81) further amended the Moratorium Protection Act by, among other things, expanding the scope of information that can be used for the identification of nations and entities to three years for the IUU fishing and bycatch provisions (see 16 U.S.C. 1826j–1826k). In December 2016, the Ensuring Access to Pacific Fisheries Act (Pub. L. 114–327) amended the Moratorium Protection Act by also expanding the scope of information that can be used for the identification of nations and entities to three years for the shark provisions (see 16 U.S.C. 1826k).

The seventh biennial report to Congress was submitted in August 2021 and is available online at: *https://media.fisheries.noaa.gov/2021-08/2021ReporttoCongressonImprovingInternationalFisheries Management.pdf.* The report identified seven nations and entities for IUU fishing and 29 nations and entities for the bycatch of PLMRs without a regulatory program comparable in effectiveness to that of the United States.

In fulfillment of its requirements under the Moratorium Protection Act, NMFS is preparing the eighth biennial report to Congress, and will consider whether information exists to support the identification of nations or entities whose vessels are engaged in IUU fishing; fishing practices that result in bycatch of PLMRs without a regulatory program comparable in effectiveness to that of the United States; and/or fishing activities in waters beyond any national jurisdiction that target or incidentally catch sharks without a regulatory program comparable to that of the United States.

IUU Fishing

The Moratorium Protection Act requires the Secretary to identify in a biennial report to Congress those nations and entities whose fishing vessels are engaged, or have been engaged at any point during the preceding three years, in IUU fishing. The definition of IUU fishing can be found at 50 CFR 300.201 and includes:

(1) Fishing activities that violate conservation and management measures required under an international fishery management agreement to which the United States is a party, including catch limits or quotas, capacity restrictions, bycatch reduction requirements, shark conservation measures, and data reporting;

(2) In the case of non-parties to an international fishery management agreement to which the United States is a party, fishing activities that would undermine the conservation of the resources managed under that agreement;

(3) Overfishing of fish stocks shared by the United States, for which there are no applicable international conservation or management measures or in areas with no applicable international fishery management organization or agreement, that has adverse impacts on such stocks;

(4) Fishing activity that has an adverse impact on vulnerable marine ecosystems such as seamounts, hydrothermal vents, cold water corals and other vulnerable marine ecosystems located beyond any national jurisdiction, for which there are no applicable conservation or management measures or in areas with no applicable international fishery management organization or agreement; and

(5) Fishing activities by foreign-flagged vessels in U.S. waters without authorization of the United States.

PLMR Bycatch

In addition, the Secretary must identify in the biennial report those nations and entities whose fishing vessels are engaged, or have been engaged at any point during the preceding three years in fishing activities in waters beyond any national jurisdiction that result in bycatch of a PLMR, or beyond the U.S. exclusive economic zone (EEZ) that result in bycatch of a PLMR shared by the United States, and that have not implemented measures to address that bycatch that are comparable in effectiveness to U.S. regulatory requirements. In this context, PLMRs are defined as non-target fish (including sharks), sea turtles, or marine mammals that are protected under U.S. law or international agreement, including the Marine Mammal Protection Act, the Endangered Species Act, the Shark Finning Prohibition Act, and the Convention on International Trade in Endangered Species of Wild Flora and Fauna. PLMRs do not include species, except sharks, managed under the Magnuson-Stevens Fishery Conservation and Management Act, the Atlantic Tunas Convention Act, or any international fishery management

agreement. A list of species considered as PLMRs for the purposes of identification under the Moratorium Protection Act is available online at: *https://media.fisheries.noaa.gov/dam-migration/plmr_list_2019.pdf.*

Shark Catch in Waters Beyond Any National Jurisdiction

Furthermore, the Moratorium Protection Act requires that the Secretary identify nations and entities in the biennial report to Congress whose fishing vessels are engaged, or have been engaged during the preceding three years in fishing activities or practices in waters beyond any national jurisdiction that target or incidentally catch sharks and when the nation has not adopted a regulatory program to provide for the conservation of sharks, including measures to prohibit removal of any of the fins of a shark (including the tail) and discarding the carcass of the shark at sea, that is comparable to that of the United States, taking into account different conditions. When determining whether to identify nations or entities for these activities, NMFS will take into account all relevant matters including, but not limited to, the history, nature, circumstances, duration, and gravity of the fishing activity of concern.

Information Solicited

NMFS is soliciting information from the public that could be relevant to the identification of nations and entities engaged in activities that meet the criteria described above for IUU fishing, PLMR bycatch, or shark catch in waters beyond any national jurisdiction. Some types of information that may prove relevant to the process include:

- Documentation (photographs, verifiable catch data, *etc.*) of IUU fishing activity, fishing vessels engaged in PLMR bycatch, or catch of sharks on the high seas;
- Documentation (photographs, *etc.*) of fishing vessels engaged in bycatch of shared PLMRs in any waters beyond the U.S. EEZ;
- Documentation (photos, video, witness testimony, publicly available data, *etc.*) of illegal shark fishing in contravention of shark conservation and management measures adopted by Regional Fisheries Management Organizations (RFMOs) to which the United States is a Party (shark finning without full utilization of the carcass, non-reporting of shark catch, retention of prohibited shark species, *etc.*);
- Reports from off-loading facilities, port-side government officials, enforcement agents, military personnel, port inspectors, transshipment vessel workers and fish importers;
- Sightings of vessels included on RFMO IUU vessel lists;
- RFMO catch documents and statistical document programs;
- Nations' domestic regulations for bycatch and shark conservation and management, including any regulations that prohibit the removal of any of the fins of a shark (including the tail) and discarding the carcass of the shark at sea;
- Action or inaction at the national level, resulting in non-compliance with RFMO conservation and management measures, such as exceeding quotas or catch limits, or failing to report or misreporting data of the nation's fishing activities; and
- Relevant reports from governments, international organizations, or nongovernmental organizations.

NMFS will consider all available information, as appropriate, when making a determination whether or not to identify a particular nation or entity in the biennial report to Congress. As stated previously, NMFS is limited in the time frame for data it may use as the basis of a nation's identification. Appropriate information includes IUU fishing activity, bycatch of PLMRs, and shark fishing activity in waters beyond any national jurisdiction that occurred in 2020, 2021, and 2022. Information should be as specific as possible as this will assist NMFS in its review. NMFS will consider several criteria when determining whether information is appropriate for use in making identifications, including but not limited to:

- Corroboration of information;
- Whether multiple sources have been able to provide information in support of an identification;
- The methodology used to collect the information;
- Specificity of the information provided;
- Susceptibility of the information to falsification and alteration;
- Credibility of the individuals or organization providing the information; and
- Ability to share the provided information with a nation or entity in the event that it is identified, so that the nation can take specific corrective actions.

More information regarding the identification process and how the information received will be used in that process can be found at 16 U.S.C. 1826j–1826k and in the regulations codified at 50 CFR 300.200 *et seq.* Note that the timeframe for activities to be considered for IUU fishing, bycatch, and shark identifications has not yet been changed in the implementing regulations to reflect the amendments in the Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015 and the Ensuring Access to Pacific Fisheries Act of 2016, which extend the timeframe to three years in each case. Such conforming amendments to the implementing regulations are under development.

Dated: April 8, 2022.

Alexa Cole,

Director, Office of International Affairs, Trade, and Commerce, National Marine Fisheries Service.

[FR Doc. 2022–07944 Filed 4–13–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent To Prepare an Environmental Impact Statement Addressing the KC–46A Main Operating Base #6 (MOB 6) Beddown at MacDill Air Force Base, Florida or Fairchild Air Force Base, Washington

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: The Department of the Air Force (DAF) is issuing this Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) to assess the potential social, economic, and environmental impacts associated with the KC–46A Main Operating Base #6 (MOB 6) Beddown. The DAF is proposing to beddown KC–46A tanker aircraft, personnel, and associated infrastructure in support of the MOB 6 mission at MacDill Air Force Base (AFB), Florida, or, as an alternative, Fairchild AFB in Washington State.

DATES: A public scoping period of 30 days will take place starting from the date of this NOI publication in the **Federal Register**. Identification of potential alternatives, information, and analyses relevant to the proposed action are requested and will be accepted at any time during the EIS process. To ensure DAF has sufficient time to consider public input in the preparation of the Draft EIS, scoping comments should be submitted in writing to the website or the address listed below within the 30-day scoping period. The Draft EIS is anticipated in Winter 2022/2023 and the Final EIS is anticipated in Fall 2023. The Record of Decision would be approved and signed 30 days after the Final EIS.

ADDRESSES: Scoping comments may be submitted to Helen Kellogg, AFCEC/

CZN; Attn: KC–46A MOB 6 EIS; 2261 Hughes Ave., Suite 155; JBSA Lackland, TX 78236–9853 or Email: *Helen.Kellogg.1@us.af.mil.* The project website (*www.kc46amob6eis.com*) provides information on the EIS and the scoping process, and can be used to submit scoping comments online. EIS inquiries and requests for digital or print copies of scoping materials are available upon request at the email or mailing address provided. For printed material requests, the standard U.S. Postal Service shipping timeline will apply. Members of the public who want to receive future mailings informing them on the availability of the Draft and Final EIS are encouraged to submit a comment that includes their name and email or postal mailing address.

FOR FURTHER INFORMATION CONTACT: Helen Kellogg, AFCEC/CZN; Attn: KC–46A MOB 6 EIS; 2261 Hughes Ave., Suite 155; JBSA Lackland, TX 78236–9853; Telephone: 210–925–7843; or Email: *Helen.Kellogg.1@us.af.mil.*

SUPPLEMENTARY INFORMATION: The MOB 6 mission includes the beddown of 24 KC–46A aircraft in two squadrons of 12 at MacDill AFB in Florida under the Proposed Action or, as an alternative, at Fairchild AFB in Washington State. The KC–46A aircraft would recapitalize the aging KC–135 tanker fleet and would continue supporting the mission of providing worldwide refueling, cargo, and aeromedical evacuation support.

The purpose of the Proposed Action is to recapitalize aging tanker aircraft currently utilized by DAF with the KC–46A model to better address future mission requirements, offer expanded capability, and provide life-cycle cost savings in comparison to continued operation of existing KC–135 Stratotanker. The Proposed Action is needed because the KC–46A will provide capabilities currently lacking in the existing tanker fleet, resulting in a fully capable, combat operational tanker force to accomplish aerial refueling and related worldwide missions.

Resource areas being analyzed for impacts under the Proposed Action include: Noise, biological resources, cultural resources, socioeconomics, soils and geology, water resources, infrastructure and transportation, land use, hazardous materials and wastes, health and safety, air quality, and environmental justice and other sensitive receptors. Potential impacts under the Proposed Action at MacDill AFB or the Fairchild AFB alternative are anticipated to be less than significant or mitigatable to less than significant. Permits may be required for the Proposed Action at MacDill AFB, Florida or at Fairchild AFB, Washington. If so, the DAF will get all appropriate permits. In addition, the DAF will comply with the substantive requirements of the Florida Coastal Management Program. The DAF will also consult with appropriate resource agencies and Native American tribes to determine the potential for significant impacts. Consultation will be incorporated into the preparation of the EIS and will include, but not be limited to, consultation under Section 7 of the Endangered Species Act and consultation under Section 106 of the National Historic Preservation Act.

Scoping and Agency Coordination: To effectively define the full range of issues to be evaluated in the EIS, DAF will determine the scope of the analysis by soliciting comments from interested local, state, and federal elected officials and agencies, Tribes, as well as, interested members of the public and others. Implementation of the KC–46A MOB 6 mission at MacDill AFB would have the potential to be located in a floodplain and/or wetland. Consistent with the requirements and objectives of Executive Order (E.O.) 11990, ''Protection of Wetlands,'' and E.O. 11988, ''Floodplain Management,'' state and federal regulatory agencies with special expertise in wetlands and floodplains, such as the Federal Emergency Management Agency, U.S. Army Corps of Engineers, Florida Department of Environmental Protection, and the Florida State Floodplain Management Office will be contacted and asked to comment. Consistent with E.O. 11988 and E.O. 11990, this Notice of Intent initiates early public review of the Proposed Action and alternatives and invites public comments and identification of potential alternatives.

Concurrent with the publication of this notice of intent, public scoping notices will be announced locally. In accordance with DAF guidance, in-person public scoping meetings will not be held. Public scoping will instead be accomplished remotely, in accordance with the 2020 version of 40 CFR part 1506.6, via the project website at *www.kc46amob6eis.com.* The project website provides posters, a presentation, an informational fact sheet, downloadable comment forms to fill out and return by mail, and the capability for the public to submit scoping comments online. Scoping materials are also available at the following libraries: MacDill AFB Library (8102 Condor Street, Tampa, FL 3362), Port Tampa City Public Library (4902 W Commerce St, Tampa, FL 33616), Fairchild AFB Library (2 W Castle Street, Fairchild AFB, WA 99011), and Spokane Public Library (906 W Main Ave., Spokane, WA 99201).

Adriane Paris,

Air Force Federal Register Liaison Officer.

[FR Doc. 2022–08030 Filed 4–13–22; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Occupational Safety and Health Programs for Federal Employees

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice; request for comments.

SUMMARY: The U.S. Army Corps of Engineers (USACE) Safety and Health Requirements Manual (EM 385–1–1) is the gold standard for Safety and Occupational Health regulations. The manual holds a long history dating back to 1941 and is designed to facilitate the standardization of all safety programs. The EM 385–1–1 prescribes the safety and health requirements for all Corps of Engineers activities and operations. The USACE is soliciting comments on the proposed revisions to EM 385–1–1. USACE intends to update the manual and periodically thereafter, to reflect such public input, experience, and innovation. The agency will address significant comments received in the next revision of this manual.

DATES: Consideration will be given to all comments received by June 13, 2022.

ADDRESSES: You may submit comments, identified by docket number COE–2019–0015, by any of the following methods:

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

Mail: Safety and Occupational Health Office, Headquarters, U.S. Army Corps of Engineers, 441 G Street NW, Washington, DC 20314.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: If submitting comments through the Federal eRulemaking Portal, direct your comments to docket number COE–2019–0015. All comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the commenter indicates that the comment includes information claimed to be Confidential Business Information

(CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through *regulations.gov* or email. The *regulations.gov* website is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to the Corps without going through *regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment we recommend that you include your name and other contact information in the body of your comment and with any compact disc you submit. If we cannot read your comment because of technical difficulties and cannot contact you for clarification we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

Docket: For access to the docket to read background documents or comments received, go to *regulations.gov*. All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: William Eggleston, Headquarters, U.S. Army Corps of Engineers, Safety and Occupational Health Office, in Washington, DC at 202–909–9367.

SUPPLEMENTARY INFORMATION: Executive Order (E.O.) 12196, Occupational Safety and Health Programs for Federal Employees, Executive Order 11988, Floodplain Management, was issued in 1980 and directed agencies heads to (1) Furnish to employees places and conditions of employment that are free from recognized hazards that are causing or are likely to cause death or serious physical harm; (2) Operate an occupational safety and health program in accordance with the requirements of this order and basic program elements promulgated by the Secretary. DoDI 6055.1 was issued in 2014 (incorporated changes in 2018) and the DoD policy applies to all Military Departments to:

1. Protect DoD personnel from accidental death, injury, or occupational illness.
2. Apply this instruction to all personnel at all operations worldwide with certain limitations.
3. Apply risk management strategies to eliminate occupational injury or illness and loss of mission capability and resources both on and off duty.
4. Use SOH management systems across all military operations and activities, including acquisition, procurement, logistics, and facility management.
5. Apply this instruction to off-duty military personnel, except for OSHA standards.

Following issuance of DoD Safety and Occupational Health (SOH) Program DODI 6055.01; the AR–385–10, Army Safety Program implements the requirements of the Occupational Safety and Health Act of 1970 as implemented in E.O. 12196; 29 CFR 1960; DODI 6055.1; DoDI6055.4; and DoDI6055.7. It provides new policy on Army safety management procedures with special emphasis on responsibilities and organizational concepts. AR 385–10 is applicable to the Active Army, the Army National Guard/Army National Guard of the United States, and the U.S. Army Reserve, unless otherwise stated. It also applies to Army civilian employees and the U.S. Army.

Following the issuance of the AR–385–10; the EM 385–1–1 U.S. Army Corps of Engineers Safety and Health Requirements Manual prescribes the safety and health requirements for all Corps of Engineers activities and operations. The manual applies to Headquarters, U.S. Army Corps of Engineers (HQUSACE) elements, major subordinate commands, districts, centers, laboratories, and field operating activities (FOA), as well as USACE contracts and those administered on behalf of USACE. Applicability extends to occupational exposure for missions under the command of the Chief of Engineers, whether accomplished by military, civilian, or contractor personnel.

Instructions for Providing Comments

USACE is requesting assistance in the form of data, comments, literature references, or field experiences, to help clarify the policy requirements for implementing Safety and Occupational Health activities for both Corps and contractor personnel. The draft version of the Safety and Health Requirements Manual (EM 385–1–1, April 2022) is available for review on the USACE Publications website: *https://usace.contentdm.oclc.org/utils/getfile/collection/p16021coll9/id/2559.* While USACE welcomes any and all feedback on this Engineering Manual, detailed responses to the questions provided will be particularly helpful to USACE in clarifying, revising, adding, or deleting information in a particular area/section/chapter. The most useful comments will be derived from on-the-job experiences that are covered within the topics of the manual. Commenters should use their knowledge of working with USACE on various types of federal actions as well as their understanding of consensus standards and other federal Safety and Health regulations.

Future Actions

Feedback and comments provided through this notice will be considered and the draft version of the Safety and Health Requirements Manual (EM 385–1–1, April 2022) will be updated as appropriate. When the manual is finalized and published on the USACE Safety and Occupational Health Office website *https://www.usace.army.mil/Missions/Safety-and-Occupational-Health/,* and the document itself will be made available through the typical U.S. Army publication process.

Michael L. Connor,

Assistant Secretary of the Army, (Civil Works).

[FR Doc. 2022–07998 Filed 4–13–22; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0048]

Agency Information Collection Activities; Comment Request; Part 601 Preferred Lender Arrangements

AGENCY: Federal Student Aid (FSA), 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 June 13, 2022.

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–2022–SCC–0101. 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: Part 601 Preferred Lender Arrangements.

OMB Control Number: 1845–0101.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Individuals and Households; Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 18,623,389.

Total Estimated Number of Annual Burden Hours: 3,801,989.

Abstract: 34 CFR part 601—Institution and Lender Requirements Relating to Education Loans is a section of the regulations governing private education loans offered at covered institutions. These regulations assure the Secretary that the integrity of the program is protected from fraud and misuse of program funds and places requirements on institutions and lenders to ensure that borrowers receive additional disclosures about Title IV, HEA program assistance prior to obtaining a private education loan. The Department is submitting the unchanged Private Education Loan Applicant Self-Certification for OMB's continued approval. While information about the applicant's cost of attendance and estimated financial assistance must be provided to the student, if available, the student will provide the data to the private loan lender who must collect and maintain the self-certification form prior to disbursement of a Private Education Loan. The Department will not receive the Private Education Loan Applicant Self-Certification form and therefore will not be collecting and maintaining the form or its data.

Dated: April 8, 2022.

Kun 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. 2022–07961 Filed 4–13–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0047]

Agency Information Collection Activities; Comment Request; Loan Cancellation in the Federal Perkins Loan Program

AGENCY: Federal Student Aid (FSA), 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 June 13, 2022.

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–2022–SCC–0047. 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: Loan Cancellation in the Federal Perkins Loan Program.

OMB Control Number: 1845–0100.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; Individuals and Households; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 116,872.

Total Estimated Number of Annual Burden Hours: 43,832.

Abstract: This is a request for an extension of the current OMB approval for the recordkeeping requirements contained in 34 CFR 674.53, 674.56, 674.57, 674.58 and 674.59. The information collections in these regulations are necessary to determine Federal Perkins Loan (Perkins Loan) Program borrower's eligibility to receive program benefits and to prevent fraud and abuse of program funds. There has been no change to the regulatory requirements. Due to the effects of the COVID–19 pandemic and the suspension of the collection of loans, the Department lacks sufficient data to allow for more accurate updates to the usage of the regulations.

Dated: April 8, 2022.

Kun 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. 2022–07960 Filed 4–13–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an online virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge. The Federal Advisory Committee Act requires that public notice of this online meeting be announced in the **Federal Register**.

DATES: Wednesday, May 11, 2022; 6:00 p.m.–7:30 p.m.

ADDRESSES: Online Virtual Meeting. To attend, please send an email to: *orssab@orem.doe.gov* by no later than 5:00 p.m. EDT on Wednesday, May 4, 2022.

FOR FURTHER INFORMATION CONTACT: Melyssa P. Noe, Alternate Deputy Designated Federal Officer, U.S. Department of Energy (DOE), Oak Ridge Office of Environmental Management (OREM), P.O. Box 2001, EM–942, Oak Ridge, TN 37831; Phone (865) 241–3315; or email: *Melyssa.Noe@orem.doe.gov*. Or visit the website at *https://www.energy.gov/orem/services/community-engagement/oak-ridge-site-specific-advisory-board*.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Comments from the Deputy Designated Federal Officer (DDFO)
- Comments from the DOE, Tennessee Department of Environment and Conservation, and Environmental Protection Agency Liaisons
- Presentation: *Discussion on EM Disposal Facility/Waste Disposal Capacity*
- Public Comment Period
- Motions/Approval of March 9, 2022 Meeting Minutes
- Status of Outstanding Recommendations
- Alternate DDFO Report
- Committee Reports

Public Participation: The online meeting is open to the public. Written statements may be filed with the Board via email either before or after the meeting as there will not be opportunities for live public comment during this online virtual meeting. Public comments received by no later than 5:00 p.m. EDT on Wednesday, May 4, 2022 will be read aloud during the virtual meeting. Comments will be accepted after the meeting, by no later than 5:00 p.m. EDT on Monday, May 16, 2022. Please submit comments to *orssab@orem.doe.gov*. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to submit public comments should email them as directed above.

Minutes: Minutes will be available by emailing or calling Melyssa P. Noe at the email address and telephone number listed above. Minutes will also be available at the following website: *https://www.energy.gov/orem/listings/oak-ridge-site-specific-advisory-board-meetings*.

Signed in Washington, DC, on April 11, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–08006 Filed 4–13–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an online virtual committee meeting of the whole of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford. The Federal Advisory Committee Act requires that public notice of this online virtual meeting be announced in the **Federal Register**.

DATES: Tuesday, May 17, 2022; 9:00 a.m.–4:30 p.m.

ADDRESSES: Online Virtual Meeting. To receive the meeting access information and call-in number, please contact the Federal Coordinator, Gary Younger, at the telephone number or email listed below by five days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Gary Younger, Federal Coordinator, U.S. Department of Energy, Hanford Office of Communications, Richland Operations Office, P.O. Box 550, Richland, WA 99354; Phone: (509) 372–0923; or Email: *gary.younger@rl.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

- Future Site Usage
- Discussion of Board Business

Public Participation: The online meeting is open to the public. The EM SSAB, Hanford, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gary Younger at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or within five business days after the meeting. Individuals who wish to make oral statements pertaining to agenda items

should contact Gary Younger. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available at the following website: *http://www.hanford.gov/page.cfm/hab/FullBoardMeetingInformation.*

Signed in Washington, DC, on April 11, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–08007 Filed 4–13–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–77–002]

Tenaska Clear Creek Wind, LLC v. Southwest Power Pool, Inc.; Notice of Protest and Amended Complaint

Take notice that on April 1, 2022, Tenaska Clear Creek Wind, LLC (Tenaska or Complainant) filed a protest to Southwest Power Pool, Inc.'s (SPP or Respondent) March 11, 2022 compliance filing in the above-captioned proceeding. Tenaska states that to the extent the Commission deems its protest to be raising issues or arguments outside the scope of its original complaint or SPP's compliance filing, it submits the pleading as an amendment to its complaint against SPP, pursuant to sections 206, 306, and 309 of the Federal Power Act, 16 U.S.C. 824e, 825e, and 825h and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206.

The Complainant certifies that copies of the pleading were served on the contacts listed for Respondent in the Commission's list of Corporate Officials.

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. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://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: 5:00 p.m. Eastern Time on April 21, 2022.

Dated: April 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–07983 Filed 4–13–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–90–000.

Applicants: Laurel Mountain Interconnection, LLC.

Description: Laurel Mountain Interconnection, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 4/7/22.

Accession Number: 20220407–5167.

Comment Date: 5 p.m. ET 4/28/22.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–50–000.

Applicants: East Kentucky Power Cooperative, Inc.

Description: Petition of East Kentucky Power Cooperative, Inc. for Enforcement of PURPA.

Filed Date: 4/8/22.

Accession Number: 20220408–5112.

Comment Date: 5 p.m. ET 4/29/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–1633–001.

Applicants: Silver Run Electric, LLC, PJM Interconnection, L.L.C.

Description: Compliance filing: Silver Run Electric, LLC submits tariff filing per 35: Silver Run Electric Amendment to Order No. 864 Compliance Filing to be effective 5/25/2020.

Filed Date: 4/8/22.

Accession Number: 20220408–5080.

Comment Date: 5 p.m. ET 4/29/22.

Docket Numbers: ER22–496–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment: 2022–04–08_Deficiency Response to Minimum Capacity Obligation Filing to be effective 9/1/2022.

Filed Date: 4/8/22.

Accession Number: 20220408–5128.

Comment Date: 5 p.m. ET 4/29/22.

Docket Numbers: ER22–1101–001.

Applicants: Cascade Energy Storage, LLC.

Description: Tariff Amendment: Second Supplement to Application for Market-Based Rate Authority to be effective 2/24/2022.

Filed Date: 4/7/22.

Accession Number: 20220407–5173.

Comment Date: 5 p.m. ET 4/18/22.

Docket Numbers: ER22–1102–001.

Applicants: Sierra Energy Storage, LLC.

Description: Tariff Amendment: Second Supplement to Application for Market-Based Rate Authority to be effective 2/24/2022.

Filed Date: 4/7/22.

Accession Number: 20220407–5174.

Comment Date: 5 p.m. ET 4/18/22.

Docket Numbers: ER22–1103–001.

Applicants: BRP Capital & Trade LLC.

Description: Tariff Amendment: Second Supplement to Application for Market-Based Rate Authority to be effective 4/25/2022.

Filed Date: 4/7/22.
Accession Number: 20220407–5179.
Comment Date: 5 p.m. ET 4/18/22.

Docket Numbers: ER22–1602–000.
Applicants: Midcontinent Independent System Operator, Inc., Cooperative Energy.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2022–04–07_ROE Married Sheets to be effective 10/1/2016.
Filed Date: 4/7/22.
Accession Number: 20220407–5184.
Comment Date: 5 p.m. ET 4/28/22.

Docket Numbers: ER22–1603–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii): Crimson Solar (Enterprise Solar) LGIA Filing to be effective 3/25/2022.
Filed Date: 4/8/22.
Accession Number: 20220408–5122.
Comment Date: 5 p.m. ET 4/29/22.

Docket Numbers: ER22–1604–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2022–04–08 Central Procurement Entities Tariff Amendment to be effective 8/15/2022.
Filed Date: 4/8/22.
Accession Number: 20220408–5137.
Comment Date: 5 p.m. ET 4/29/22.

Docket Numbers: ER22–1605–000.
Applicants: Pacific Gas and Electric Company.
Description: Tariff Amendment: Termination of Shelter Cove WPA (SA 382) to be effective 6/7/2022.
Filed Date: 4/8/22.
Accession Number: 20220408–5139.
Comment Date: 5 p.m. ET 4/29/22.

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: April 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–07986 Filed 4–13–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2701–061]

Erie Boulevard Hydropower, L.P.; Notice of Reasonable Period of Time for Water Quality Certification Application

On March 10, 2022, Erie Boulevard Hydropower, L.P. submitted to the Federal Energy Regulatory Commission (Commission) evidence of its application for a Clean Water Act section 401(a)(1) water quality certification filed with New York State Department of Environmental Conservation (New York DEC), in conjunction with the above captioned project. Pursuant to section 401 of the Clean Water Act [1] and section 5.23(b) of the Commission's regulations,[2] a state certifying agency is deemed to have waived its certifying authority if it fails or refuses to act on a certification request within a reasonable period of time, which is one year after the date the certification request was received. Accordingly, we hereby notify New York DEC of the following:

Date that New York DEC Received the Certification Request: March 9, 2022.

If New York DEC fails or refuses to act on the water quality certification request on or before March 9, 2023, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: April 7, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–08032 Filed 4–13–22; 8:45 am]

BILLING CODE 6717–01–P

[1] 33 U.S.C. 1341(a)(1).

[2] 18 CFR [4.34(b)(5)/5.23(b)/153.4/157.22].

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–813–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Remove Expired Agmts from Tariff eff 4–8–2022 to be effective 4/8/2022.

Filed Date: 4/8/22.

Accession Number: 20220408–5010.

Comment Date: 5 p.m. ET 4/20/22.

Docket Numbers: RP22–814–000.

Applicants: Double E Pipeline, LLC.

Description: Compliance filing: Order 587–Z Update to NASEB Standards to be effective 6/1/2022.

Filed Date: 4/8/22.

Accession Number: 20220408–5055.

Comment Date: 5 p.m. ET 4/20/22.

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.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

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: April 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–07985 Filed 4–13–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3211–010]

Power Authority of the State of New York; Notice of Reasonable Period of Time for Water Quality Certification Application

On March 11, 2022, the Power Authority of the State of New York submitted to the Federal Energy Regulatory Commission (Commission) evidence of its application for a Clean Water Act section 401(a)(1) water quality certification filed with New York State Department of Environmental Conservation (New York DEC), in conjunction with the above captioned project. Pursuant to section 401 of the Clean Water Act [1] and section 5.23(b) of the Commission's regulations,[2] a state certifying agency is deemed to have waived its certifying authority if it fails or refuses to act on a certification request within a reasonable period of time, which is one year after the date the certification request was received. Accordingly, we hereby notify New York DEC of the following:

Date that New York DEC Received the Certification Request: March 11, 2022.

If New York DEC fails or refuses to act on the water quality certification request on or before March 11, 2023, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: April 7, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–08036 Filed 4–13–22; 8:45 am]

BILLING CODE 6717–01–P

[1] 33 U.S.C. 1341(a)(1).

[2] 18 CFR [4.34(b)(5)/5.23(b)/153.4/157.22].

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RD22–2–000]

Commission Information Collection Activities (FERC–725a, FERC–725d, FERC–725g, FERC–725m and FERC–725Z)

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–725A, FERC–725D, FERC–725G, FERC–725M and FERC–725Z) the proposed retirement of FAC–010–3, the proposed FAC–011–4, FAC–014–3, IRO–008–3, TOP–001–6 and proposed corresponding revisions to FAC–003–5, PRC–002–3, PRC–023–5 and PRC–026–2 Reliability Standards.

DATES: Comments on the collection of information are due June 13, 2022.

ADDRESSES: You may submit comments (identified by Docket No. RD22–2–000) by one of the following methods:

Electronic filing through *http://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:
  - ○ *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.
  - ○ *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All 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, FERC–725D, FERC–725G, FERC–725M and FERC–725Z.

OMB Control No.: OMB Control No: 1902–244 (FERC–725A), 1902–247 (FERC–725D), 1902–252 (FERC–725G), 1902–263 (FERC–725M) and 1902–276 (FERC–725Z).

Type of Request: Three-year approval of the FERC–725A, FERC–725D, FERC–725G, FERC–725M and FERC–725Z information collection requirements with changes to the current reporting requirements as follows.

Abstract: The Electricity Modernization Act of 2005, which is Title XII of the Energy Policy Act of 2005 [1] (EPAct 2005), was enacted into law. Reliability Standards that NERC proposes to the Commission may include Reliability Standards that are proposed by a Regional Entity to be effective in that region.[2] Section 215 of the FPA requires a Commission-certified ERO to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by the ERO subject to Commission oversight or by the Commission independently.

The number of respondents below is based on an estimate of the NERC compliance registry for balancing authority, transmission operator, generator operator, generator owner and reliability coordinator. The Commission based its paperwork burden estimates on the NERC compliance registry as of January 7, 2022. According to the registry, there are 98 balancing authorities (BAs), 325 transmission owners (TOs), 168 transmission operators (TOPs), 204 transmission planners (TPs), 1,068 generator owners (GOs), 945 generator operators (GOPs), 302 distribution providers (DPs), 63 planning coordinators (PCs) and 12 reliability coordinators (RCs). The estimates are based on the change in burden from the current standards to the standards approved in this Order. The Commission based the burden estimates on staff experience, knowledge, and expertise.

The estimates are based combination on one-time (years 1 and 2) and ongoing execution (year 3) obligations to follow the revised Reliability Standards.

The Project 2015–09 Establish and Communicate System Operating Limits Standard Drafting Team (SDT): (1) Developed proposed revisions to Reliability Standards and their applicable functional entities: FAC–011–4 (RC), FAC–014–3 (PC, RC, TO, TP), IRO–008–3 (RC), and TOP–001–6 (BA, TO, GO, DP); (2) proposed the retirement of FAC–010–3 (PA/PC) and developed corresponding revisions to FAC–003–5 (TO, GO), PRC–002–3 (RC, TO, GO), PRC–023–5 (TO, GO, DP, PC), and PRC–026–2 (TO, GO, PC) Reliability Standards to remove or replace references to system operating limits

[1] 16 U.S.C. 824d(a).

[2] 16 U.S.C. 824o(e)(4). A Regional Entity is an entity that has been approved by the Commission to enforce Reliability Standards under delegated authority from the ERO. *See* 16 U.S.C. 824o(a)(7) and (e)(4).

(SOLs) and interconnection reliability operating limits (IROLs) established by planning entities.

The developed proposed revisions to Reliability Standards are:

• FAC–011–4 is applicable to the RC and its purpose is to ensure that SOLs used in the reliable operation of the bulk electric system are determined based on an established RC methodology or methodologies. NERC clarified acceptable system performance criteria for the operations horizon and developed an SOL risk-based notification framework through the RC's SOL methodology.

• FAC–014–3 is applicable to the PC, RC, TOP and TP and its purpose is to ensure that SOLs used in the reliable operation of the bulk electric system are determined based on an established RC methodology or methodologies and that Planning Assessment performance criteria is coordinated with these methodologies. NERC removed references to planning horizon SOLs and IROLs and clearly delineate specific functional entity responsibility for determining and communicating each type of SOL used in operations.

• IRO–008–3 is applicable to the RC and requires RCs to perform analyses and assessments to prevent instability, uncontrolled separation, or cascading. NERC added a new requirement requiring a RC to use its SOL methodology when determining SOL exceedances for its analyses and assessments and further revised a requirement requiring the RC to use its SOL risk-based notification framework when communicating SOL or IROL exceedances.

• TOP–001–6 is applicable to the BA, TOP, GOP, and DP but the proposed revisions only impact the TOP. NERC added a new requirement requiring a TOP to use its RC SOL methodology when determining SOL exceedances and further revised a requirement requiring TOP notifications regarding SOL exceedances to be done according to the risk-based approach in the RC's SOL methodology.

NERC further proposes the retirement of currently effective Reliability Standard FAC–010–3 that requires PCs and TPs to establish SOLs for the planning horizon. The proposed retirement of FAC–010–3 is mainly due to its redundancy with currently effective TPL–001–4 Standard and new requirements in proposed FAC–014–3.

In addition, the proposed retirement of FAC–010–3 developed corresponding revisions to proposed Reliability Standards FAC–003–5, PRC–002–3, PRC–023–5, and PRC–026–2 as follows:

• FAC–003–5 is applicable to TOs and GOs and NERC proposes to modify Applicability Sections 4.2.2 and 4.3.1.2 of FAC–003–5 to replace references to ''elements of an IROL under NERC Standard FAC–014 by the Planning Coordinator'' with references to facilities:

> ''identified by the Planning Coordinator or Transmission Planner, per its Planning Assessment of the Near-Term Transmission Planning Horizon as a Facility that if lost or degraded are expected to result in instances of instability, Cascading, or uncontrolled separation that adversely impacts the reliability of the Bulk Electric System for a planning event.''

• PRC–002–3 is applicable to the RC, TO and GO and NERC proposes to modify the applicability of the PRC–002–3 standard to remove PCs as a responsible entity subject to the standard and replace any references in the standard that would have included PCs with references to RCs. NERC concluded that the RC was the appropriate entity to carry out the duties that currently apply to PCs in certain interconnections, including the identification of BES elements that are part of an IROL or stability-related SOL.

• PRC–023–5 is applicable to the TO, GO, DP and PC and NERC proposes to modify Section B2 of Attachment B to PRC–023–5 as follows:

> ''B2. The circuit is selected by the Planning Coordinator or Transmission Planner based on Planning Assessments of the Near-Term Transmission Planning Horizon that identify instances of instability, Cascading, or uncontrolled separation, that adversely impact the reliability of the Bulk Electric System for planning events.''

Attachment B sets the criteria used to determine the circuits in a Planning Coordinator area for which Transmission Owners, Generator Owners, and Distribution Providers must comply with certain requirements in the standard applicable to protective relays.

• PRC–026–2 is applicable to the GO, PC and TO and NERC proposes modification to the PRC–026–2 standard, Requirement R1, Criteria 1, 2, and 4 to replace references to planning horizon SOLs with references to the TPL–001–4 Planning Assessment.

The Commission estimates that the NERC proposal, which would retire FAC–010–3, moves impacted and revised Reliability Standards without adding new obligations on registered entities resulting in a change in burden for industry of 128 hours. The proposed retirement of FAC–010–3 is mainly due to its redundancy with currently effective TPL–001–4 Standard and new requirements in proposed FAC–014–3. The Commission based the change in burden estimates on staff experience, knowledge, and expertise.

PROPOSED CHANGES DUE TO THE APPROVAL OF NERC'S PROPOSED RELIABILITY STANDARDS AND THE RETIREMENT OF FAC–010–3 IN DOCKET NO. RD22–2

Reliability standard	Type [3] and number of entity	Number of annual responses per entity	Total number of responses	Average number of burden hours per response	Total burden hours
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
FERC–725D					
FAC–010–3 [4] Retire (marked in red).	PA/PC (63)	1	(63)	(220.6 hrs.); ($19,192)	(13,898 hrs.); ($1,209,109).
FAC–010–2.1, R5 [5] (FERC–725D).	PA	1	(63)	(25.4 hrs.); ($2,209.8)	(1,600 hrs.); ($139,217).
Total Retirement for FAC–010–3 [6].	PA	1	(63)	(246)	(15,498 hrs.); ($1,348,326).
One Time Estimate Years 1 and 2:					
FAC–011–4	RC (12)	1	12	176 hrs.; $15,312	2,112 hrs.; $183,744.
FAC–014–3	RC (12)	1	12	64 hrs.; $5,568	768 hrs.; $66,816.

PROPOSED CHANGES DUE TO THE APPROVAL OF NERC'S PROPOSED RELIABILITY STANDARDS AND THE RETIREMENT OF FAC–010–3 IN DOCKET NO. RD22–2—Continued

Reliability standard	Type [3] and number of entity (1)	Number of annual responses per entity (2)	Total number of responses (1) * (2) = (3)	Average number of burden hours per response (4)	Total burden hours (3) * (4) = (5)
FAC–014–3	PA/PC (63)	1	63	96 hrs.; $8,352	6,048 hrs.; $526,176.
FAC–014–3	TP (204)	1	204	96 hrs.; $8,352	19,584 hrs.; $1,703,808.
FAC–014–3	TOP (168)	1	168	32 hrs.; $2,784	5,376 hrs.; $467,712.
Ongoing Estimate Year 3 ongoing:					
FAC–011–4	RC (12)	1	12	16 hrs.; $1,392	192 hrs.; $16,704.
FAC–014–3	RC (12)	1	12	16 hrs.; $1,392	192 hrs.; $16,704.
FAC–014–3	PA/PC (63)	1	63	16 hrs.; $1,392	1,008 hrs.; $87,696.
FAC–014–3	TP (204)	1	204	16 hrs.; $1,392	3,264 hrs.; $334,080.
FAC–014–3	TOP (168)	1	168	16 hrs.; $1,392	2,688 hrs.; $233,856.
Sub-Total for FERC–725D.			918		41,232hrs; $3,637,296.
FERC–725M [7]					
One Time Estimate Years 1 and 2:					
FAC–003–5	TO (325)	4	1,300	8 hrs.; $696	10,400 hrs.; $904,800.
FAC–003–5	GO (1068)	4	4,272	8 hrs.; $696	34,176 hrs.; $2,973,312.
Ongoing Estimate Year 3 ongoing:					
Sub-Total for FERC–725M.			5,572		44,576hrs; $3,878,112.
FERC–725G					
One Time Estimate Years 1 and 2:					
PRC–002–3 [8]	RC (12)	1	12	32 hrs.; $2,784	384 hrs.; $33,408.
PRC–002–3 [9] Retired (marked in red).	PA/PC (35)	1	(35)	(32 hrs.); ($2,784)	(2,016 hrs.); ($175,392).
PRC–023–5 [10]	PA/PC (63)	1	63	32 hrs.; $2,784	2,016 hrs.; $175,392.
PRC–026–2 [11]	PA/PC (63)	1	63	32 hrs.; $2,784	2,016 hrs.; $175,392.
Ongoing Estimate Year 3 ongoing:					
PRC–002–3	RC (12)	1	12	16 hrs.; $1,392	192 hrs.; $16,704.
Sub-Total for FERC–725G.			150		4,608hrs; $400,896.
FERC–725Z					
One Time Estimate Years 1 and 2:					
IRO–008–3	RC (12)	1	12	32 hrs.; $2784	384 hrs.; $33,408.
Ongoing Estimate Year 3 ongoing:					
IRO–008–3	RC (12)	1	12	16 hrs.; $1,392	144 hrs.; $16,704.
Sub-Total for FERC–725Z.			24		528 hrs.; $50,112.

PROPOSED CHANGES DUE TO THE APPROVAL OF NERC'S PROPOSED RELIABILITY STANDARDS AND THE RETIREMENT OF FAC–010–3 IN DOCKET NO. RD22–2—Continued

Reliability standard	Type [3] and number of entity	Number of annual responses per entity	Total number of responses	Average number of burden hours per response	Total burden hours
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
FERC–725A					
One Time Estimate Years 1 and 2: TOP–001–6 [12] ..	TOP (168)	1	168	32 hrs.; $2,784	5,376 hrs.; $467,712.
Ongoing Estimate Year 3 ongoing: TOP–001–6	TOP (168)	1	168	16 hrs.; $1,392	2,688hrs; $233,856.
Sub-Total for FERC–725A.	.....	.....	336	.....	8,064 hrs.; $701,568.
Total Reductions Due to Docket No. RD22–2–000.	.....	.....	.....	.....	99,008 hrs.; $8,667,984.

Titles: FERC–725A, Mandatory Reliability Standard: TOP–001–6; FERC–725D, Mandatory Reliability Standards for the Bulk Power System: Reliability Standards FAC–010, FAC–011, FAC–014; FERC–725G, Mandatory Reliability Standards for Bulk-Power System: Reliability Standard PRC; FERC–725Z, Mandatory Reliability Standards for the Bulk-Power System: Reliability Standard IRO; FERC–725M, Mandatory Reliability Standards:

Action: Changes to Existing Collections of Information, FERC–725A, FERC–725G, FERC–725M, FERC–725Z, 725D, and Elimination of Collections of Information.

OMB Control Nos: 1902–0244 (FERC–725A); 1902–0247 (FERC–725D); 1902–0252 (FERC–725G); 1902–0263 (FERC–725M) and 1902–0276 (FERC–725Z).

Respondents: Business or other for profit, and not for profit institutions.

Frequency of Responses: On occasion (and proposed for deletion).

Necessity of the Information: This proceeding approves the retirement of FAC–010–3 (System Operating Limits Methodology for the Planning Horizon) Reliability Standards. Reliability Standards FAC–011–4 (System Operating Limits Methodology for the Operations Horizon), FAC–014–3 (Establish and Communicate System Operating Limits), FAC–003–5 (Transmission Vegetation Management), PRC–002–3 (Disturbance Monitoring and Reporting Requirements), PRC–023–5 (Transmission Relay Load-ability), PRC–026–2 (Transmission Relay Load-ability), IRO–008–3 (Reliability Coordinator Operational Analyses and Real-time Assessments), TOP–001–6 (Transmission Operations) are part of the implementation of the Congressional mandate of the Energy Policy Act of 2005 to develop mandatory and enforceable Reliability Standards to better ensure the reliability of the nation's Bulk Power system. Specifically, the revised standards ensure generating resources are prepared for local cold weather events and that entities will effectively communicate information need operating the Bulk Power System.

Internal review: The Commission has reviewed NERC's proposal and determined that its action is necessary to implement section 215 of the FPA. The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden reduction estimates associated with the information requirements approved for retirement.

Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, Office of the Executive Director, 888 First Street NE, Washington, DC 20426 [Attention: Ellen Brown, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

Comments concerning the information collections and requirements approved for retirement in this Final Rule and the associated

[3] RC=Reliability Coordinator; BA=Balancing Authority; TP=Transmission Planner; TOP=Transmission Operator; TO=Transmission Owner; GO=Generator Owner; DP=Distribution Provider; PA/PC=Planning Coordinator; and RC=Reliability Coordinator.

[4] FAC–010–2, FAC–011–2 and FAC–014 –2 were all approved by the Commission in ((Docket No. IC14–5–000 COMMISSION INFORMATION COLLECTION ACTIVITIES (FERC–725D); COMMENT REQUEST; EXTENSION (February 21, 2014)) with a burden of 138,979 hours. Staff estimates that the PC burden under FAC–010–3 from that estimate is 10 percent of the total or 13,898 hours. FERC staff estimates that industry costs for salary plus benefits are similar to Commission costs. The FERC 2021 average salary plus benefits for one FERC full-time equivalent (FTE) is $180,703/year (or $87.00/hour) posted by the Bureau of Labor Statistics for the Utilities sector (available at *https://www.bls.gov/oes/current/naics3_221000.htm*).

[5] In Docket No. RM13–8–000 FERC 725D OMB Control: From 1902–0247 for the FAC–010–2.1 Requirement R5 burden of 1,600hrs should be retired with full retirement of FAC–010–3.

[6] The total of manhours associated FAC–010–3 equals the sum of 13,898 hrs. + 1,600 hrs. = 15,498 hrs.

[7] Proposed revision is a one-time change to align updated terminology in the NERC Standards.

[8] Proposed revision adds burden to the RC only.

[9] The removal of the PC from PRC–002–3 is a one-time reduction in burden. Eastern and ERCOT interconnection impacted.

[10] Proposed revision adds burden to the PA/PC only and is a one-time change to align updated terminology in the NERC Standards.

[11] Proposed revision adds burden to the PA/PC only and is a one-time change to align updated terminology in the NERC Standards.

[12] Proposed revision adds burden to the TOP only.

burden estimates, should be sent to the Commission in this docket and may also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments should be sent by email to OMB at the following email address: *oira_submission@omb.eop.gov.* Please refer to the appropriate OMB Control Number(s) and Docket No. RD22–2–000 in your submission.

Environmental Analysis

The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[13] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.[14] The actions approved here fall within this categorical exclusion in the Commission's regulations.

Document Availability

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*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

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By direction of the Commission.

Dated: April 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–07987 Filed 4–13–22; 8:45 am]

BILLING CODE 6717–01–P

[13] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

[14] 18 CFR 380.4(a)(2)(ii).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–44–000]

LA Storage, LLC; Notice of Availability of the Final Environmental Impact Statement for the Proposed Hackberry Storage Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) for the Hackberry Storage Project (Project), proposed by LA Storage, LLC (LA Storage) in the above-referenced docket. LA Storage requests authorization to construct and operate natural gas storage and transmission facilities in Louisiana. The Project is designed to provide 20.03 billion cubic feet of working gas storage capacity and 1.5 billion cubic feet per day of gas deliverability and injectability, and interconnecting with the Cameron Interstate Pipeline (CIP) facilities operated by Cameron Interstate Pipeline, LLC and the Port Arthur Pipeline Louisiana Connector (PAPLC) facilities to be operated by Port Arthur Pipeline, LLC.

The final EIS assesses the potential environmental effects of the construction and operation of the Project in accordance with the requirements of the National Environmental Policy Act. FERC staff concludes that approval of the proposed Project, with the mitigation measures recommended in the EIS, would result in some adverse environmental impacts; however, with the exception of climate change impacts, those impacts would not be significant. The EIS does not characterize the Project's greenhouse gas emissions as significant or insignificant because the Commission is conducting a generic proceeding to determine whether and how the Commission will conduct climate change significance determinations going forward.[1]

The final EIS addresses the potential environmental effects of the construction and operation of the following Project facilities: The Project would involve the conversion of three existing salt dome caverns to natural gas storage service and the development of one new salt dome cavern for additional natural gas storage service, all within a permanent natural gas storage facility on a 160-acre tract of land owned by LA Storage in Cameron Parish, Louisiana. In addition to the storage caverns, LA Storage would construct and operate on-site compression facilities (Pelican Compressor Station) and up to six solution mining water supply wells at the storage facility on LA Storage's property. LA Storage would also construct and operate the following natural gas facilities in Cameron and Calcasieu Parishes, Louisiana: The Hackberry Pipeline, consisting of approximately 11.1 miles of 42-inch-diameter natural gas pipeline connecting the certificated PAPLC pipeline (CP18–7) to the natural gas storage caverns; the CIP Lateral, an approximately 4.9-mile-long, 42-inch-diameter natural gas pipeline extending from the existing CIP to the planned natural gas storage caverns; metering and regulating at the CIP and PAPLC interconnects; and an approximately 6.2-mile-long, 16-inch-diameter brine disposal pipeline that would transport brine from the caverns to four saltwater disposal wells located on two new pads north of the facility.

The Commission mailed a copy of the *Notice of Availability of the Final Environmental Impact Statement for the Proposed Hackberry Storage Project* to federal, state, and local government representatives and agencies; local libraries; newspapers; elected officials; Native American Tribes; and other interested parties. The final EIS 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 final EIS 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 (*i.e.,* CP21–44–000). 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.

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC

[1] *Consideration of Greenhouse Gas Emissions in Natural Gas Infrastructure Project Reviews,* 178 FERC ¶ 61,108 (2022); 178 FERC ¶ 61,197 (2022).

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 that 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: April 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–07984 Filed 4–13–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15261–000]

Nevada Hydro, Inc.; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On February 8, 2022, Nevada Hydro Company, Inc. filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Lake Elsinore Advanced Pumped Storage Project to be located on Lake Elsinore and San Juan Creek near the city of Lake Elsinore in Riverside and San Diego Counties, California. The project would occupy about 845 acres of federal land administered by the U.S. Department of Agriculture, Forest Service.

The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of: (1) A new upper reservoir (Decker Canyon) with a gross storage volume of 5,750 acre-feet and a surface area of approximately 70 acres at a normal reservoir surface elevation of 2,790 feet above mean sea level (msl); (2) a 262-foot-high main dam located on the southwest side of the upper reservoir; (3) a water conduit system consisting of a 1,248-foot-long, 25-foot-diameter concrete-lined power shaft and a 8,247-foot-long, 15-foot-diameter power tunnel transitioning to two, 250-foot-long, 12-foot-diameter steel penstocks; (4) an underground powerhouse with two, reversible Francis-type pump-turbine units with a total installed capacity of 500 megawatts; (5) the existing Lake Elsinore, to be used as a lower reservoir, with a surface area of about 3,412 acres at a normal reservoir surface elevation of 1,249 feet above msl; (6) two 2,450-foot-long, 25-foot-wide, and 25-foot-high concrete-lined tailrace tunnels; (7) about 32 miles of 500-kilovolt transmission line connecting the project to an existing transmission line owned by Southern California Edison that is located north of the proposed project and to an existing San Diego Gas and Electric Company transmission line located to the south; and (8) appurtenant facilities. The estimated annual generation of the project would be 1,560 gigawatt-hours.

Applicant Contacts: Mr. Michael Swiger, Van Ness Feldman LLP, 1050 Thomas Jefferson Street NW, Washington, DC 20007; (202) 298–1891; *mas@vnf.com;* and Mr. Paul Anderson, Nevada Hydro Company, Inc., 2416 Cades Way, Vista, California 92081; (951) 585–3277; *paul@leapsphs.com.*

FERC Contact: Tim Konnert, (202) 502–6359.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications 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. The first page of any filing should include docket number P–15261–000.

More information about this project, including a copy of the application, can be viewed, or printed on the ''eLibrary'' link of the Commission's website at *https://elibrary.ferc.gov/eLibrary/search.* Enter the docket number (P–15261) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: April 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–07982 Filed 4–13–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2014–0859; FRL–9719–02–ORD]

Supplement to the 2019 Integrated Science Assessment for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of a final document titled, ''Supplement to the 2019 Integrated Science Assessment for Particulate Matter (Final)'' ([EPA/600/R–22/028]). The document was prepared by the Center for Public Health and Environmental Assessment (CPHEA) within EPA's Office of Research and Development (ORD) as part of the reconsideration of the EPA's 2020 final action reviewing the National Ambient Air Quality Standard (NAAQS) for particulate matter (PM). The Supplement represents a targeted review of peer-reviewed studies published since the literature cutoff date (*i.e.,* ~January 2018) of the 2019 Integrated Science Assessment for Particulate Matter (PM ISA). The Supplement and the 2019 p.m. ISA provide the scientific basis for EPA's decisions, in conjunction with additional technical and policy assessments, for the reconsideration of the EPA's 2020 review of the NAAQS and the appropriateness of possible alternative standards.

DATES: The document will be available on or about May 13, 2022.

ADDRESSES: The ''Supplement to the 2019 Integrated Science Assessment for Particulate Matter (Final)'' will be available primarily via the internet on EPA's Integrated Science Assessment for Particulate Matter at the public docket at *http://www.regulations.gov,* Docket ID: [EPA–HQ–ORD–2014–0859]. A limited number of CD–ROM copies will be available. Contact Ms. Marieka Boyd by phone: 919–541–0031; or email: *boyd.marieka@epa.gov* to request a CD–ROM, and please provide your name, your mailing address, and the document title, ''Supplement to the 2019 Integrated Science Assessment for Particulate Matter (Final)'' to facilitate processing of your request.

FOR FURTHER INFORMATION CONTACT: For technical information, contact Jason Sacks; phone: 919–541–9729; or email: *sacks.jason@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information About the Document

Section 108(a) of the Clean Air Act directs the Administrator to identify certain air pollutants which, among other things, ''cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare''; and to issue air quality criteria for them. The air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air . . . .''. Under section 109 of the Act, EPA is then to establish NAAQS for each pollutant for which EPA has issued criteria. Section 109(d)(1) of the Act subsequently requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. EPA is also required to review and, if appropriate, revise the NAAQS, based on the revised air quality criteria (for more information on the NAAQS review process, see *https://www.epa.gov/naaqs*).

EPA has established NAAQS for six criteria pollutants. In conducting periodic reviews of the air quality criteria and NAAQS, EPA reviews the scientific basis for these standards by preparing an Integrated Science Assessment (ISA; formerly called an Air Quality Criteria Document). The ISA provides the scientific basis for EPA's decisions, in conjunction with additional technical and policy assessments, on the adequacy of the current NAAQS and the appropriateness of possible alternative standards. The Clean Air Scientific Advisory Committee (CASAC), an independent science advisory committee whose review and advisory functions are mandated by Section 109(d)(2) of the Clean Air Act, is charged (among other things) with independent scientific review of the EPA's air quality criteria.

On June 10, 2021, the EPA announced its decision to reconsider the 2020 p.m. NAAQS final action, available at: *https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged.* The EPA also announced that, as a part of the reconsideration, a supplement to the Integrated Science Assessment (ISA) for Particulate Matter (PM), which was finalized in December 2019, would be developed. The ''Supplement to the 2019 Integrated Science Assessment for Particulate Matter (External Review Draft)'' was released for public comment and review by the CASAC on September 30, 2021 (*https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=352823*).

The CASAC PM panel met at a virtual public meeting on November 17–19, 2021, to review the draft Supplement to the 2019 p.m. ISA (86 FR 52673, September 22, 2021). A virtual public meeting was then held on February 25, 2022–March 4, 2022, and during this meeting on February 28, 2022, the chartered CASAC considered the CASAC PM Panel's draft letter to the Administrator on the draft Supplement to the 2019 p.m. ISA. This meeting was announced in the **Federal Register** on January 7, 2022 (87 FR 958). Subsequently, on March 18, 2022, the chartered CASAC provided a consensus letter of their review to the Administrator of the EPA (*https://casac.epa.gov/ords/sab/f?p=113:0:9895873668768:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1093*). The EPA has considered comments by the chartered CASAC and by the public in preparing this final Supplement to the 2019 p.m. ISA.

Wayne Cascio,

Director, Center for Public Health and Environmental Assessment, Office of Research and Development.

[FR Doc. 2022–07938 Filed 4–13–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2010–0396; FRL–9705–01–ORD]

Availability of the Draft IRIS Toxicological Review of Formaldehyde (Inhalation)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 60-day public comment period associated with release of the draft Integrated Risk Information System (IRIS) Toxicological Review of Formaldehyde (Inhalation). The draft document was prepared by the Center for Public Health and Environmental Assessment (CPHEA) within EPA's Office of Research and Development (ORD). EPA is releasing this draft IRIS assessment for public comment in advance of an external peer review conducted by the National Academy of Sciences, Engineering, and Medicine (NASEM). Public comments received will be provided to the external peer reviewers. NASEM, a contractor to EPA, will convene a public meeting to discuss the draft report with the public during Step 4 of the IRIS Process. The external peer reviewers will consider public comments submitted in response to this notice and provided at the public meeting when reviewing this document. EPA will consider all comments received when revising the document post-peer review. This draft assessment is not final as described in EPA's information quality guidelines, and it does not represent, and should not be construed to represent Agency policy or views.

DATES: The 60-day public comment period begins April 14, 2022 and ends June 13, 2022. Comments must be received on or before June 13, 2022.

ADDRESSES: The IRIS Toxicological Review of Formaldehyde (Inhalation) will be available via the internet on the IRIS website at *https://www.epa.gov/iris/iris-recent-additions* and in the public docket at *http://www.regulations.gov,* Docket ID No. EPA–HQ–ORD–2010–0396.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202–566–1752; facsimile: 202–566–9744; or email: *Docket_ORD@epa.gov.*

For technical information on the IRIS Toxicological Review of Formaldehyde

(Inhalation) contact Dr. Andrew Kraft, CPHEA; telephone: 202–564–0286; or email: *kraft.andrew@epa.gov.* The IRIS Program will provide updates through the IRIS website (*https://www.epa.gov/iris*) and via EPA's IRIS listserv. To register for the IRIS listserv, visit the IRIS website (*https://www.epa.gov/iris*) or visit *https://www.epa.gov/iris/forms/staying-connected-integrated-risk-information-system#connect.*

For information about the peer review, please visit the NASEM Review of EPA's 2021 Draft Formaldehyde Assessment website: *https://www.nationalacademies.org/our-work/review-of-epas-2021-draft-formaldehyde-assessment.*

SUPPLEMENTARY INFORMATION:

I. How to Submit Technical Comments to the Docket at https://www.regulations.gov. Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2010–0396 for the Formaldehyde (Inhalation) IRIS Assessment, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: Docket_ORD@epa.gov.*
- *Fax:* 202–566–9744. Due to COVID–19, there may be a delay in processing comments submitted by fax.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. The phone number is 202–566–1752. Due to COVID–19, there may be a delay in processing comments submitted by mail.

For information on visiting the EPA Docket Center Public Reading Room, visit *https://www.epa.gov/dockets.* Due to public health concerns related to COVID–19, the EPA Docket Center and Reading Room may be closed to the public with limited exceptions. The telephone number for the Public Reading Room is 202–566–1744. The public can submit comments via *www.regulations.gov* or email.

Instructions: Direct your comments to docket number EPA–HQ–ORD–2010–0396 for IRIS Toxicological Review of Formaldehyde (Inhalation). Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through *www.regulations.gov* or email that you consider to be CBI or otherwise protected. The *www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *www.epa.gov/epahome/dockets.htm.*

Docket: Documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Wayne Cascio,

Director, Center for Public Health & Environmental Assessment.

[FR Doc. 2022–07964 Filed 4–13–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee on Community Banking; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Community Banking. The Advisory Committee will provide advice and recommendations on a broad range of policy issues that have particular impact on small community banks throughout the United States and the local communities they serve. The meeting is open to the public. Out of an abundance of caution related to current and potential coronavirus developments, the public's means to observe this meeting of the Advisory Committee on Community Banking will be via a Webcast live on the internet. In addition, the meeting will be recorded and subsequently made available on-demand approximately two weeks after the event. To view the live event, visit *http://fdic.windrosemedia.com.*

DATES: Tuesday, May 3, 2022, from 1:00 p.m. to 5:00 p.m.

ADDRESSES: To view the recording, visit *http://fdic.windrosemedia.com/index.php?category=Community+Banking+Advisory+Committee.* If you require a reasonable accommodation to participate, please contact *DisabilityProgram@fdic.gov* or call 703–562–2096 to make necessary arrangements.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Debra A. Decker, Committee Management Officer of the FDIC at (202) 898–8748.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of current issues affecting community banking. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: This meeting of the Advisory Committee on Community Banking will be Webcast live via the internet *http://fdic.windrosemedia.com.* For optimal viewing, a high-speed internet connection is recommended.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on April 11, 2022.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–08003 Filed 4–13–22; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0051]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment.

DATES: The meeting will be held on April 20, 2022, from 11:00 a.m. to 4:00 p.m., EDT (date and times subject to change). The meeting will be webcast live via the World Wide Web. Written comments must be received on or before April 27, 2022.

ADDRESSES: You may submit comments identified by Docket No. CDC–2022–0051 by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–4027, Attn: April 20, 2022, ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.* Do not submit comments by email. CDC does not accept comments by email.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–4027; Telephone: (404) 639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at *http://www.cdc.gov/vaccines/acip/index.html.* In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters to be Considered: The agenda will include discussions on COVID–19 vaccine booster doses. A recommendation vote(s) is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda, visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

The meeting will be webcast live via the World Wide Web; for more information on ACIP, please visit *http://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before April 27, 2022.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the April 20, 2022, ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EDT, April 18, 2022, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 12:00 p.m., EDT, April 19, 2022. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to three minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–08050 Filed 4–12–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0789]

Diversity Plans To Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials.'' The purpose of this guidance is to provide recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan (referred to as the ''Plan'') to enroll adequate numbers of participants in clinical trials from underrepresented racial and ethnic populations in the United States.

DATES: Submit either electronic or written comments on the draft guidance by June 13, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0789 for ''Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lola Fashoyin-Aje, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0205; or Office of Communication, Outreach and Development, Center of Biologics Evaluation and Research, 800–835–4709 or 240–402–8010; or Center for Devices and Radiological Health, *CDRHClinicalEvidence@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials.'' The purpose of this guidance is to provide recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan (referred to as the ''Plan'') to help enroll adequate numbers of participants in clinical trials from underrepresented racial and ethnic

populations in the United States, such as Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, Native Hawaiian and Other Pacific Islanders, and other persons of color. Adequate representation in clinical trial(s) and studies supporting regulatory submissions helps ensure that the data generated in the development program reflects the racial and ethnic diversity of intended use population for the medical product, if approved, and may potentially identify safety or efficacy outcomes that may be associated with, or occurring more frequently, within these populations. This is one of many efforts by FDA to help address the participation of underrepresented populations in clinical trials relating to FDA regulated products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Diversity Plans to Improve Enrollment of Participants from Unrepresented Racial and Ethnic Populations in Clinical Trials.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 800 have been approved under OMB control number 0910–0625; and the collections of information pertaining to submission of a biologics license application under section 351(k) of the Public Health Service Act have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07978 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4533]

Compounding Animal Drugs From Bulk Drug Substances; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry (GFI) #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' This guidance describes FDA's current thinking about compounding animal drugs from bulk drug substances, identifies our enforcement priorities with respect to drugs compounded from bulk drug substances, and describes circumstances under which FDA generally does not intend to take action against veterinarians or pharmacists in either State-licensed pharmacies or Federal facilities, who compound animal drugs from bulk drug substances. We are also 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: The announcement of the guidance is published in the **Federal Register** on April 14, 2022. Submit written comments (including recommendations) on the collection of information by May 16, 2022.

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–NEW. Also include the FDA docket number found in brackets in the heading of this document.

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

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–4533 for ''Compounding Animal Drugs from Bulk Drug Substances.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

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

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Cindy Burnsteel, Office of Surveillance and Compliance (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7011.

Regarding the proposed collection of information: 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:

I. Background

In the **Federal Register** of November 20, 2019 (84 FR 64085), FDA published the notice of availability for draft GFI #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances'' with a 90-day comment period. In response to requests from interested parties, we extended the comment period to July 17, 2020, and then to October 15, 2020. We requested comments on the draft guidance with respect to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment option exists. This final GFI #256 describes FDA's current thinking about compounding animal drugs from bulk drug substances, identifies our enforcement priorities with respect to drugs compounded from bulk drug substances, and describes circumstances under which FDA generally does not intend to take action against veterinarians or pharmacists in either State-licensed pharmacies or Federal facilities, who compound animal drugs from bulk drug substances. FDA does not intend to take action under sections 501(a)(2)(B) and (a)(5), 502(f), and 512(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B) and (a)(5), 352(f), and 360(b)) under the circumstances described in GFI #256.

FDA received numerous comments on the draft guidance, which were considered as the guidance was finalized. Changes made in response to comments include identifying compliance with relevant State and local laws as the standard for compounding methods and eliminating references to United States Pharmacopeia and National Formulary Chapters <795> ''Pharmaceutical Compounding—Nonsterile Preparations'' and <797> ''Pharmaceutical Compounding—Sterile Preparations.'' We also revised the recommended label statement regarding reporting of adverse events to include reporting to the pharmacy as well as FDA.

We also made a number of changes related to recommendations for copies of approved products. We simplified the definition of ''copy'' used in the guidance and clarified that ''clinical difference'' includes issues affecting patient compliance and the safety of these who administer the drug, but excludes cost differences between approved and compounded products. The final guidance includes examples of how to briefly describe the medical rationale for making a copy, such as the compounding pharmacist contacting the prescribing veterinarian to obtain the rationale and noting it in the compounding records as an alternative to the veterinarian noting the rationale on the prescription. It also provides examples of rationales to explain why an approved drug cannot be used in a legal extralabel manner to compound a drug with the same active moiety.

We also made changes to lists of bulk drug substances for compounding office stock for nonfood-producing animals or antidotes for food-producing animals. As outlined in the Appendix to the final guidance,[1] we streamlined the nomination process for these bulk drug substances, reducing the information requested by FDA to support a nomination. The list of bulk substances to compound drugs for use in food-producing animals has been expanded to encompass nominations of sedatives or anesthetics for free-ranging wildlife species.

In addition, editorial changes were made to improve clarity in the final guidance. The guidance announced in this notice finalizes the draft guidance dated November 2019. However, as explained in section II of this notice, the information collection recommendations footnoted with an asterisk are subject to OMB review and approval and are not for current implementation.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on compounding animal drugs from bulk drug substances. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

[1] Elsewhere in this issue of the **Federal Register**, FDA is requesting nominations or renominations for bulk drug substances to be included on the ''Lists of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species'' for inclusion on a list of bulk drug substances for compounding certain animal drugs without a patient specific prescription (*i.e.,* office stock) for use in nonfood-producing animals or for inclusion on a list of compounded drugs for use as antidotes for food-producing animals or for use as sedatives or anesthetics for free-ranging wildlife species as described in GFI #256. That **Federal Register** notice describes information requested by FDA to evaluate nominations and explains when FDA will include bulk drug substances on a list. Such nominations will be collected in a separate docket.

II. Paperwork Reduction Act of 1995

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. FDA is issuing this guidance as final, footnoting with an asterisk recommendation that include information collection subject to review and approval by OMB under the PRA. FDA will implement the information collection recommendations if OMB approves them. At that time, FDA will announce OMB approval in the **Federal Register** and update the guidance to reflect this approval.

Title: Compounding Animal Drugs from Bulk Drug Substances (OMB Control Number 0910–NEW).

Description of Respondents: The respondents to the information collection are pharmacists in either State-licensed pharmacies or Federal facilities, or veterinarians who compound animal drugs from bulk drug substances.

Description: The Center for Veterinary Medicine has developed GFI #256 to address a need for Agency guidance in its work with the animal health industry. The guidance describes FDA's current thinking, based on our current understanding of the risks of animal drugs compounded from bulk drug substances, and describes the circumstances under which FDA generally does not intend to take enforcement action against pharmacists and veterinarians who compound animal drugs from bulk drug substances.

In the **Federal Register** of November 20, 2019 (84 FR 64085), we published a notice of availability announcing draft guidance GFI #256, including an analysis under the PRA, and solicited public comment on the proposed collection of information. Comments regarding the information collection included concerns that the guidance document will impose requirements not placed on other prescribers. In any other setting, the comments suggested, the prescription itself serves as documentation of the veterinarian's determination of clinical need. We disagree with these comments suggesting that a prescription serves the same purpose as the medical rationale documentation recommended in GFI #256. The documentation of the medical rationale by the compounding pharmacist is recommended for copies of approved products because a prescription demonstrates an animal's need for a prescription drug but does not explain why an approved product could not be used legally to treat the animal. The medical rationale addresses the clinical need for an animal drug compounded from a bulk drug substance when there is an approved product available.

Our exercise of discretion is dependent upon our ability to assess whether the circumstances under which FDA intends to exercise such discretion, as described in the guidance, exist. FDA staff may use pharmacy and veterinary records, among other things, to determine the circumstances surrounding the compounding activity. Except with regard to the recommendations that compounders document rationales for prescribing a compounded product from a bulk drug substance, routine business records kept by pharmacists who compound animal drugs from bulk drug substances and veterinarians who compound animal drugs from bulk drug substances, as well as veterinarians prescribing compounded animal drugs within a valid veterinarian-client-patient relationship, should be adequate to demonstrate that the circumstances described in the guidance exist. While we believe it is usual and customary business practice for veterinarians to document medical rationales for prescribing a compounded product as recommended in the guidance, we acknowledge that documenting this information by the pharmacist compounder, as well as documenting the rationale for using a bulk drug substance as the source of the active ingredient by the veterinarian/pharmacist compounder, may not be usual and customary practice. We have therefore included an estimate for recordkeeping to account for burden beyond that which may be usual and customary for respondents who follow the recommended documentation of rationales for compounding the drug product from bulk drug substance as discussed in the guidance.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping	Total hours
Documenting rationales by licensed veterinarian/pharmacist compounder.	7,500	1,134	8,505,000	0.017 (1 minute) ..	144,585

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the nearest whole number.

We have revised figures from our 60-day notice to reflect a more recent review of our experience with the information collection.

Sections III.A.5 and III.A.6 of the guidance describe circumstances under which FDA recommends veterinarian and pharmacist compounders document the prescribing veterinarian's medical rationale and the reason that a bulk drug substance is being used as the source of the active ingredient. Based on our evaluation, we believe it is usual and customary business practice for veterinarians to document the medical rationale, as recommended in the guidance. However, we believe pharmacist compounders may not document the information recommended in the guidance as a usual and customary business practice. According to the American Pharmacists Association, of the approximately 56,000 community-based pharmacies in the United States, about 7,500 pharmacies specialize in compounding services.[2] We assume 11,339,400 prescriptions will be written for compounded animal drugs annually. Based on our experience with the regulation of compounded animal drugs, we assume 50 to 75 percent of these prescriptions will result in documenting rationales as discussed in the guidance. Using the upper-bound estimate of 75 percent, approximately 8,504,550 prescriptions (0.75 ×

[2] American Pharmacists Association, ''Frequently Asked Questions About Pharmaceutical Compounding,'' n.d., *https://www.pharmacist.com/Practice/Patient-Care-Services/Compounding/Compounding-FAQs* (accessed September 15, 2021).

We currently have no data on the number of veterinarians who compound drugs for individual patients, specifically, compound drugs from bulk drug substances for individual patients; therefore, we are including this class of respondents in our burden estimate.

11,339,400 prescriptions) will necessitate documenting rationales. Averaging this figure equally among 7,500 compounding pharmacies, 1,134 (rounded to the nearest whole number) rationales will be documented annually, for a total of 8,505,000 records. We estimate it will take 1 minute (0.017 hours) to document the rationales described in the guidance, for a total of 144,585 hours, as reported in table 1.

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 activities. If the compounded drug is compounded for use as an antidote for food-producing animals or for use as a sedative or anesthetic for free-ranging wildlife species, section III.C.3 of the guidance recommends that the veterinarian establishes and documents a scientifically based withdrawal time that ensures residues of the: (1) Antidote and the underlying toxin or (2) sedative or anesthetic are not present in the animal at the time of slaughter or harvest or the veterinarian ensures the animal does not enter the food supply. We believe that it is usual and customary for veterinarians to establish and document a scientifically based withdrawal time as a matter of maintaining an adequate medical record in routine practice and, therefore, estimate no burden for the time it would take for a veterinarian to make this record. See 5 CFR 1320.3(b)(2).

In addition, the guidance makes a number of recommendations regarding the labeling of animal drugs compounded from bulk drug substances. In sections III.A.8, III.B.6, and III.C.6, the guidance recommends basic information that pharmacists and veterinarians should include on the label of the compounded drug, such as the name and strength of the drug and the name, address, and contact information for the compounding pharmacy or compounding veterinarian. We believe that it is usual and customary for pharmacists and veterinarians to include such information on the labels of compounded animal drugs in the normal course of their activities, and therefore, estimate no burden for the time it would take to prepare such labeling. See 5 CFR 1320.3(b)(2). Sections III.A.8, III.B.6, and III.C.6 of the guidance also recommend compounders (pharmacists and veterinarians) include several specific statements on the label of animal drugs compounded from bulk drug substances (*e.g.,* ''This is a compounded drug. Not an FDA approved or indexed drug.''). Because these recommended labeling statements are public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)), they are exempt from OMB review and approval under the PRA.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08092 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0470]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cellular, Tissue and Gene Therapies Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on scientific issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on June 9, 2022, from 10 a.m. to 6 p.m. and June 10, 2022, from 10 a.m. to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

The online web conference meeting will be available at the following link on the day of the meeting: Day 1 June 9 link: *https://youtu.be/RvtTK3KNl5g* and Day 2 June 10 link: *https://youtu.be/Eo2BXnGienc.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–0470. The docket will close on June 8, 2022. Submit either electronic or written comments on this public meeting on or before June 8, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 8, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 8, 2022. 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.

Comments received on or before June 2, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–N–0470 for ''Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA 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 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 the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Christina Vert or Tonica Burke, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1244, Silver Spring, MD 20993–0002, *ctgtac@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss two biologics license applications (BLAs) from bluebird bio, Inc.: (1) BLA 125755 for elivaldogene autotemcel (autologous CD34+ stem cells genetically modified with a lentiviral vector to contain an adenosine triphosphate-binding cassette, sub-family D, member 1 gene that encodes a functional adrenoleukodystrophy protein); the applicant has requested an indication for the treatment of patients younger than 18 years of age with early cerebral adrenoleukodystrophy who do not have an available and willing human leukocyte antigen-matched sibling hematopoietic stem cell donor and (2) BLA 125717 for betibeglogene autotemcel (autologous CD34+ stem cells genetically modified with a lentiviral vector to contain a gene encoding functional beta-globin); the applicant has requested an indication for the treatment of patients with β-thalassemia who require regular red blood cell transfusions.

The morning session of June 9, 2022, will include presentations of the effectiveness and product-specific safety results from the clinical trials in BLA 125755. The afternoon session will include presentations of safety concerns relevant to both products, followed by committee discussion of BLA 125755. On June 10, 2022, the morning session will include presentations of the effectiveness and product-specific safety results from the clinical trials in BLA 125717. The afternoon session will include committee discussion of BLA 125717.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before June 2, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Eastern Time on June 9, 2022, and between approximately 1 p.m. and 2 p.m. Eastern Time on June 10, 2022. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 25, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 26, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert at *ctgtac@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08022 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0108]

Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' This guidance is intended to assist abbreviated new drug application (ANDA) applicants that reference a drug product intended for parenteral, ophthalmic, or otic use in seeking approval of a drug that is qualitatively (Q1) different or quantitatively (Q2) different from the reference listed drug (RLD) with respect to the pH adjuster(s). This draft guidance describes how FDA intends to evaluate a request for a waiver of Agency requirements for a Q1 or Q2 difference in pH adjuster, including recommendations on the type of information to provide in support of such a waiver request. This draft guidance also includes recommendations on the timing and process for submitting such waiver requests.

DATES: Submit either electronic or written comments on the draft guidance by June 13, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0108 for ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Mannion, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–2747.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) does not require an ANDA to have the same inactive ingredients as the RLD.[1] Section 505(j)(4)(H) of the FD&C Act (21 U.S.C. 355(j)(4)(H)) does, however, state that an ANDA shall not be approved if information submitted in the application (or other information available) shows (1) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (2) the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included is unsafe under such conditions.[2]

The Agency has interpreted section 505(j)(4)(H) of the FD&C Act as permitting the Agency to deny approval of an ANDA ''if there is a reasonable basis to conclude that its inactive ingredients or composition raise serious questions about the drug's safety.'' [3]

The regulations at § 314.94(a)(9)(iii) and (iv) (21 CFR 314.94(a)(9)(iii) and (iv)), with parallel provisions in the approval regulations at § 314.127(a)(8)(ii)(B) and (C) (21 CFR 314.127(a)(8)(ii)(B) and (C)), specify that FDA will consider an inactive ingredient in, or the composition of, a generic drug product intended for parenteral, ophthalmic, or otic use to be unsafe and will refuse to approve the ANDA unless the generic drug product contains the same inactive ingredients (with certain listed exceptions) in the same concentration as the RLD. These regulations also identify permissible differences in certain inactive ingredients for drug products intended for parenteral, ophthalmic, or otic use, commonly referred to as ''exception excipients,'' if the ANDA contains sufficient information to demonstrate that any such differences do not affect the safety or efficacy of the drug. The regulations do not, however, expressly identify pH adjusters as one of these ''exception excipients,'' and, as such, the inactive ingredient requirements in § 314.94(a)(9)(iii) and (iv) apply to pH adjusters.

Under § 314.99(b) (21 CFR 314.99(b)), however, an applicant may ask FDA to waive any requirement that applies to the applicant under §§ 314.92 through 314.99 (21 CFR 314.92 through 314.99). Such a request under § 314.99(b) must comply with the requirements at 21 CFR 314.90. FDA may grant a § 314.99(b) waiver if the Agency finds one of the following: (1) The applicant's compliance with the requirement is unnecessary for the Agency to evaluate the ANDA or compliance cannot be achieved; (2) the applicant's alternative submission satisfies the requirement; or (3) the applicant's submission otherwise justifies a waiver. Even if FDA grants a waiver of a requirement in §§ 314.92 through 314.99 in a particular application, the application still must meet all applicable statutory requirements for approval. If FDA grants the applicant's waiver request with respect to a requirement under §§ 314.92 through 314.99, the waived requirement will not constitute a basis for refusal to approve an ANDA under § 314.127. Thus, an ANDA applicant for a drug product intended for parenteral, ophthalmic, or otic use who seeks to use a pH adjuster(s) that is Q1 or Q2 different from the RLD may ask the Agency to waive the inactive ingredient requirements at § 314.94(a)(9)(iii) or (iv) for the pH adjuster(s). This draft guidance document provides recommendations on (1) the type of information that applicants should consider submitting with a § 314.99(b) waiver request when an ANDA applicant asks the Agency to waive the inactive ingredient requirements for pH adjusters and (2) the format and process for submitting such waiver requests.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 320 been approved under OMB control numbers 0910–0014 and 0910–0291; and the collections of information for the submission of controlled correspondence related to generic drug development and FDA approval have been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08012 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

[1] See section 505(j)(2)(A) of the FD&C Act (setting forth the required contents of an ANDA).

[2] Section 505(j)(4)(H) of the FD&C Act.

[3] 21 CFR 314.127(a)(8)(ii); 54 FR 28871 at 28903 (July 10, 1989).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0313]

Lisett Raventos: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Lisett Raventos from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Lisett Raventos was convicted of a felony under Federal law for conduct that relates to the development or approval, including the process of development or approval, of a drug product under the FD&C Act. Ms. Raventos was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be

debarred. As of December 29, 2021 (30 days after receipt of the notice), Ms. Raventos had not responded. Ms. Raventos's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable April 14, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On March 5, 2021, Ms. Raventos was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against her in the U.S. District Court for the Southern District of Florida, after her plea of guilty to one count of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 1349.

The factual basis for this conviction is as follows: Ms. Raventos was a clinical study coordinator at Unlimited Medical Research, LLC. From about September 2013 through June 2016, Ms. Raventos conspired with others to unlawfully enrich herself by making materially false representations about clinical trials; fabricating data and the participation of subjects in those clinical trials; concealing from FDA, sponsors, and contract research organizations the fact that the data and participation of subjects had been fabricated; and inducing sponsors and contract research organizations to pay money for Ms. Raventos and her co-conspirators' own benefit. Specifically, one of Ms. Raventos's co-conspirators entered into a contract with a Contract Research Organization (CRO), retained by a drug manufacturer (Sponsor) to hire clinical investigators and to manage clinical trials. Ms. Raventos's co-conspirator entered into a contract with the CRO to conduct a clinical trial at Unlimited Medical Research site in return for payment. The clinical trial was for an investigational drug intended to treat pediatric asthma in children between the ages of 4 and 11 years.

Ms. Raventos represented herself to be the Site Director, Director of Clinical Operations, and the Study Coordinator for this clinical trial. In those roles, Ms. Raventos was responsible for complying with the study protocol, including administering the study drug to subjects in the study and preparing written records, known as case histories, which documented the participation of subjects in the clinical trial. Ms. Raventos participated in a scheme to defraud the Sponsor by fabricating the data and participation of subjects in the clinical trial in a variety of ways: Ms. Raventos and her co-conspirators falsified medical records to portray persons as legitimate study subjects when they were not. In addition, Ms. Raventos and her co-conspirators made it appear as though pediatric subjects made scheduled visits to Unlimited Medical Research when they had not, made it appear as though subjects had taken the study's drugs as required when they had not, and made it appear that the study subjects had received checks as payment when they had not.

As a result of this conviction, FDA sent Ms. Raventos by certified mail on November 19, 2021, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Ms. Raventos was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Ms. Raventos an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Raventos received the proposal on November 29, 2021. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Raventos has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Raventos is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see section 306(a)(2)(A) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Raventos, in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Raventos provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Ms. Raventos during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd)).

Any application by Ms. Raventos for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2021–N–0313 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08025 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the CDRH Patient Engagement Advisory Committee. The general function of the committee is to provide advice to the Commissioner of Food and Drugs, or designee, on complex scientific issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

DATES: The meeting will take place virtually on July 12, 2022, from 10 a.m. to 4 p.m. Eastern Time and on July 13, 2022, from 10 a.m. to 2 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* Information on how to access the webcast will be made available no later than 2 business days prior to the meeting at *https://www.fdalive.com/peac.*

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, *letise.williams@fda.hhs.gov,* 301–796–8398, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On July 12 and 13, 2022, the committee will discuss and make recommendations on the topic of ''Augmented Reality (AR) and Virtual Reality (VR) Medical Devices.'' AR/VR devices are increasingly applied to healthcare settings across the patients' care continuum. From diagnostics to clinical decision making, to surgical support, and to directly treating patients, AR/VR devices are used across multiple medical specialties. These devices have novel attributes and considerations for the end users that impact FDA's evaluation of the device's safety and effectiveness. The novel attributes of digital health visualization, tracking techniques, embedded software among other factors present unique challenges for pre- and postmarked evaluation. The recommendations provided by the committee will address factors FDA and industry should consider when evaluating the benefits, risks, and the extent of uncertainty in the benefit-risk information for AR/VR medical devices. The committee will also consider specific challenges related to specific populations (*e.g.,* pediatric or cognitively impaired) who may use this technology. Additionally, the committee will discuss ways patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the healthcare provider decision-making process related to using or prescribing the technology.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials will be available at *https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee.* Select the link for the 2022 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations from the public will be scheduled on July 12, 2022, between approximately 2:30 p.m. Eastern Time to 3:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 10, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 14, 2022. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the committee may send written submissions to the contact person on or before June 20, 2022.

Virtual Breakout Session: Individuals interested in participating in the virtual breakout scenario discussions will need to sign up to participate on or before June 28, 2022. The signup sheet, as well as additional information pertaining to the virtual scenario discussions, will be available at *https://www.fdalive.com/peac.* Everyone who signs up in advance and provides a valid email address will receive an email at least 2 days prior to the meeting with information on how to access the virtual platform that will host the virtual breakout scenario discussions. Please note that due to limited technology capacity, participation in the virtual breakout scenario discussions will be limited to 150 participants. Once capacity reaches 150 participants, the breakout session will be closed to additional participants. Additional information regarding the virtual breakout scenario discussions will be provided at *https://www.fdalive.com/peac.*

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to

accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov,* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings. Please be advised that, during the virtual scenario breakout discussions, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08013 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3324]

Reconditioning of Fish and Fishery Products by Segregation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry entitled ''Reconditioning of Fish and Fishery Products by Segregation.'' This guidance is intended to provide industry with an explanation of two potential approaches to recondition fish and fishery products by effectively segregating adulterated portions of an article from portions not containing the adulterant to ensure that only safe and wholesome product reaches consumers.

DATES: The announcement of the guidance is published in the **Federal Register** on April 14, 2022.

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

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–3324 for ''Reconditioning of Fish and Fishery Products by Segregation.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Steven Bloodgood, Division of Seafood Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–5316; or Lauren Kleinman, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Reconditioning of Fish and Fishery Products by Segregation.'' We are issuing the guidance consistent with our

good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

This guidance is intended to help owners of fish and fishery products, or their representatives, interested in bringing adulterated products into compliance with the Federal Food, Drug, and Cosmetic Act by means of segregating non-violative product from adulterated product. Specifically, this document provides guidance on:

- Segregation based on a production-related rationale supported by production records or information identifying the cause of the adulteration along with sampling and testing to confirm that the segregation was successful; or
- Segregation based on the results of statistically significant sampling and testing.

In the **Federal Register** of September 17, 2019 (84 FR 48935), we announced a draft guidance for industry entitled ''Reconditioning of Fish and Fishery Products by Segregation'' and gave interested parties an opportunity to submit comments by November 18, 2019, for us to consider before beginning work on the final version of the guidance. We received comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include the addition of a detailed explanation for our more robust sampling recommendations. The guidance announced in this notice finalizes the draft guidance dated September 2019.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 1.94(b) and 21 CFR 1.95(a) and (b) using Form FDA 766 have been approved under the OMB control number 0910–0025.

III. Electronic Access

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

Dated: April 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07979 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4626]

Lists of Bulk Drug Substances for Compounding: Office Stock Drugs for Use in Nonfood-Producing Animals or Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing updated information for interested parties to nominate bulk drug substances or renominate bulk drug substances that were previously nominated without adequate supporting information, for inclusion on a list of bulk drug substances for compounding certain animal drugs without a patient specific prescription (*i.e.,* office stock) for use in nonfood-producing animals or for inclusion on a list of compounded drugs for use as antidotes for food-producing animals or for use as sedatives or anesthetics for free-ranging wildlife species, as described in the guidance for industry #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' Individuals may also comment on bulk drug substances that have been reviewed by FDA and added to these lists, or nominations that are currently under FDA review.

DATES: You may submit either electronic or written nominations and comments at any time.

ADDRESSES: You may submit nominations and comments by any of the following methods.

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 in the following ways:

- *Mail/Hand Delivery/Courier (for 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–2018–N–4626 for ''Lists of Bulk Drug Substances for Compounding: Office Stock Drugs for Use in Nonfood-Producing Animals or Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' 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 nominations and comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Cindy Burnsteel, Office of Surveillance and Compliance (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, Rockville, MD 20855, 240–402–7011, *cvmcompliance@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Except with respect to the limited exemption provided by the Federal Food, Drug, and Cosmetic Act (FD&C Act) described in the following paragraph, statutory provisions applicable to manufactured animal drugs under the FD&C Act also apply to animal drugs compounded from bulk drug substances (also known as active pharmaceutical ingredients (APIs)).[1]

Sections 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)) provide a limited exemption from certain requirements for compounded animal drugs made from already FDA-approved animal or human drugs. Such use is considered an extralabel use. The FD&C Act provides that a compounded drug is exempt from the approval requirements in section 512(a) of the FD&C Act and requirements for adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if it meets the conditions set out in the statute and the extralabel use regulations at 21 CFR part 530.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of guidance for industry #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances'' (GFI #256).[2] Animal drugs compounded from bulk drug substances by pharmacists and veterinarians violate the FD&C Act because they do not meet the requirements for approval, current good manufacturing practice (CGMP) requirements, or adequate directions for use. The guidance describes circumstances under which FDA generally does not intend to take action against veterinarians, or pharmacists in either State-licensed pharmacies or Federal facilities, who compound animal drugs from bulk drug substances. FDA does not intend to take action under sections 512(a), 502(f), and 501(a)(2)(B) and (a)(5) (21 U.S.C 351(a)(2)(B) and (a)(5)) of the FD&C Act under the circumstances described in GFI #256.

II. Nominating Bulk Drug Substances

In a **Federal Register** notice published November 19, 2019, FDA established a public docket (FDA–2018–N–4626) so that interested parties could nominate bulk drug substances to a list of bulk drug substances for compounding office stock drugs for use in nonfood-producing animals or antidotes for food-producing animals (the List) and comment on nominated and evaluated bulk drug substances (the 2019 request for nominations notice).

In conjunction with finalizing GFI #256, FDA is expanding nominations to include drugs compounded for use as sedatives or anesthetics for free-ranging wildlife species. We are also reorganizing the List into two separate Lists:

1. The List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals[3] and
2. The List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species[4]

Interested parties can nominate bulk drug substances to either List, renominate bulk drug substances with adequate supporting information that were previously nominated without adequate supporting information, or comment on previously nominated bulk drug substances that have been added to a List. This docket will remain open indefinitely so that individuals may nominate and comment on bulk drug substances at any time.

A. When will FDA include a bulk drug substance on either of the Lists?

FDA intends to include a bulk drug substance on either of the Lists when:

1. There is no marketed FDA-approved, conditionally approved, or indexed animal drug(s) that can be used as labeled to treat the condition;

2. There is no marketed FDA-approved, conditionally approved, or indexed animal or human drug(s) with the same active ingredient(s) that could be used in an extralabel manner to treat the condition; and

3. FDA has not identified a significant safety concern specific to the use of the bulk drug substance in animals.

For bulk drug substances used to compound drugs intended as office stock for nonfood-producing animals, in addition to 1 to 3 above:

4. Urgent treatment with the compounded drug is necessary to avoid animal suffering or death, or to protect public safety.

For bulk drug substances used to compound drugs intended for use as antidotes in food-producing animals or for use as sedatives or anesthetics for free-ranging wildlife species, in addition to 1 to 3 above:

5. There is sufficient scientific information for the prescribing veterinarian to determine appropriate withdrawal, withholding, or discard time(s) for meat, milk, eggs, or any food that might be derived from the treated animal(s).

[1] FDA regulations define ''bulk drug substance'' and ''active pharmaceutical ingredient'' as ''any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.'' The terms do not include intermediates used in the synthesis of the substance. 21 CFR 207.1. ''Active ingredient'' is defined as ''any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.'' 21 CFR 210.3(b)(7). Any component other than an active ingredient is an ''inactive ingredient.'' 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients.

[2] *https://www.fda.gov/media/132567/download.*

[3] Available at *https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals.*

[4] Available at *https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-drugs-use-food-producing-animals-or-free-ranging-wildlife.*

B. How do I submit a nomination for one of the Lists?

You may submit nominations and comments to the docket through *https://www.regulations.gov.* The information to support nominations can be uploaded as attachments to your comment. The docket number is FDA–2018–N–4626.

You may submit written submissions to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All submissions must include the Docket No. FDA–2018–N–4626 for ''Lists of Bulk Drug Substances for Compounding: Office Stock Drugs for Use in Nonfood-Producing Animals or Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species.''

C. What information should I submit with the nomination?

You may nominate specific bulk drug substances for inclusion on either of the Lists. Each bulk drug substance should be submitted to the docket as its own, separate nomination. Submissions to the docket containing more than one bulk drug substance will not be considered an adequate nomination and will not be reviewed. Nominated substances that do not meet the definition of a bulk drug substance will not be evaluated for inclusion on a List.

For FDA to evaluate a bulk drug substance for inclusion on a List, you should submit the following information about the bulk drug substance and the compounded animal drug in the nomination:

1. Description of the Bulk Drug Substance:

(a) Chemical name(s);

(b) common name(s);

2. Description of the Animal Drugs That Will be Compounded with the Nominated Bulk Drug Substance:

(a) Dosage form(s) into which the bulk drug substance will be compounded (*e.g.,* capsule, tablet, suspension);

(b) strength(s) of the compounded drug(s); and

(c) intended route(s) of administration of the compounded drug(s) (*e.g.,* oral, topical, injection, etc.).

3. Information Requested for FDA to Evaluate Bulk Drug Substances for Inclusion on a List:

(a) The species the drug to be compounded with the nominated bulk drug substance is intended to treat;

(b) The disease or condition(s) the drug to be compounded with the nominated bulk drug substance is intended to treat;

(c) If there is a marketed FDA-approved, conditionally approved, or indexed animal drug(s) that addresses the same condition(s) in the same species, an explanation of why a compounded drug is necessary (*e.g.,* why FDA-approved, conditionally approved, or indexed animal drug(s) is not suitable for a particular animal population);

(d) Confirmation that there is no marketed FDA-approved, conditionally approved, or indexed drug(s) that could be prescribed to treat the condition in the species that the drug compounded with the nominated substance is intended to address;

(e) If known by the nominator, if the bulk drug substance is an active ingredient in a marketed FDA-approved, conditionally approved, or indexed animal or human drug(s), an explanation of why the animal drug cannot be compounded from the marketed FDA-approved, conditionally approved, or indexed animal or human drug(s).

(f) If known by the nominator, a description of any human user or animal safety concerns associated with use of the nominated bulk drug substance or finished compounded drug for the condition(s) in the species that the compounded drug is intended to address. If there are concerns, an explanation of why the concerns should not preclude inclusion of that bulk drug substance on the List;

(g) For compounded drugs intended as office stock for nonfood-producing animals, an explanation of why the animal drug to be compounded with the nominated bulk drug substance is important to be available to the veterinarian for urgent treatment to avoid animal suffering or death, *e.g.,* why animal suffering or death will result if treatment is delayed until a compounded animal drug can be obtained pursuant to a prescription for an individually identified animal; and

(h) For compounded drugs intended for use as antidotes to treat toxicoses in food-producing animals, or as sedatives or anesthetics for free-ranging wildlife species, relevant scientific literature or other evidence that demonstrates that the prescribing veterinarian has a basis for determining appropriate withdrawal, withholding, or discard time(s) for meat, milk, eggs, or any food which might be derived from the treated animal(s).

4. Contact information for FDA should there be followup questions regarding the nomination.

D. What about drugs that have been nominated for one of the Lists and are still under review?

FDA identifies those bulk drug substances that have been nominated and under review at ''Bulk Drug Substances Currently Under Review.'' [5] At this time, FDA generally intends to refrain from taking enforcement action when these bulk drug substances currently under review are used to compound a finished drug as described in the nomination. Bulk drug substances will remain on ''Bulk Drug Substances Currently Under Review'' only during FDA's review of their nomination. If FDA completes its review and declines to place the bulk drug substance on a List based on the information provided, FDA will place the bulk drug substance on ''Bulk Drug Substances Reviewed and Not Listed''; [6] however, FDA will continue to accept and review any adequate additional information submitted by any party that supports the previously reviewed nomination. Should adequate additional information be provided such that FDA can conduct further substantial review, the bulk drug substance will again be placed on ''Bulk Drug Substances Currently Under Review.''

E. What happens when FDA approves or indexes a drug made with a bulk substance as described on one of the Lists?

FDA intends to remove a bulk substance from a List if a finished drug containing that substance in the appropriate dosage form and strength is approved or indexed. Please see ''Bulk Drug Substances Reviewed and Not Listed.''

F. What happens when FDA reviews a bulk drug substance and determines that it cannot be placed on a List because of insufficient information or because of other reasons (e.g., safety concerns)?

Please see ''Bulk Drug Substances Reviewed and Not Listed'' for those bulk drug substances that have been reviewed by FDA but are not on either List.

In a **Federal Register** notice published on May 19, 2015 (80 FR 28622), FDA invited all interested parties to nominate bulk drug substances for inclusion on a list of bulk drug substances that could be used by outsourcing facilities registered under the FD&C Act to compound animal drugs under the conditions described in draft GFI #230, ''Compounding Animal Drugs from Bulk Drug Substances'' (announced in the same issue of the

[5] Available at: *https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-currently-under-review.*

[6] Available at *https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-reviewed-and-not-listed.*

Federal Register (80 FR 28624)) (the 2015 request for nominations notice).

Although that draft guidance was subsequently withdrawn in November 2017, FDA received over 30 comments containing nominations for multiple bulk drug substances in response to the 2015 request for nominations notice. FDA's approach for determining whether to include a bulk drug substance on the list described in the 2015 request for nominations notice was substantially the same as the approach described above for including a bulk drug substance on the ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals'' in accordance with GFI #256. Therefore, and in keeping with our intention as stated in the 2019 request for nomination notice, the Agency is including certain of these nominated bulk drug substances on this List. For other of these nominated bulk drug substances, finished drugs containing the bulk drug substances in the appropriate dosage form and strength have subsequently been approved; thus, these nominated bulk drug substances will not appear on the List.

Some bulk drug substances were nominated in response to the 2015 request for nominations notice with insufficient supporting information. FDA subsequently searched for additional supporting information for these bulk substances, conducted further review, and added those with sufficient supporting information to the ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals.''

In addition, on its own initiative, FDA has identified certain bulk drug substances that are used in minor species. Several have been evaluated and are included on the ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals.'' Those identified bulk drug substances still under evaluation are included on ''Bulk Drug Substances Currently Under Review.'' As FDA continues to identify and evaluate bulk drug substances that are used in minor species, we also encourage outside nominations.

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08018 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Mechanisms of Memory and Sound Processing.

Date: April 26, 2022.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sepandarmaz Aschrafi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040D, Bethesda, MD 20892, (301) 451.4251, *Armaz.aschrafi@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. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 8, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07958 Filed 4–13–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 Dental and Craniofacial Research Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

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 Dental and Craniofacial Research Council.

Date: May 18, 2022.

Open: 10:00 a.m. to 1:30 p.m.

Agenda: Report of the Director, NIDCR and concept clearances.

Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lynn M. King, Ph.D., Executive Secretary, Division of Extramural Activities, National Institute of Dental Craniofacial Research, 6701 Democracy Blvd., Room 960, Bethesda, MD 20892–4878, (301) 594–5006, *Lynn.King@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: *http://www.nidcr.nih.gov/about,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 8, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07957 Filed 4–13–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–13]

Notice of Emergency Approval of an Information Collection: Economic Development Initiative Community Project Funding Grants; OMB Control No.: 2506–0217

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 21, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.* Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Holly A. Kelly, Congressional Grants Division, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone number 202–402–6324 ext. 6324 (this is not a toll-free number). Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number). Interested persons may also email: *CPFGrants@hud.gov.*

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Economic Development Initiative—Community Project Funding Congressional Earmarks.

OMB Approval Number: 2506–0217.

Type of Request: New.

Form Number: SF424, SF424B, SFLLL, SF1199A, HUD27054, HUD27056.

Description of the need for the information and proposed use: This information will be collected to provide funding to congressional identified grantees.

Respondents: State, local governments, non-profit organizations, tribal communities as identified by congress.

Estimated Number of Respondents: 1,000.

Estimated Number of Responses: 1,000.

Frequency of Response: On occasion.

Average Hours per Response: 4.

Total Estimated Burdens: 4,000.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2022–07956 Filed 4–13–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R2–ES–2022–0018; FXES111302WOLF0–223–FF02ENWF00]

Endangered and Threatened Wildlife and Plants; Draft Recovery Plan for the Mexican Wolf, Second Revision

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of our Mexican Wolf (*Canis lupus baileyi*) Draft Recovery Plan, Second Revision (draft revised recovery plan). The Mexican wolf is listed as endangered under the Endangered Species Act of 1973, as amended (ESA), and is currently found in Arizona and New Mexico in the United States, and in Sonora and Chihuahua, Mexico. The draft revised recovery plan includes new site-specific management actions to address the threat of human-caused mortality, including illegal take, in response to a court-ordered remand of the Mexican Wolf Recovery Plan, First Revision (2017 recovery plan). These new actions, as well as their time and cost estimates, are incorporated into the draft revised recovery plan implementation schedule. We provide the rationale for each action in a new section of the draft revised recovery plan (''Recovery Actions Added to the Implementation Schedule to Address Human-Caused Mortality''). The draft revised recovery plan provides minor clarifying updates to explain the addition of the recovery actions but does not alter the recovery strategy or recovery criteria for the Mexican wolf. We request review and comment on the draft recovery plan from local, State, and Federal agencies; Tribes; and the public, in both the United States and Mexico.

DATES: We must receive written comments on or before May 16, 2022. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**) must be received by 11:59 p.m. Eastern Time on the closing date. Due to a court-ordered deadline, we will not be able to extend the date for public review and comment on this document.

ADDRESSES: *Obtaining documents:* The draft revised recovery plan, and any comments and other materials that we receive, will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–R2–ES–2022–0018. The 2017 recovery plan will be available in the docket as a supporting document.

Submitting Comments: If you wish to comment on the draft revised recovery plan, please submit your comments in writing by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–R2–ES–2022–0018.

• *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS–R2–ES–2022–0018; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

We request that you send written comments by only the methods described above.

For more information, see Public Availability of Comments under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Brady McGee, Mexican Wolf Recovery Coordinator, by telephone at 505–761–4704 or via email at *brady_mcgee@fws.gov.* You may also visit the Mexican Wolf Recovery Program's website at *https://www.fws.gov/program/mexican-wolf* for information about Mexican wolf recovery. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft revised recovery plan for the Mexican wolf (*Canis lupus baileyi*).

Recovery Planning and Implementation

Section 4(f) of the ESA requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species. Also pursuant to section 4(f) of the ESA, a recovery plan must, to the maximum extent practicable, include:

1. A description of site-specific management actions as may be necessary to achieve the plan's goals for the conservation and survival of the species;

2. Objective, measurable criteria that, when met, would support a determination under section 4(a)(1) that the species should be removed from the List of Endangered and Threatened Species; and

3. Estimates of the time and costs required to carry out those measures needed to achieve the plan's goal and to achieve intermediate steps toward that goal.

In 2016, the Service revised its approach to recovery planning, and is now using a process termed recovery planning and implementation (RPI) (see *https://www.fws.gov/endangered/esa-library/pdf/RPI.pdf*). The RPI approach is intended to reduce the time needed to develop and implement recovery plans, increase recovery plan relevance over a longer timeframe, and add flexibility to recovery plans so that they can be adjusted to new information or circumstances. Under RPI, a recovery plan addresses the statutorily required elements under section 4(f) of the ESA, including site-specific management actions, objective and measurable recovery criteria, and the estimated time and cost to recovery. The RPI recovery plan is supported by two supplementary documents that are incorporated into the recovery plan by reference: A species status assessment or biological report, which describes the best available scientific information related to the biological needs of the species and assessment of threats; and a recovery implementation strategy, which details the particular near-term activities needed to implement the recovery actions identified in the recovery plan. Under this approach, we can more nimbly incorporate new information on species biology or details of recovery implementation by updating these supplementary documents without concurrent revision of the entire recovery plan, unless changes to statutorily required elements are necessary.

Background of Recovery Planning for the Mexican Wolf

The original recovery plan for the Mexican wolf was finalized in 1982 (Service 1982). We revised the 1982 recovery plan in 2017 using the RPI process (82 FR 57288; December 4, 2017). The Mexican Wolf Recovery Plan, First Revision (2017 recovery plan), contains statutorily required elements, including measurable criteria, site-specific management actions, and estimates of time and costs, along with a concise introduction and our strategy for how we plan to recover the Mexican wolf. It specifies the establishment and maintenance of a demographically and genetically robust population of wolves in the United States, and a second population in Mexico. In the United States, Mexican wolves inhabit the Mexican Wolf Experimental Population Area (MWEPA) in Arizona and New Mexico (80 FR 2512; January 16, 2015). We began reintroducing Mexican wolves from captivity into the MWEPA in 1998 and continue to focus recovery efforts in the United States on this population.

On October 14, 2021, the District Court of Arizona remanded the 2017 recovery plan back to the Service to include site-specific management actions to address the threat of human-caused mortality, including illegal killing (No: 4:18–CV–00047–TUC–JGZ (Lead); No. 4:18–CV–00048–TUC–JGZ (Member)). The court order specified that the Service must produce a draft recovery plan for public comment within 6 months and a final plan no later than 6 months after the draft recovery plan. The draft revised recovery plan maintains the recovery strategy, criteria, and actions from the 2017 recovery plan and includes new recovery actions to alleviate the threat of human-caused mortality, including illegal killing. These new actions, as well as their time and cost estimates, are incorporated into the draft revised recovery plan implementation schedule. We provide the rationale for each action in a new section of the draft revised recovery plan (''Recovery Actions Added to the Implementation Schedule to Address Human-Caused Mortality'').

It is our intention that the actions we have added to the draft revised recovery plan will help alleviate the threat of excessive human-caused mortality, including illegal killing. We will adapt our implementation of recovery actions over time to address sources of human-caused mortality, as we assess population performance, the contribution of specific sources to overall mortality levels, the availability of resources needed for implementation of specific actions, and other considerations.

Currently, at least 74 percent of documented Mexican wolf mortalities in the MWEPA between 1998 and 2020 are attributed to human causes. Illegal killing has been the largest source of human-caused mortality in the MWEPA between 1998 and 2020 (119 of 216 total documented mortalities), followed by vehicle collision (27 mortalities) and other human-caused mortalities (14 mortalities) (Service files). Some of the mortalities that we attribute to ''unknown'' causes (24 mortalities) may also be human caused. Since the completion of the 2017 recovery plan, human-caused mortality in the MWEPA has been variable, with totals of 7, 15, 12, and 25 Mexican wolf mortalities each year, respectively, during the period 2017–2020 (Service files). In Mexico, mortalities of 7, 4, 1, 2, and 4 were documented respectively during the consecutive years 2017–2021; these included mortalities from poison (7 mortalities), unknown causes (6 mortalities), vehicular collision (3 mortalities), trapping (1 mortality), and firearm (1 mortality) (Universidad Autónoma de Querétaro/Comisión Nacional de Áreas pers. comm.).

As we described in our January 16, 2015, final rule to list the Mexican wolf as an endangered subspecies (80 FR 2488), different wolf populations can

sustain themselves under varying levels of human-caused mortality (80 FR 2488, p. 2501). Based on population viability modeling conducted for the 2017 recovery plan, we expect the Mexican wolf population to grow or remain stable if the mean adult mortality rate is less than 25 percent, combined with mean subadult mortality rates less than 33 percent and mean pup mortality less than 13 percent (Service 2017, p. 21). Therefore, while some human-caused mortality can be sustained during the recovery effort, mean mortality rates from all sources of mortality (natural and human-caused) need to remain below threshold levels in order for the Mexican wolf to achieve demographic recovery criteria.

Further, we recognize that multiple sources of mortality occurring in combination have a greater potential to affect the Mexican wolf than some single sources (80 FR 2488, p. 2508). Therefore, while one source of human-caused mortality, such as vehicular collision, may not occur at a level that hinders the recovery of the Mexican wolf independent of other sources of mortality, it may contribute to an overall level of mortality that is too high for the population performance necessary to achieve recovery. Because of this, recovery actions to address a specific source of human-caused mortality may contribute to the recovery effort even if that source is not independently hindering population growth.

Species Background and Current Status

The Mexican wolf is listed as an endangered subspecies throughout its range, without critical habitat, due to the individual and cumulative effects of excessive human-caused mortality, including illegal killing; genetic issues, including inbreeding, loss of heterozygosity, and loss of adaptive potential; and demographic stochasticity (decreases in survival or reproduction) associated with small population size (80 FR 2488, January 16, 2015). For detailed listing history, biological background, and additional information on recovery and reintroduction efforts, including previous Federal actions for the Mexican wolf subspecies and experimental population, see our final rule to list the Mexican wolf as an endangered subspecies on January 16, 2015 (80 FR 2488); our notice of availability of the 2017 recovery plan on December 4, 2017 (82 FR 57288); and our proposed rule to revise the nonessential experimental population of the Mexican wolf on October 29, 2021 (86 FR 59953).

The Service and our regional and binational partners continue to implement the recovery strategy and actions in the 2017 recovery plan to address threats to the Mexican wolf and achieve recovery in the United States and Mexico. Although the Mexican wolf remains critically endangered, population growth in the wild in recent years has improved the status of the species and the outlook for recovery. We and our partners are employing adaptive management to utilize new field techniques in the United States such as diversionary food caching to prevent depredations and cross-fostering to support the genetic needs of the expanding population in the MWEPA in Arizona and New Mexico (Service 2019). In addition, the captive population, numbering 55 facilities housing 369 wolves as of June 30, 2020, remains robust and capable of supporting the reintroduction and recovery efforts in both countries, while also enabling scientists to engage in reproductive and genetic research that may contribute to the ongoing genetic management of the captive and wild populations (Scott et al. 2020, entire).

Progress toward the demographic and genetic recovery criteria in the 2017 recovery plan is documented annually. Due to disparate timing and methods of data collection between the United States and Mexico, available information as of January 19, 2022, varies between the two countries. The minimum population count for the MWEPA at the end of 2020 was 186 wolves, with 7 released wolves (wolves born in captivity) surviving to breeding age in the spring of 2020. The MWEPA 2021 minimum population count and a report on the number of released wolves surviving to breeding age as of the spring of 2021 will be available in February and March 2022, respectively. In Mexico, the population was estimated at approximately 40 wolves at the end of 2021, with 4 released wolves surviving to breeding age as of the end of 2021 (Service files; UAQ/CONANP pers. comm.). In 2023, the Service will conduct an evaluation of progress toward recovery, using data from both countries' programs through 2022, as specified in the 2017 recovery plan (see Service 2017, p. 26).

Request for Public Comments

Section 4(f) of the ESA requires us to provide public notice and an opportunity for public review and comment during recovery plan development. It is also our policy to request peer review of draft recovery plans (59 FR 34270, July 1, 1994). We will summarize and respond to the comments the public and peer reviewers provide and make our responses available to the public. Substantive comments may or may not result in changes to the recovery plan. Comments regarding recovery plan implementation will be forwarded as appropriate to Federal or other entities for consideration as the Service implements recovery actions. Pursuant to the court order, the Service must produce a final revised recovery plan by October 14, 2022.

We invite written comments on the draft revised recovery plan. In particular, we are interested in comments or additional information pertaining to the new recovery actions in the implementation schedule of the draft revised recovery plan, including:

1. Will these new actions reduce the threat of excessive human-caused mortality?

2. Do these actions support achieving the recovery criteria for the Mexican wolf?

3. Is there additional information pertaining to the time and cost estimates for the new actions we have recommended?

4. Are there additional actions that could reduce the threat of excessive human-caused mortality? Please provide a description of the action, your rationale, and any supporting data or literature.

We will accept comments about the Mexican wolf at any time, but due to the court-ordered deadline on this action, only comments received during the comment period that are germane to the remand will be taken into account as we develop the final revised recovery plan. We do not intend to revise any part of the recovery plan other than the recovery actions. Prior to final approval of the plan, we will consider all comments we receive by the date specified in **DATES**.

Public Availability of Comments

All comments received, including names and addresses, will become part of the administrative record and will be available to the public. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—will be publicly available. While you may request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We developed our draft recovery plan and publish this notice under the authority of section 4(f) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Amy L. Lueders,

Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2022–07914 Filed 4–13–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2021–N175; FXES11140800000–212–FF08EVEN00]

Endangered and Threatened Wildlife and Plants; Draft Habitat Conservation Plan and Draft Categorical Exclusion for the California Red-Legged Frog and the Southwestern Pond Turtle; Tajiguas Landfill and ReSource Center Project, Santa Barbara County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments; correction.

SUMMARY: On April 8, 2022, we, the U.S. Fish and Wildlife Service, published a notice announcing the availability for public comment of a draft habitat conservation plan (HCP) and draft categorical exclusion (CatEx) for activities associated with an application for an incidental take permit. Our notice inadvertently did not give the correct web address for obtaining documents for review. In addition, it published with out-of-date telecommunications relay services information. In this notice, we correct those errors.

DATES: Written comments should be received on or before May 9, 2022.

ADDRESSES:

Obtaining Documents: You may download copies of the draft HCP and draft CatEx at *https://www.fws.gov/media/us-fish-and-wildlife-service-seeks-public-comment-draft-habitat-conservation-plan-and-draft,* or you may request copies by phone at 805–677–3307 or by U.S. mail (below).

Submitting Written Comments: Please send us your written comments using one of the following methods:

- *U.S. mail:* Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003.
- *Email: kirby_bartlett@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Kirby Bartlett, Fish and Wildlife Biologist, by email at *kirby_bartlett@fws.gov* or via phone at 805–677–3307. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: On April 8, 2022, we, the U.S. Fish and Wildlife Service, published a notice announcing the availability for public comment of a draft habitat conservation plan and draft categorical exclusion for activities associated with an application for an incidental take permit (87 FR 20881). Our notice inadvertently did not give the correct web address for obtaining documents in the **ADDRESSES** section. In addition, it published with out-of-date telecommunications relay services information in the **FOR FURTHER INFORMATION CONTACT** section. Please see corrected information above.

Madonna Baucum,

Regulations and Policy Chief, Policy and Regulations Branch, Division of Policy, Economics, Risk Management, and Analytics, U.S. Fish and Wildlife Service.

[FR Doc. 2022–07976 Filed 4–13–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[223A2100DD/AAKC001030/A0A501010.999900]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact in the State of South Dakota

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Amendment to the Gaming Compact (Amendment) between the Oglala Sioux Tribe (Tribe) and the State of South Dakota (State).

DATES: The Amendment takes effect on April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, *paula.hart@bia.gov,* (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Amendment permits the Tribe to operate sports wagering within the Pine Ridge Reservation, defines terms for sports wagering and requires the Tribe to meet or exceed South Dakota's hardware and software specifications. The Amendment is approved.

Wizipan Garriott,

Principal Deputy Assistant Secretary—Indian Affairs, Exercising by delegation the authority of the Assistant Secretary—Indian Affairs.

[FR Doc. 2022–07965 Filed 4–13–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAC01000.223L1109AF.L13100000.DF00000 MO#4500160418]

Notice of Public Meetings of the Central California Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Central California Resource Advisory Council (RAC) will meet as follows.

DATES: The RAC will hold a virtual public meeting via Zoom on Wednesday, June 22, 2022, from 8:30 a.m. to 12:30 p.m. with public comments accepted at 12 p.m.

The RAC will hold a virtual public meeting via Zoom on Wednesday, Sept. 14, 2022, from 8:30 a.m. to 12:30 p.m., with public comments accepted at 12 p.m.

The RAC will hold both a virtual and in-person public meeting on Wednesday, Nov. 2, 2022, from 1 p.m. to 5 p.m. at the BLM Bishop Field Office with public comments accepted at 4:30 p.m. The RAC will conduct a field tour on Thursday, Nov. 3, 2022, from 8:30 a.m. to 12:30 p.m. to the Alabama Hills National Scenic Area.

The RAC will hold both a virtual and in-person public meeting on

Wednesday, Feb. 22, 2023, from 1 p.m. to 5 p.m., at the BLM Ukiah Field Office with public comments accepted at 4:30 p.m. The RAC will conduct a field tour on Thursday, Feb. 23, 2023, from 8:30 a.m. to 12:30 p.m. to the South Cow Mountain OHV Management Area.

The meetings and field tours are open to the public.

ADDRESSES: Meeting links and participation instructions will be made available to the public via news media, social media, the BLM California RAC web page at *https://go.usa.gov/xH9ya,* and through personal contact 2 weeks prior to the meeting.

- The June 22 meeting will be held virtually via Zoom.
- The Sept. 14 meeting will be held virtually via Zoom.
- The Nov. 2 meeting will be held virtually and at the BLM Bishop Field Office, 351 Pacu Lane, Suite 100, Bishop, CA 93514. On Nov. 3, participants will meet at the BLM Bishop Field Office for a field tour to the Alabama Hills National Scenic Area.
- The Feb. 22, 2023, meeting will be virtually and held at the BLM Ukiah Field Office, 2550 North State Street, Suite 2, Ukiah, CA 95482. On Feb. 23, participants will meet at the BLM Ukiah Field Office for a field tour to the South Cow Mountain OHV Management Area.

You may send written comments pertaining to any of the meetings to the BLM Central California District Office, 5152 Hillsdale Circle, El Dorado Hills, CA 95762, Attention: RAC meeting comments, or email comments can be submitted to Public Affairs Officer Serena Baker, *sbaker@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Public Affairs Officer Serena Baker, email: *sbaker@blm.gov* or telephone: (916) 941–3146. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Baker. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Central California RAC advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with BLM-managed public lands in central California. Topics for these meetings are as follows:

June 22, 2022: The RAC will hear about the Recreation Area Management Plan anticipated to be developed for the Keysville Special Recreation Management Area and determine how it will participate in the process. The RAC will also be briefed on the impacts on BLM-managed public lands due to increased outdoor recreation during the pandemic, and hear reports from the district and field offices, including a wildland fire pre-season forecast.

Sept. 14, 2022: The RAC will be briefed on business plans being developed with potential fee increases at BLM-managed recreation sites within the jurisdictions of the Mother Lode and Central Coast field offices, which would require recommendations from the RAC. The RAC will also hear reports from the district and field offices.

November 2 and 3, 2022: On November 2, the RAC will discuss implementation of the Alabama Hills Management Plan. The RAC will also learn about the Casa Diablo IV Geothermal Development Project, hear reports from the district and field offices, including a post-season wildland fire assessment, and schedule additional meeting dates for 2023. On November 3, the RAC will tour the Alabama Hills National Scenic Area to see the improvements made under the Management Plan, including new signs indicating areas that are now day use only; added portable restrooms in two locations; and designated campsites in some areas.

February 22 and 23, 2023: On February 22, the RAC will be briefed on the progress of the South Cow Mountain OHV Management Area Implementation Plan and determine how it will participate in the planning process. The RAC will hear an update on the BLM Trails and Travel Management Plan for the Berryessa Snow Mountain National Monument and hear reports from the district and field offices. On February 23, 2023, the RAC will tour the South Cow Mountain OHV Management Area to view conditions and opportunities for improving off-highway vehicle facilities at the South Cow Mountain OHV Management Area.

All meetings are open to the public. Each RAC meeting has time allocated for public comments. Depending on the number of persons wishing to speak and the time available, the amount of time for oral comments may be limited. Written public comments may be sent to the BLM Central California District Office listed in the **ADDRESSES** section of this notice. All comments received at least 1 week in advance of the meeting will be provided to the RAC.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Members of the public are welcome on field tours but must provide their own transportation and meals. Individuals who plan to attend and need special assistance, such as sign language interpretation and other reasonable accommodations, should contact the BLM (see **FOR FURTHER INFORMATION CONTACT**) at least 2 weeks in advance of the field tours. In-person meetings and the field tours will follow current Centers for Disease Control COVID–19 guidance regarding social distancing and wearing of masks.

Detailed minutes for the RAC meetings will be maintained in the BLM Central California District Office. Minutes will also be posted to the BLM California RAC web page at *https://go.usa.gov/xH9ya.*

(Authority: 43 CFR 1784.4–2)

Christopher M. Heppe,

District Manager, Central Coast District.

[FR Doc. 2022–08048 Filed 4–13–22; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAD01000.LL07772200.XZ0000 (MO#4500160196)]

Meetings of the California Desert District Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) California Desert District Advisory Council (Council) will meet as follows.

DATES: The Council will hold virtual meetings on Saturday, May 14, 2022; Saturday, Aug. 27, 2022; and Saturday, Dec. 10, 2022. All meetings start at 9 a.m. and conclude at 4:30 p.m.

ADDRESSES: The meeting links and participation instructions will be made available to the public via a BLM news release, social media, on the Council's web page at *https://go.usa.gov/xH8Cw,*

and through personal contact 2 weeks prior to the meeting.

Written comments for the Council may be sent electronically in advance of the scheduled meetings to Public Affairs Officer Michelle Van Der Linden at *mvanderlinden@blm.gov,* or in writing to BLM, California Desert District/Public Affairs, 1201 Bird Center Drive, Palm Springs, CA 92262.

FOR FURTHER INFORMATION CONTACT: Michelle Van Der Linden, BLM California Desert District Office, telephone: (760) 833–7172, email: *mvanderlinden@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Van Der Linden. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Council provides recommendations to the Secretary of the Interior concerning the planning and management of the public land resources located within the BLM's California Desert District and offers advice on the implementation of the comprehensive, long-range plan for management, use, development, and protection of the public lands within the California Desert Conservation Area. Agenda topics for the May meeting include presentations on Amargosa Vole Conservation efforts; the King of the Hammers off-road race and related Special Recreation Permit; the Fire and Fuels Program; abandoned mine lands; and overviews from the district and field offices. Agenda topics for the August meeting include presentations on the California Coastal National Monument; BLM landholdings and issues in the South Coast Area; threatened, endangered, and sensitive species relating to the Stephen's Kangaroo Rat; and overviews from the district and field offices. Agenda topics for the December meeting include an update on Castle Mountain Project; discussions on upcoming trail work and visitor impacts within the Amboy Crater National Natural Landmark; discussions on rockhounding within the Marble Mountain Fossil Bed; a presentation on resources within the California Desert District; and overviews from the district and field offices.

All Council meetings are open to the public and public comment periods will be offered at 2:45 p.m. at each meeting. While each of the Saturday meetings is scheduled from 9 a.m. to 4:30 p.m., they may end earlier or later depending on the needs of group members. Therefore, members of the public interested in a specific agenda item or discussion should schedule their arrival accordingly.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR 1784.4–2)

Gregory Miller,

Acting California Desert District Manager.

[FR Doc. 2022–08021 Filed 4–13–22; 8:45 am]

BILLING CODE 4310–40–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–470–471 and 731–TA–1169–1170 (Second Review)]

Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From China and Indonesia; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping and countervailing duty orders on certain coated paper suitable for high-quality print graphics using sheet-fed presses (''coated paper'') from China and Indonesia would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: March 7, 2022.

FOR FURTHER INFORMATION CONTACT: Caitlyn Hendricks (202–205–2058), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: *Background.*—On March 7, 2022, the Commission determined that the domestic interested party group response to its notice of institution (86 FR 68272, December 1, 2021) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at 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.

Staff report.—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on April 21, 2022. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party

[1] A record of the Commissioners' votes is available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the joint response to its notice of institution filed on behalf of Verso Corporation, and Sappi North America, Inc., two U.S. producers of coated paper, and from the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC, which represents workers at domestic coated paper production facilities, to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

other than an interested party to the reviews may file written comments with the Secretary on what determinations the Commission should reach in the reviews. Comments are due on or before April 28, 2022, and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by April 28, 2022. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: April 11, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–08020 Filed 4–13–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB 1140–0081]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Appeals of Background Checks

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection (IC) is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until June 13, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, contact: Shawn Stevens, ATF National Services Center, Federal Explosives Licensing Center, by mail at 244 Needy Road, Martinsburg, WV 25405, email at *Shawn.Stevens@atf.gov,* or telephone at 304–616–4400.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Extension Without Change of a Currently Approved Collection.

2. *The Title of the Form/Collection:* Appeals of Background Checks.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households.

Other (if applicable): Business or other for-profit.

Abstract: This information collection allows a responsible person or an employee authorized to possess explosive materials, to appeal an adverse background check determination, by submitting appropriate documentation to the Bureau of Alcohol Tobacco Firearms and Explosives.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 500 respondents will respond to this collection once annually, and it will take each respondent approximately 2 hours to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 1,000 hours, which is equal to 500 (total respondents) * 1 (# of response per respondent) * 2 (# of hours or the time taken to prepare each response).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3.E–405A, Washington, DC 20530.

Dated: April 11, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–07990 Filed 4–13–22; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF LABOR

Employment and Training Administration

Final Finding of No Significant Impact, Homestead Job Corps Center Proposed Disposal and Reuse, With a Mailing Address of 12350 SW 285th Street, Homestead, FL 33033 With the Closest Physical Address at 470 Bougainville Boulevard, Homestead, FL

AGENCY: Employment and Training Administration, Labor.

ACTION: Final finding of no significant impact, Homestead Job Corps Center Proposed Disposal and Reuse, with a mailing address of 12350 SW 285th Street, Homestead, FL 33033 with the closest physical address at 470 Bougainville Boulevard, Homestead, FL.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration, pursuant to the Council on Environmental Quality Regulations (40 CFR part 1500–08) implementing procedural provisions of the National Environmental Policy Act (NEPA), in accordance with 29 CFR 11.11(d), gives final notice of the proposed disposal of the Homestead Job Corps Center totaling 41 acres and that this project will not have a significant adverse impact on the environment.

DATES: These findings are effective as of April 14, 2022.

ADDRESSES: For further information contact Derrek Sanks, Department of Labor, 200 Constitution Avenue NW, Room N–4460, Washington, DC 20210; Telephone (202) 693–9972 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Derrek Sanks at (202) 693–9972 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: A public notice of availability of the draft environmental assessment (EA) was published in the Miami Herald in Miami, Florida, on January 28, 2022. The review period extended for 30 days, ending on February 28, 2022. No public comments were received. No changes to the findings of the EA have been made.

Implementation of the proposed action alternative will not have significant impacts on the human environment. The determination is sustained by the analysis in the EA, agency, consultation, the inclusion and consideration of public review, and the capability of mitigations to reduce or avoid impacts. Any adverse environmental effects that could occur are no more than minor in intensity, duration and context and less-than-significant. As described in the EA, there are no highly uncertain or controversial impacts, unique or unknown risks, significant cumulative effects, or elements of precedence. There are no previous, planned, or implemented actions, which, in combination with the proposed action alternative, would have significant effects on the human environment. Requirements of NEPA have been satisfied, and preparation of an Environmental Impact Statement is not required.

Angela Hanks,

Acting Assistant Secretary for Employment and Training Administration.

[FR Doc. 2022–07973 Filed 4–13–22; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Public Meeting of the Advisory Committee on Apprenticeship (ACA)

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice of a public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), notice is hereby given to announce a public meeting of the ACA to be held on Thursday, April 28, 2022. The meeting will be held in-person at the U.S. Department of Labor (DOL), Francis Perkins Building, 200 Constitution Avenue NW, Washington, DC 20210. All meetings of the ACA are open to the public.

DATES: The meeting will begin at approximately 9:30 a.m. Eastern Standard Time on Thursday, April 28, 2022, and adjourn at approximately 5:00 p.m. Due to COVID–19 safety protocols, and the need to limit the number of in-person participants, members of the public are asked to join the meeting virtually. The DOL can accommodate 3,000 virtual participants. For any member of the public unable to join the meeting virtually on April 28, 2022, please note that a meeting summary will be posted on the Office of Apprenticeship's website at: *https://www.apprenticeship.gov/advisory-committee-apprenticeship/meetings.*

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer, Mr. John V. Ladd, Administrator, Office of Apprenticeship, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room C–5321, Washington, DC 20210; Email: *AdvisoryCommitteeonApprenticeship@dol.gov;* Telephone: (202) 693–2796 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The ACA is a discretionary committee reestablished by the Secretary of Labor on May 4, 2021, in accordance with FACA (5 U.S.C. app. 2 10), as amended in 5 U.S.C. app. 2, and its implementing regulations (41 CFR 101–6 and 102–3). The first meeting of the ACA was held on Wednesday, October 6, 2021, the second meeting of the ACA was held on Wednesday, January 26, 2022, the third meeting is being held on Thursday, April 28, 2022.

Instructions to Attend the Meeting: All meetings are open to the public and in order to promote openness, and increase public participation, webinar and audio conference technology will be used to convene the meeting. The login instructions outlined below will also be posted prominently on the Office of Apprenticeship's website at: *https://www.apprenticeship.gov/advisory-committee-apprenticeship/meetings.* If individuals have special needs and/or disabilities that will require special accommodations, please contact Kenya Huckaby at (202) 693–3795 or via email at *huckaby.kenya@dol.gov* no later than Thursday, April 21, 2022.

Virtual Log-In Instructions: Members of the public should join the meeting virtually using the following link, please use the access code if you are joining by phone and use the event password if you are joining by computer.

Link: https://usdolevents.webex.com/usdolevents/j.phpMTID=m647e892b37421c5f37431b836ab6ff56.

Telephone Users: VoIP or dial 877–465–7975; Access code: 2761 990 0648.

Computer Users: Event password: Welcome!24.

Any member of the public who wishes to file written data or comments pertaining to the agenda may do so by sending the data or comments to Mr. John V. Ladd via email at *AdvisoryCommitteeonApprenticeship@dol.gov,* subject line ''April 2022 ACA Meeting.'' Such submissions will be included in the record for the meeting if received by Thursday, April 21, 2022. See below regarding members of the public wishing to speak at the ACA meeting.

Purpose of the Meeting and Topics To Be Discussed: The primary purpose of the April meeting is for the ACA to discuss and approve the final Six-Month Interim report. Anticipated agenda topics for this meeting include the following:

- Subcommittee Final Presentations and Discussion
- Departmental Remarks
- Full Committee Vote on Six-Month Interim Report
- Industry and Federal Workforce Initiatives
- Road Map Ahead and Implications for Future Topics
- Public Comment
- Adjourn

The agenda and meeting logistics may need to be updated should priority items emerge between the time of this publication and the scheduled date of the ACA meeting. All meeting updates will be posted to the Office of Apprenticeship's website at: *https://www.apprenticeship.gov/advisory-committee-apprenticeship/meetings.* Any member of the public who wishes to speak at the meeting should indicate the nature of the intended presentation and the amount of time needed by furnishing a written statement to the Designated Federal Officer, Mr. John V. Ladd, via email at *AdvisoryCommitteeonApprenticeship@dol.gov,* by Thursday, April 21, 2022. The Chairperson will announce at the beginning of the meeting the extent to which time will permit the granting of such requests.

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–07974 Filed 4–13–22; 8:45 am]

BILLING CODE 4510–FR–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Required Elements of an Unemployment Insurance (UI) Reemployment Services and Eligibility Assessments (RESEA) Grant State Plan

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Required Elements of an Unemployment Insurance (UI) Reemployment Services and Eligibility Assessments (RESEA) Grant State Plan.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by June 13, 2022.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Ellen Wright by telephone at (202) 693–9995, TTY 1–877–889–5627 (this is not a toll-free number), or by email at *Wright.Ellen.d@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance Room S–4524, 200 Constitution Avenue NW, Washington, DC 20210; by email: *Burns.Lawrence@dol.gov,* or by fax (202) 693–3975.

FOR FURTHER INFORMATION CONTACT: Lawrence Burns by telephone at (202) 693–3141 (this is not a toll-free number) or by email at *Burns.Lawrence@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The federal-state UI program is a required partner in the comprehensive, integrated workforce system. Individuals who have lost employment through no fault of their own and have earned sufficient wage credits may receive UI benefits if they meet initial and continuing eligibility requirements. Since 2005, one of the ways that the Department and participating state UI agencies have been addressing individual reemployment needs of UI claimants and working to prevent and detect UI improper payments is through the voluntary UI Reemployment and Eligibility Assessment (REA) program. Beginning in FY 2015, states transitioned from REA to the voluntary RESEA program.

The Bipartisan Budget Act of 2018, Public Law 115–123 (BBA), enacted on February 9, 2018, included amendments to the Social Security Act (SSA) creating a permanent authorization for the RESEA program. The RESEA provisions are contained in Section 30206 of the BBA, enacting new section 306 of the SSA. Section 306(e), SSA, provides the authorization and specific requirements for an annual RESEA state plan. To receive an RESEA grant, a state must submit an annual RESEA state plan that responds to all required elements and is approved by the Secretary of Labor. In 2019, ETA developed this state plan data collection to closely align with the statutory annual report requirements detailed in Section 306(3), SSA, and the essential administrative information necessary to complete the review, execution, and oversight of RESEA grants. ETA proposes to renew this data collection with several revisions intended to reflect recent changes to the RESEA program, to remove elements that are no longer routinely used to support grant management, and to provide states with the opportunity to include additional narrative descriptions that more fully reflect the state's planned RESEA activities and the economic or other factors that the state considered during the planning process. These proposed revisions include:

- Narrative boxes will be added to plan elements to allow states to provide additional information, clarifications, or other information relevant for the Department's wholistic review of planned RESEA activities;
- All response length limitations will be removed;
- Elements related to service delivery strategies will be revised to reflect recent program changes that allow for virtual and remote services;
- Information about administrative and staff-costs associated with specific RESEA services will no longer be collected; and
- To support the fiscal year 2023 implementation of section 303(c)(2), SSA, which requires states to devote a specific percentage of their RESEA funding to evidence-based components with a high or moderate causal rating that show a demonstrated capacity to improve employment and earnings outcomes for program participants, elements identifying planned evidence-based components will be revised to include funding-level information.

42 U.S.C. 506(e) authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is

approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB No. 1205–0538.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Revision.

Title of Collection: Required Elements of an Unemployment Insurance (UI) Reemployment Services and Eligibility Assessments (RESEA) Grant State Plan.

Form: Annual RESEA State Plan Template.

OMB Control Number: 1205–0538.

Affected Public: State Workforce Agencies.

Estimated Number of Respondents: 53.

Frequency: Annual.

Total Estimated Annual Responses: 53.

Estimated Average Time per Response: 44 hours.

Estimated Total Annual Burden Hours: 2,332.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–07972 Filed 4–13–22; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Information Collection Activities; Comment Request

AGENCY: Bureau of Labor Statistics, Department of Labor.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed extension without change of the ''American Time Use Survey.'' A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the Addresses section of this notice on or before June 13, 2022.

ADDRESSES: Send comments to Erin Good, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE, Washington, DC 20212. Written comments also may be transmitted by email to *BLS_PRA_Public@bls.gov.*

FOR FURTHER INFORMATION CONTACT: Erin Good, BLS Clearance Officer, at 202–691–7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The ATUS is the Nation's first federally administered, continuous survey on time use in the United States. It measures, for example, time spent with children, working, sleeping, or doing leisure activities. In the United States, several existing Federal surveys collect income and wage data for individuals and families, and analysts often use such measures of material prosperity as proxies for quality of life. Time-use data substantially augment these quality-of-life measures. The data also can be used in conjunction with wage data to evaluate the contribution of non-market work to national economies. This enables comparisons of production between nations that have different mixes of market and non-market activities.

The ATUS develops nationally representative estimates of how people spend their time. Respondents also report who was with them during activities, where they were, how long each activity lasted, and if they were paid. All of this information has numerous practical applications for sociologists, economists, educators, government policymakers, businesspersons, health researchers, and others, answering questions such as:

- Do the ways people use their time vary across demographic and labor force characteristics, such as age, sex, race, ethnicity, employment status, earnings, and education?
- How much time do parents spend in the company of their children, either actively providing care or being with them while socializing, relaxing, or doing other things? How has this changed over time?
- How are earnings related to leisure time—do those with higher earnings spend more or less time relaxing and socializing?
- How much time do people spend working at their workplaces and in their homes?

The ATUS data are collected on an ongoing basis nearly every day of the year, allowing analysts to identify changes in how people spend their time.

II. Current Action

Office of Management and Budget clearance is being sought for the American Time Use Survey (ATUS). This survey collects information on how individuals in the United States use their time. Collection is done on a continuous basis with the sample drawn monthly. The survey sample is drawn from households completing their 8th month of interviews for the Current Population Survey (CPS). Households

are selected to ensure a nationally-representative demographic sample, and one individual from each household is selected to take part in one Computer Assisted Telephone Interview. Interviewers ask respondents to report all of their activities for one pre-assigned 24-hour day, the day prior to the interview. A short series of summary questions and CPS updates follows the core time diary collection. After each full year of collection, annual national estimates of time use for an average day, weekday, and weekend day are published.

Because the ATUS sample is a subset of households completing interviews for the CPS, the same demographic information collected from that survey is available for ATUS respondents. Comparisons of activity patterns across characteristics such as sex, race, age, disability status, and education of the respondent, as well as the presence of children and the number of adults living in the respondent's household, are possible.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Title of Collection: American Time Use Survey.

OMB Number: 1220–0175.

Type of Review: Extension.

Affected Public: Individuals or Households.

Total Respondents: 9,435.

Frequency: Annually.

Total Responses: 9,435.

Average Time per Response: 21.5 minutes.

Estimated Total Burden Hours: 3,381 hours.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, on April 7, 2022.

Eric Molina,

Acting Chief, Division of Management Systems.

[FR Doc. 2022–07971 Filed 4–13–22; 8:45 am]

BILLING CODE 4510–24–P

OFFICE OF MANAGEMENT AND BUDGET

[OMB Control No. 0348–NEW]

Information Collection; Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

AGENCY: Office of Management and Budget.

ACTION: Notice; request for comment.

SUMMARY: The Office of Management and Budget (OMB) has under review the following proposed Information Collection Request ''Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)'' for approval under the Paperwork Reduction Act (PRA).

DATES: Comments must be received by May 16, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Amira Boland, Office of Management and Budget, 725 17th St. NW, Washington, DC 20006, 202–395–0380, or via email to *amira.c.boland@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Whether seeking a loan, Social Security benefits, veterans benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet on Forrester's 2020 CX Index, the Federal sector's average score is 10.7 points behind the private sector average and lower than any other industry or sector studied. Nearly half of the bottom 5% of the U.S. CX Index Rankings are Federal agencies.

The President's Management Agenda (*see https://www.performance.gov/PMA*) prioritizes efforts to improve the experience of those the Government serves—all of the people, families, businesses, organizations, and communities across America, especially those communities that are underserved by Government, when they use Government services. This focus on customer experience will not only improve the delivery, efficiency, security, and effectiveness of our Government programs, it will advance equity and enhance everyday interactions with public services and uplift the lives of those who need them the most. To support this, OMB Circular A–11 Section 280 establishes Government-wide standards for mature customer experience organizations in government. In order for Federal programs to design and deliver the experience taxpayers deserve, they must often undertake three general categories of activities: conduct ongoing customer research, gather and share customer feedback, and test services and digital products. Both the PMA and Section 280 charge the President's Management Council—the primary Government-wide body that advises the President and OMB on management issues that span agencies—with the routine designation of cross-agency ''life experiences'' for improvement (such as turning 65, surviving a natural disaster, or having a child) that do not fit neatly within one agency's mission area.

For these projects, OMB designers and staff, such as those on the Federal Customer Experience team or at the U.S. Digital Service, may lead and coordinate information collections in service of cross-agency life experience improvement efforts. These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video, and audio collections), interviews, questionnaires, surveys, and focus groups. OMB will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request, where appropriate.

The data collected will be evaluated and used to improve the delivery of Federal services and programs and, in particular, those experiences that are more Government-wide in nature. It will include the creation of customer personas, customer journey maps (for definitions of—and more information

on—customer personas and journey maps, see *https://performance.gov/cx/projects*), and reports and summaries of customer feedback data and user insights. It will also provide Government-wide data on customer experience that can be displayed on Performance.gov to help build transparency and accountability of Federal programs to the customers they serve.

As a general matter, these information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

OMB will only submit collections if they meet the following criteria:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used for general service improvement and program management purposes;
- Upon agreement between OMB and the agency all or a subset of information may be released as part of A–11, Section 280 requirements only on *performance.gov;*
- Summaries of customer research and user testing activities may be included in public-facing customer journey maps or summaries; and
- Additional release of data must be coordinated with OMB.

These responses will inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on services will be unavailable.

Current Action: New Collection of Information.

Type of Review: New.

Affected Public: Individuals and households; businesses and organizations; State, local, territorial, or Tribal governments.

Estimated Number of Respondents: Below is a preliminary estimate of the aggregate burden hours for this new collection. OMB will provide refined estimates of burden in subsequent notices.

Average Expected Annual Number of Activities: Approximately five types of customer experience activities such as feedback surveys, focus groups, user testing, and interviews.

Average Number of Respondents per Activity: 1 response per respondent per activity.

Annual Responses: 2,001,550.

Average Minutes per Response: 2–60 minutes, dependent upon activity.

Burden Hours: OMB estimates approximately 101,125 burden hours.

Request for Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. In general, comments submitted in response to this notice will be summarized and/or included in the request for approval of this information collection; they also will become a matter of public record.

Jason S. Miller,

Deputy Director of Management.

[FR Doc. 2022–07977 Filed 4–13–22; 8:45 am]

BILLING CODE 3110–01–P

MORRIS K. UDALL AND STEWART L. UDALL FOUNDATION

Sunshine Act Meetings

TIME AND DATE: 9:00 a.m. to 2:00 p.m. (PDT), Wednesday, April 27, 2022.

PLACE: The University of Arizona President's Office Conference Room, Old Main, Room 200, 1200 East University Boulevard, Tucson, Arizona, 85721.

STATUS: This meeting will be open to the public. Members of the public who would like to attend this meeting may request remote access by contacting Elizabeth Monroe at *monroe@udall.gov* prior to April 27 to obtain the teleconference connection information.

MATTERS TO BE CONSIDERED: (1) Call to Order and Chair's Remarks; (2) University of Arizona's Remarks and Welcome; (3) Council on Environmental Quality's Remarks; (4) Executive Director's Remarks; (5) Consent Agenda Approval (Minutes of the October 28, 2021, Board of Trustees Meeting; Board Reports submitted for Data and Information Technology, Education Programs, Finance and Internal Controls, John S. McCain III National Center for Environmental Conflict Resolution, and Udall Center for Studies in Public Policy-Native Nations Institute for Leadership, Management, and Policy-The University of Arizona Libraries, Special Collections; resolution regarding Amendment of Operating Procedures of the Board of Trustees of the Morris K. Udall and Stewart L. Udall Foundation; and Board takes notice of any new and updated personnel policies and internal control methodologies); (6) Update on Udall Foundation–University of Arizona Collaborations; (7) Grants, Gifts, and Donations Update; (8) Office Relocation of Udall Foundation Tucson, Arizona Headquarters; (9) Recognition of Former Trustee and Former Executive Director; (10) Recognition of Long-Serving Board Officers; and (11) Trustee Ethics Training.

CONTACT PERSON FOR MORE INFORMATION: David P. Brown, Executive Director, 130 South Scott Avenue, Tucson, AZ 85701, (520) 901–8560.

Dated: April 12, 2022.

David P. Brown,

Executive Director, Morris K. Udall and Stewart L. Udall Foundation, and Federal Register Liaison Officer.

[FR Doc. 2022–08129 Filed 4–12–22; 4:15 pm]

BILLING CODE 6820–FN–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's Committee on Strategy's Subcommittee on Technology, Innovation and Partnerships hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Monday, April 18, 2022, from 11:15 a.m.–12:00 p.m. EDT.

PLACE: This meeting will be held by teleconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Subcommittee Chair's Opening Remarks; Approval of Minutes from February 11, 2022; and Discussion of Technology, Innovation, and

Partnerships Programmatic Plans and Budget Scenarios.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–08054 Filed 4–12–22; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Monday, April 18, 2022, from 1:00 p.m.–2:00 p.m. EDT.

PLACE: This meeting will be held by teleconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: NSB Chair's Opening Remarks; Action Item—McMurdo Pier Project; Presentation and Discussion; and Vote.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–08052 Filed 4–12–22; 11:15 am]

BILLING CODE 7555–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94646; File No. SR–OCC–2022–006]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by The Options Clearing Corporation Concerning Weekly Options and Short Term Options

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 25, 2022, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change would amend the definitions of ''weekly option'' and ''short term option'' in Article I of OCC's By-Laws. The proposed rule change would amend these definitions to align with the rules of participant options exchanges by clarifying that weekly options and short term options may expire and/or be opened in accordance with the rules of the exchange on which they are traded. The proposed changes to OCC's By-Laws are included in Exhibit 5 of File No. SR–OCC–2022–006. Material proposed to be added to OCC's By-Laws as currently in effect is underlined and material proposed to be deleted is marked in strikethrough text. All capitalized terms not defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The purpose of this proposed rule change is to more clearly align certain existing definitions in OCC's By-Laws for options products with Exchange Rules related to those products. OCC currently facilitates the clearance and settlement of weekly options and short term options on behalf of participant options exchanges. The term ''weekly option'' is currently defined in Article I of OCC's By-Laws as ''an option of a series of stock options or index options that expires on any Friday of a calendar month other than the third Friday of such calendar month.''[4] The definition was first introduced in 2010.[5] The term ''short term option'' is currently defined as ''an option of a series of options that expires one week after it is opened for trading'' and further specifies that short term options ''may be opened on a Friday that is a business day and shall expire, at the expiration time, on the next Friday that is a business day; provided, however, that if a Friday is not a business day, the series shall be opened (or shall expire) on the first business day immediately prior to that Friday.''[6] The definition was first introduced in 2005 in connection with a pilot program for short term options that was eventually made permanent in 2009.[7]

Currently, participant options exchanges list and trade weekly options that expire on other days of the week, such as Monday or Wednesday,[8] and a participant options exchange has recently filed a proposed rule change to list and trade weekly options that expire on Tuesday and Thursday.[9] These exchanges also list short term options that may be opened on days other than a Friday and expire on days other than Friday.[10] Because pursuant to Exchange

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] OCC's By-Laws and Rules can be found on OCC's public website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

[4] The definition of ''weekly option'' also states that ''[t]he term 'weekly index option' means a weekly option on an index.'' OCC is not proposing changes to this part of the weekly option definition.

[5] *See* Exchange Act Release No. 63293, 75 FR 70055 (November 16, 2010) (approval order establishing weekly options and monthly options).

[6] The definition of ''short term option'' also specifies that a short term option series may be opened in any option class. OCC is not proposing changes to this part of the short term option definition.

[7] *See* Exchange Act Release No. 52010, 70 FR 41469 (July 19, 2005) (SR–OCC–2005–06) (approval order to support the short term options pilot program). *See also e.g.,* Exchange Act Release Nos. 52011 (July 12, 2005), 70 FR 41451 (July 19, 2005) (SR–CBOE–2004–63) (approval order establishing Weeklys Pilot Program) and 59824 (April 27, 2009), 74 FR 20518 (May 4, 2009) (SR–CBOE–2009–018) (approval order permanently establishing Weeklys Program). CBOE refers to its short term option program as the ''Weeklys Program.''

[8] *See e.g.,* Cboe Rule 4.13(e)(1) (''The Exchange may open for trading Weekly Expirations on any broad-based index eligible for standard options trading to expire on any *Monday, Wednesday,* or Friday (other than the third Friday-of-the-month or days that coincide with an EOM [end of month] expiration.'')(emphasis added).

[9] *See* Exchange Act Release No. 94292, 87 FR 11102 (February 28, 2022) (SR–CBOE–2022–005) (notice of filing of proposed rule change to permit P.M.-settled S&P 500 index options that expire on Tuesday or Thursday).

[10] *See e.g.,* Cboe Rule 4.5(d) (''Short Term Option Series Program. After an option class has been

Rules weekly options may expire on days other than Friday and short term options may be opened and expire on days other than Friday, OCC proposes making clarifying changes to these definitions to more closely align them with options Exchange Rules and with how these options trade today.

Accordingly, OCC proposes to amend the definition of a weekly option to provide that a weekly option means ''an option of a series of stock options or index options that has a weekly tenor and that expires on any day as provided in Exchange Rules. The term 'weekly index option' means a weekly option on an index.'' Similarly, OCC proposes to amend the definition of a short term option to provide that a short term option means ''an option of a series of options that pursuant to Exchange Rules expires one week after it is opened for trading. Short term option series may be opened in any option class.'' In both cases, OCC proposes to remove language specifying particular days of the week on which weekly options or short term options may expire and/or be opened and to instead reference the relevant options Exchange Rules for information on expirations and any opening conditions. OCC believes that the proposed amendments would promote clarity in OCC's By-Laws regarding when weekly options and short term options may be opened and/or expire and, as noted, promote greater consistency with options Exchange Rules.

(2) Statutory Basis

Section 17A(b)(3)(F) [11] of the Exchange Act requires, among other things, that the rules of a clearing agency be designed, in general, to protect investors and the public interest. OCC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act.[12] As noted above, the proposed rule change would promote clarity in OCC's By-Laws regarding when weekly options and short term options may be opened and/or expire and consistency with options Exchange Rules. OCC believes that the proposed amendments to the ''weekly option'' and ''short term option'' definitions would protect investors and the public interest by setting forth clear definitions that are consistent with options Exchange Rules and in turn facilitate a clear understanding of the regulatory framework for weekly options and short term options. Additionally, OCC believes that making clarifying changes to its definitions of a weekly option and short term option to better align with options Exchange Rules helps foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions between and among OCC and the options exchanges that rely on OCC to clear and settle trades, consistent with Section 17A(b)(3)(F) of the Act.[13] Additionally, the proposed rule change is not inconsistent with the existing rules of OCC, including any other rules proposed to be amended.

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act [14] requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. OCC does not believe that the proposed amendments to the definitions of ''weekly option'' and ''short term option'' would impose any burden on competition because they would merely modify the definitions to promote consistency with options Exchange Rules and to reflect how these options trade today pursuant to those Exchange Rules. The proposed changes would not inhibit access to OCC's services in any way, would apply to all Clearing Members uniformly and does not disadvantage or favor any particular user in relationship to another user. Accordingly, OCC does not believe that the proposed rule change would have any impact or impose a burden on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii) [15] of the Act, and Rule 19b–4(f)(1) and (4) thereunder,[16] the proposed rule change is filed for immediate effectiveness. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.[17]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–OCC–2022–006 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2022–006. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the

approved for listing and trading on the Exchange, the Exchange may open for trading on any *Thursday* or Friday that is a business day . . . Monday and Wednesday SPY, IWM and QQQ Expirations. The Exchange may open for trading on any Friday or *Monday* that is a business day series of options on the SPDR S&P 500 ETF Trust (''SPY'') . . . that expire at the close of business each of the next five Mondays that are business days . . . The Exchange may also open for trading on any *Tuesday* or *Wednesday* that is a business day series of SPY options . . . that expire at the close of business on each of the next five Wednesdays . . . .'').

[11] 15 U.S.C. 78q–1(b)(3)(F).

[12] *Id.*

[13] *Id.*

[14] 15 U.S.C. 78q–1(b)(3)(I).

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(1), (4).

[17] Notwithstanding its immediate effectiveness, implementation of this rule change will be delayed until this change is deemed certified under CFTC Regulation 40.6.

public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–OCC–2022–006 and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–07948 Filed 4–13–22; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94652; File No. SR–PEARL–2022–10]

Self-Regulatory Organizations: MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Equities Fee Schedule

April 8, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 31, 2022, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the fee schedule (the ''Fee Schedule'') applicable to MIAX Pearl Equities, an equities trading facility of the Exchange.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's Fee Schedule to (i) adopt a new Liquidity Code and associated rebate to the Liquidity Indicator Codes and Associated Fees table; (ii) adopt new Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers to improve market quality on the Exchange by offering an enhanced rebate for executions that Add Liquidity at the Midpoint of the PBBO[3] using a Midpoint Peg Order[4] in securities priced at or above $1.00 per share that add liquidity and are pegged to the midpoint of the bid and ask; and (iii) amend section 1(d) Remove Volume Tiers table to increase the fee.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 17% of the total market share of executed volume of equities trading, and the Exchange currently represents approximately 1% of the overall market share.[5]

Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Equity Members[6] (''Members'') with opportunities to qualify for higher rebates or lower fees when certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Adoption of Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers

The Exchange is now proposing to introduce a new tiered pricing structure applicable to rebates provided for executions that add liquidity to the Exchange at the Midpoint of the PBBO using a Midpoint Peg Order (such orders, ''Midpoint Peg Add Orders executed at the Midpoint''). Specifically, the Exchange proposes to adopt new volume-based tiers, referred to by the Exchange as, ''Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers,'' in which the Exchange will provide an enhanced rebate for executions of Midpoint Peg Add Orders executed at the Midpoint for Members that meet certain volume thresholds on the Exchange.

The Exchange currently provides a standard rebate of $0.0021 per share for executions of Added Non-Displayed Liquidity.[7] The Exchange now proposes to introduce a tiered pricing structure in which it will provide an enhanced, incremental rebate of $0.0004 per share for an effective total rebate of $0.0025

[3] The term ''PBBO'' means the best bid or offer on MIAX Pearl. *See* Exchange Rule 100.

[4] A Midpoint Peg Order is a non-displayed Limit Order that is assigned a working price pegged to the midpoint of the PBBO. A Midpoint Peg Order receives a new timestamp each time its working price changes in response to changes in the midpoint of the PBBO. *See* Exchange Rule 2614(a)(3).

[5] *See* MIAX's ''The Market at a Glance'', available at *https://www.miaxoptions.com/* (last visited March 24, 2022).

[6] The term ''Equity Member'' is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. *See* Exchange Rule 1901.

[7] The Exchange notes that the standard rebate of $0.0021 per share for executions of Added Non-Displayed Liquidity in securities priced at or above $1.00 is not changing under this proposal.

for executions of Midpoint Peg Add Orders executed at the Midpoint for Members that qualify for Tier 1 of the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers by achieving a Midpoint ADAV [8] equal to or greater than 500,000 shares. The Exchange also proposes to provide an enhanced, incremental rebate of $0.0006 per share for an effective total rebate of $0.0027 for executions of Midpoint Peg Add Orders executed at the Midpoint for Members that qualify for Tier 2 of the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers by achieving a Midpoint ADAV equal to or greater than 1,000,000 shares. The rebates provided for by the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers will be applicable to executions of orders that yield fee code ''Ap'' as described below and will be provided in place of the standard rebate of $0.0021 per share for executions of Added Non-Displayed Volume. The Exchange notes that the rebates described above will not apply to executions of orders in securities priced below $1.00 per share.

The purpose of the proposed enhanced rebate for executions of Midpoint Peg Add Orders executed at the Midpoint is to encourage Members that provide liquidity through non-displayed orders to strive for a higher Midpoint ADAV on the Exchange in order to qualify for the enhanced rebates for executions of Midpoint Peg Add Orders executed at the Midpoint, and as such, encourages Members to maintain or increase their order flow (particularly in the form of liquidity adding non-displayed Midpoint Peg Orders that execute at the Midpoint) to the Exchange, thereby contributing to a deeper and more liquid market to the benefit of all market participants.

The Exchange's pricing structure is generally designed to encourage the provision of liquidity, thus the proposed enhanced rebates for executions of Midpoint Peg Add Orders executed at the Midpoint is designed to encourage Members that use non-displayed orders to provide additional non-displayed liquidity through the use of orders that are designed to execute at the midpoint of the PBBO. The Exchange believes that providing enhanced rebates for executions of Midpoint Peg Add Orders executed at the Midpoint is a reasonable means to incentivize Members to provide additional liquidity at the midpoint of the PBBO, which in turn would increase the attractiveness of the Exchange as a destination venue, as Members seeking price improvement would be more motivated to direct their orders to the Exchange because they would have a heightened expectation of the availability of liquidity at the midpoint of the PBBO. The Exchange notes that the proposed enhanced rebate is comparable to, and competitive with, the rebate provided by at least one other exchange for executions of non-displayed orders in securities priced at or above $1.00 per share that are pegged to the midpoint.[9]

New Liquidity Indicator Code

In conjunction with the Exchange's proposal to (i) provide an enhanced, incremental rebate of $0.0004 per share for Midpoint Peg Orders that Add Liquidity and meet the Tier 1 requirements of the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers; and (ii) provide an enhanced, incremental rebate of $0.0006 per share for Midpoint Peg Orders that Add Liquidity and meet the Tier 2 requirements of the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers, the Exchange proposes to update the Liquidity Indicator Code and Associated Fees Table as follows:

- Add new liquidity indicator code Ap, Adds Liquidity and Executes at the Midpoint, Non-Displayed Midpoint Peg Order (All Tapes). The Liquidity Indicator Code and Associated Fees table would specify that orders that yield liquidity indicator code Ap would receive a rebate of $0.0021 per share in securities priced at or above $1.00 and 0.05% of the transaction's dollar value in securities priced below $1.00.

The Exchange also proposes to add the above liquidity indicator code to the Standard Rates table. Specifically, liquidity indicator code Ap would be added to the ''Added Liquidity Non-Displayed Order'' column.

Increase Fee for Remove Volume Tiers

Currently, the Exchange charges a standard fee of $0.0029 for all executions of Removed Volume.[10] The Exchange also offers a two-tiered pricing structure for fees charged for executions of Removed Volume on the Exchange for Members that meet certain thresholds. Members that qualify for Tier 1 by achieving an ADV [11] that is equal to or greater than 0.10% of TCV [12] are charged $0.0027 per share for executions of Removed Volume. Members that qualify for Tier 2 by achieving an ADV that is equal to or greater than 0.15% of TCV are charged a fee of $0.00265 per share for Executions of Removed Volume.

The Exchange now proposes to increase the fees charged for Removed Volume in Tier 1 and Tier 2 to $0.0028 and $0.0027 respectively, an increase of $0.0001 and $0.00005 respectively. The purpose of increasing the fee for executions of Removed Volume is for business and competitive reasons. The requirements necessary to qualify for Tier 1 and Tier 2 will remain unchanged under this proposal. The Exchange notes that despite the proposed increase the proposed fee changes for Removed Volume Tiers remain comparable to, and competitive with, the fees charged for executions of liquidity-removing orders charged by other exchanges under similar volume-based tiers.[13]

[8] For this program, Midpoint ADAV will refer to the average daily added volume consisting of Midpoint Peg Add Orders executed at the Midpoint (as described herein) for the current month calculated similarly to ADAV. ''ADAV'' means average daily added volume calculated as the number of shares added per day and ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day. ADAV and ADV are calculated on a monthly basis. The Exchange excludes from its calculation of ADAV and ADV shares added or removed on any day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during regular trading hours (''Exchange System Disruption''), on any day with a scheduled early market close, and on the ''Russell Reconstitution Day'' (typically the last Friday in June). Routed shares are not included in the ADAV or ADV calculation. With prior notice to the Exchange, an Equity Member may aggregate ADAV or ADV with other Equity Members that control, are controlled by, or are under common control with such Equity Member (as evidenced on such Equity Member's Form BD). *See* MIAX Pearl Equities Fee Schedule, ''Definitions,'' available at (*https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Equities_Fee_Schedule_01032022.pdf*).

[9] *See* MEMX trading fee schedule on its public website (available at *https://info.memxtrading.com/fee-schedule/*) which reflects a rebate of $0.0028 per share for added non-displayed liquidity under Tier 1 of its Non-Display Add Tiers; and a rebate of $0.0024 per share for added non-displayed liquidity under Tier 2 of its Non-Display Add Tiers.

[10] The Exchange notes that the standard fee of $0.0029 for orders removing liquidity in securities priced at or above $1.00 is not changing under this proposal.

[11] *See supra* note 8.

[12] ''TCV'' means total consolidated volume calculated as the volume in shares reported by all exchanges and reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply. The Exchange excludes from this calculation of TCV volume on any given day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Trading Hours, on any day with a scheduled early market close, and on the ''Russell Reconstitution Day'' (typically the last Friday in June). *See* MIAX Pearl Equities Fee Schedule, ''Definitions,'' available at *https://www.miaxoptions.com/fees/pearl-equities*).

[13] *See* the Cboe EDGX equities trading fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/*) which reflects fees charged under ''Remove Volume Tiers''—tiers based on a member achieving certain step-up ADAV and ADV volume thresholds of $0.00275 per share for removing volume from the Cboe EDGX exchange; *See also*

Continued

Additionally, the Exchange notes that the Remove Volume Tiers, as modified, would continue to be available to all Members.

Implementation

The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal on April 1, 2022.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [14] in general, and furthers the objectives of Section 6(b)(4) of the Act [15] in particular, in that it is an equitable allocation of reasonable fees and other charges among its Equity Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5) [16] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, and to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange operates in a highly fragmented and competitive market in which market participants can readily direct their order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of sixteen registered equities exchanges, and there are a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 17% of the total market share of executed volume of equities trading.[17] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange currently represents less than 1% of the overall market share. The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [18]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance liquidity and market quality to the benefit of all Members and market participants.

Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers

The Exchange believes that the proposed Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers are reasonable because they would provide Members with an additional incentive to achieve certain volume thresholds on the Exchange. The Exchange notes that volume-based incentives and discounts have been widely adopted by exchanges,[19] and are reasonable, equitable, and not unfairly discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and the introduction of higher volumes of orders into the price and volume discovery processes. The Exchange believes that the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, to enhance market quality and to provide price improvement through the use of orders that are designed to execute at the midpoint of the PBBO through the provision of enhanced rebates for executions of Midpoint Peg Add Orders executed at the Midpoint for Members that qualify for one of the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers.[20] The Exchange believes its proposal will promote price improvement and increased liquidity on the Exchange which will benefit all market participants.

Additionally, the Exchange believes that the proposed enhanced, incremental rebate for executions of Midpoint Peg Add Orders executed at the Midpoint under Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier 1 (*i.e.,* $0.0004 per share) is reasonable, in that it does not reflect a disproportionate increase above the standard rebate of $0.0021 per share provided to all Members with respect to Added Non-Displayed Liquidity. Additionally, the Exchange believes that the proposed enhanced, incremental rebate for executions of Midpoint Peg Add Orders executed at the Midpoint under Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier 2 (*i.e.,* $0.0006 per share) is reasonable, in that it does not reflect a disproportionate increase above the enhanced rebate of $0.0004 per share provided to Members that satisfy the requirements of Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier 1.

The Exchange believes the proposed new criteria is equitable and non-discriminatory because all Members will continue to be eligible to qualify for Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers 1 and 2 and have the opportunity to receive the corresponding enhanced rebate if such criteria is achieved.

MEMX fee schedule on its public website (available at *https://info.memxtrading.com/fee-schedule/*) which reflects a fee per share charge of $0.00285 under ''Liquidity Removal Tier'' for a Member that has (1) an ADAV ≥0.30% of the TCV; or (2) an ADV ≥0.60% of the TCV.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(4).

[16] 15 U.S.C 78f(b)(5).

[17] *See supra* note 5.

[18] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37499 (June 29, 2005).

[19] *See* Cboe EDGX equities trading fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/*); Cboe BZX equities trading fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/*); and MEMX equities trading fee schedule on its public website (available at *https://info.memxtrading.com/fee-schedule/*).

[20] The Exchange notes that Members that do not qualify for one of the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier will receive the standard rebate of $0.0021 for Non-Displayed Midpoint Peg Orders that Add Liquidity in securities priced at or above $1.00.

The Exchange further believes that the proposed new criteria for Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier 1, and Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier 2, are reasonable, in that the proposed new criteria for Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier 2 is incrementally more difficult to achieve than that of Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier 1, thus, Midpoint Peg Order Adding Liquidity at Midpoint Volume Tier 2 appropriately offers a higher rebate commensurate with the corresponding higher Midpoint ADAV requirement. Therefore, the Exchange believes the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers, as proposed, are consistent with an equitable allocation of fees and rebates, as the more stringent criteria correlates with the corresponding tier's higher rebate.

The Exchange further believes that the enhanced rebates provided under the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers, as proposed, (*i.e.,* $0.0004 per share for Tier 1; and $0.0006 per share for Tier 2) are reasonable, consistent with an equitable allocation of fees, and that it is not unfairly discriminatory to pay such higher rebates for executions of Midpoint Peg Add Orders executed at the Midpoint to Members that qualify for either Tier 1 or Tier 2 under the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers in comparison with the standard rebate in recognition of the benefits to the Exchange and market participants as described above, particularly as the magnitude of the enhanced rebate is not unreasonably high and is reasonably related to the enhanced market quality it is designed to achieve. Additionally, the Exchange believes that the proposed rebates are reasonable as such rebates are comparable to, and competitive with, the rebates for executions of liquidity-adding non-displayed orders provided by at least one other exchange under similar volume-based tiers.[21]

The Exchange believes that providing an enhanced rebate for Midpoint Peg Add Orders executed at the Midpoint that is higher than the standard rebate for executions of other non-displayed orders in securities priced at or above $1.00 per share that add liquidity to the Exchange is reasonable, as the Exchange believes this would encourage Members that provide liquidity through non-displayed orders to do so, to a greater extent, through orders designed to execute at the midpoint of the PBBO. Because such orders provide price improvement to the benefit of other market participants, the Exchange believes it is reasonable and consistent with an equitable allocation of fees to provide an enhanced rebate to encourage their use, while still maintaining an overall pricing structure that places greater emphasis on the value of liquidity in advancing transparency and price discovery.

New Liquidity Indicator Code

The Exchange believes its proposal to add new liquidity indicator code ''Ap'' to the Liquidity Indicator Codes and Associated Fees table and to add liquidity indicator code ''Ap'' to the ''Adding Liquidity Non-Displayed Order'' column, is reasonable and equitable because it will apply equally to all Members of the Exchange that submit Midpoint Peg Orders. This liquidity indicator code would be returned on the real-time trade reports sent to the Member that submitted the order. The use of liquidity indicator codes is not unique to the Exchange as liquidity indicator codes are currently utilized and described in the fee schedules of other equity exchanges.[22]

Remove Volume Tier

The Exchange believes that the proposed fee change to the Remove Volume Tiers is reasonable, consistent with an equitable allocation of fees, and not unfairly discriminatory to provide a discounted fee for executions of Remove Volume for Members that satisfy the requirements associated with Tier 1 and Tier 2. The Exchange believes the proposed fee changes are reasonable because the magnitude of the increase is not unreasonably high and is also reasonably related to the enhanced market quality it is designed to achieve.

The Exchange believes the proposed increased fee for executions of Removed Volume for a qualifying Member (*i.e.,* $0.0028 and $0.0027 for Tier 1 and Tier 2 respectively) is reasonable, as competing exchanges offer tiered pricing structures similar to the proposed Remove Volume Tier, including schedules of rebates and fees that apply based upon Members achieving certain volume thresholds, and the Exchange believes the proposed Remove Volume Tier's criteria are reasonable when compared to such tiers provided for by other exchanges. For example, Cboe EDGX charges lower fees for removing volume from Cboe EDGX under its ''Remove Volume Tiers'' at $0.00275 per share, compared to its standard fee of $0.0030 per share, but requires different, but similar, criteria than the Exchange's proposed Remove Volume Tier, which are also based upon a Member's volume.[23] MEMX also charges a lower fee for removing volume from MEMX under its ''Liquidity Removal Tier'' at $0.00285 per share, compared to its standard fee of $0.0030 per share, but requires different, but similar, criteria than the Exchange's Remove Volume Tier, which are also based upon a Member's volume.[24]

The Exchange further believes the proposed Remove Volume Tier fees are fair, equitable and not unfairly discriminatory because they are available to all Members. Further, the proposed Remove Volume Tier fee changes are comparable to the fees charged for executions of liquidity-removing orders charged by Cboe EDGX and MEMX under similar volume based tiers.[25]

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed fees and rebates described herein are appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed change would encourage Members to maintain or increase their order flow to the Exchange, thereby contributing to a deeper and more liquid market to the benefit of all market participants and enhancing the attractiveness of the Exchange as a trading venue. As a

[21] *See supra* note 9.

[22] *See* the fee schedule of MEMX LLC (''MEMX'') available on their public website at *https://info.memxtrading.com/fee-schedule/;* and the fee schedule of the Investors Exchange LLC (''IEX'') available on their public website at *https://exchange.iex.io/resources/trading/fee-schedule/.*

[23] *See* Cboe EDGX equities trading fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/*).

[24] *See* MEMX trading fee schedule on its public website (available at *https://info.memxtrading.com/fee-schedule/*).

[25] *See supra* notes 23 and 24.

result, the Exchange believes the proposal would enhance its competitiveness as a market that attracts actionable orders, thereby making it a more desirable destination venue for its customers. For these reasons, the Exchange believes that the proposal furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [26]

Intramarket Competition

The Exchange believes that the proposal would incentivize Members to maintain or increase their order flow, thereby contributing to a deeper and more liquid market to the benefit of all market participants and enhance the attractiveness of the Exchange as a trading venue, and to provide price improvement through the use of orders that are designed to execute at the midpoint of the PBBO, which the Exchange believes, in turn, would continue to encourage participants to direct order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. The opportunity to qualify for enhanced, incremental rebates under the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers would be available to all Members that meet the associated requirements in any month. The Exchange believes the requirements in the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers are reasonably related to the enhanced market quality that the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers are designed to promote. Similarly, the proposed enhanced rebate for executions of Midpoint Peg Orders would apply equally to all Members. As such, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The opportunity to qualify for the Remove Volume Tier, and thus receive the proposed lower fee for executions of Removed Volume, would be available to all Members that meet the associated volume requirement in any month. The Exchange believes that meeting the volume requirement of the Remove Volume Tier is attainable for market participants, as the Exchange believes the thresholds are relatively low and reasonably related to the enhanced liquidity and market quality that the Remove Volume Tier is designed to promote. As such, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The Exchange believes its proposal will benefit competition, and the Exchange notes that it operates in a highly competitive market. Members have numerous alternative venues they may participate on and direct their order flow to, including fifteen other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than 17% of the total market share of executed volume of equities trading.[27] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow in response to new or different pricing structures being introduced to the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates generally, including with respect to executions of Removed Volume, and market participants can readily choose to send their orders to other exchanges and off-exchange venues if they deem fee levels at those other venues to be more favorable.

As described above, the proposal is designed to enhance market quality on the Exchange and to encourage more Members to maintain or increase their order flow, thereby contributing to a deeper and more liquid market to the benefit of all market participants and enhancing the attractiveness of the Exchange as a trading venue, and to encourage Members to provide price improvement through the use of orders that are designed to execute at the midpoint of the PBBO. In turn, the Exchange believes that the proposed enhanced rebates for executions of Midpoint Peg Add Orders executed at the Midpoint that qualify for an enhanced rebate under the Midpoint Peg Order Adding Liquidity at Midpoint Volume Tiers would encourage the submission of additional order flow to the Exchange, particularly in the form of Midpoint Peg Add Orders executed at the Midpoint, thereby promoting market depth, enhanced execution opportunities, price improvement, and price discovery to the benefit of all Members and market participants. The opportunity to qualify for discounted fees for Removed Volume under the Exchange's Remove Volume Tiers continues to be available to all Members that meet the associated volume criteria. The Exchange believes the discounted fees provided under the Remove Volume Tiers are reasonably related to the enhanced market quality that such tiers are designed to promote.

As described above the Exchange's proposal is a competitive proposal designed to encourage additional order flow to the Exchange through a combination of volume based incentives and discounts, which have been widely adopted by exchanges, and standard pricing that is comparable to, and/or competitive with, pricing for similar executions in place at other exchanges.[28]

Accordingly, the Exchange believes its proposal would not burden, but rather promote, intermarket competition by enabling it to better compete with other exchanges that offer similar standard pricing for Added Midpoint Volume and Removed Volume, as well as similar pricing incentives and discounts to market participants that achieves certain volume criteria and thresholds.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [29] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. circuit stated: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their routing agents, have a wide range of choices of where

[26] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 47396 (June 29, 2005).

[27] *See supra* note 5.

[28] *See supra* notes 9, 13, 19, 23 and 24.

[29] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possess a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . .''.[30] Accordingly, the Exchange does not believe its proposed pricing changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[31] and Rule 19b–4(f)(2)[32] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2022–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–PEARL–2022–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2022–10 and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Jill M. Peterson,

Assistant Secretary.

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[30] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

[31] 15 U.S.C. 78s(b)(3)(A)(ii).

[32] 17 CFR 240.19b–4(f)(2).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94643; File No. SR–FINRA–2022–007]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rule 2360 (Options) To Increase the Position and Exercise Limits for Conventional Options on Certain Exchange-Traded Funds

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 29, 2022, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Rule 2360 (Options) to increase the position and exercise limits for conventional options on certain exchange-traded funds (''ETFs'').

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA Rule 2360(b)(3)(A) imposes a position limit on the number of equity options contracts in each class on the same side of the market that can be held or written by a member, a person associated with a member, or a customer or a group of customers acting in concert. Position limits are intended to prevent the establishment of options positions that can be used to manipulate or disrupt the underlying market or might create incentives to manipulate or disrupt the underlying market so as to benefit the options position. In addition, position limits serve to reduce the potential for disruption of the options market itself, especially in illiquid options classes.[4] This consideration has been balanced by the concern that the limits ''not be established at levels that are so low as to discourage participation in the options market by institutions and other investors with substantial hedging needs or to prevent specialists and market makers from adequately meeting their obligations to maintain a fair and orderly market.'' [5]

Rule 2360(b)(3)(A)(i) does not independently establish a position limit for standardized equity options. Rather, the position limit established by the rules of an options exchange for a particular equity option is the applicable position limit for purposes of Rule 2360.[6] Rule 2360(b)(3)(A)(iii) provides that conventional equity options [7] are subject to a basic position limit of 25,000 contracts or a higher tier for conventional option contracts on securities that underlie exchange-traded options qualifying for such higher tier as determined by the rules of the options exchanges. In addition, FINRA lists position limits for options on securities that have higher position limits—currently, only the ETFs listed in Rule 2360(b)(3)(A)(iii)a.6.—that also generally mirror the options exchange position limits. At this time, FINRA proposes to conform its conventional options position limits to the Cboe Exchange, Inc.'s (''Cboe'') recent amendments that increased the position limit options due to an ongoing increase in demand in options on the following ETFs: (1) iShares iBoxx $ Investment Grade Corporate Bond ETF (''LQD''), and (2) VanEck Vectors Gold Miners ETF (''GDX'') (together, the ''Underlying ETFs'').[8]

The proposed rule change would add to the table provided in Rule 2360(b)(3)(A)(iii)a.6. as follows, with the effect of each ETF being increased from the current position limit of 250,000 contracts:

- The position limit for options on LQD would be increased to 500,000 contracts.
- The position limit for options on GDX would be increased to 500,000 contracts.

FINRA notes the proposed position limits for options on LQD and GDX are consistent with current position limits for options on the iShares MSCI Brazil Capped ETF (''EWZ''), iShares 20+Year Treasury Bond Fund ETF (''TLT''), iShares MSCI Japan ETF (''EWJ''), and iShares iBoxx High Yield Corporate Bond Fund (''HYG'').

In support of the proposed rule change, as noted by Cboe, position limits are determined by the option exchange's rules.[9] The ETFs that underlie options subject to the proposed rule change are highly liquid and are based on a broad set of highly liquid securities and other reference assets. The above listed ETFs are listed on various national securities exchanges and meet their listing standards.

In supporting the proposed position limit increases, FINRA considered the liquidity of the Underlying ETFs, the value of the underlying securities or index components and relevant marketplace, the share and option volume for the Underlying ETFs, and, where applicable, the availability or comparison of economically equivalent products to options on the Underlying ETFs.

FINRA notes that Cboe has compiled the following trading statistics regarding shares of and options on the Underlying ETFs and the values of the Underlying ETFs and their component securities or index components, as applicable:

Product	ADV [10] (ETF shares millions)	ADV (option contracts)	Shares outstanding [11] (millions)	Fund Market Capitalization [12] (USD millions)	Share value [13] (USD) (NAV)
LQD	14.1	30,300	308.1	54,113.7	130.13
GDX	39.4	166,000	419.8	16,170.5	33.80

FINRA notes Cboe collected the same trading statistics, where applicable, as above regarding a sample of other ETFs, as well as the current position limits for options on such ETFs, to draw comparisons in support of proposed position limit increases for options on the Underlying ETFs (see further discussion below):

Product	ADV (ETF shares millions)	ADV (option contracts)	Shares outstanding (millions)	Fund Market Capitalization (USD millions)	Share value (USD) (NAV)	Current position limit
EWZ	29.2	139,400	173.8	6,506.8	33.71	500,000

[4] *See* Securities Exchange Act Release No. 40969 (January 22, 1999), 64 FR 4911, 4912–13 (February 1, 1999) (Order Approving File No. SR–CBOE–98–23) (citing H.R. No. IFC–3, 96th Cong., 1st Sess. at 189–91 (Comm. Print 1978)).

[5] *See supra* note 4, at 4913.

[6] *See e.g.,* Cboe Rule 8.30; ISE Options 9 Section 13; Nasdaq PHLX Options 9 Section 13; NYSE American Rule 904; NYSE Arca Rule 6.8–0; MIAX Rule 307; BOX Rule 3120 and IM–3120–2; Nasdaq Options 9 Section 13; BX Options 9 Section 13; and BZX Rule 18.7.

[7] Conventional options are over-the-counter options and are defined in Rule 2360(a)(9) as ''(A) any option contract not issued, or subject to issuance, by The Options Clearing Corporation; or (B) an OCC Cleared OTC Option.''

[8] *See* Securities Exchange Act Release No. 93525 (November 4, 2021), 86 FR 62584 (November 10, 2021) (Order Approving File No. SR–CBOE–2021–029).

[9] *See e.g.,* CBOE Rule 8.30, Interpretation and Policy .02.

[10] Average daily volume (ADV) data for ETF shares and option contracts, as well as for ETF shares and options on the comparative ETFs presented below, are for all of 2020. Additionally, reference to ADV in ETF shares and ETF options, and indexes herein this proposal are for all of calendar year 2020, unless otherwise indicated.

[11] Shares Outstanding and Net Asset Values (''NAV''), as well as for the comparative ETFs presented below, are as of April 5, 2021.

[12] Fund Market Capitalization data, as well as for the comparative ETFs presented below, are as of January 14, 2021.

[13] *See supra* note 11.

Product	ADV (ETF shares millions)	ADV (option contracts)	Shares outstanding (millions)	Fund Market Capitalization (USD millions)	Share value (USD) (NAV)	Current position limit
TLT	11.5	111,800	103.7	17,121.3	136.85	500,000
EWJ	8.2	15,500	185.3	13,860.7	69.72	500,000
HYG	30.5	261,600	254.5	24,067.5	86.86	500,000

FINRA echoes the Cboe's belief that, overall, the liquidity in the shares of the Underlying ETFs and in their overlying options, the larger market capitalizations for each of the Underlying ETFs, and the overall market landscape relevant to each of the Underlying ETFs support the proposal to increase the position limits for each option class. Given the robust liquidity in and value of the Underlying ETFs and their component securities, FINRA does not anticipate that the proposed increase in position limits would create significant price movements as the relevant markets are large enough to adequately absorb potential price movements that may be caused by larger trades.

The following analyses for the Underlying ETFs, which FINRA agrees with in support of the proposed rule change, as well as the statistics presented in support thereof, were presented by Cboe in their rule filing, which was approved by the Commission.

LQD tracks the performance of the Markit iBoxx USD Liquid Investment Grade (''IBOXIG'') Index, which is an index designed as a subset of the broader U.S. dollar-denominated corporate bond market which can be used as a basis for tradable products, such as ETFs, and is comprised of over 8,000 bonds.[14] From 2019 through 2020, ADV has grown significantly in shares of LQD and in options on LQD, from approximately 9.7 million shares in 2019 to 14.1 million through 2020, and from approximately 8,200 option contracts in 2019 to 30,300 through 2020. LQD also continued to experience significant growth in ADV in the first quarter of 2021 with an ADV of approximately 140,200 option contracts. Further, LQD generally experiences higher ADV in shares than both TLT (11.5 million shares) and EWJ (8.2 million shares) and almost double the ADV in option contracts than EWJ (15,500 option contracts). Options on each EWZ, TLT and EWJ are currently subject to a position limit of 500,000 contracts—the proposed limit for options on LQD. The NAV of LQD is also higher than, or comparable to, that of the NAV of the ETFs underlying the options that are currently subject to a position limit of 500,000 option contracts (as presented in the table above), which is indicative that the total value of its underlying components is generally higher or comparable. Per the tables above, LQD's total market capitalization of approximately $54.1 billion is also higher than or comparable to the total market capitalization of the ETFs underlying the options currently subject to a position limit of 500,000 contracts. In addition to this, although there are currently no options listed for trading on the IBOXIG Index, the components[15] of the IBOXIG Index, which can be used in creating a basket of securities that equate to the LQD ETF, are made up of over 8,000 bonds for which the outstanding face value of each must be greater than or equal to $2 billion.[16] FINRA echoes Cboe's belief that the total value of the bonds in the IBOXIG Index, coupled with LQD's share and option volume, total market capitalization, and NAV price indicates that the market is large enough to absorb potential price movements caused by a large trade in LQD. Also, as evidenced above, trading volume in LQD shares has increased over the past few years and market participants' need for options have continued to grow alongside the ETF. Particularly, Cboe notes in its filing that in the last year, market participants have sought more cost-effective hedging strategies through the use of LQD options as a result of the borrow on other fixed income ETFs, such as HYG. Therefore, FINRA agrees with Cboe's belief that because LQD options are being increasingly utilized as an alternative to similar products, such as HYG options, then it is appropriate that options on LQD be subject to the same 500,000 contract position limit that currently exists for options on HYG.

GDX seeks to replicate as closely as possible the price and yield performance of the NYSE Arca Gold Miners (''GDMNTR'') Index, which is intended to track the overall performance of companies involved in the gold mining industry.[17] ADV in GDX options has increased from 2019 through 2020, with an ADV of approximately 117,400 option contracts in 2019 to an ADV of approximately 166,000 option contracts in 2020.

ADV in GDX shares did not increase from 2019 to 2020. GDX options also experienced an ADV of approximately 287,800 option contracts in the first quarter of 2021. The ADV in GDX shares (39.4 million) and options on GDX (166,000 option contracts) are greater than the ADV in EWZ (29.2 million shares and 139,300 option contracts), TLT (11.5 million shares and 111,800 option contracts), EWJ (8.2 million shares and 15,500 option contracts) and HYG (30.5 million shares and 261,600 option contracts), each of which is currently subject to a position limit of 500,000 option contracts—the proposed limit for options on GDX. GDX also experiences a comparable, or higher, market capitalization (approximately $16.2 billion) than EWZ, TLT and EWJ. Cboe noted that many of the Brazil-based gold mining constituents included in GDX are also included in EWZ, which tracks the investment results of an index composed of Brazilian equities, and that there have been no identified issues with the continued listing and trading of EWZ options or any adverse market impact on EWZ in connection with the current 500,000 position limit in place for EWZ options. Additionally, like that of LDQ above, there is currently no index option analogue for the GDX ETF on the GDMNTR Index approved for options trading, however, the components of the GDMNTR Index, which can be used to create the GDX ETF, currently must each have a market capitalization greater than $750 million, an ADV of at least 50,000 shares, and an average daily value traded of at least $1 million in order to be eligible for inclusion in the GDMNTR Index. FINRA echoes Cboe's belief that the GDMNTR Index component inclusion requirements, as well as GDX's share and option volume and total market capitalization, indicate that the GDX market is sufficiently large and liquid enough to absorb price

[14] *See* Markit iBoxx USD Liquid Investment Grade Index, available at *https://cdn.ihsmarkit.com/www/pdf/MKT-iBoxx-USD-Liquid-Investment-Grade-Index-factsheet.pdf* (March 3, 2021).

[15] Investment grade corporate bonds.

[16] *See supra* note 14.

[17] *See* VanEck Vectors Gold Miners ETF, available at *https://www.vaneck.com/library/vaneck-vectors-etfs/gdx-fact-sheet-pdf* (February 28, 2022).

movements as a result of potentially oversized trades.

FINRA believes that increasing the position limits for conventional options subject to the proposed rule change would lead to a more liquid and competitive market for these options, which will benefit customers interested in these products.

Creation and Redemption for ETFs

FINRA believes that the creation and redemption process for ETFs subject to this proposed rule change will lessen the potential for manipulative activity with options on the Underlying ETFs. Regarding ETFs, when an ETF provider wants to create more shares, it looks to an Authorized Participant (generally a market maker or other large financial institution) to acquire the securities the ETF is to hold. For instance, when an ETF is designed to track the performance of an index, the Authorized Participant can purchase all the constituent securities in the exact same weight as the index, then deliver those shares to the ETF provider. In exchange, the ETF provider gives the Authorized Participant a block of equally valued ETF shares, on a one-for-one fair value basis. The price is based on the net asset value, not the market value at which the ETF is trading. The creation of new ETF units can be conducted during an entire trading day, and is not subject to position limits. This process works in reverse where the ETF provider seeks to decrease the number of shares that are available to trade. The applicable creation and redemption processes for the Underlying ETFs creates a direct link to the underlying components of the ETF and serves to mitigate potential price impact of the ETF shares that might otherwise result from increased position limits for the options on the Underlying ETFs.

FINRA understands that the ETF creation and redemption process seeks to keep an ETF's share price trading in line with the product's underlying net asset value. Because an ETF trades like a stock, its share price will fluctuate during the trading day, due to simple supply and demand. If demand to buy an ETF is high, for instance, the ETF's share price might rise above the value of its underlying securities. When this happens, the Authorized Participant or issuer believes the ETF may now be overpriced, so it may buy shares of the component securities and then sell ETF shares in the open market. This may drive the ETF's share price back toward the underlying net asset value or indicative index value. Likewise, if the ETF share price starts trading at a discount to the securities it holds or its index components, the Authorized Participant or issuer can buy shares of the ETF and redeem them for the underlying securities or index component instruments. Buying undervalued ETF shares may drive the share price of the ETF back toward fair value. This arbitrage process helps to keep an ETF's share price in line with the value of its underlying portfolio or index components.

Surveillance and Reporting

FINRA believes that the increased position limits provisions are appropriate in light of the existing surveillance procedures and reporting requirements at FINRA,[18] the options exchanges, and at the several clearing firms, which are capable of properly identifying unusual or illegal trading activity. These procedures use daily monitoring of market movements by automated surveillance techniques to identify unusual activity in both options and underlying stocks.[19]

In addition, large stock holdings must be disclosed to the Commission by way of Schedules 13D or 13G.[20] Options positions are part of any reportable positions and cannot legally be hidden. Moreover, the previously noted Rule 2360(b)(5) requirement that members must file reports with FINRA for any customer that held aggregate large long or short positions of any single class for the previous day will continue to serve as an important part of FINRA's surveillance efforts.

Finally, FINRA believes that the current financial requirements imposed by FINRA and by the Commission adequately address financial responsibility concerns that a member or its customer will maintain an inordinately large unhedged position in any option with a higher position limit. Current margin and risk-based haircut methodologies serve to limit the size of positions maintained by any one account by increasing the margin or capital that a member must maintain for a large position. Under Rule 4210(f)(8)(A), FINRA also may impose a higher margin requirement upon a member when FINRA determines a higher requirement is warranted. In addition, the Commission's net capital rule[21] imposes a capital charge on members to the extent of any margin deficiency resulting from the higher margin requirement.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so FINRA can implement the proposed rule change immediately.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[22] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change promotes consistent regulation by harmonizing position limits with those of the other self-regulatory organizations. FINRA further believes that increasing the position limit on conventional options promotes consistent regulation by harmonizing the position limit with its standardized counterpart. In addition, FINRA believes the proposed rule change will be beneficial to large market makers and institutions (which generally have the greatest ability to provide liquidity and depth in products that may be subject to higher position limits as has been the case with recently approved increased position limits),[23] as well as retail traders and public customers, by providing them with a more effective trading and hedging vehicle.

In addition, FINRA believes that the structure of the Underlying ETFs, the considerable market capitalization of the funds, underlying component securities and indexed component securities, and the liquidity of the markets for the applicable options and underlying component securities will mitigate concerns regarding potential manipulation of the products or disruption of the underlying markets upon increasing the relevant position limits. As a general principle, increases in market capitalizations, active trading volume, and deep liquidity of securities tend to deter manipulation or disruption. This general principle applies to the recently observed increased levels of market capitalization, trading volume, and liquidity in shares of and options on the Underlying ETFs (as described above). FINRA does not believe that the options

[18] *See* Rule 2360(b)(5) for the options reporting requirements.

[19] These procedures have been effective for the surveillance of options trading and will continue to be employed.

[20] 17 CFR 240.13d–1.

[21] 17 CFR 240.15c3–1.

[22] 15 U.S.C. 78*o*–3(b)(6).

[23] *See supra* note 8.

markets or underlying markets would become susceptible to manipulation or disruption as a result of the proposed position limit increases.

Increased position limits for select actively traded options, such as those proposed herein, are not novel and have been previously approved by the Commission.[24] Furthermore, FINRA notes that the proposed position limits for options on LQD and GDX are consistent with existing position limits for options on comparable ETFs in Rule 2360(b)(3)(A)(iii)a.6.

FINRA's existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior that might arise from changing position and exercise limits.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Analysis

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the potential economic impacts, including anticipated costs, benefits, and distributional and competitive effects, transfers of wealth, relative to the current baseline, and the alternatives FINRA considered in assessing how to best meet its regulatory objectives.

Regulatory Objective

FINRA is proposing to amend Rule 2360 to harmonize FINRA's position limits for conventional options with the position limit for standardized options.[25]

Economic Baseline

Per FINRA Rule 2360(b)(3)(A)(iii) conventional equity options are subject to a basic position limit of 25,000 contracts or higher for conventional option contracts on securities that underlie exchange-traded options qualifying for a higher tier as determined by option exchange rules. The existing position limits for conventional options on LQD and GDX are 250,000 contracts. Cboe has recently increased position limits for options on these ETFs.

Economic Impact

Benefits

As noted above, the proposed rule change would amend Rule 2360 to harmonize FINRA's position limits for conventional options with the position limits for standardized options.[26] If the existing position limits for conventional equity options on select ETFs constrains trading in these ETFs, then investors may be able to better manage risk and trade on information when the position limit is relaxed. In general, the improvement in risk management and informational efficiency may increase more when position limits are increased. We acknowledge, however, that the conventional options on these ETFs, the ETFs themselves, and the securities underlying these ETFs are liquid, so improvements in informational efficiency may be relatively small.

For investors that trade conventional equity options, there is likely to be a natural size for an executed order that minimizes fixed and variable transaction costs, including but not limited to, the bid-ask spread, price impact, and transaction fees. If the existing position limits for conventional equity options on select ETFs constrains the order size such that fixed and variable transaction costs are higher than optimal, then investors may benefit if the new position limit is no less than the natural size. In such an event, the cost to hedge an ETF would decline, thereby making it less costly to manage downside risk.

In addition, if the existing position limits serve as a constraint, then an increase in the position limits for conventional options on select ETFs could permit investors to more easily find a counterparty. If the number of counterparties increases, then the cost of hedging should decline as the half-spread narrows, thereby making it less expensive to manage downside risk.

The extent of the constraint imposed by the current limit on conventional options is related to the ability of an investor to achieve similar economic exposure through other means. If there are other securities, such as an option on a closely related index, that exist and provide similar economic exposure less expensively, then the value of lessening the position limits on conventional options on ETFs is lower.

Members may rely on information and data feeds from the Options Clearing Corporation to assist in their monitoring position limits. Because position limits on the standardized and conventional side have traditionally been consistent, members have relied on this feed for both standardized and conventional options. If the position limits between standardized and conventional options are conformed, then the cost from monitoring position limits should decline for member firms. Having the same position limits on standardized and conventional options, reduces the potential for excess loss that may be incurred when different limits are applied to the standardized versus conventional options on the same ETF. The economic loss may arise from building and maintaining trading and compliance systems to support the different regimes. Furthermore, the harmonization of position limits on standardized and conventional options eliminates the potential risk and cost arising from regulatory arbitrage.

Costs

The proposed rule change may impose limited operational cost on member firms that trade conventional options on ETFs, as these same firms would need to revise position limits that are used in trading systems. However, the proposed rule change should not impose additional costs, because it is difficult to disrupt or manipulate the underlying market, create an incentive to disrupt or manipulate the underlying market for the purpose of profiting from the options position, or disrupt or manipulate the options market for conventional options on ETFs affected by this proposed rule. ETFs that underlie options subject to the proposed rule change are highly liquid and are based on a broad set of highly liquid securities, which makes the market difficult to manipulate or disrupt. In fact, options on certain broad-based security indexes have no position limits. Furthermore, the applicable creation and redemption process for these ETFs reduces the potential for disruptive or manipulative activity. New ETF units may be created at any time during the trading day and are not subject to position limits. Consequently, there is a direct link between the underlying components of the ETF, which keeps ETF's share prices trading in line with the ETF's underlying net asset value.

Alternatives

No further alternatives are under consideration.

[24] *See supra* note 8. *See also* Securities Exchange Act Release Nos. 88768 (April 29, 2020), 85 FR 26736 (May 5, 2020) (Order Approving File No. SR–CBOE–2020–015); 83415 (June 12, 2018), 83 FR 28274 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–CBOE–2018–042); and 68086 (October 23, 2012), 77 FR 65600 (October 29, 2012) (Order Approving File No. SR–CBOE–2012–066).

[25] *See supra* note 8.

[26] *See supra* note 8.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act [27] and Rule 19b–4(f)(6) [28] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [29] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[30] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. FINRA has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. FINRA states that waiver of the operative delay would be consistent with the protection of investors and the public interest because it would enable FINRA to immediately harmonize position limits with those of other self-regulatory organizations to ensure consistent regulation. For this reason, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[31]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2022–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2022–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2022–007 and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Jill M. Peterson,

Assistant Secretary.

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BILLING CODE 8011–01–P

[27] 15 U.S.C. 78s(b)(3)(A).

[28] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. FINRA has satisfied this requirement.

[29] 17 CFR 240.19b–4(f)(6).

[30] 17 CFR 240.19b–4(f)(6)(iii).

[31] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34556; File No. 812–15255]

Stellus Capital Investment Corporation, et al.

April 11, 2022.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an Order to permit certain business development companies (''BDCs'') and certain closed-end management investment companies to co-invest in portfolio companies with each other and with affiliated investment entities.

APPLICANTS: Stellus Capital Investment Corporation (the ''Company''); Stellus Private Credit BDC (the ''SPBDC''); Stellus Credit Master Fund I, LLC, Stellus Credit VCOC Fund I, LLC, Stellus Credit Master Fund II, LLC, Stellus Credit VCOC Fund II, LLC, Stellus Credit VCOC Fund III, LLC, Stellus Credit Master Fund III, LLC, Stellus Senior Secured Loan Fund, LLC, Stellus Credit Funds Investor A, LLC, and Stellus Credit Funds Investor B, LP (collectively, ''Existing Affiliated Funds''); Stellus Capital SBIC LP, Stellus Capital SBIC GP, LLC, SCIC–Consolidated Blocker 1, Inc., SCIC–CC Blocker 1, Inc., SCIC–ERC Blocker 1, Inc., SCIC–SKP Blocker 1, Inc., SCIC–APE Blocker 1, Inc., SCIC–HUF Blocker 1, Inc., SCIC–Hollander Blocker 1, Inc., Stellus Capital SBIC II, LP, SCIC–Invincible Blocker 1, Inc., SCIC–FBO Blocker 1, Inc., SCIC–ICD Blocker 1, Inc., SCIC–Venbrook Blocker 1, Inc., PBDC Consolidated Blocker, LLC

(collectively, ''Existing Wholly-Owned Subsidiaries''); Stellus Capital Management, LLC (''SCM''); and Stellus Private BDC Advisor, LLC (''SPBDC Advisor'' and collectively with the Company, SPBDC, the Existing Affiliated Funds, the Existing Wholly-Owned Subsidiaries, and SCM, the ''Applicants'').

FILING DATES: The application was filed on August 12, 2021 and amended on February 18, 2022, March 21, 2022, and April 6, 2022.

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, 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 Commission by 5:30 p.m. on May 6, 2022, 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 emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Robert T. Ladd, Stellus Capital Investment Corporation, *rladd@stelluscapital.com;* Anne Oberndorf, *anneoberndorf@eversheds-sutherland.com;* Stephani Hildebrandt, *stephanihildebrandt@eversheds-sutherland.com;* Daniel Wolman, *danielwolman@eversheds-sutherland.com.*

FOR FURTHER INFORMATION CONTACT: Taylor Evenson, Senior Counsel, at (202) 551–6719, or Marc Mehrespand, Branch Chief, at (202) 551–6825 (Chief Counsel's Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' third amended and restated application, dated April 6, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

Introduction

1. The Applicants request an Order of the Commission under sections 17(d) and 57(i) of the Act and rule 17d–1 under the Act to permit, subject to the terms and conditions set forth in the application (the ''Conditions''), one or more Regulated Funds [1] (including one or more BDC Downstream Funds) and/or one or more Affiliated Funds [2] to enter into Co-Investment Transactions with each other. ''Co-Investment Transaction'' means any transaction in which one or more Regulated Funds (or its Wholly-Owned Investment Sub) participated together with one or more Affiliated Funds and/or one or more other Regulated Funds in reliance on the Order. ''Potential Co-Investment Transaction'' means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub) could not participate together with one or more Affiliated Funds and/or one or more other Regulated Funds without obtaining and relying on the Order.[3]

2. The Order sought by the application would supersede the Prior Order (as defined below) issued by the Commission to Stellus Capital Investment Corporation, et al. on December 4, 2018, [4] with the result that no person will continue to rely on the Prior Order if the Order is granted.

Applicants

3. The Company is a closed-end management investment company incorporated in Maryland that has elected to be regulated as a BDC under the Act.[5] The Company's Board [6] currently consists of five members, of which three members are Independent Directors.[7]

4. SPBDC is a closed-end management investment company organized as a Delaware statutory trust that has elected to be regulated as a BDC under the Act. SPBDC's Board currently consists of five members, of which three members are Independent Directors.

5. SPBDC Advisor, a Delaware limited liability company that is registered under the Advisers Act, serves as the investment adviser to SPBDC pursuant to an investment advisory agreement.

6. SCM, a Delaware limited liability company that is registered under the Advisers Act, serves as the investment adviser to the Company pursuant to an investment advisory agreement. SCM

[1] ''Regulated Funds'' means the Company, SPBDC, the Future Regulated Funds and the BDC Downstream Funds. ''Future Regulated Fund'' means a closed-end management investment company (a) that is registered under the Act or has elected to be regulated as a BDC, (b) whose investment adviser (and sub-adviser(s), if any) are an Adviser, and (c) that intends to participate in the Co-Investment Program. ''BDC Downstream Fund'' means, with respect to any Regulated Fund that is a BDC, an entity (i) that the BDC directly or indirectly controls, (ii) that is not controlled by any person other than the BDC (except a person that indirectly controls the entity solely because it controls the BDC), (iii) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act, (iv) whose investment adviser (and sub-adviser(s), if any) are an Adviser, (v) that is not a Wholly-Owned Investment Sub (defined below), and (vi) that intends to participate in the Co-Investment Program. ''Adviser'' means SCM and SPBDC Advisor together with any future investment adviser that (i) controls, is controlled by or is under common control with SCM, (ii) (a) is registered as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act'') or (b) is an exempt reporting adviser pursuant to rule 203(m) of the Advisers Act, and (iii) is not a Regulated Fund or a subsidiary of a Regulated Fund.

[2] ''Affiliated Fund'' means the Existing Affiliated Funds, any Future Affiliated Fund or any Stellus Proprietary Account. Applicants represent that no Existing Affiliated Fund is a BDC Downstream Fund. ''Future Affiliated Fund'' means any entity (a) whose investment adviser (and sub-adviser(s), if any) are an Adviser, (b) that would be an investment company but for section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act, (c) that intends to participate in the Co-Investment Program, and (d) that is not a BDC Downstream Fund. ''Stellus Proprietary Account'' means any account of an Adviser or its affiliates or any company that is an indirect, wholly- or majority-owned subsidiary of an Adviser or its affiliates, which, from time to time, may hold various financial assets in a principal capacity.

[3] All existing entities that currently intend to rely on the Order have been named as Applicants and any existing or future entities that may rely on the Order in the future will comply with the terms and Conditions set forth in the application.

[4] Stellus Capital Investment Corporation, *et al.,* Investment Company Act Rel. Nos. 33289 (Nov. 6, 2018)(notice) and 33316 (Dec. 4, 2018)(order) (''Prior Order'').

[5] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in section 55(a)(1) through 55(a)(3) and makes available significant managerial assistance with respect to the issuers of such securities.

[6] ''Board'' means (i) with respect to a Regulated Fund other than a BDC Downstream Fund, the board of directors (or the equivalent) of the Regulated Fund and (ii) with respect to a BDC Downstream Fund, the Independent Party of the BDC Downstream Fund.

[7] ''Independent Director'' means a member of the Board of any relevant entity who is not an ''interested person'' as defined in section 2(a)(19) of the Act. No Independent Director of a Regulated Fund (including any non-interested member of an Independent Party) will have a financial interest in any Co-Investment Transaction, other than indirectly through share ownership in one of the Regulated Funds. ''Independent Party'' means, with respect to a BDC Downstream Fund, (i) if the BDC Downstream Fund has a board of directors (or the equivalent), the board or (ii) if the BDC Downstream Fund does not have a board of directors (or the equivalent), a transaction committee or advisory committee of the BDC Downstream Fund.

also serves as investment adviser to each Existing Affiliated Fund.

7. Applicants represent that each Existing Affiliated Fund is a separate and distinct legal entity and each would be an investment company but for section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act.

8. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment Subs.[8] Such a subsidiary may be prohibited from investing in a Co-Investment Transaction with a Regulated Fund (other than its parent) or any Affiliated Fund because it would be a company controlled by its parent Regulated Fund for purposes of section 57(a)(4) and rule 17d–1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of the applicable parent Regulated Fund that owns it and that the Wholly-Owned Investment Sub's participation in any such transaction be treated, for purposes of the Order, as though the parent Regulated Fund were participating directly.

Applicants' Representations

A. Allocation Process

9. Applicants represent that the Advisors have established processes for allocating initial investment opportunities, opportunities for subsequent investments in an issuer and dispositions of securities holdings reasonably designed to treat all clients fairly and equitably. Further, Applicants represent that these processes will be extended and modified in a manner reasonably designed to ensure that the additional transactions permitted under the Order will both (i) be fair and equitable to the Regulated Funds and the Affiliated Funds and (ii) comply with the Conditions.

10. If the requested Order is granted, the Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that when such opportunities arise, the Advisers to the relevant Regulated Funds are promptly notified and receive the same information about the opportunity as any other Adviser considering the opportunity for its clients. In particular, consistent with Condition 1, if a Potential Co-Investment Transaction falls within the then-current Objectives and Strategies[9] and any Board-Established Criteria[10] of a Regulated Fund, the policies and procedures will require that the Adviser to such Regulated Fund receive sufficient information to allow such Adviser's investment committee to make its independent determination and recommendations under the Conditions.

11. The Adviser to each applicable Regulated Fund will then make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances. If the Adviser to a Regulated Fund deems the Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate, it will formulate a recommendation regarding the proposed order amount for the Regulated Fund.

12. Applicants state that, for each Regulated Fund and Affiliated Fund whose Adviser recommends participating in a Potential Co-Investment Transaction, such Adviser's investment committee will approve an investment amount to be allocated to each Regulated Fund and/or Affiliated Fund participating in the Potential Co-Investment Transaction. Applicants state further that, each proposed order amount may be reviewed and adjusted, in accordance with the applicable Adviser's written allocation policies and procedures, by the applicable Adviser's investment committee.[11] The order of a Regulated Fund or Affiliated Fund resulting from this process is referred to as its ''Internal Order.'' The Internal Order will be submitted for approval by the Required Majority of any participating Regulated Funds in accordance with the Conditions.[12]

13. If the aggregate Internal Orders for a Potential Co-Investment Transaction do not exceed the size of the investment opportunity immediately prior to the submission of the orders to the underwriter, broker, dealer or issuer, as applicable (the ''External Submission''), then each Internal Order will be fulfilled as placed. If, on the other hand, the aggregate Internal Orders for a Potential Co-Investment Transaction exceed the size of the investment opportunity immediately prior to the External Submission, then the allocation of the opportunity will be made pro rata on the basis of the size of the Internal Orders.[13] If, subsequent to such External

[8] ''Wholly-Owned Investment Sub'' means an entity (i) that is a wholly-owned subsidiary of a Regulated Fund (with such Regulated Fund at all times holding, beneficially and of record, 95% or more of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of such Regulated Fund (and, in the case of a SBIC Subsidiary (defined below), maintains a license under the SBA Act (defined below) and issues debentures guaranteed by the SBA (defined below)); (iii) with respect to which such Regulated Fund's Board has the sole authority to make all determinations with respect to the entity's participation under the Conditions; and (iv) (A) that would be an investment company but for section 3(c)(1), 3(c)(5)(C), or 3(c)(7) of the Act, or (B) that qualifies as a real estate investment trust within the meaning of Section 856 of the Internal Revenue Code of 1986, as amended, because substantially all of its assets would consist of real properties. ''SBIC Subsidiary'' means a Wholly-Owned Investment Sub that is licensed by the Small Business Administration (the ''SBA'') to operate under the Small Business Investment Act of 1958, as amended, (the ''SBA Act'') as a small business investment company. The Existing Wholly-Owned Subsidiaries are Wholly-Owned Investment Subs.

[9] ''Objectives and Strategies'' means (i) with respect to any Regulated Fund other than a BDC Downstream Fund, its investment objectives and strategies, as described in its most current registration statement on Form N–2 or Form 10, other current filings with the Commission under the Securities Act of 1933 (the ''Securities Act'') or under the Securities Exchange Act of 1934, as amended, and its most current report to stockholders and (ii) with respect to any BDC Downstream Fund, those investment objectives and strategies described in its disclosure documents (including private placement memoranda and reports to equity holders) and organizational documents (including operating agreements).

[10] ''Board-Established Criteria'' means criteria that the Board of a Regulated Fund may establish from time to time to describe the characteristics of Potential Co-Investment Transactions regarding which the Adviser to such Regulated Fund should be notified under Condition 1. The Board-Established Criteria will be consistent with the Regulated Fund's Objectives and Strategies. If no Board-Established Criteria are in effect, then the Regulated Fund's Adviser will be notified of all Potential Co-Investment Transactions that fall within the Regulated Fund's then-current Objectives and Strategies. Board-Established Criteria will be objective and testable, meaning that they will be based on observable information, such as industry/sector of the issuer, minimum EBITDA of the issuer, asset class of the investment opportunity or required commitment size, and not on characteristics that involve a discretionary assessment. The Adviser to the Regulated Fund may from time to time recommend criteria for the Board's consideration, but Board-Established Criteria will only become effective if approved by a majority of the Independent Directors. The Independent Directors of a Regulated Fund may at any time rescind, suspend or qualify their approval of any Board-Established Criteria, though Applicants anticipate that, under normal circumstances, the Board would not modify these criteria more often than quarterly.

[11] The reason for any such adjustment to a proposed order amount will be documented in writing and preserved in the records of each Adviser.

[12] ''Required Majority'' means a required majority, as defined in section 57(o) of the Act. In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to section 57(o). In the case of a BDC Downstream Fund with a board of directors (or the equivalent), the members that make up the Required Majority will be determined as if the BDC Downstream Fund were a BDC subject to section 57(o). In the case of a BDC Downstream Fund with a transaction committee or advisory committee, the committee members that make up the Required Majority will be determined as if the BDC Downstream Fund were a BDC subject to section 57(o) and as if the committee members were directors of the fund.

[13] Each Adviser will maintain records of all proposed order amounts, Internal Orders and

Submission, the size of the opportunity is increased or decreased, or if the terms of such opportunity, or the facts and circumstances applicable to the Regulated Funds' or the Affiliated Funds' consideration of the opportunity, change, the participants will be permitted to submit revised Internal Orders in accordance with written allocation policies and procedures that the Advisers will establish, implement and maintain.[14]

B. Follow-On Investments

14. Applicants state that from time to time the Regulated Funds and Affiliated Funds may have opportunities to make Follow-On Investments [15] in an issuer in which a Regulated Fund and one or more other Regulated Funds and/or Affiliated Funds previously have invested.

15. Applicants propose that Follow-On Investments would be divided into two categories depending on whether the prior investment was a Co-Investment Transaction or a Pre-Boarding Investment.[16] If the Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Follow-On Investment would be subject to the Standard Review Follow-Ons described in Condition 8. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Follow-On Investment would be subject to the Enhanced-Review Follow-Ons described in Condition 9. All Enhanced Review Follow-Ons require the approval of the Required Majority. For a given issuer, the participating Regulated Funds and Affiliated Funds need to comply with the requirements of Enhanced-Review Follow-Ons only for the first Co-Investment Transaction. Subsequent Co-Investment Transactions with respect to the issuer would be governed by the requirements of Standard Review Follow-Ons.

16. A Regulated Fund would be permitted to invest in Standard Review Follow-Ons either with the approval of the Required Majority under Condition 8(c) or without Board approval under Condition 8(b) if it is (i) a Pro Rata Follow-On Investment [17] or (ii) a Non-Negotiated Follow-On Investment.[18] Applicants believe that these Pro Rata and Non-Negotiated Follow-On Investments do not present a significant opportunity for overreaching on the part of any Adviser and thus do not warrant the time or the attention of the Board. Pro Rata Follow-On Investments and Non-Negotiated Follow-On Investments remain subject to the Board's periodic review in accordance with Condition 10.

C. Dispositions

17. Applicants propose that Dispositions [19] would be divided into two categories. If the Regulated Funds and Affiliated Funds holding investments in the issuer have previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Disposition would be subject to the Standard Review Dispositions described in Condition 6. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Disposition would be subject to the Enhanced Review Dispositions described in Condition 7. Subsequent Dispositions with respect to the same issuer would be governed by Condition 6 under the Standard Review Dispositions.[20]

18. A Regulated Fund may participate in a Standard Review Disposition either with the approval of the Required Majority under Condition 6(d) or without Board approval under Condition 6(c) if (i) the Disposition is a Pro Rata Disposition [21] or (ii) the securities are Tradable Securities [22] and

External Submissions in conjunction with Potential Co-Investment Transactions. Each applicable Adviser will provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with the Conditions. ''Eligible Directors'' means, with respect to a Regulated Fund and a Potential Co-Investment Transaction, the members of the Regulated Fund's Board eligible to vote on that Potential Co-Investment Transaction under section 57(o) of the Act.

[14] The Board of the Regulated Fund will then either approve or disapprove of the investment opportunity in accordance with condition 2, 6, 7, 8 or 9, as applicable.

[15] ''Follow-On Investment'' means (i) with respect to a Regulated Fund, an additional investment in the same issuer in which the Regulated Fund is currently invested; or (ii) with respect to an Affiliated Fund, (X) an additional investment in the same issuer in which the Affiliated Fund and at least one Regulated Fund are currently invested; or (Y) an investment in an issuer in which at least one Regulated Fund is currently invested but in which the Affiliated Fund does not currently have an investment. An investment in an issuer includes, but is not limited to, the exercise of warrants, conversion privileges or other rights to purchase securities of the issuer.

[16] ''Pre-Boarding Investments'' are investments in an issuer held by a Regulated Fund as well as one or more Affiliated Funds and/or one or more other Regulated Funds that were acquired prior to participating in any Co-Investment Transaction: (i) In transactions in which the only term negotiated by or on behalf of such funds was price in reliance on one of the JT No-Action Letters (defined below); or (ii) in transactions occurring at least 90 days apart and without coordination between the Regulated Fund and any Affiliated Fund or other Regulated Fund.

[17] A ''Pro Rata Follow-On Investment'' is a Follow-On Investment (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investments in the issuer or security, as appropriate, immediately preceding the Follow-On Investment, and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in the pro rata Follow-On Investments as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Follow-On Investments, in which case all subsequent Follow-On Investments will be submitted to the Regulated Fund's Eligible Directors in accordance with Condition 8(c).

[18] A ''Non-Negotiated Follow-On Investment'' is a Follow-On Investment in which a Regulated Fund participates together with one or more Affiliated Funds and/or one or more other Regulated Funds (i) in which the only term negotiated by or on behalf of the funds is price and (ii) with respect to which, if the transaction were considered on its own, the funds would be entitled to rely on one of the JT No-Action Letters. ''JT No-Action Letters'' means SMC Capital, Inc., SEC No-Action Letter (pub. avail. Sept. 5, 1995) and Massachusetts Mutual Life Insurance Company, SEC No-Action Letter (pub. avail. June 7, 2000).

[19] ''Disposition'' means the sale, exchange or other disposition of an interest in a security of an issuer.

[20] However, with respect to an issuer, if a Regulated Fund's first Co-Investment Transaction is an Enhanced Review Disposition, and the Regulated Fund does not dispose of its entire position in the Enhanced Review Disposition, then before such Regulated Fund may complete its first Standard Review Follow-On in such issuer, the Eligible Directors must review the proposed Follow-On Investment not only on a stand-alone basis but also in relation to the total economic exposure in such issuer (*i.e.,* in combination with the portion of the Pre-Boarding Investment not disposed of in the Enhanced Review Disposition), and the other terms of the investments. This additional review is required because such findings were not required in connection with the prior Enhanced Review Disposition, but they would have been required had the first Co-Investment Transaction been an Enhanced Review Follow-On.

[21] A ''Pro Rata Disposition'' is a Disposition (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investment in the security subject to Disposition immediately preceding the Disposition; and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in pro rata Dispositions as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Dispositions, in which case all subsequent Dispositions will be submitted to the Regulated Fund's Eligible Directors.

[22] ''Tradable Security'' means a security that meets the following criteria at the time of Disposition: (i) It trades on a national securities exchange or designated offshore securities market as defined in rule 902(b) under the Securities Act; (ii) it is not subject to restrictive agreements with

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the Disposition meets the other requirements of Condition 6(c)(ii). Pro Rata Dispositions and Dispositions of a Tradable Security remain subject to the Board's periodic review in accordance with Condition 10.

D. Delayed Settlement

19. Applicants represent that under the terms and Conditions of the application, all Regulated Funds and Affiliated Funds participating in a Co-Investment Transaction will invest at the same time, for the same price and with the same terms, conditions, class, registration rights and any other rights, so that none of them receives terms more favorable than any other. However, the settlement date for an Affiliated Fund in a Co-Investment Transaction may occur up to ten business days after the settlement date for the Regulated Fund, and vice versa. Nevertheless, in all cases, (i) the date on which the commitment of the Affiliated Funds and Regulated Funds is made will be the same even where the settlement date is not and (ii) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other.

E. Holders

20. Under Condition 15, if an Adviser, its principals, or any person controlling, controlled by, or under common control with the Adviser or its principals, and the Affiliated Funds (collectively, the ''Holders'') own in the aggregate more than 25 percent of the outstanding voting shares of a Regulated Fund (the ''Shares''), then the Holders will vote such Shares as directed by an independent third party when voting on matters specified in the Condition.

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit participation by a registered investment company and an affiliated person in any ''joint enterprise or other joint arrangement or profit-sharing plan,'' as defined in the rule, without prior approval by the Commission by order upon application. Section 17(d) of the Act and rule 17d–1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Similarly, with regard to BDCs, section 57(a)(4) of the Act generally prohibits certain persons specified in section 57(b) from participating in joint transactions with the BDC or a company controlled by the BDC in contravention of rules as prescribed by the Commission. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d–1 also applies to joint transactions with Regulated Funds that are BDCs.

3. Co-Investment Transactions are prohibited by either or both of rule 17d–1 and section 57(a)(4) without a prior exemptive order of the Commission to the extent that the Affiliated Funds and the Regulated Funds participating in such transactions fall within the category of persons described by rule 17d–1 and/or section 57(b), as applicable, vis-à-vis each participating Regulated Fund. Each of the participating Regulated Funds and Affiliated Funds may be deemed to be affiliated persons vis-à-vis a Regulated Fund within the meaning of section 2(a)(3) by reason of common control because (i) SCM manages and may be deemed to control the Existing Affiliated Funds, (ii) an Adviser will manage and may be deemed to control any Future Affiliated Fund, (iii) SCM manages and may be deemed to control the Company pursuant to its investment advisory agreement, (iv) SPBDC Advisor manages and may be deemed to control SPBDC pursuant to its investment advisory agreement (v) any future Regulated Fund will be managed by and may be deemed to be controlled by an Adviser, (vi) each BDC Downstream Fund will be deemed to be controlled by its BDC parent and/or its BDC parent's investment adviser and (vii) the Advisers are under common control. Thus, each of the Affiliated Funds could be deemed to be a person related to the Regulated Funds that are BDCs, including the Company and SPBDC and any BDC Downstream Fund, in a manner described by section 57(b) and related to Future Regulated Funds that are registered investment companies in a manner described by rule 17d–1; and therefore the prohibitions of rule 17d–1 and section 57(a)(4) would apply respectively to prohibit the Affiliated Funds from participating in Co-Investment Transactions with the Regulated Funds. Each Regulated Fund would also be related to each other Regulated Fund in a manner described by section 57(b) or rule 17d–1, as applicable, and thus prohibited from participating in Co-Investment Transactions with each other. Further, because the Wholly-Owned Investment Subs are controlled by the Regulated Funds, the Wholly-Owned Investment Subs are subject to section 57(a)(4) (or section 17(d) in the case of Wholly-Owned Investment Subs controlled by Regulated Funds that are registered under the Act), and thus also subject to the provisions of rule 17d–1, and therefore would be prohibited from participating in Co-Investment Transactions. In addition, because the Stellus Proprietary Accounts are or will be directly or indirectly controlled by an Adviser or its affiliates and, therefore, may be under common control with the Company, SPBDC, any future Advisers, and any Future Regulated Funds, the Stellus Proprietary Accounts could be deemed to be persons related to the Regulated Funds (or a company controlled by the Regulated Funds) in a manner described by section 57(b) and also prohibited from participating in the Co-Investment Program.

4. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

5. Applicants state that in the absence of the requested relief, in many circumstances the Regulated Funds would be limited in their ability to participate in attractive and appropriate investment opportunities. Applicants state that, as required by rule 17d–1(b), the Conditions ensure that the terms on which Co-Investment Transactions may be made will be consistent with the participation of the Regulated Funds being on a basis that it is neither different from nor less advantageous than other participants, thus protecting the equity holders of any participant from being disadvantaged. Applicants further state that the Conditions ensure that all Co-Investment Transactions are reasonable and fair to the Regulated Funds and their shareholders and do not involve overreaching by any person concerned, including the Advisers. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions in accordance with the Conditions will be consistent

the issuer or other security holders; and (iii) it trades with sufficient volume and liquidity (findings as to which are documented by the Advisers to any Regulated Funds holding investments in the issuer and retained for the life of the Regulated Fund) to allow each Regulated Fund to dispose of its entire position remaining after the proposed Disposition within a short period of time not exceeding 30 days at approximately the value (as defined by section 2(a)(41) of the Act) at which the Regulated Fund has valued the investment.

with the provisions, policies, and purposes of the Act and would be done in a manner that is not different from, or less advantageous than, that of other participants.

Applicants' Conditions

Applicants agree that the Order will be subject to the following Conditions:

1. *Identification and Referral of Potential Co-Investment Transactions.*

(a) The Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that each Adviser is promptly notified of all Potential Co-Investment Transactions that fall within the then-current Objectives and Strategies and Board-Established Criteria of any Regulated Fund the Adviser manages.

(b) When an Adviser to a Regulated Fund is notified of a Potential Co-Investment Transaction under Condition 1(a), the Adviser will make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. *Board Approvals of Co-Investment Transactions.*

(a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the Advisers to be invested in the Potential Co-Investment Transaction by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application. Each Adviser to a participating Regulated Fund will promptly notify and provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with these Conditions.

(c) After making the determinations required in Condition 1(b) above, each Adviser to a participating Regulated Fund will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and each participating Affiliated Fund) to the Eligible Directors of its participating Regulated Fund(s) for their consideration. A Regulated Fund will enter into a Co-Investment Transaction with one or more other Regulated Funds or Affiliated Funds only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its equity holders and do not involve overreaching in respect of the Regulated Fund or its equity holders on the part of any person concerned;

(ii) the transaction is consistent with:

(A) The interests of the Regulated Fund's equity holders; and

(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Fund(s) or Affiliated Fund(s) would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from, or less advantageous than, that of any other Regulated Fund(s) or Affiliated Fund(s) participating in the transaction; provided that the Required Majority shall not be prohibited from reaching the conclusions required by this Condition 2(c)(iii) if:

(A) The settlement date for another Regulated Fund or an Affiliated Fund in a Co-Investment Transaction is later than the settlement date for the Regulated Fund by no more than ten business days or earlier than the settlement date for the Regulated Fund by no more than ten business days, in either case, so long as: (x) The date on which the commitment of the Affiliated Funds and Regulated Funds is made is the same; and (y) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other; or

(B) any other Regulated Fund or Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors, the right to have a board observer or any similar right to participate in the governance or management of the portfolio company so long as: (x) The Eligible Directors will have the right to ratify the selection of such director or board observer, if any; (y) the Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and (z) any fees or other compensation that any other Regulated Fund or Affiliated Fund or any affiliated person of any other Regulated Fund or Affiliated Fund receives in connection with the right of one or more Regulated Funds or Affiliated Funds to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among any participating Affiliated Funds (who may, in turn, share their portion with their affiliated persons) and any participating Regulated Fund(s) in accordance with the amount of each such party's investment; and

(iv) the proposed investment by the Regulated Fund will not involve compensation, remuneration or a direct or indirect [23] financial benefit to the Advisers, any other Regulated Fund, the Affiliated Funds or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by Condition 14, (B) to the extent permitted by section 17(e) or 57(k), as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction, or (D) in the case of fees or other compensation described in Condition 2(c)(iii)(B)(z).

3. *Right to Decline.* Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. *General Limitation.* Except for Follow-On Investments made in accordance with Conditions 8 and 9 below,[24] a Regulated Fund will not invest in reliance on the Order in any issuer in which a Related Party has an investment.[25]

[23] For example, procuring the Regulated Fund's investment in a Potential Co-Investment Transaction to permit an affiliate to complete or obtain better terms in a separate transaction would constitute an indirect financial benefit.

[24] This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

[25] ''Related Party'' means (i) any Close Affiliate and (ii) in respect of matters as to which any Adviser has knowledge, any Remote Affiliate. ''Close Affiliate'' means the Advisers, the Regulated Funds, the Affiliated Funds and any other person described in section 57(b) (after giving effect to rule 57b–1) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) except for limited partners included solely by reason of the reference in section 57(b) to section 2(a)(3)(D). ''Remote Affiliate'' means any person described in section 57(e) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) and any limited partner

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5. *Same Terms and Conditions.* A Regulated Fund will not participate in any Potential Co-Investment Transaction unless (i) the terms, conditions, price, class of securities to be purchased, date on which the commitment is entered into and registration rights (if any) will be the same for each participating Regulated Fund and Affiliated Fund and (ii) the earliest settlement date and the latest settlement date of any participating Regulated Fund or Affiliated Fund will occur as close in time as practicable and in no event more than ten business days apart. The grant to one or more Regulated Funds or Affiliated Funds, but not the respective Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this Condition 5, if Condition 2(c)(iii)(B) is met.

6. *Standard Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of an interest in a security and one or more Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then:

(i) The Adviser to such Regulated Fund or Affiliated Fund [26] will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition.

(b) *Same Terms and Conditions.* Each Regulated Fund will have the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund.

(c) *No Board Approval Required.* A Regulated Fund may participate in such a Disposition without obtaining prior approval of the Required Majority if:

(i) (A) The participation of each Regulated Fund and Affiliated Fund in such Disposition is proportionate to its then-current holding of the security (or securities) of the issuer that is (or are) the subject of the Disposition; [27] (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such Dispositions on a pro rata basis (as described in greater detail in the application); and (C) the Board of the Regulated Fund is provided on a quarterly basis with a list of all Dispositions made in accordance with this Condition; or

(ii) each security is a Tradable Security and (A) the Disposition is not to the issuer or any affiliated person of the issuer; and (B) the security is sold for cash in a transaction in which the only term negotiated by or on behalf of the participating Regulated Funds and Affiliated Funds is price.

(d) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

7. *Enhanced Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of a Pre-Boarding Investment in a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that:

(i) The Disposition complies with Condition 2(c)(i), (ii), (iii)(A), and (iv); and

(ii) the making and holding of the Pre-Boarding Investments were not prohibited by section 57 or rule 17d–1, as applicable, and records the basis for the finding in the Board minutes.

(c) *Additional Requirements.* The Disposition may only be completed in reliance on the Order if:

(i) *Same Terms and Conditions.* Each Regulated Fund has the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund;

(ii) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(iii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iv) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial [28] in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date,

holding 5% or more of the relevant limited partner interests that would be a Close Affiliate but for the exclusion in that definition.

[26] Any Stellus Proprietary Account that is not advised by an Adviser is itself deemed to be an Adviser for purposes of conditions 6(a)(i), 7(a)(i), 8(a)(i) and 9(a)(i).

[27] In the case of any Disposition, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Disposition.

[28] In determining whether a holding is ''immaterial'' for purposes of the Order, the Required Majority will consider whether the nature and extent of the interest in the transaction or arrangement is sufficiently small that a reasonable person would not believe that the interest affected the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement.

currency, or denominations may be treated as the same security; and

(v) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

8. *Standard Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer and the Regulated Funds and Affiliated Funds holding investments in the issuer previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund.

(b) *No Board Approval Required.* A Regulated Fund may participate in the Follow-On Investment without obtaining prior approval of the Required Majority if:

(i) (A) The proposed participation of each Regulated Fund and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer or the security at issue, as appropriate,[29] immediately preceding the Follow-On Investment; and (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application); or

(ii) it is a Non-Negotiated Follow-On Investment.

(c) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority makes the determinations set forth in Condition 2(c). If the only previous Co-Investment Transaction with respect to the issuer was an Enhanced Review Disposition the Eligible Directors must complete this review of the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms of the investment.

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them *pro rata* based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

9. *Enhanced Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer that is a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds holding investments in the issuer have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority reviews the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms and makes the determinations set forth in Condition 2(c). In addition, the Follow-On Investment may only be completed in reliance on the Order if the Required Majority of each participating Regulated Fund determines that the making and holding of the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable. The basis for the Board's findings will be recorded in its minutes.

(c) *Additional Requirements.* The Follow-On Investment may only be completed in reliance on the Order if:

(i) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(ii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iii) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial in amount,

[29] To the extent that a Follow-On Investment opportunity is in a security or arises in respect of a security held by the participating Regulated Funds and Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Follow-On Investment using the most recent available valuation thereof. To the extent that a Follow-On Investment opportunity relates to an opportunity to invest in a security that is not in respect of any security held by any of the participating Regulated Funds or Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the issuer immediately preceding the Follow-On Investment using the most recent available valuation thereof.

including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(iv) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity,

then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

10. *Board Reporting, Compliance and Annual Re-Approval.*

(a) Each Adviser to a Regulated Fund will present to the Board of each Regulated Fund, on a quarterly basis, and at such other times as the Board may request, (i) a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or any of the Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria that were not made available to the Regulated Fund, and an explanation of why such investment opportunities were not made available to the Regulated Fund; (ii) a record of all Follow-On Investments in and Dispositions of investments in any issuer in which the Regulated Fund holds any investments by any Affiliated Fund or other Regulated Fund during the prior quarter; and (iii) all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Independent Directors, may determine whether all Potential Co-Investment Transactions and Co-Investment Transactions during the preceding quarter, including those investments that the Regulated Fund considered but declined to participate in, comply with the Conditions.

(b) All information presented to the Regulated Fund's Board pursuant to this Condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

(c) Each Regulated Fund's chief compliance officer, as defined in rule 38a–1(a)(4), will prepare an annual report for its Board each year that evaluates (and documents the basis of that evaluation) the Regulated Fund's compliance with the terms and Conditions of the application and the procedures established to achieve such compliance. In the case of a BDC Downstream Fund that does not have a chief compliance officer, the chief compliance officer of the BDC that controls the BDC Downstream Fund will prepare the report for the relevant Independent Party.

(d) The Independent Directors will consider at least annually whether continued participation in new and existing Co-Investment Transactions is in the Regulated Fund's best interests.

11. *Record Keeping.* Each Regulated Fund will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these Conditions were approved by the Required Majority under section 57(f).

12. *Director Independence.* No Independent Director (including the non-interested members of any Independent Party) of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise be an ''affiliated person'' (as defined in the Act) of any Affiliated Fund.

13. *Expenses.* The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective advisory agreements with the Regulated Funds and the Affiliated Funds, be shared by the Regulated Funds and the participating Affiliated Funds in proportion to the relative amounts of the securities held or being acquired or disposed of, as the case may be.

14. *Transaction Fees.*[30] Any transaction fee (including break-up, structuring, monitoring or commitment fees but excluding brokerage or underwriting compensation permitted by section 17(e) or 57(k)) received in connection with any Co-Investment Transaction will be distributed to the participants on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by the Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1), and the account will earn a competitive rate of interest that will also be divided pro rata among the participants. None of the Advisers, the Affiliated Funds, the other Regulated Funds or any affiliated person of the Affiliated Funds or the Regulated Funds will receive any additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction other than (i) in the case of the Regulated Funds and the Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in Condition 2(c)(iii)(B)(z), (ii) brokerage or underwriting compensation permitted by section 17(e) or 57(k) or (iii) in the case of the Advisers, investment advisory compensation paid in accordance with investment advisory agreements between the applicable Regulated Fund(s) or Affiliated Fund(s) and its Adviser.

15. *Independence.* If the Holders own in the aggregate more than 25 percent of the Shares of a Regulated Fund, then the Holders will vote such Shares in the same percentages as the Regulated Fund's other shareholders (not including the Holders) when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) any other matter under either the Act or applicable State law affecting the Board's composition, size or manner of election.

[30] Applicants are not requesting and the Commission is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94657; File No. SR–MEMX–2022–08]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt on a Permanent Basis the Pilot Program for Market-Wide Circuit Breakers

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 7, 2022, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to make permanent the pilot program related to the market-wide circuit breaker in Rule 11.16. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On March 16, 2022, the Commission approved the proposal of the New York Stock Exchange LLC (''NYSE''), to adopt on a permanent basis the pilot program for Market-Wide Circuit Breakers (''MWCB'') in NYSE Rule 7.12.[5] The Exchange now proposes to adopt the same change to make permanent the pilot program related to the market-wide circuit breaker in Rule 11.16.

The Pilot Rules

The MWCB rules, which for the Exchange are contained in Exchange Rule 11.16, provide an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant stress when cash equities securities experience extreme market-wide declines. The MWCB rules are designed to slow the effects of extreme price declines through coordinated trading halts across both cash equity and equity options securities markets.

The cash equities rules governing MWCBs were first adopted in 1988 and, in 2012, all U.S. cash equity exchanges and FINRA amended their cash equities uniform rules on a pilot basis (the ''Pilot Rules,'' *i.e.,* Rule 11.16(a)–(d), (f)–(g)).[6] The Pilot Rules currently provide for trading halts in all cash equity securities during a severe market decline as measured by a single-day decline in the S&P 500 Index (''SPX'').[7] Under the Pilot Rules, a market-wide trading halt will be triggered if SPX declines in price by specified percentages from the prior day's closing price of that index. The triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. and before 3:25 p.m. would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. would not halt market-wide trading. (Level 1 and Level 2 halts may occur only once a day.) A market decline that triggers a Level 3 halt at any time during the trading day would halt market-wide trading for the remainder of the trading day.

The Commission approved the Pilot Rules, the term of which was to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the ''LULD Plan''),[8] including any extensions to the pilot period for the LULD Plan.[9] In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[10] In conjunction with the proposal to make the LULD Plan permanent, all U.S. cash equity exchanges and FINRA filed to untie the Pilot Rules' effectiveness from that of the LULD Plan and to extend the Pilot Rules' effectiveness to the close of business on October 18, 2019.[11] On May 4, 2020, the Commission approved MEMX's Form 1 Application to register as a national securities exchange with rules including, on a pilot basis expiring on October 18, 2020, the Pilot Rules.[12] The Exchange subsequently amended Rule 11.16 to extend the Pilot Rules' effectiveness for an additional year to the close of business on October 18, 2021,[13] March 18, 2022,[14] and April 18, 2022.[15]

The MWCB Working Group Study

Beginning in February 2020, at the outset of the COVID–19 pandemic, the markets experienced increased volatility, culminating in four MWCB

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 94441 (March 16, 2022) (SR–NYSE–2021–40).

[6] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS–2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE–2011–61; SR–NASDAQ–2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex–2011–73; SR–NYSEArca–2011–68; SR–Phlx–2011–129) (''Pilot Rules Approval Order'').

[7] The rules of the equity options exchanges similarly provide for a halt in trading if the cash equity exchanges invoke a MWCB Halt. *See, e.g.,* NYSE Arca Rule 6.65–O(d)(4).

[8] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

[9] *See, e.g.,* Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSE–2011–48) (Approval Order); and 68784 (January 31, 2013), 78 FR 8662 (February 6, 2013) (SR–NYSE–2013–10).

[10] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

[11] *See, e.g.,* Securities Exchange Act Release No. 85560 (April 9, 2019), 84 FR 15247 (April 15, 2019) (SR–NYSE–2019–19).

[12] *See* Securities Exchange Release No. 88806 (May 4, 2020), 85 FR 27451 (May 8, 2020).

[13] *See* Securities Exchange Act Release No. 90159 (October 13, 2020), 85 FR 66373 (October 19, 2020) (SR–MEMX–2020–12).

[14] *See* Securities Exchange Act Release No. 93362 (October 15, 2021), 86 FR 58364 (October 21, 2021) (SR–MEMX–2021–14).

[15] *See* Securities Exchange Act Release No. 94449 (March 17, 2022), 87 FR 16535 (March 23, 2022) (SR–MEMX–2022–04).

Level 1 halts on March 9, 12, 16, and 18, 2020. In each instance, pursuant to the Pilot Rules, the markets halted as intended upon a 7% drop in SPX and did not start the process to resume trading until the prescribed 15-minute halt period ended.

On September 17, 2020, the Director of the Commission's Division of Trading and Markets asked the SROs to conduct a study of the design and operation of the Pilot Rules and the LULD Plan during the period of volatility in March 2020. In response to the request, the SROs created a MWCB ''Working Group'' composed of SRO representatives and industry advisers that included members of the advisory committees to both the LULD Plan and the NMS Plans governing the collection, consolidation, and dissemination of last-sale transaction reports and quotations in NMS Stocks. The Working Group met regularly from September 2020 through March 2021 to consider the Commission's request, review data, and compile its study.

On March 31, 2021, the MWCB Working Group submitted its study (the ''Study'') to the Commission.[16] The Study included an evaluation of the operation of the Pilot Rules during the March 2020 events and an evaluation of the design of the current MWCB system. In the Study, the Working Group concluded: (1) The MWCB mechanism set out in the Pilot Rules worked as intended during the March 2020 events; (2) the MWCB halts triggered in March 2020 appear to have had the intended effect of calming volatility in the market, without causing harm; (3) the design of the MWCB mechanism with respect to reference value (SPX), trigger levels (7%/13%/20%), and halt times (15 minutes) is appropriate; (4) the change implemented in Amendment 10 to the LULD Plan did not likely have any negative impact on MWCB functionality; and (5) no changes should be made to the mechanism to prevent the market from halting shortly after the opening of regular trading hours at 9:30 a.m.

In light of those conclusions, the MWCB Working Group also made several recommendations, including that (1) the Pilot Rules should be made permanent without any changes, and (2) SROs should adopt a rule requiring all designated Regulation SCI firms to participate in at least one Level 1/Level 2 MWCB test each year and to verify their participation via attestation.[17]

Proposal To Make the Pilot Rules Permanent

On July 16, 2021, NYSE proposed a rule change to make the Pilot Rules permanent, consistent with the Working Group's recommendations.[18] On March 16, 2022, the Commission approved NYSE's proposal to make the Pilot Rules permanent.[19] Consistent with the Commission's approval of NYSE's proposal, the Exchange now proposes that the Pilot Rules (*i.e.,* paragraphs (a)–(d) and (f)–(g) of Rule 11.16) be made permanent. To accomplish this, the Exchange proposes to remove the preamble to Rule 11.16, which currently provides that the rule is in effect during a pilot period that expires at the close of business on April 18, 2022. The Exchange does not propose any changes to paragraphs (a)–(d) or (f)–(g) of the Rule.

Further consistent with the Commission's approval of NYSE's proposal, the Exchange proposes to add new paragraphs (h), (i), and (j) to Rule 11.16, as follows:

(h) Market-Wide Circuit Breaker (''MWCB'') Testing.

(1) The Exchange will participate in all industry-wide tests of the MWCB mechanism. Members designated pursuant to paragraph (a) of Rule 2.4 to connect to the Exchange/s backup systems and participate in testing of such systems are required to participate in at least one industry-wide MWCB test each year and to verify their participation in that test by attesting that they are able to or have attempted to:

(A) Receive and process MWCB halt messages from the securities information processors (''SIP'');

(B) receive and process resume messages from the SIPs following a MWCB halt;

(C) receive and process market data from the SIPs relevant to MWCB halts; and

(D) send orders following a Level 1 or Level 2 MWCB halt in a manner consistent with their usual trading behavior.

(2) To the extent that a Member participating in a MWCB test is unable to receive and process any of the messages identified in paragraph (h)(1)(A)–(D) of this Rule, its attestation should notify the Exchange which messages it was unable to process and, if known, why.

(3) Members not designated pursuant to standards established in paragraph (a) of Rule 2.4 are permitted to participate in any MWCB test.

(f)[sic] In the event that a halt is triggered under this Rule following a Level 1, Level 2, or Level 3 Market Decline, the Exchange, together with other SROs and industry representatives (the ''MWCB Working Group''), will review such event. The MWCB Working Group will prepare a report that documents its analysis and recommendations and will provide that report to the Commission within 6 months of the event.

(g)[sic] In the event that there is (1) a Market Decline of more than 5%, or (2) an SRO implements a rule that changes its reopening process following a MWCB Halt, the Exchange, together with the MWCB Working Group, will review such event and consider whether any modifications should be made to this Rule. If the MWCB Working Group recommends that a modification should be made to this Rule, the MWCB Working Group will prepare a report that documents its analysis and recommendations and provide that report to the Commission.

2. Statutory Basis

The Exchange believes that the proposal to make the Pilot Rules permanent is consistent with Section 6(b) of the Act,[20] in general, and furthers the objectives of Section 6(b)(5) of the Act,[21] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Pilot Rules set out in Rule 11.16(a)–(d) and (f)–(g) are an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant market stress when securities markets experience broad-based declines. The four MWCB halts that occurred in March 2020 provided the Exchange, the other SROs, and market participants with real-world experience as to how the Pilot Rules actually function in practice. Based on the Working Group's Study and the Exchange's own analysis of those events, the Exchange believes that making the Pilot Rules permanent would benefit market participants, promote just and equitable principles of trade, remove impediments to and

[16] *See Report of the Market-Wide Circuit Breaker (''MWCB'') Working Group Regarding the March 2020 MWCB Events,* submitted March 31, 2021 (the ''Study''), available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/Report_of_the_Market-Wide_Circuit_Breaker_Working_Group.pdf.*

[17] *See id.* at 46.

[18] *See* Securities Exchange Act Release No. 92428 (July 16, 2021), 86 FR 38776 (July 22, 2021) (SR–NYSE–2021–40).

[19] *See supra* note 5.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest.

Specifically, the Exchange believes that making the Pilot Rules permanent would benefit market participants, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest, because the Pilot Rules worked as intended during the March 2020 events. As detailed above, the markets were in communication before, during, and after each of the MWCB Halts that occurred in March 2020. All 9,000+ equity symbols were successfully halted in a timely manner when SPX declined 7% from the previous day's closing value, as designed. The Exchange believes that market participants would benefit from having the Pilot Rules made permanent because such market participants are familiar with the design and operation of the MWCB mechanism set out in the Pilot Rules, and know from experience that it has functioned as intended on multiple occasions under real-life stress conditions. Accordingly, the Exchange believes that making the Pilot Rules permanent would enhance investor confidence in the ability of the markets to successfully halt as intended when under extreme stress.

The Exchange further believes that making the Pilot Rules permanent would benefit market participants, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest, because the halts that were triggered pursuant to the Pilot Rules in March 2020 appear to have had the intended effect of calming volatility in the market without causing harm. As detailed above, after studying a variety of metrics concerning opening and reopening auctions, quote volatility, and other factors, the Exchange concluded that there was no significant difference in the percentage of securities that opened on a trade versus on a quote for the four days in March 2020 with MWCB Halts, versus the other periods studied. In addition, while the post-MWCB Halt reopening auctions were smaller than typical opening auctions, the size of those post-MWCB Halt reopening auctions plus the earlier initial opening auctions in those symbols was on average equal to opening auctions in January 2020. The Exchange believes this indicates that the MWCB Halts on the four March 2020 days did not cause liquidity to evaporate. Finally, the Exchange observes that while quote volatility was generally higher on the four days in March 2020 with MWCB Halts as compared to the other periods studied, quote volatility stabilized following the MWCB Halts at levels similar to the January 2020 levels, and LULD Trading Pauses worked as designed to address any additional volatility later in the day. From this evidence, the Exchange concludes that the Pilot Rules actually calmed volatility on the four MWCB Halt days in March 2020, without causing liquidity to evaporate or otherwise harming the market. As such, the Exchange believes that making the Pilot Rules permanent would remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest.

The Exchange believes that that making the Pilot Rules permanent without any changes would benefit market participants, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest, because the current design of the MWCB mechanism as set out in the Pilot Rules remains appropriate. As detailed above, the Exchange considered whether SPX should be replaced as the reference value, whether the current trigger levels (7%/13%/20%) and halt times (15 minutes for Level 1 and 2 halts) should be modified, and whether changes should be made to prevent the market from halting shortly after the opening of regular trading hours at 9:30 a.m., and concluded that the MWCB mechanism set out in the Pilot Rules remains appropriate, for the reasons cited above. The Exchange believes that public confidence in the MWCB mechanism would be enhanced by the Pilot Rules being made permanent without any changes, given investors' familiarity with the Pilot Rules and their successful functioning in March 2020.

The Exchange believes that proposed paragraph (h) regarding MWCB testing is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Working Group recommended that all cash equities exchanges adopt a rule requiring all designated Regulation SCI firms to participate in MWCB testing and to attest to their participation. The Exchange believes that these requirements would promote the stability of the markets and enhance investor confidence in the MWCB mechanism and the protections that it provides to the markets and to investors. The Exchange further believes that requiring firms participating in a MWCB test to identify any inability to process messages pertaining to such MWCB test would contribute to a fair and orderly market by flagging potential issues that should be corrected. The Exchange would preserve such attestations pursuant to its obligations to retain books and records of the Exchange.[22]

The Exchange believes that proposed paragraph (i) would benefit market participants, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. Having the MWCB Working Group review any halt triggered under Rule 11.16 and prepare a report of its analysis and recommendations would permit the Exchange, along with other market participants and the Commission, to evaluate such event and determine whether any modifications should be made to Rule 11.16 in the public interest. Preparation of such a report within 6 months of the event would permit the Exchange, along with the MWCB Working Group, sufficient time to analyze such halt and prepare their recommendations.

The Exchange believes that proposed paragraph (j) would benefit market participants, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. Having the MWCB Working Group review instances of a Market Decline of more than 5% or an SRO implementing a rule that changes its reopening process following a MWCB Halt would allow the MWCB Working Group to identify situations where it recommends that Rule 11.16 be modified in the public interest. In such situations where the MWCB Working Group recommends that a modification should be made to Rule 11.16, the MWCB Working Group would prepare a report that documents its analysis and recommendations and provide that report to the Commission, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system while protecting investors and the public interest.

[22] *See* 17 CFR 240.17a–1.

For the foregoing reasons, the Exchange believes that the proposed change is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not intended to address competition, but rather, makes permanent the current MWCB Pilot Rules for the protection of the markets. The Exchange believes that making the current MWCB Pilot Rules permanent would have no discernable burden on competition at all, since the Pilot Rules have already been in effect since 2012 and would be made permanent without any changes. Moreover, because the MWCB mechanism contained in the Pilot Rules requires all exchanges and all market participants to cease trading at the same time, making the Pilot Rules permanent would not provide a competitive advantage to any exchange or any class of market participants.

Further, the Exchange understands that the other SROs will submit substantively identical proposals to the Commission. Thus, the proposed rule change will help to ensure consistency across SROs without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [23] and Rule 19b–4(f)(6) thereunder.[24] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [25] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[26] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30 day operative delay so that the proposal may become operative immediately upon filing. Waiver of the 30-day operative delay would allow the Exchange to immediately provide the protections included in this proposal in the event of a MWCB halt, which is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[27]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MEMX–2022–08 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2022–08. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions.

You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2022–08 and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Jill Peterson,

Assistant Secretary.

[FR Doc. 2022–07954 Filed 4–13–22; 8:45 am]

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[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6)(iii).

[27] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94653; File No. SR–MEMX–2022–07]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Clarify the Information Disseminated in the MEMOIR Top Data Feed

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the

''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 1, 2022, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend Rule 13.8(b) to clarify what information is disseminated in the MEMOIR Top data feed. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 13.8(b) to clarify what information is disseminated in the MEMOIR Top data feed. The Exchange does not propose any changes to the information that is disseminated in the MEMOIR Top data feed, or any changes to the Exchange's System functionality, order handling, or operation, in this filing. Instead, this proposed change merely corrects an inadvertent drafting error contained in the Exchange's initial Rules in order to clarify what information is disseminated in the MEMOIR Top data feed today. Specifically, the Exchange's Rule 13.8(b) currently states that MEMOIR Top is an uncompressed data feed that offers top of book quotations and execution information based on equity orders entered into the System, however, the information actually published through MEMOIR Top is limited to top of book quotations. Accordingly, the Exchange proposes to eliminate the reference to execution information from Rule 13.8(b). The proposed change is therefore intended to add clarity and promote transparency around the Exchange's current operation and Rules for the benefit of its Users and all market participants.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. As described above, the Exchange simply proposes to eliminate the reference to execution information from Rule 13.8(b) to correct an inadvertent drafting error contained in the Exchange's initial Rules and clarify what information is disseminated in the MEMOIR Top data feed today. Accordingly, the Exchange believes the proposed change is consistent with the Act because it is intended to add clarity and promote transparency around the Exchange's current operation and Rules, which would help to avoid confusion for the benefit of its Users and all market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the proposed change would add clarity and promote transparency around the Exchange's current operation and its Rules for the benefit of its Users and all market participants, as described above. No changes to the Exchange's System functionality, order handling, or operation are contemplated by these proposed changes, which would merely clarify the Exchange's current operation and its Rules. As such, the proposal does not address competitive issues but is concerned solely with the administration of the Exchange and its Rules. Accordingly, as the Exchange is not proposing any changes to the Exchange's System functionality, order handling, or operation, the Exchange does not believe the proposed rule change could have any impact on competition (intermarket or intramarket).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6)[8] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[1] 15 U.S.C. 78s(b)(1).
[2] 17 CFR 240.19b–4.
[3] 15 U.S.C. 78s(b)(3)(A)(iii).
[4] 17 CFR 240.19b–4(f)(6).
[5] 15 U.S.C. 78f(b).
[6] 15 U.S.C. 78f(b)(5).
[7] 15 U.S.C. 78s(b)(3)(A).
[8] 17 CFR 240.19b–4.

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MEMX–2022–07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2022–07. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2022–07 and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–07953 Filed 4–13–22; 8:45 am]

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[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94654; File No. SR–FINRA–2022–009]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Amend Certain FINRA Rules To Permit, and in Some Instances Require, Electronic Service and Filing of Documents in Disciplinary and Other Proceedings and Appeals

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 6, 2022, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rules 1012, 1015, 6490, 9132, 9133, 9135, 9146, 9321, 9341, 9349, 9351, 9522, 9524, 9525, 9559 and 9630 to permit, and in some instances require, electronic service and filing of documents in disciplinary and other proceedings and appeals.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Several of FINRA's rules regarding method of service and filing have been amended temporarily to permit, and in some instances require, electronic filing and service during the period in which FINRA's operations have been impacted by the COVID–19 pandemic.[3] These temporary amendments pertain to disciplinary proceedings before the Office of Hearing Officers (OHO), and to appeals before the National Adjudicatory Council (NAC), among other types of administrative proceedings.[4] However, the temporary amendments do not permit electronic service of an initial complaint on a respondent. FINRA did not temporarily change the method of serving the initial complaint due to heightened fair process concerns.[5] Likewise, the proposed rule change would not change how initial complaints are served. The only permissible methods of serving the

[3] *See* Securities Exchange Act Release No. 88917 (May 20, 2020), 85 FR 31832 (May 27, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–015); Securities Exchange Act Release No. 89055 (June 12, 2020), 85 FR 36928 (June 18, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–017); Securities Exchange Act Release No. 89423 (July 29, 2020), 85 FR 47278 (August 4, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–022); Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–042); Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2021–006); Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2021–031); Securities Exchange Act Release No. 94430 (March 16, 2022), 87 FR 16262 (March 22, 2022) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2022–004).

[4] The filings to establish and extend the temporary amendments involving electronic service and filing also included additional temporary amendments to provide extensions of time to FINRA staff, respondents and other parties in connection with certain adjudicatory and review processes. *See* Securities Exchange Act Release No. 88917 (May 20, 2020), 85 FR 31832 (May 27, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–015). For example, under original Rule 6490(e), the time to appeal was seven calendar days, and a subcommittee was required to convene once each calendar month to consider all appeals received during the prior month. Under the temporary amendments to Rule 6490(e), the time to appeal was extended to 30 calendar days, and the time for the subcommittee to convene was extended to once every 90 days. The time frames under the proposed rule change are reverting back to their original form, so the timing requirements under the proposed rule change are the same as they were under the original rule.

[5] *See* 85 FR 31832, *supra* note 3.

initial complaint are by hand, mail or courier.[6]

FINRA is proposing to make the temporary amendments regarding electronic service and filing permanent, with some modifications. FINRA believes that advances in technology and its availability have made filing and service more efficient under the temporary amendments than under the original rules.[7] In addition, FINRA believes that operating under the temporary amendments since May 2020 has demonstrated that electronic service and filing is beneficial for parties, panelists and FINRA staff. FINRA further notes that the SEC also amended its rules in November 2020 to require electronic filing and service of documents in its administrative proceedings.[8] FINRA further believes that the proposed rule change will similarly improve and modernize FINRA's operations.

Background

The FINRA Rule 1000, 6400, 9100, 9300, 9520, 9550 and 9600 Series contain filing, service and other procedural requirements. The temporary amendments to these rules allowed, and in some instances required, FINRA (in its capacity as an Adjudicator) to serve certain documents on parties by electronic mail (''email'') and required parties to file or serve documents by email, unless the parties agreed to an alternative method of service.[9]

The proposed rule change includes provisions to allow, and in some instances require, FINRA to serve certain documents on parties by email and require parties to file or serve documents by email, unless another method of service is ordered by the Adjudicator. Several of the proposed rule changes differ from the temporary amendments, which required email service unless the parties agreed to an alternative method.[10] FINRA has observed that a more effective approach would be to require email service unless the Adjudicator orders otherwise. As discussed further below, the proposal will allow all parties who lack the ability to use or access email to request relief to use an alternative method of service upon a showing of good cause. But unlike the temporary amendments, the parties' agreement to use an alternative method of service would be insufficient unless the parties also obtained an order from the Adjudicator permitting use of the alternative method of service.

In addition, to support the transition to email service and filing, FINRA proposes to require parties in OHO proceedings to file and serve all parties with their current email address and contact information at the time of their first appearance, and to file and serve any change in email address or contact information during the course of the proceeding.

Proposed Rule Change To Allow or Require Email Filing and Service

FINRA rules, with few exceptions, do not provide for service by email.[11] The proposed rule change would permit FINRA to serve documents other than the initial complaint by email among various other methods of service, such as personal service, mail and courier, and to provide that service by email is deemed complete upon sending.[12]

FINRA has elected email service whenever possible while the temporary amendments have been in effect, and it is FINRA's intention to continue to do so under the proposed rule change. If FINRA has knowledge that the address used for service is not current or not functional (*i.e.,* FINRA receives a bounce back or other message indicating that there was a failure to deliver the email), FINRA will use other permissible methods of service until it can verify the party's email address.[13] FINRA notes that, in most cases, FINRA and the relevant party, or their counsel, will have already engaged in communications prior to the service of documents or other information. Accordingly, in most cases, FINRA will already have information regarding the relevant party, or their counsel's, preferred method of service.

Further, to the extent an applicant, respondent or other party lacks the ability to use or access technology needed to file, serve or accept service by email, FINRA intends to provide reasonable accommodations to them. The process for requesting an alternative method of service or filing will be posted to FINRA's website, as well as explained in the Notice of Complaint and in the Code and Guide letter.[14] If a party shows good cause, the Adjudicator will order that filing or service occur by hard copy.

The proposed rule change to amend the FINRA Rule 1000, 6400, 9100, 9300, 9520, 9550 and 9600 Series is substantially the same as the temporary amendments currently in effect unless otherwise noted, below.

The FINRA Rule 1000 Series (Member Application and Associated Person Registration) governs, among other things, the process for (i) applying for FINRA membership; (ii) FINRA members to seek approval of a change in ownership, control or business operations, and (iii) an applicant to request that FINRA's appellate body, the NAC, review a FINRA decision rendered under the Rule 1000 Series. In connection with these processes, applicants and FINRA are required to file or serve certain documents using the prescribed methods set forth in FINRA Rule 1012(a), which do not include email.[15] FINRA proposes to permanently amend Rule 1012(a)(4) to permit FINRA to serve documents under the Rule 1000 Series by email and to amend Rule 1015(f)(1),[16] which requires the NAC to serve a notice of a hearing before the NAC by facsimile or overnight courier, to allow service of the notice by email.[17] The proposed rule

[6] *See* FINRA Rule 9134(a).

[7] For ease of reference in this filing, FINRA refers to the pre-pandemic rules as ''original rules'' and to the temporary changes to the original rules as ''temporary amendments.'' Some of the original rules were amended while the temporary amendments were in effect. Those amendments to the original rules have been incorporated into the temporary amendments. *See, e.g.,* FINRA Rule 9321 (amended by SR–FINRA–2020–011, eff. April 15, 2021).

[8] *See* Amendments to the Commission's Rules of Practice, Securities Exchange Act Release No. 90442 (November 17, 2020), 85 FR 86464 (File No. S7–18–15) (December 30, 2020) (codified at 17 CFR 201 (2020)).

[9] *See supra* note 3.

[10] *See* FINRA Rules 6490(e), 9133(b), 9146(l), 9524(a)(3) and 9559(h).

[11] Prior to the temporary amendments, FINRA permitted service by email under some of its original rules. For example, FINRA Rule 6490(d)(5) (Processing of Company-Related Actions; Procedures for Reviewing Submissions; Notice Issuance) permits a notice under that provision to be issued by facsimile or email, or pursuant to Rule 9134. Rule 9134 does not permit service by email, however.

[12] FINRA sometimes serves documents in its capacity as the Adjudicator. In other instances, FINRA is a party, for example, in its capacity as the Department of Enforcement.

[13] As indicated in the proposed rule text, FINRA will consider service by email complete upon sending of the relevant document or other information. This is consistent with service by mail under the original rules and service by email under the temporary amendments.

[14] When the Department of Enforcement files an initial complaint on a respondent, the Notice of Complaint tells the respondent how to file the answer and other documents with OHO. In addition, once OHO receives an initial complaint, it sends a Code and Guide letter to each respondent to notify them of the complaint. That letter also includes instructions on how to file with OHO.

[15] FINRA Rule 1012(a) (General Provisions; Filing by Applicant or Service by FINRA) governs the filing and service requirements for the Rule 1000 Series.

[16] FINRA Rule 1015(f) (Review by National Adjudicatory Council; Hearing).

[17] In an effort to streamline processes and avoid duplication, FINRA is also proposing to amend Rule 1015(a) to eliminate the requirement that the applicant simultaneously file by first-class mail a copy of the request for review pursuant to Rule 1015(a) to the district office where the applicant filed its application.

change would also amend Rule 1012(a)(3) to require applicants to file an application or any document or information requested under the Rule 1000 Series by email except where FINRA has otherwise prescribed an alternative filing process, while permitting the applicant to also file a requested document or information by another method if the Department and the Applicant agree.[18]

FINRA Rule 6490 codifies the requirements in Exchange Act Rule 10b–17 for issuers of a class of publicly traded securities to provide timely notice to FINRA of certain corporate actions (*e.g.,* dividend or other distribution of cash or securities, stock split or reverse split, rights or subscription offering). FINRA reviews related documentation and, under certain circumstances, the documentation may not be processed if it is deemed deficient. Rule 6490(e) sets forth the process for appealing such a determination.[19] The proposed rule change would require the requesting party to file an appeal by email unless an alternative method of service is ordered by the Adjudicator.[20]

The FINRA Rule 9000 Series, among other things, sets forth the procedure for FINRA proceedings for disciplining a member, associated person or formerly associated person. The Rule 9100 Series is of general applicability to all proceedings set forth in the Rule 9000 Series, unless a rule specifically provides otherwise. Rules 9132(b),[21] 9133(b),[22] and 9146(l)[23] provide that the documents and other information governed by those rules be served pursuant to Rule 9134, which permits service on the parties using the following methods: (1) Personal service, (2) mail, or (3) courier. Rule 9134 does not permit service by email. The proposed rule change would amend Rule 9132(b) to allow FINRA to serve the relevant documents or information by email, and Rules 9133(b) and 9146(l) to require parties to serve documents by email, unless an alternative method of service is ordered by the Adjudicator.

In addition, to support the transition to email service and filing, FINRA proposes to amend Rule 9135 to add paragraph (d), which would require parties in OHO proceedings to file and serve the parties with their current email address and contact information at the time of their first appearance, and to file and serve any change in email address or contact information during the course of the proceeding. Based on the experience of operating under the temporary amendments, FINRA believes this proposed rule change, which was not part of the temporary amendments, will help ensure that documents are successfully sent from and received at a valid email address. It will also ensure that all participants, including FINRA, applicants, respondents and any other parties, have accurate contact information for all parties.

The FINRA Rule 9300 Series sets forth the procedures for review of disciplinary proceedings by the NAC and FINRA Board and for applications for SEC review. FINRA Rules 9321,[24] 9341(c),[25] 9349(c),[26] and 9351(e)[27] require FINRA to serve documents in connection with those proceedings. Service under those rules is governed by Rule 9134, which does not permit email as a method of service. FINRA proposes to permanently amend Rules 9321, 9341(c), 9349(c), and 9351(e) to allow for email as a method of service.

The FINRA Rule 9520 Series sets forth the procedures for eligibility proceedings and review of those proceedings by the NAC and FINRA Board. Rules 9522(a)(4),[28] 9524(a)(3)(A) and (B),[29] 9524(b)(3),[30] and 9525(e)[31] require FINRA to serve documents in connection with those proceedings, but do not allow for email as a method of service. The proposed rule change would permanently amend those rules to allow for email as a method of service. Further, under the proposed change to Rule 9524(a)(3)(A) and (B), the disqualified member or sponsoring member would be required to serve documents and the exhibit and witness lists by email unless an alternative method of service is ordered by the Adjudicator.[32]

The FINRA Rule 9550 Series sets forth the procedures for expedited proceedings and the ability of the NAC to call for review a proposed decision prepared under the Rule 9550 Series. Rule 9559(h)(2)[33] sets forth the timing and method of service requirements for the parties' exchange of proposed exhibit and witness lists in advance of an expedited proceeding.[34] Rule 9559(q)(2)[35] requires the NAC to serve its decision when it issues one and Rule 9559(q)(5) requires the NAC to serve the decision on the parties and all members with which the respondent is associated. Rule 9559(q)(2) and (5) do not allow for email as a method of service. FINRA proposes to permanently amend Rule 9559(h)(2) to require FINRA to serve its exhibit and witness lists by email, unless an alternative method of service is ordered by the Adjudicator. The proposed rule change would amend Rule 9559(q)(2) and (5) to allow for email as a method of service.

The FINRA Rule 9600 Series sets forth the procedures for members to seek exemptive relief from a variety of FINRA rules. Rule 9630(e)(1) and (2)[36] require the NAC to serve its decision pursuant to Rule 9134, which does not allow for email as a method of service. The proposed rule change would amend Rule 9630(e) to allow for email as a method of service.

As discussed in detail in Item 3(b), FINRA believes the proposal will modernize the rules and make service

[18] FINRA is also proposing a non-substantive change to delete the word ''electronic'' from the description of the ''alternative filing process'' because it is superfluous.

[19] FINRA Rule 6490(e) (Processing of Company-Related Actions; Request for an Appeal to Subcommittee of Uniform Practice Code Committee).

[20] FINRA is also proposing several non-substantive, technical changes including, for example, deleting the parenthetical references to the numerals ''3'' and ''7,'' which originally followed those words in FINRA Rule 6490(e). As noted *supra* note 4, the time frames under the proposed rule change are reverting back to their original form, so the time to appeal and for appellate review under the proposed rule change are the same as they were under the original rule.

[21] FINRA Rule 9132(b) (Service of Orders, Notices, and Decisions by Adjudicator; How Served).

[22] FINRA Rule 9133(b) (Service of Papers Other Than Complaints, Orders, Notices or Decisions; How Served).

[23] FINRA Rule 9146(l) (Motions; General).

[24] FINRA Rule 9321 (Transmission of Record).

[25] FINRA Rule 9341(c) (Oral Argument; Notice Regarding Oral Argument).

[26] FINRA Rule 9349(c) (National Adjudicatory Council Formal Consideration; Decision; Issuance of Decision After Expiration of Call for Review Period).

[27] FINRA Rule 9351(e) (Discretionary Review by FINRA Board; Issuance of Decision After Expiration of Call for Review Period).

[28] FINRA Rule 9522(a)(4) (Initiation of Eligibility Proceeding; Member Regulation Consideration; Service).

[29] FINRA Rule 9524(a)(3)(A) and (B) (National Adjudicatory Council Consideration; Transmission of Documents).

[30] FINRA Rule 9524(b)(3) (National Adjudicatory Council Consideration; Issuance of Decision After Expiration of Call for Review Period).

[31] FINRA Rule 9525(e) (Discretionary Review by the FINRA Board; Issuance of Decision).

[32] FINRA is also proposing a non-substantive, technical change to replace the numeral ''10'' with the word ''ten'' in Rule 9524(a)(3)(B).

[33] FINRA Rule 9559(h) (Hearing Procedures for Expedited Proceedings Under the Rule 9550 Series; Transmission of Documents). Rule 9559(h) currently permits email as a method of service.

[34] As with the proposed rule change to amend Rule 1015(a) noted *supra* note 17, FINRA proposes to amend Rule 9559(h) to also eliminate the requirements in Rule 9559(h)(1) and (2) that, if the specified documents are served by facsimile or email, they must also be served by either overnight courier or personal delivery.

[35] FINRA Rule 9559(q) (Hearing Procedures for Expedited Proceedings Under the Rule 9550 Series; Call for Review by the National Adjudicatory Council).

[36] FINRA Rule 9630(e) (Procedures for Exemptions; Appeal; Decision).

and filing more efficient and effective. Email technology is widely available, and use of electronic methods of service and filing is common practice in the courts and other regulatory agencies, including the SEC.[37] At the same time, the proposal provides for alternative methods of service for parties who lack the ability to use or access technology needed to send or receive documents electronically.

FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice.*[38]

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[39] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change is also consistent with Section 15A(b)(8) of the Act,[40] which requires, among other things, that FINRA rules provide a fair procedure for the disciplining of members and persons associated with members.

FINRA believes that the proposed rule change protects investors and the public interest by requiring use of broadly available technology to make service and filing processes more efficient and effective. FINRA's disciplinary and eligibility proceedings and other review processes serve a critical role in providing investor protection and maintaining fair and orderly markets by, for example, sanctioning misconduct and preventing further customer harm by members and associated persons.

The proposed rule change promotes efficiency in these processes by permitting electronic service and filing in most instances. To ensure that documents are effectively sent and received, FINRA is proposing to require parties to provide and update their contact information, including their email address, during the course of a proceeding. These amendments reduce the reliance on paper documents in favor of more efficient electronic formats. FINRA believes adopting permanent rules on electronic service and filing is especially important as hybrid and remote work become more common.

At the same time, the proposed rule change includes safeguards to ensure fairness. For example, there are procedures in place for persons who lack the ability to use or access technology necessary to send or receive documents electronically. Such parties will have the ability to request relief from the Adjudicator to file or serve documents by another method. Based on FINRA's experience of operating under the temporary amendments, which have permitted electronic service and filing since mid-2020, FINRA anticipates that requests to use non-electronic methods of service will be rare. In addition, the proposed rule change balances the interests of fairness and efficiency. As discussed, service of the initial complaint will continue to occur by hand, mail or courier, rather than by electronic means, thus ensuring there is satisfactory notice and fair process.

Thus, the proposed rule change represents a significant step toward modernizing the service and filing processes in a manner that will protect investors and the public interest by promoting efficiency while preserving fair process.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the regulatory need for the proposed rule change, its potential economic impacts, including anticipated costs, benefits, and distributional and competitive effects, relative to the current baseline, and the alternatives FINRA considered in assessing how best to meet FINRA's regulatory objectives.

Regulatory Need

Several of FINRA's rules regarding method of service and filing have been amended temporarily to permit, and in some circumstances require, electronic filing and service during the period in which FINRA's operations have been impacted by the COVID–19 pandemic.[41] As stated earlier, the proposed rule change is intended to make these temporary amendments permanent considering the positive experience of operating while the temporary amendments have been in effect. The implementation of those temporary amendments suggests that advances in technology and its availability have made filing and service more efficient under the temporary amendments than under the original rules.

Economic Baseline

The economic baseline for the proposed rule change consists of the original rules together with the experience gained by broker-dealers, their associated persons, and FINRA in complying with the temporary amendments to the original rules. As discussed above, FINRA Rules 1000, 6400, 9100, 9300, 9520, 9550 and 9600 Series set forth filing and service requirements pertaining to expedited and disciplinary proceedings before OHO and to appeals before the NAC, among other types of FINRA proceedings. These rules, with few exceptions, do not allow FINRA to use email or require others to use email to meet certain filing and service requirements. FINRA temporarily amended these rules to permit, and in some instances require, electronic filing and service.

The proposed rule change is expected to affect parties to disciplinary proceedings before OHO and to appeals before the NAC. FINRA thus has collected information detailing the number of new cases filed in OHO and NAC proceedings and the number of respondents in association with these proceedings in the past three years. The numbers are presented below. Note that ''Registered Rep'' includes both current and former registered representatives and the numbers of new OHO filings include both expedited and disciplinary proceedings before OHO. The numbers show that the majority of respondents in OHO filings and NAC appeals consist of current and former registered representatives.[42]

[37] *See supra* note 8.

[38] FINRA intends to minimize any gap between the expiration of the temporary amendments on electronic service and filing and the implementation date of this proposed rule change.

[39] 15 U.S.C. 78*o*–3(b)(6).

[40] 15 U.S.C. 78*o*–3(b)(8).

[41] *See supra* note 3.

[42] The proposal also amends filing and service requirements for eligibility proceedings under FINRA Rule 9522(a)(4) and for appeals of determinations regarding the documentation of certain corporate actions under FINRA Rule 6490(e). There were 22 eligibility proceedings in 2018 and 14 in 2019; there have been no appeals of determinations under Rule 6490(e) since the temporary requirements came into effect in May 2020.

	2020	2019	2018
OHO Filings	69	95	90
OHO Respondents: Firms Only	2	7	9
OHO Respondents: Registered Rep Only	65	85	76
OHO Respondents: Both Firms and Registered Rep	2	3	5
NAC Appeals	13	17	22
NAC Respondents: Firms Only	2	2	3
NAC Respondents: Registered Rep Only	9	11	15
NAC Respondents: Both Firms and Registered Rep	2	4	4

Economic Impacts

The proposed rule change will directly impact current and former member firms and associated persons, including registered representatives. With limited exceptions, these individuals would be applicants, respondents, or other related parties to disciplinary proceedings before OHO and to appeals before the NAC. The proposed rule change will not directly impact the customers of those firms.

Parties in relevant proceedings will benefit from savings on time and money on printing, shipping, and storage of paper documents as filing and serving paper copies will generally not be required following the proposed rule change. The proposed rule change would also improve the overall efficiency of FINRA's operations in collecting, preserving, and distributing documents to parties in these proceedings relative to the original rules. Such benefits are anticipated to accrue to firms and individuals as well as to FINRA in its capacity as an adjudicator. In particular, FINRA believes that the benefits to member firms from the proposal will likely be larger for those using hybrid and remote work models or in situations where access to physical office locations is limited or restricted.

The extent of the cost savings is likely not uniform across parties and cannot be estimated in aggregate for two reasons. First, FINRA does not know the frequencies of filing and service and the size of the documents in association with relevant proceedings. The expected cost savings will likely be greater for parties that file and serve large documents more frequently. Second, FINRA does not know how parties agreed to serve documents, by email, paper, or other alternative methods, during the pre-pandemic period.

Certain parties may bear incremental burdens over pre-pandemic filing and service practices. FINRA does not know the extent to which, under the proposed rule change, certain parties will incur some costs to scan documents. Anecdotally, FINRA understands that this group is small. The proposals to have a valid email address and to require filing by email are not expected to impose significant new costs because anecdotal evidence suggests that this method of filing was already adopted by most parties to OHO and NAC proceedings before the pandemic.[43] FINRA notes that OHO and the NAC have not received any complaints regarding the temporary amendments on method of service and filing during the pandemic. FINRA also notes that the SEC recently finalized a rule to require electronic filing and service of documents in SEC administrative proceedings.[44] The Commission received only seven comments on the proposed rule and reported that commenters generally supported electronic filing.[45]

The proposal will likely impose a higher cost on parties who have limited access to the internet and to any hardware and software that may be involved in processing the documents. For example, it is unlikely that member firms or current registered representatives would face these challenges, but former registered representatives may. There have been a few such individuals in recent proceedings before OHO and the NAC.[46] The proposal will allow reasonable accommodations for such individuals. Service of an initial complaint on a respondent would not be subject to the proposed rule change on electronic service and filing, mitigating any risk that a respondent would be unaware of the complaint.

The overall benefits and costs of the proposal will depend on the expected volume of the relevant proceedings and the number of respondents associated with these proceedings. As described earlier, there have been only a limited number of new cases or appeals filed annually in OHO and NAC proceedings in the past three years. The majority of these cases or appeals involved only one respondent. Based on these historical numbers, the overall economic impact is likely to be small.

Alternatives Considered

In developing the proposal, FINRA sought to preserve the efficiencies in filing and service practices that were achieved during the pandemic. No significant alternatives to these requirements were considered.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

[43] It can be difficult to assess potential cost increases following the proposal to require service by email because FINRA does not know the extent to which parties agreed to service by email during the pre-pandemic period.

[44] *See supra* note 8.

[45] *See supra* note 8. The comments are available at *https://www.sec.gov/comments/s7-19-15/s71915.shtml.*

[46] For example, over the year 2020, there were 65 OHO filings with registered representatives as the sole respondents. Among them, 21 OHO filings had former registered representatives as respondents. In addition, there were 27 and 26 OHO filings, respectively, with former registered representatives as respondents in year 2019 and 2018.

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2022–009 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2022–009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2022–009 and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[47]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–07955 Filed 4–13–22; 8:45 am]

BILLING CODE 8011–01–P

[47] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94645; File No. SR–CboeEDGX–2022–020]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Applicable to Various Market Data Products

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 1, 2022, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (''EDGX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to amend the fees applicable to various market data products. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*) [sic], at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Market Data section of its Fees Schedule for its equities trading platform (''EDGX Equities''). Particularly, the Exchange proposes to adopt a free trial program for Exchange market data products, effective April 1, 2022.

The Exchange proposes a 30-day free trial for any User or Distributor that subscribes to or distributes, respectively, an Exchange real-time market data product (''Product'') listed on the Fee Schedule for the first time. As proposed, a first-time User would be any entity or individual that has not previously subscribed to a particular Product and a first-time Distributor would be any entity that has not previously distributed, internally or externally, a particular Product. A first-time User or Distributor of a particular Exchange market data product would not be charged any applicable fees listed in the Fee Schedule for that product for the duration of the 30 days.[3] For example, a firm that currently subscribes to EDGX Top would be eligible to receive a free 30-day trial of EDGX Depth, whether in a display-only format or for non-display use. However, a firm that currently receives EDGX Depth for non-display use would not be eligible to receive a free 30-day trial of EDGX Depth in a display-only format. The Exchange would provide the 30-day free trial for each particular product to each first-time User or Distributor once.

The Exchange believes that providing a 30-day free trial to Exchange real-time market data products listed on the Exchange's Fee Schedule would enable potential Users and Distributors to determine whether a particular Exchange market data product provides value to their business models or investment strategies, as applicable, before fully committing to expend development and implementation costs related to the receipt or distribution of that product, and is intended to encourage increased use of the Exchange's market data products by defraying some of the development and implementation costs Users or Distributors would ordinarily have to expend before using a product. The

[3] For example, if a User that has elected to participate in the free trial program for EDGX Top data is approved on April 15, 2022, that User will not be subject to any applicable fees (*i.e.,* User Fee) through May 14, 2022.

Exchange notes that other exchanges have similar free trial programs.[4]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[5] in general, and furthers the objectives of Section 6(b)(4),[6] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data. In addition, the Exchange believes that the proposed rule change is consistent with Section 11(A) of the Act as it supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets, and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.[7] Finally, the proposed rule change is also consistent with Rule 603 of Regulation NMS,[8] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

The Exchange believes that adopting a free trial program for real-time market data products listed in its Fees Schedule is equitable and reasonable. Particularly, providing Exchange real-time market data products to new Users and Distributors free-of-charge for the first 30 days is reasonable because it would allow vendors and subscribers to become familiar with the feeds and determine whether they suit their needs without incurring fees. It is also intended to incentivize Distributors to enlist more Users to subscribe to Exchange market data products in an effort to broaden the products' distribution. Making a new market data product available for free for a trial period is also consistent with offerings of other exchanges. For example, NYSE and Nasdaq offer similar free trial programs.[9]

The Exchange believes the proposal to provide the Exchange market data products to new Users or Distributors free-of-charge for their first 30 days subscribing or distributing the data, as applicable, is equitable and not unfairly discriminatory because it applies to any first-time User or Distributor, regardless of the use they plan to make of the feed. As proposed, any first-time User or Distributor would not be charged any applicable fee listed in the Fee Schedule for any of the Exchange's real-time market data products listed in the Fee Schedule for 30 days. The Exchange believes it is equitable to restrict the availability of this free trial to Users or Distributors that have not previously subscribed to, or distributed, respectively the particular market data product, since Users or Distributors who are current or previous subscribers or Distributors, respectively of that product are already familiar with the product and whether it would suit their needs.

The Exchange believes that the proposed rule change providing for a free trial period to test is not unfairly discriminatory because the financial benefit of the fee waiver would be available to all Users subscribing to, and all Distributors distributing, an Exchange Product for the first time on a free-trial basis. The Exchange believes there is a meaningful distinction between Users and Distributors that are subscribing to or distributing a market data product for the first time, who may benefit from a period within which to set up and test use of the product before it becomes fee liable, and Users and Distributors that are already receiving or distributing the Exchange's market data products and are deriving value from such use. The Exchange believes that the limited period of the free trial would not be unfairly discriminatory to other users of the Exchange's market data products because it is designed to provide a reasonable period of time to set up and test a new market data product. The Exchange further believes that providing a free trial for 30 days would ease administrative burdens for data recipients to subscribe to or distribute a new data product and eliminate fees for a period before such users are able to derive any benefit from the data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment, and its ability to price these data products is constrained by competition among exchanges that offer similar data products to their customers. The Exchange believes that the proposed free trial program does not put any market participants at a relative disadvantage compared to other market participants. As discussed, the proposed trial would apply to first time Users and Distributors on an equal and non-discriminatory basis. Further, the Exchange believes that the proposed program does not impose a burden on competition or on other SROs that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposal would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges are free to lower their prices or provide a free trial to better compete with the Exchange's offering. Indeed, other national securities exchanges already offer similar free trial programs today.[10] The proposed amendments are also designed to enhance competition by providing an incentive to Distributors to enlist new subscribers and Users to subscribe to Exchange real-time market data products.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and paragraph (f) of Rule 19b–4[12] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[4] *See* The Nasdaq Stock Market LLC (''Nasdaq'') Equity 7 Pricing Schedule, Section 112(b)(1) and New York Stock Exchange LLC (''NYSE'') Proprietary Market Data Fees Schedule, General.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78k–1.

[8] *See* 17 CFR 242.603.

[9] *See* Nasdaq Equity 7 Pricing Schedule, Section 112(b)(1) and NYSE Proprietary Market Data Fees Schedule, General.

[10] *See* Nasdaq Equity 7 Pricing Schedule, Section 112(b)(1) and NYSE Proprietary Market Data Fees Schedule, General.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2022–020 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGX–2022–020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2022–020, and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–07947 Filed 4–13–22; 8:45 am]

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[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94648; File No. SR–CboeEDGA–2022–007]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Applicable to Various Market Data Products

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 1, 2022, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (''EDGA'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to amend the fees applicable to various market data products. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Market Data section of its Fees Schedule for its equities trading platform (''EDGA Equities''). Particularly, the Exchange proposes to adopt a free trial program for Exchange market data products, effective April 1, 2022.

The Exchange proposes a 30-day free trial for any User or Distributor that subscribes to or distributes, respectively, an Exchange real-time market data product (''Product'') listed on the Fee Schedule for the first time. As proposed, a first-time User would be any entity or individual that has not previously subscribed to a particular Product and a first-time Distributor would be any entity that has not previously distributed, internally or externally, a particular Product. A first-time User or Distributor of a particular Exchange market data product would not be charged any applicable fees listed in the Fee Schedule for that product for the duration of the 30 days.[3] For example, a firm that currently subscribes to EDGA Top would be eligible to receive a free 30-day trial of EDGA Depth, whether in a display-only format or for non-display use. However, a firm that currently receives EDGA Depth for non-display use would not be eligible to receive a free 30-day trial of EDGA Depth in a display-only format. The Exchange would provide the 30-day free trial for each particular product to each first-time User or Distributor once.

The Exchange believes that providing a 30-day free trial to Exchange real-time market data products listed on the Exchange's Fee Schedule would enable potential Users and Distributors to determine whether a particular Exchange market data product provides value to their business models or investment strategies, as applicable, before fully committing to expend development and implementation costs related to the receipt or distribution of that product, and is intended to encourage increased use of the Exchange's market data products by defraying some of the development and implementation costs Users or Distributors would ordinarily have to expend before using a product. The

[3] For example, if a User that has elected to participate in the free trial program for EDGA Top data is approved on April 15, 2022, that User will not be subject to any applicable fees (*i.e.,* User Fee) through May 14, 2022.

Exchange notes that other exchanges have similar free trial programs.[4]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[5] in general, and furthers the objectives of Section 6(b)(4),[6] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data. In addition, the Exchange believes that the proposed rule change is consistent with Section 11(A) of the Act as it supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets, and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.[7] Finally, the proposed rule change is also consistent with Rule 603 of Regulation NMS,[8] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

The Exchange believes that adopting a free trial program for real-time market data products listed in its Fees Schedule is equitable and reasonable. Particularly, providing Exchange real-time market data products to new Users and Distributors free-of-charge for the first 30 days is reasonable because it would allow vendors and subscribers to become familiar with the feeds and determine whether they suit their needs without incurring fees. It is also intended to incentivize Distributors to enlist more Users to subscribe to Exchange market data products in an effort to broaden the products' distribution. Making a new market data product available for free for a trial period is also consistent with offerings of other exchanges. For example, NYSE and Nasdaq offer similar free trial programs.[9]

The Exchange believes the proposal to provide the Exchange market data products to new Users or Distributors free-of-charge for their first 30 days subscribing or distributing the data, as applicable, is equitable and not unfairly discriminatory because it applies to any first-time User or Distributor, regardless of the use they plan to make of the feed. As proposed, any first-time User or Distributor would not be charged any applicable fee listed in the Fee Schedule for any of the Exchange's real-time market data products listed in the Fee Schedule for 30 days. The Exchange believes it is equitable to restrict the availability of this free trial to Users or Distributors that have not previously subscribed to, or distributed, respectively the particular market data product, since Users or Distributors who are current or previous subscribers or Distributors, respectively of that product are already familiar with the product and whether it would suit their needs.

The Exchange believes that the proposed rule change providing for a free trial period to test is not unfairly discriminatory because the financial benefit of the fee waiver would be available to all Users subscribing to, and all Distributors distributing, an Exchange Product for the first time on a free-trial basis. The Exchange believes there is a meaningful distinction between Users and Distributors that are subscribing to or distributing a market data product for the first time, who may benefit from a period within which to set up and test use of the product before it becomes fee liable, and Users and Distributors that are already receiving or distributing the Exchange's market data products and are deriving value from such use. The Exchange believes that the limited period of the free trial would not be unfairly discriminatory to other users of the Exchange's market data products because it is designed to provide a reasonable period of time to set up and test a new market data product. The Exchange further believes that providing a free trial for 30 days would ease administrative burdens for data recipients to subscribe to or distribute a new data product and eliminate fees for a period before such users are able to derive any benefit from the data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment, and its ability to price these data products is constrained by competition among exchanges that offer similar data products to their customers. The Exchange believes that the proposed free trial program does not put any market participants at a relative disadvantage compared to other market participants. As discussed, the proposed trial would apply to first time Users and Distributors on an equal and non-discriminatory basis. Further, the Exchange believes that the proposed program does not impose a burden on competition or on other SROs that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposal would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges are free to lower their prices or provide a free trial to better compete with the Exchange's offering. Indeed, other national securities exchanges already offer similar free trial programs today.[10] The proposed amendments are also designed to enhance competition by providing an incentive to Distributors to enlist new subscribers and Users to subscribe to Exchange real-time market data products.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and paragraph (f) of Rule 19b–4[12] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[4] *See* The Nasdaq Stock Market LLC (''Nasdaq'') Equity 7 Pricing Schedule, Section 112(b)(1) and New York Stock Exchange LLC (''NYSE'') Proprietary Market Data Fees Schedule, General.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78k–1.

[8] *See* 17 CFR 242.603.

[9] *See* Nasdaq Equity 7 Pricing Schedule, Section 112(b)(1) and NYSE Proprietary Market Data Fees Schedule, General.

[10] *See* Nasdaq Equity 7 Pricing Schedule, Section 112(b)(1) and NYSE Proprietary Market Data Fees Schedule, General.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGA–2022–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGA–2022–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGA–2022–007, and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Jill M. Peterson,

Assistant Secretary.

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[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94649; File No. SR–ICEEU–2022–008]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Operational Risk Management Policy and Risk Identification Framework

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 31, 2022, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared primarily by ICE Clear Europe. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed amendments is for ICE Clear Europe to (i) modify its Operational Risk Management Policy (the ''Operational Risk Management Policy'') to update the Clearing House's operational risk management practices, and (ii) adding to the Clearing House's rule framework the Risk Identification Framework (''Risk Identification Framework'') which is a document that provides ICE Clear Europe with a structure to explore, identify and monitor risks. The updates would also make certain other amendments to remove outdated provisions and to make certain other non-substantive amendments.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is proposing to amend its Operational Risk Management Policy to make certain clarifications and enhancements to (i) ICE Clear Europe's approach to remediating identified control vulnerabilities and monitoring, (ii) transition to dynamic risk assessment where each risk would be assessed at least annually via a rolling review process, and (iii) the operational risk review process by linking it with the Enterprise Risk Register (described further below), as well as descriptive updates to the Enterprise Risk Register. The appendices to the Operational Risk Management Policy would also be updated to provide certain additional descriptive detail relating to current practices, including titles and impact guidelines and guidance charts in Appendix C. Various other typographical, clarificatory and stylistic improvements would also be made.

ICE Clear Europe is also proposing to add to the Clearing House's set of rules the Risk Identification Framework which would provide the Board with a structure to assist it in exploring, identifying and monitoring risks, as described below.

I. Operational Risk Management Policy

The overall description of operational risk management contained in Section 3 would be clarified to include management as well as identification, management [sic], monitoring and reporting of risk. The same section would also provide that risks would be documented within the Enterprise Risk Register.

Section 3.1 (previously titled ''Risk Identification'') would be deleted in its entirety and replaced with a new section titled ''Enterprise Risk Register''. The section would describe the Enterprise Risk Register (attached to the policy as Appendix A, and also referred to as the Risk Register Dashboard) which would serve as an inventory of the material risks faced by the Clearing House, incorporating the Risk Taxonomy (as discussed below). The section would also describe the purpose of the Enterprise Risk Register, which would be to strengthen the businesses' understanding of their risks and allow them to demonstrate to the relevant risk committees and the Board that the risks are managed. The section would also describe the responsibilities with respect to the Enterprise Register, including that the Risk Owners would be responsible for updating and

maintaining their assigned risks in the Enterprise Risk Register, as well as discuss the responsibilities of the Risk Oversight Department (''ROD''), the Executive Risk Committee (''ERC'') and the Board Risk Committee (''BRC''). The section would also describe the register (as attached as Appendix A to the policy) which would be a dynamically updated living statement of the Clearing House's risks that form part of the ERC and BRC standing agenda. Each risk would be assessed at least annually through a rolling review process.

Section 3.2 (Risk Assessment) would be updated to describe the following five components for facilitating the effective management of enterprise risk: (1) Risk Identification, (2) Level 3 Risk Assessment,[3] (3) Risk Management, (4) Risk Monitoring and (5) Risk Reporting, as described further below. Stylistic and formatting updates would be made to this section to clarify that the five aforementioned components fall under the umbrella of risk assessment.

Firstly, a new subsection 3.2.1 (Risk Identification) would be added and would describe risk identification as the process by which each department identifies risks which should be documented within the Risk Taxonomy and the Enterprise Risk Register. The Risk Taxonomy is the list of risks that the Clearing House is exposed to which is reviewed annually for completeness; those risks (and the related control assessment of those risks) are reflected in the Enterprise Risk Register. The amendments would also add that the risk identification could be performed more frequently than annually as part of a dynamic update.

The substance of previous Section 3.3 (Risk Response) would be replaced by new subsections 3.2.2, 3.2.3 and 3.2.3, as described herein. However, the ownership and nature of the Clearing House's risk responses would be substantively unchanged. New subsection 3.2.2. (Control Assessment) would provide descriptions of the Clearing House's risk assessment policies and processes, including the roles of Risk Owners. Risk Owners would be required to assess the expected level of mitigation that each control is expected to provide (High/Medium/Low—more information would be provided in Appendix D), as well as the effectiveness of each control (Satisfactory/Needs Improvement/Unsatisfactory). Key controls would be considered for control monitoring to further review effectiveness of controls. The amendments provide that the control assessment process should be performed at least once a year or more frequently as part of a dynamic control assessment. Dynamic control assessments would be performed to reflect material risk changes. Enterprise Risk Management (''ERM'') would be responsible for providing review and challenge of the Risk Owners control assessment. The 'Worst-of Principle' would be applied to Level 1 and 2 ratings, where the parent overall control rating would adopt the 'worst-of' overall control rating of the level below.

The subsection describing the Clearing House's risk assessment processes (now Section 3.2.3) would be updated to provide the role of inherent and residual risk assessments (attached as Appendix C to the policy). In the absence of mitigating controls risks identified are assessed by Risk Owners on an Inherent Risk basis and a Residual Risk basis (taking into consideration mitigating controls) at Level 3. To determine the Residual Risk, Risk Owners would take account of key risk data points.

The risk assessment process would be performed at least once a year through a rolling review process or more frequently as part of a dynamic risk assessments which are performed to reflect material risk changes. ERM would be responsible for providing review and challenge of the Risk Owners risk assessment. The 'Worst-of Principle' would be applied to Level 1 and 2 ratings, where the Parent Overall Control Rating would adopt the 'worst-of' rating of the level below across both inherent and residual risk.

New subsection 3.2.4 (Risk Management) would describe the Clearing House's risk management policies. Residual risks above agreed thresholds would require remediation actions to address the control vulnerability and reduce the level of residual risk to an acceptable level. Such thresholds refer to the Board-approved risk appetite metrics which are currently set as Medium (see Appendix B for Risk Assessment Ratings Grid). Any Risks assessed by the Risk Owners as High or Very High would require remediation actions, which will depend on the particular circumstances and risks involved. Proposed remediations would be escalated to senior management and applicable risk committees or Board. In certain circumstances, risk acceptance may be deemed appropriate dependent upon the Clearing House's risk appetite and Board approval. Recommendations would be assigned a priority rating and remediation timeline as a function of the expected level of risk mitigation and the control effective rating (attached as Appendix E). Remediation recommendations would be entered in the Issue Problems and Threat workflow unless already formally tracked.

The section describing risk monitoring (now subsection 3.2.5) would be updated to provide that in order to ensure that controls identified during the assessment are operating effectively and performing in line with the assessed control ratings; the Clearing House would perform periodic control monitoring on controls considered as ''Key'' which would be ''High'' mitigating controls mapped against ''Very High'' or ''High'' Inherent Risks. ERM would coordinate with the First, Second and Third Lines to develop control monitoring plans for key controls (described further in Appendix D).

Additionally, a new paragraph would be added providing that to ensure that key controls identified during the assessment are operating effectively, the Clearing House would perform control monitoring, and include a description of such processes. Control monitoring would be performed by either the First Line (Clearing Risk Team), the Second Line (Risk Oversight Department), the Clearing House's internal audit team or independent third parties. The results would be reviewed by the Chief Risk Officer and presented to the senior management team and other governance committees as appropriate.

The amendments would provide that Risk Owners would monitor operational risks on an on-going rather than a daily basis. They would also clarify that the Risk Oversight Department (''ROD'') would monitor risks daily or monthly (rather than only daily) and would monitor operational incidents raised by the Risk Owners.

The section describing risk reporting (now subsection 3.2.6) would be revised to include a new paragraph that describes the approval process for the Enterprise Risk Register as being approved monthly at each ERC and reported to each BRC and Board meeting. Stylistic changes would also be made to this section to replace certain terms with their acronym in order to aid with readability. Additionally, information regarding the roles of the Board, ERC and other groups that has been moved to other sections the document would be deleted from this section in order to avoid superfluousness.

Section 4.3 (Oversight of the Policy) would be updated to provide that the

[3] The risk level (Level 1, 2 or 3) represents a hierarchy of risks with Level 3 being the level at which risks are assessed by the relevant Risk Owners. Level 1 and 2 risks are aggregated from Level 3 risk ratings and are listed in the Enterprise Risk Register.

document would be subject to the oversight of the ROD (and not also the Audit Committee).

Descriptive titles would be added to the appendices in order to aid with readability. Additionally, a table would be added to Appendix C that would describe the meaning of certain impact guidelines (severe/major/moderate/minor/incidental), the numerical score assigned to such guidelines, and the guidance applied with respect to the risk posed to such impact. A description would be added to Appendix G—Risk Mitigation to provide that the methodology to determine ICE Clear Europe's residual risk involves assessing the impact of ICE Clear Europe's control landscape on its inherent risks as shows by the matrix set out in the appendix.

II. Risk Identification Framework

The amendments would include the formal adoption of the Risk Identification Framework that are intended to formalize certain practices relating to the identification of risks. Section 1 (Introduction) of the Risk Identification Framework would provide an overarching description of the document and its purpose. The purpose of the Risk Identification Framework is to provide the Board with a structure to explore, identify and monitor risks as well as ensure that risk tolerance is articulated and documented, with responsibilities and accountabilities clearly assigned, as described further below. This framework would also support the Board in risk avoidance, mitigation or acceptance.

Section 2 (Components of the Risk Identification Framework) would describe the four components of the Risk Identification Framework: Risk Taxonomy, which provides a single universal risk structure, terminology and hierarchy; Enterprise Risk Register, which serves as an inventory of the material risks faced by the Clearing House; Risk Assessment, which requires risk owners to rate inherent risk, overall control rating and residual risk for each level 3 risk; and Emerging Risk Assessment, which facilitates ongoing identification, discussion and mitigation of emerging risks as Board and executive level. The subsections that follow would provide further descriptions of each component and the responsibilities and frequency relating to review of each.

Section 3 (Review and Governance) would describe the documentation ownership and governance processes in respect of the Risk Identification Framework. The document would be owned by the Chief Risk Officer, any material changes to the document would require Executive Risk Committee and Board Approval. The Executive Risk Committee and Board would review the Risk Identification Framework annually.

The appendices referenced throughout the document would follow and would include appendices providing for a risk register dashboard, rating guidance impact and likelihood and emerging business risks.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments to the Operational Risk Management Policy and the adoption of the Risk Identification Framework are consistent with the requirements of Section 17A of the Act [4] and the regulations thereunder applicable to it. In particular, Section 17A(b)(3)(F) of the Act [5] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest.

The proposed changes to the Operational Risk Management Policy and the adoption of the Risk Identification Framework are designed to strengthen ICE Clear Europe's tools to manage the risk of losses resulting from operational errors or failures. The amendments and adoption would update and clarify the processes, controls and escalations with respect to the testing and reviewing of the Clearing House's operations as well as outline the responsibilities of the Clearing House's committees, management and the Board in relation to each document. Through better managing risks in operational failure scenarios providing the policies and framework to identify, manage and monitor such risks, the proposed amendments to the Operational Risk Management Policy and the adoption of the Risk Identification Framework would promote the stability of the Clearing House and the prompt and accurate clearance and settlement of cleared contracts. The enhanced risk management is therefore also generally consistent with the protection of investors and the public interest in the safe operation of the Clearing House. (ICE Clear Europe would not expect the amendments to affect the safeguarding of securities and funds in ICE Clear Europe's custody or control or for which it is responsible.) Accordingly, the amendments satisfy the requirements of Section 17A(b)(3)(F).[6]

The amendments to the Operational Risk Management Policy and the adoption of the Risk Identification Framework are also consistent with relevant provisions of Rule 17Ad–22.[7] Rule 17Ad–22(e)(3)(i) provides that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonable designed to, as applicable [. . .] identify, measure, monitor and manage the range of risks that arise in or are borne by the covered clearing agency''.[8] As set forth above, the amendments to the Operational Risk Management Policy are intended to clarify and enhance the Clearing House's policies and practices that address operational and other risks, including with respect to the ongoing review, categorization and assessment of risks faced by the Clearing House. The adoption of the Risk Identification Framework would assist the Board in evaluation of risks and consequently facilitate risk avoidance, mitigation or acceptance by the Clearing House. The amendments would thus strengthen the management of operational risks and risk management more generally. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad–22(e)(3)(i).[9]

Rule 17Ad–22(e)(2) provides that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonable designed to, as applicable [. . .] provide for governance arrangements that are clear and transparent'' [10] and ''[s]pecify clear and direct lines of responsibility''.[11] The amendments to the Operational Risk Management Policy and the adoption of the Risk Identification Framework each would clarify or provide the responsibilities of the Clearing House's committees, management and the Board in relation to each such document. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad–22(e)(2).[12]

The proposed amendments are also consistent with Rule 17Ad–22(e)(17)(i),

[4] 15 U.S.C. 78q–1.

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] 17 CFR 240.17Ad–22.

[8] 17 CFR 240.17Ad–22(e)(3)(i).

[9] 17 CFR 240.17Ad–22(e)(3)(i).

[10] 17 CFR 240.17Ad–22(e)(2)(i).

[11] 17 CFR 240.17Ad–22(e)(2)(v).

[12] 17 CFR 240.17Ad–22(e)(2).

which provides that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonable designed to, as applicable [. . .] manage the clearing agency's operational risks by identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls''.[13] The amendments to the Operational Risk Management Policy facilitate ongoing identification of operational risks and better mitigate their impact through improved procedures and controls resulting from more detailed governance and review processes with respect to risk identification, assessment, management, monitoring and reporting. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad–22(e)(17)(i).[14]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments are being adopted to update and clarify the Clearing House's Operational Risk Management Policy and to adopt the Risk Identification Framework, all of which relate to the Clearing House's internal processes for operational risk management. ICE Clear Europe does not believe the amendments and adoption would affect the costs of clearing, the ability of market participants to access clearing, or the market for clearing services generally. Therefore, ICE Clear Europe does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any written comments received with respect to the proposed rule change and adoption.

[13] 17 CFR 240.17Ad–22(e)(17)(i).

[14] 17 CFR 240.17Ad–22(e)(17)(i).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2022–008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2022–008. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.* All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2022–008 and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94650; File No. SR–ICC–2022–004]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the ICC Recovery Plan and the ICC Wind-Down Plan

April 8, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4,[2] notice is hereby given that on April 1, 2022, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the ICC Recovery Plan and the ICC Wind-Down Plan (collectively, the ''Plans''). These revisions do not require any changes to the ICC Clearing Rules (the ''Rules'').

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes revising the ICC Recovery Plan and the ICC Wind-Down Plan, which serve as plans for the recovery and orderly wind-down of ICC necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, consistent with Rule 17Ad–22(e)(3)(ii).[3] ICC proposes to make such changes effective following Commission approval of the proposed rule change. The proposed rule change is described in detail as follows.

ICC Recovery Plan

Consistent with the regulations applicable to ICC, the Recovery Plan is designed to establish ICC's actions to maintain its viability as a going concern to address any uncovered credit loss, liquidity shortfall, capital inadequacy, or business, operational or other structural weakness that threatens ICC's viability. ICC proposes general updates and edits to promote clarity and to ensure that the information provided is current. The proposed amendments reflect and relate to changes that impacted ICC in the past year, including changes to the composition of the ICC Board of Managers (collectively, the ''Board'' and each, a ''Manager'') and the responsibilities and membership composition of internal committees.

ICC proposes general updates to ensure that the information in the Recovery Plan is current. In Section I and throughout the document, the proposed changes specify that the information provided is current as of December 31, 2021, unless otherwise stated. Namely, the proposed changes ensure that relevant information regarding ICC for recovery planning, such as information about ICC's ownership and operation, is current with respect to:

- Activities of Intercontinental Exchange, Inc. (''ICE'' or collectively, the ''ICE Group'' of affiliated companies with ICE as the ultimate parent) in Section II.A;
- clearing Index Swaptions by ICC in Section IV.A;
- data regarding ICC revenues, volumes, and expenses in Section IV.D;
- ICC personnel and facilities in Section VI.A;
- financial resources for recovery in Section X;
- ICC and ICE Group financial information in Section XI; and
- Financial service providers (''FSPs'') that hold Clearing Participant (''CP'') cash and collateral in Appendix C in Section XIII.

Additionally, ICC proposes to amend the composition of the Board and the descriptions of internal committees to reflect changes that impacted ICC in 2021. In Section IV.C.1, ICC proposes to change the Board size from eleven to nine managers, consistent with the adoption of the Sixth Amended and Restated Operating Agreement of ICC in 2021 (the ''Sixth A&R Operating Agreement''), and to revise Manager titles as necessary.[4] In Section IV.C.3, the proposed changes update the responsibilities and membership composition of the Participant Review Committee (''PRC'') and Credit Review Subcommittee of the PRC (''CRS''), which are internal committees that assist in fulfilling counterparty review responsibilities, consistent with changes to their charters in 2021.[5] ICC proposes corresponding changes in Section VI.B.1 to describe the advisory role of the CRS in making recommendations to the PRC and the role of the PRC in approving FSPs.

ICC proposes additional updates to promote clarity and consistency in the Recovery Plan. Amended Section IV.E.4 notes that ICC monitors FSPs daily, intraday, and monthly, consistent with the processes described in the ICC Counterparty Monitoring Procedures.[6] In Section VII.B, ICC proposes to remove a metric that is no longer utilized to measure ICC performance and to update a reference to a policy section. Amended Section VII.C specifies that ICC will make required disclosures pursuant to applicable regulations once the Recovery Plan is initiated and includes updated regulatory contacts. In Section VIII.B.2, ICC proposes minor language clarifications in describing the purpose of its Liquidity Risk Management Framework. In Section VIII.B.3, ICC proposes updates regarding the insurance coverage maintained at the ICE Group level, which may be used as a recovery tool in a non-CP default scenario.

ICC proposes changes related to seeking additional capital from the ICE Group in Section VIII.B.3, which is another recovery tool that may be used in a non-CP default scenario. The proposed changes include updated financial information, which is intended to establish that the ICE Group is capable of making such infusion. Given the changes in Board composition, ICC proposes revised procedures for seeking such additional capital, including the individual within the ICE Group with whom such discussions would begin. The proposed changes identify the role of this individual within the ICE Group and update the composition of certain ICE Group boards. Additionally, ICC proposes to include updated financial information that is relevant to the execution of other recovery tools that may be utilized in a non-CP default scenario.

ICC proposes additional minor edits for clarity and consistency. In Section IX, ICC proposes to clarify that the Recovery Plan is made available to regulators in accordance with relevant regulations and to incorporate a reference to the ICC Default Management Procedures for details on ICC's default management testing. In Section XIV, the proposed changes update the index of exhibits with the current versions of policies and procedures, consistent with updated footnote references. Finally, ICC proposes minor typographical fixes in the Recovery Plan as well as conforming changes in in the Wind-Down Plan, including updates to entity names, and grammatical and formatting changes.

ICC Wind-Down Plan

The Wind-Down Plan is designed to establish how ICC could be wound-down in an orderly manner. ICC proposes corresponding changes to the Wind-Down Plan. ICC proposes general updates and edits to promote clarity and to ensure that the information provided is current. The proposed amendments reflect and relate to changes that have impacted ICC in the past year, including changes to the composition of the Board.

[3] 17 CFR 240.17Ad–22(e)(3)(ii).

[4] See SR–ICC–2021–017 for additional information on the adoption of the Sixth A&R Operating Agreement.

[5] See SR–ICC–2021–015 for additional information on the roles and responsibilities of the PRC and CRS.

[6] See SR–ICC–2021–021 for additional information on ICC's counterparty monitoring processes and procedures.

ICC proposes general updates to ensure that the information in the Wind-Down Plan is current. In Section I and throughout the document, the proposed changes specify that the information provided is current as of December 31, 2021, unless otherwise stated. The proposed revisions ensure that relevant information regarding ICC for wind-down planning, such as information about ICC's ownership and operation, is current with respect to:

- Activities of ICE in Section II.A;
- ICC personnel and facilities in Section VII.C;
- financial resources to support wind-down in Section IX; and
- FSPs that hold CP cash and collateral in Appendix C in Section XI.

ICC also proposes amendments with respect to the composition of the Board to reflect changes that impacted ICC in 2021. In Section IV.B.1, ICC proposes to change the Board size from eleven to nine managers, consistent with the adoption of the Sixth A&R Operating Agreement in 2021, and revise manager titles as needed.

ICC proposes additional updates and edits to promote clarity and consistency in the Wind-Down Plan. Amended Section VI.A specifies that ICC will make required disclosures pursuant to applicable regulations once the decision to wind-down is made and includes updated regulatory contacts. Furthermore, given the changes in Board composition, ICC proposes revised procedures for seeking certain required consultations or approvals identified in the Wind-Down Plan, including the individual within the ICE Group with whom such discussions would begin. The proposed changes identify the role of this individual within the ICE Group and include information on the composition of a relevant ICE Group board. In Section X, ICC proposes to note that the Wind-Down Plan is made available to regulators in accordance with relevant regulations and to clarify the testing of the Wind-Down Plan. In Section XII, the proposed changes update the index of exhibits with the current versions of policies and procedures, consistent with updated footnote references.

(b) Statutory Basis

ICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act [7] and the regulations thereunder applicable to it, including the applicable standards under Rule 17Ad–22.[8] In particular, Section 17A(b)(3)(F) of the Act [9] requires that the rule change be consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest.

ICC believes the proposed changes would enhance its ability to effectuate a successful recovery as well as to execute an orderly wind-down by providing updates and additional clarity with respect to ICC's recovery and wind-down processes and procedures. As discussed herein, the proposed revisions ensure that relevant information regarding ICC for recovery and wind-down planning is current, including updated information regarding personnel and facilities, finances and operations, and financial resources for recovery and wind-down. The proposed amendments also reflect and relate to changes that impacted ICC in the past year, including changes to the Board composition from the adoption of the Sixth A&R Operating Agreement and the responsibilities and membership composition of internal committees based on their amended charters. Such changes ensure that the Plans clearly and accurately set out the functions of the Board and committees to remain effective and to ensure that these groups carry out their required functions. To support and enhance the implementation of the Plans, additional language clarifications or edits are included so that the Plans remain up-to-date, transparent, and focused on clearly articulating the policies and procedures used to support ICC's recovery and wind-down efforts. Such revisions include additional details regarding required disclosures, references to relevant policies, updated information regarding recovery tools, and amended language that is intended to be more precise. The Plans would thus promote ICC's ability to continue providing clearing services with as little disruption as possible, and should continuation not be feasible, promote ICC's ability to discontinue clearing services in an orderly manner with minimum negative impact to the marketplace and stakeholders. Accordingly, in ICC's view, the proposed rule change is consistent with the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[10]

The proposed rule change would also satisfy the relevant requirements of Rule 17Ad–22.[11] Rule 17Ad–22(e)(2) [12] requires ICC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are (i) clear and transparent; (iii) support the public interest requirements of Section 17A of the Act [13] applicable to clearing agencies, and the objectives of owners and participants; and (v) specify clear and direct lines of responsibility. The Plans clearly and transparently set forth the governance arrangements that are relevant to recovery and wind-down, including the roles and responsibilities of the Board, applicable committees, and management. The Plans assign and document responsibility and accountability for key recovery and wind-down decisions, such as activating the Recovery Plan and deciding to wind-down the business, and require consultation or approval from relevant parties. Given the change in Board composition, the proposed changes update procedures for seeking additional capital in a recovery scenario and update procedures for seeking required consultations or approvals in a wind-down scenario from the ICE Group. The amendments ensure that the procedures for implementing these actions in a recovery or wind-down scenario are up-to-date, transparent, and effective such that responsible parties can act promptly without unnecessary delay. Moreover, the governance arrangements in the Plans promote the safety and efficiency of ICC and support the public interest requirements in Section 17A of the Act [14] applicable to clearing agencies, and the objectives of owners and participants, by describing the roles and responsibilities of relevant stakeholders to ensure that such groups or individuals are able to discharge their responsibilities. As such, ICC believes that the proposed rule change is consistent with the requirements of Rule 17Ad–22(e)(2).[15]

Rule 17Ad–22(e)(3)(ii) [16] requires ICC to establish, implement, maintain, and enforce written policies and procedures

[7] 15 U.S.C. 78q–1.

[8] 17 CFR 240.17Ad–22.

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] *Id.*

[11] 17 CFR 240.17Ad–22.

[12] 17 CFR 240.17Ad–22(e)(2).

[13] 15 U.S.C. 78q–1.

[14] *Id.*

[15] 17 CFR 240.17Ad–22(e)(2).

[16] 17 CFR 240.17Ad–22(e)(3)(ii).

reasonably designed to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by ICC, which includes plans for the recovery and orderly wind-down of ICC necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses. The Recovery Plan continues to establish ICC's actions to maintain its viability as a going concern to address any uncovered credit loss, liquidity shortfall, capital inadequacy, or business, operational or other structural weakness that threatens ICC's viability. The Wind-Down Plan continues to establish how ICC could be wound-down in an orderly manner should its recovery efforts fail. As described above, the proposed changes include updates and edits to promote clarity and to ensure that the information in the Plans is current, such as updated information regarding financial resources for recovery and wind-down, updated information regarding recovery tools, including updated procedures for seeking additional capital from the ICE Group, and updated procedures for seeking required consultations or approvals in a wind-down scenario. In ICC's view, such changes would ensure that the Plans remain useful and effective in a recovery and wind-down scenario. The proposed rule change would thus promote ICC's ability to carry out a successful recovery or orderly wind-down, consistent with the requirements of Rule 17Ad–22(e)(3)(ii).[17]

Rule 17Ad–22(e)(15)[18] requires ICC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to identify monitor, and manage ICC's general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that ICC can continue operations and services as a going concern if those losses materialize, including by (i) determining the amount of liquid net assets funded by equity based upon its general business risk profile and the length of time required to achieve a recovery or orderly wind-down, as appropriate, of its critical operations and services if such action is taken; (ii) holding liquid net assets funded by equity equal to the greater of either (x) six months of ICC's current operating expenses, or (y) the amount determined by the Board to be sufficient to ensure a recovery or orderly wind-down of critical operations and services of ICC, as contemplated by the plans established under Rule 17Ad–22(e)(3)(ii);[19] and (iii) maintain a viable plan, approved by the Board and updated at least annually, for raising additional equity should its equity fall close to or below the amount required under Rule 17Ad–22(e)(15)(ii).[20] The Plans continue to analyze ICC's particular circumstances and risks to ensure that ICC maintains financial resources necessary to implement both Plans and that ICC remains in compliance with all regulatory capital requirements. The Plans include updated information on the financial resources maintained by ICC for recovery and to support wind-down in compliance with relevant regulations and include procedures to follow in case of any shortfall. Such changes continue to ensure that the Plans remain accurate and useful and that ICC holds sufficient liquid net assets to achieve recovery or orderly wind-down. As such, ICC believes that the proposed rule change is consistent with the requirements of Rule 17Ad–22(e)(15).[21]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition. The proposed changes to the Plans will apply uniformly across all market participants. The changes are being proposed to promote clarity and ensure that the information provided is current in the Plans. ICC does not believe the amendments would affect the costs of clearing or the ability of market participants to access clearing. Therefore, ICC does not believe the proposed rule change would impose any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ICC–2022–004 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2022–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation*.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not

[17] *Id.*

[18] 17 CFR 240.17Ad–22(e)(15).

[19] 17 CFR 240.17Ad–22(e)(3)(ii).

[20] 17 CFR 240.17Ad–22(e)(15)(ii).

[21] 17 CFR 240.17Ad–22(e)(15).

redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2022–004 and should be submitted on or before May 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–07951 Filed 4–13–22; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 11708]

30-Day Notice of Proposed Information Collection: MyTravelGov

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to May 16, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to CA/EX Special Assistant Robin Patzelt, U.S. Department of State, Bureau of Consular Affairs, Office of the Executive Director, SA–17, 7th Floor, Washington, DC 20522–1707, who may be reached on 202–485–7365 or at *PublicCommentsEX@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* MyTravelGov.
- *OMB Control Number:* None.
- *Type of Request:* New Collection.
- *Originating Office:* Bureau of Consular Affairs, Office of the Executive Director (CA/EX).
- *Form Number:* No form.
- *Respondents:* Individuals.
- *Estimated Number of Respondents:* 4,128,741 annually.
- *Estimated Number of Responses:* 4,128,741 annually.
- *Average Time per Response:* Five minutes.
- *Total Estimated Burden Time:* 344,062 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

MyTravelGov is an electronic account creation and validation portal. U.S. citizens who wish to submit applications for consular services online (electronic applications) instead of submitting paper applications must create a unique user account through MyTravelGov. The unique user account will safeguard the submission and storage of personally identifiable information necessary to process an online application. The information collected will also be used by servers to validate subsequent log-ons to the unique user account or attempts to reset the account password to ensure the security and integrity of accounts.

Methodology

Information is collected when an individual logs on to the MyTravelGov web portal and elects to create a unique user account.

Kevin E. Bryant,

Deputy Director, Office of Directives Management, Department of State.

[FR Doc. 2022–08047 Filed 4–13–22; 8:45 am]

BILLING CODE 4710–06–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36601]

Great Basin and Northern Railroad—Change in Operators Exemption—in Elko and White Pine Counties, Nev.

Great Basin and Northern Railroad (Great Basin), a Class III rail carrier, has filed a verified notice of exemption pursuant to 49 CFR 1150.41 to assume operations over 127 miles of rail line between milepost 0.0 at or near Cobre, Nev., and milepost 127.0 at or near McGill Junction in White Pine County, Nev. (the Line).[1] The Line is owned by the City of Ely (the City) and the Nevada Northern Railway Foundation (the Foundation) and currently is operated by S&S Shortline Leasing, LLC (S&S). Great Basin states that it has recently reached an agreement with the City and the Foundation to replace S&S as the operator over the Line, and that S&S has agreed to cooperate in this change.

Great Basin states that it currently possesses Board authorization to operate a connecting line extending from milepost 127.0 to milepost 146.1 at or near Keystone, Nev., and two branch lines connecting to that line segment. *See Great Basin & N. R.R.—Change in Operators Exemption—City of Ely,* FD 34506 (STB served June 7, 2004); *Great Basin & N. R.R.—Change in Operators Exemption—City of Ely,* FD 36549 (STB served Nov. 27, 2020).

Great Basin certifies that the proposed transaction does not involve a provision or agreement that may limit future interchange with a third-party connecting carrier. Great Basin also certifies that its projected revenues as a result of the transaction will not result in the creation of a Class I or Class II rail carrier and will not exceed $5 million.

Under 49 CFR 1150.42(b), a change in operator requires that notice be given to shippers. Great Basin states, however, that there are no customers on the Line.

The transaction may be consummated on or after April 28, 2022, the effective date of the exemption (30 days after the verified notice was filed).

[22] 17 CFR 200.30–3(a)(12).

[1] Great Basin states the STB previously authorized S&S Shortline Leasing, LLC, to operate the Line in *S&S Shortline Leasing, LLC—Operation Exemption—City of Ely, Nev.,* FD 35284 (STB served Aug. 14, 2009).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than April 21, 2022 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36601, should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, a copy of each pleading must be served on Great Basin's representative, Jeffrey O. Moreno, Thompson Hine LLP, 1919 M Street NW, Suite 700, Washington, DC 20036.

According to Great Basin, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: April 11, 2022.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Credit.

[FR Doc. 2022–08004 Filed 4–13–22; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Rescission of the Notice of Intent for a Supplemental Environmental Impact Statement: Erie and Cattaraugus Counties, NY

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The FHWA is issuing this notice to advise the public that we are rescinding the Notice of Intent (NOI) to prepare a Supplemental Environmental Impact Statement (SEIS) for the highway improvement project: US Route 219 Springville to Salamanca, NY Route 39 to NY Route 17 (Interstate 86), Erie and Cattaraugus Counties, New York [New York State Department of Transportation (NYSDOT) Project Identification Number 5101.84].

FOR FURTHER INFORMATION CONTACT: Richard J. Marquis, Division Administrator, FHWA, New York Division, Leo W. O'Brien Federal Building, 11A Clinton Avenue, Suite 719, Albany, New York 12207, Telephone: (518) 431–4127; or Francis P. Cirillo, Regional Director, New York State Department of Transportation, 100 Seneca Street, Buffalo, New York 14203, Telephone: (716) 847–3238.

SUPPLEMENTARY INFORMATION: The FHWA issued a Final Environmental Impact Statement (FEIS) and Record of Decision (ROD) for the US Route 219 Springville to Salamanca project in 2003. The FHWA, in cooperation with the NYSDOT, subsequently intended to prepare a SEIS to supplement the 2003 FEIS. The NOI to prepare a SEIS was published in the **Federal Register** on August 18, 2009, at 74 FR 41781.

The purpose of the project, as presented in the 2003 FEIS, was to improve capacity, address safety deficiencies, and eliminate a two-lane corridor gap between Springville and Salamanca. The SEIS would have evaluated the effects of a proposal to improve the US Route 219 highway between the Town of Ashford and I–86 near the City of Salamanca, all in Cattaraugus County, New York. As stated in the NOI to prepare the SEIS, alternatives under consideration included: (1) The Null Alternative, taking no action; (2) the Upgrade Alternative, widening the existing two-lane highway to four lanes with the possible inclusion of population center by-passes; and (3) the Freeway Alternative, constructing a four-lane limited access freeway on new location. As stated in the NOI, the proposed improvement would have involved the construction of a new route or the upgrade and rehabilitation of the existing route for a distance of about 25 miles.

Due to economic considerations and the increased demand for funding of vital infrastructure improvement projects in the region, the NOI to prepare a SEIS is hereby rescinded. In accordance with 23 CFR 771.129, the FHWA and NYSDOT will re-evaluate the 2003 FEIS and ROD to determine whether or not the conclusions in the approved NEPA Document and final project decision remain valid. Comments and questions concerning the proposed action should be directed to the NYSDOT or FHWA at the addresses provided above.

Richard J. Marquis,

Division Administrator, HDA–NY, Federal Highway Administration.

[FR Doc. 2022–07981 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0032]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 18 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. The exemptions enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: The exemptions are applicable on April 11, 2022. The exemptions expire on April 11, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2022–0032, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. 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.*

II. Background

On February 16, 2022, FMCSA published a notice announcing receipt of applications from 18 individuals requesting an exemption from the hearing requirement in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (87 FR 8916). The public comment period ended on March 18, 2022, and two comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing found in § 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 3, 1971).

III. Discussion of Comments

FMCSA received two comments in this proceeding. One comment was in support of Wallace Bostrom obtaining a hearing exemption and the other comment requests granting the exemption be based on the applicant's driving history. FMCSA reviews the driving record of each applicant to ensure each applicant demonstrates a safe driving history.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on current medical information and literature, and the 2008 Evidence Report, ''Executive Summary on Hearing, Vestibular Function and Commercial Motor Driving Safety.'' The evidence report reached two conclusions regarding the matter of hearing loss and CMV driver safety: (1) No studies that examined the relationship between hearing loss and crash risk exclusively among CMV drivers were identified; and (2) evidence from studies of the private driver's license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash. In addition, the Agency reviewed each applicant's driving record found in the Commercial Driver's License Information System, for commercial driver's license (CDL) holders, and inspections recorded in the Motor Carrier Management Information System. For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency. Each applicant's record demonstrated a safe driving history. Based on an individual assessment of each applicant that focused on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce, the Agency believes the drivers granted this exemption have demonstrated that they do not pose a risk to public safety.

Consequently, FMCSA finds that in each case exempting these applicants from the hearing standard in § 391.41(b)(11) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must report any crashes or accidents as defined in § 390.5; (2) each driver must report all citations and convictions for disqualifying offenses under 49 CFR 383 and 49 CFR 391 to FMCSA; and (3) each driver is prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 18 exemption applications, FMCSA exempts the following drivers from the hearing standard, § 391.41(b)(11), subject to the requirements cited above:

Michael Beam (MI)
Nathaniel Borton (WI)
Wallace Bostrom (MN)
Daniel Cohen (VT)
Thomas Cook (VA)
Lee Desoto (NM)
Ruben Faulkwell (TX)
Christopher Gibbons (MO)
Renier Gonzalez (FL)
Leonie Hall (IL)
Dylan Lewis (DE)
Waylon Mathern (MD)
Randall Norton (TX)
Adem Rexhepi (IL)
Fernando Rizo (CA)
ZanDraya Schwab (UT)
Arnold Vega (TX)
Larry West (TN)

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2022–07962 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2020–0031]

Petition for Approval: Union Pacific Railroad

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of petition for approval to move to phase 2 of track inspection test program.

SUMMARY: This document provides the public notice that on March 24, 2022, Union Pacific Railroad (UP) petitioned the Federal Railroad Administration (FRA) to transition from phase 1 to phase 2 of a previously approved test program and associated temporary suspension of some visual track inspections. The Test Program is designed to test track inspection technologies (*i.e.,* an autonomous track geometry measurement system) and new operational approaches to track inspections (*i.e.,* combinations of autonomous inspection and traditional visual inspections).

FOR FURTHER INFORMATION CONTACT: Yu-Jiang Zhang, Staff Director, Track and Structures Division, Office of Railroad Safety, FRA, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone (202) 493–6460 or email *yujiang.zhang@dot.gov;* Aaron Moore, Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone (202) 493–7009 or email *aaron.moore@dot.gov*.

SUPPLEMENTARY INFORMATION: On April 28, 2020, FRA conditionally approved the Test Program and UP's petition under 49 CFR 211.51 to suspend §§ 213.233(c) as applied to operations under the Test Program. A copy of the Test Program, FRA's conditional approval of the Test Program, and a previously published **Federal Register** notice explaining FRA's rationale for approving the Test Program and related suspension are available for review in the docket.[1]

As approved, the Test Program included two separate phases over 12 months, as outlined in Exhibit C of the Program.[2] Accordingly, UP began the Test Program on June 15, 2020. Subsequently, UP requested, and FRA approved, an extension of the Test Program until November 23, 2022.

UP is requesting to transition from phase 1 to 2 on one of the Test Program routes, the Sunset route. In support of its request, UP states that it has met the Test Program conditions required to move to phase 2 and has achieved an average safety metric of 0.67 unprotected geometry defects per 100 miles tested and 3.47 track inspector identified geometry defects per month in phase 1 of the Test Program. UP is not requesting to move to phase 2 on the SPCSL route.

A copy of the petition, as well as any written communications concerning the petition, if any, are available for review online at *www.regulations.gov*.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• Website: *http://www.regulations.gov*. Follow the online instructions for submitting comments.

Communications received by May 16, 2022 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. 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 *https://www.transportation.gov/privacy*. See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2022–08002 Filed 4–13–22; 8:45 am]

BILLING CODE 4910–06–P

[1] *https://www.regulations.gov/document/FRA-2020-0031-0001* (Test Program); *https://www.regulations.gov/document/FRA-2020-0031-0002* (FRA's approval decision); *https://www.regulations.gov/document/FRA-2020-0031-0005* (FRA's published notice of approval).

[2] *https://www.regulations.gov/document/FRA-2020-0031-0001.*

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice of Information Collection and Request for Public Comment

ACTION: Notice and request for public comment.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the Community Development Financial Institutions Fund (CDFI Fund), Department of the Treasury, is soliciting comments concerning the Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

DATES: Written comments should be received on or before June 13, 2022 to be assured of consideration.

ADDRESSES: Submit your comments via email to Shannon McKay, Acting Manager, Office of Financial Strategies and Research, CDFI Fund, U.S. Department of the Treasury, at *CDFI-FinancialStrategiesandResearch@cdfi.treas.gov.*

FOR FURTHER INFORMATION CONTACT: Shannon McKay CDFI Fund, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC or by phone at (202) 653–0300. Other information regarding the CDFI Fund and its programs may be obtained through the CDFI Fund's website at *https://www.cdfifund.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 1559–0041.

Type of Review: Extension without change.

Abstract: 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. Qualitative 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 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 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.

Affected Public: Businesses and other organizations.

Average Expected Annual Number of Activities: 10.

Average Estimated Annual Number of Respondents: 10,000.

Responses per Respondent: 1.

Average Minutes per Response: 60.

Total Burden Hours: 10,000.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

(Authority: Pub. L. 104–13)

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2022–07945 Filed 4–13–22; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is updating the identifying information on its Specially Designated Nationals and Blocked Persons List (''SDN List'') for a person whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism.''

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action

On April 7, 2022, OFAC published the following revised information for the following person on OFAC's SDN List whose property and interests in property are blocked pursuant to Executive Order 13224.

Individual

1. CHATAYEV, Akhmed (a.k.a. CHATAEV, Ahmed; a.k.a. CHATAEV, Akhmed Rajapovich; a.k.a. CHATAEV, Akhmet; a.k.a. CHATAYEV, Akhmad; a.k.a. CHATAYEV, Akhmet; a.k.a. SENE, Elmir; a.k.a. TSCHATAJEV, Achmed Radschapovitsch; a.k.a. TSCHATAJEV, Ahmed Radschapovitsch; a.k.a. TSCHATAYEV, Achmed Radschapovitsch; a.k.a. TSCHATAYEV, Ahmed Radschapovitsch; a.k.a. ''Akhmed Odnorukiy''; a.k.a. ''Akhmed the One-Armed''; a.k.a. ''AL–SHISHANI, Akhmed''; a.k.a. ''CHATAEV, A.R.''; a.k.a. ''Odnorukiy''; a.k.a. ''SHISHANI, Akhmad''); DOB 14 Jul 1980; POB Vedeno Village, Vedenskiy District, the Republic of Chechnya, Russia; citizen Russia; Passport 96001331958 (Russia) (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

Dated: April 7, 2022.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–07968 Filed 4–13–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date.

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action

On April 11, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. CLANCY, Bernard Patrick, 43 Senorio De Cortes, Estepona, Spain; Dubai, United Arab Emirates; DOB 04 Sep 1977; POB Ireland; citizen Ireland; Gender Male; Passport PS0129975 (Ireland); alt. Passport PG7546744 (Ireland) (individual) [TCO] (Linked To: KINAHAN ORGANIZED CRIME GROUP). Designated pursuant to section 1(a)(ii)(B) of Executive Order 13581 of July 24, 2011, ''Blocking Property of Transnational Criminal Organizations'' (E.O. 13581), as amended by E.O. 13863 of March 15, 2019, ''Taking Additional Steps to Address the National Emergency With Respect to Significant Transnational Criminal Organizations'' (E.O. 13863), for having materially assisted, sponsored, or provided financial, material, or technological support

for, or goods or services to or in support of, the KINAHAN ORGANIZED CRIME GROUP.

2. DIXON, Ian Thomas, Arabian Ranches 2, Street 2, Lila Community, Villa 80, Dubai, United Arab Emirates; DOB 17 Sep 1989; POB Dublin, Ireland; nationality Ireland; Gender Male; Passport PT5688467 (Ireland); alt. Passport PW7797470 (Ireland); Driver's License No. 177803 (United Arab Emirates); Identification Number 784198943250948 (United Arab Emirates); alt. Identification Number 161995173 (United Arab Emirates); alt. Identification Number 082093477 (United Arab Emirates); alt. Identification Number 683129 (United Arab Emirates) (individual) [TCO] (Linked To: KINAHAN, Daniel Joseph). Designated pursuant to section 1(a)(ii)(B) of E.O. 13581, as amended by E.O. 13863, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Daniel Joseph KINAHAN.

3. KINAHAN, Daniel Joseph, 14 Palm Jumeirah, Dubai 378149, United Arab Emirates; Avda Juan Ramon Jimenez 2, Urbanizacion Cortijo Blanco, San Pedro de Alcantaras, Malaga 29670, Spain; Calle Galicia No 71 A, Guadalmina Baja, Estepona, Spain; DOB 25 Jun 1977; alt. DOB 26 May 1979; POB Dublin, Ireland; nationality Ireland; citizen Ireland; alt. citizen United Kingdom; Gender Male; Passport PB1642995 (Ireland); alt. Passport PW1900911 (Ireland); alt. Passport P008448 (Ireland); alt. Passport PD4435945 (Ireland); alt. Passport 704043374 (United Kingdom); Identification Number 784197715087538 (United Arab Emirates); alt. Identification Number 076822265 (United Arab Emirates); alt. Identification Number 195762701 (United Arab Emirates) (individual) [TCO] (Linked To: KINAHAN ORGANIZED CRIME GROUP). Designated pursuant to section 1(a)(ii)(C) of E.O. 13581, as amended by E.O. 13863, for having acted or purported to act for or on behalf of, directly or indirectly, the KINAHAN ORGANIZED CRIME GROUP.

4. KINAHAN, Christopher Vincent (a.k.a. ''KINAHAN SENIOR, Christy''; a.k.a. ''O'BRIEN, Christopher''; a.k.a. ''THE DAPPER DON''), Dubai, United Arab Emirates; Calle Muntaner 325, Planta 6, 4, Barcelona 08021, Spain; Calle Los Geranios, Villa Indelo N 244, San Pedro De Alcantara, Marbella, Spain; Urbanizacion Torre Bermeja, N 1501, Estepona, Spain; DOB 23 Mar 1957; alt. DOB 19 Nov 1952; alt. DOB 23 May 1957; POB Cabra, Ireland; alt. POB Perivale, Middlesex, United Kingdom; alt. POB London, United Kingdom; alt. POB Dublin, Ireland; nationality Ireland; citizen Ireland; Gender Male; Passport PD3265994 (Ireland); alt. Passport 094456153 (United Kingdom); alt. Passport 707265430 (United Kingdom); alt. Passport C181651D (United Kingdom); alt. Passport 701191749 (United Kingdom) (individual) [TCO] (Linked To: KINAHAN ORGANIZED CRIME GROUP). Designated pursuant to section 1(a)(ii)(C) of E.O. 13581, as amended by E.O. 13863, for having acted or purported to act for or on behalf of, directly or indirectly, the KINAHAN ORGANIZED CRIME GROUP.

5. KINAHAN JUNIOR, Christopher Vincent (a.k.a. ''CHRISTY JNR.''), 1404 Iris Blue Building, Dubai Marina, P.O. Box 11850, Dubai, United Arab Emirates; Calle Edificio El Noray, 2 Piso 1 B, Marbella, Spain; Urbanizacion Acosta Los Flamingos Golf, Bloque 82 D, Benahavis, Marbella, Spain; DOB 24 Sep 1980; alt. DOB 30 May 1981; POB Dublin, Ireland; nationality Ireland; citizen Ireland; Gender Male; Passport PW2418905 (Ireland); alt. Passport PT0298836 (Ireland); alt. Passport PN8384153 (Ireland); alt. Passport 512964060 (United Kingdom); Identification Number 784198027625874 (United Arab Emirates); alt. Identification Number 166622091 (United Arab Emirates); alt. Identification Number 077449510 (United Arab Emirates) (individual) [TCO] (Linked To: KINAHAN ORGANIZED CRIME GROUP). Designated pursuant to section 1(a)(ii)(B) of E.O. 13581, as amended by E.O. 13863, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the KINAHAN ORGANIZED CRIME GROUP.

6. MCGOVERN, Sean Gerard, Dubai, United Arab Emirates; DOB 12 Feb 1986; POB Dublin, Ireland; nationality Ireland; citizen Ireland; Gender Male; Passport PJ2861371 (Ireland) (individual) [TCO] (Linked To: KINAHAN, Daniel Joseph). Designated pursuant to section 1(a)(ii)(B) of E.O. 13581, as amended by E.O. 13863, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Daniel Joseph KINAHAN.

7. MORRISSEY, John Francis (a.k.a. ''MORRISSEY, Johnny''), Dinamarca 46 B, Malaga, Spain; Marbella, Spain; DOB 20 Dec 1959; nationality Ireland; citizen Ireland; Gender Male; Passport W089513 (Ireland); alt. Passport PU8060632 (Ireland) (individual) [TCO] (Linked To: KINAHAN ORGANIZED CRIME GROUP). Designated pursuant to section 1(a)(ii)(B) of E.O. 13581, as amended by E.O. 13863, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the KINAHAN ORGANIZED CRIME GROUP.

Entities

8. DUCASHEW GENERAL TRADING LLC, Boulevard Plaza, Tower 2, Office No. 2101 and 2102, Sheikh Mohammed Bin Rashid Boulevard, Dubai 454602, United Arab Emirates; Organization Established Date 10 Oct 2016; Dubai Chamber of Commerce Membership No. 276774 (United Arab Emirates); Company Number 767691 (United Arab Emirates) [TCO]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13581, as amended by E.O. 13863, for being owned or controlled by, or has acted or purported to act for or on behalf of, directly or indirectly, Daniel Joseph KINAHAN.

9. HOOPOE SPORTS LLC (f.k.a. HOOPOE BUSINESS BROKERS LLC; f.k.a. HOOPOE SPORTS AGENT L.L.C.), Office No. 2101 and 2102, 21st Floor, Emaar Boulevard Plaza, Tower 2, Dubai, United Arab Emirates; Organization Established Date 17 May 2017; Dubai Chamber of Commerce Membership No. 289666 (United Arab Emirates); Commercial Registry Number 1286684 (United Arab Emirates); Company Number 782807 (United Arab Emirates) [TCO]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13581, as amended by E.O. 13863, for being owned or controlled by, directly or indirectly, Ian Thomas DIXON.

10. KINAHAN ORGANIZED CRIME GROUP (a.k.a. KINAHAN ORGANISED CRIME GROUP; a.k.a. ''KOCG''), Ireland; United Kingdom; Spain; Netherlands; Dubai, United Arab Emirates; Target Type Criminal Organization [TCO]. Designated pursuant to section 1(a)(ii)(A) of E.O. 13581, as amended by E.O. 13863, for being a foreign person that constitutes a significant transnational criminal organization.

11. NERO DRINKS COMPANY LIMITED (a.k.a. NERO DRINKS COMPANY SL; a.k.a. NERO VODKA), 15 Cumbernauld Road, Stepps, Glasgow, Scotland G33 6LE, United Kingdom; Unit 20310, P.O. Box 6945, London W1A 6US, United Kingdom; C Dinamarca 46 B, Urbanizacion Faro De Calaburra, Mijas, Spain; Tax ID No. B93681724 (Spain); Company Number SC591051 (United Kingdom) [TCO]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13581, as amended by E.O. 13863, for being owned or controlled by, directly or indirectly, John Francis MORRISSEY.

Dated: April 11, 2022.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–07991 Filed 4–13–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of Nonconventional Source Production Credit Reference Price for Calendar Year 2021

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: Publication of the reference price for the nonconventional source production credit for calendar year 2021.

FOR FURTHER INFORMATION CONTACT: Christopher Price, CC:PSI:6, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, Telephone Number (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The credit period for the nonconventional source production credit ended on December 31, 2013 for facilities producing coke or coke gas (other than from petroleum based products). However, the reference price continues to apply in determining the amount of the enhanced oil recovery credit under section 43 of title 26 of the U.S.C., the marginal well production credit under section 45I of title 26 of the U.S.C., and the applicable percentage

under section 613A of title 26 of the U.S.C. to be used in determining percentage depletion in the case of oil and natural gas produced from marginal properties.

The reference price under section 45K(d)(2)(C) of title 26 of the U.S.C. for calendar year 2021 applies for purposes of sections 43, 45I, and 613A for taxable year 2022.

Reference Price: The reference price under section 45K(d)(2)(C) for calendar year 2021 is $65.90.

Christopher T. Kelley,

Special Counsel to the Associate Chief Counsel, (Passthroughs and Special Industries).

[FR Doc. 2022–08019 Filed 4–13–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Credit for Renewable Electricity Production and Publication of Inflation Adjustment Factor and Reference Price for Calendar Year 2022

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of publication.

SUMMARY: The 2022 inflation adjustment factor and reference price are used in determining the availability of the credit for renewable electricity production. For calendar year 2022, the credit period for refined coal production and Indian coal production expired.

FOR FURTHER INFORMATION CONTACT: Charles Hyde, CC:PSI:6, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The 2022 inflation adjustment factor and reference price apply to calendar year 2022 sales of kilowatt hours of electricity produced in the United States or a possession thereof from qualified energy resources.

Inflation Adjustment Factor: The inflation adjustment factor for calendar year 2022 for qualified energy resources is 1.8012.

Reference Price: The reference price for calendar year 2022 for facilities producing electricity from wind is 4.09 cents per kilowatt hour. The reference prices for facilities producing electricity from closed-loop biomass, open-loop biomass, geothermal energy, municipal solid waste, qualified hydropower production, and marine and hydrokinetic renewable energy have not been determined for calendar year 2022.

Phaseout Calculation: Because the 2022 reference price for electricity produced from wind (4.09 cents per kilowatt hour) does not exceed 8 cents multiplied by the inflation adjustment factor (1.8012), the phaseout of the credit provided in section 45(b)(1) does not apply to such electricity sold during calendar year 2022. For electricity produced from closed-loop biomass, open-loop biomass, geothermal energy, municipal solid waste, qualified hydropower production, and marine and hydrokinetic renewable energy, the phaseout of the credit provided in section 45(b)(1) does not apply to such electricity sold during calendar year 2022.

Credit Amount by Qualified Energy Resource and Facility: As required by section 45(b)(2), the 1.5 cent amount in section 45(a)(1) is adjusted by multiplying such amount by the inflation adjustment factor for the calendar year in which the sale occurs. If any amount as increased under the preceding sentence is not a multiple of 0.1 cent, such amount is rounded to the nearest multiple of 0.1 cent. In the case of electricity produced in open-loop biomass facilities, landfill gas facilities, trash facilities, qualified hydropower facilities, and marine and hydrokinetic renewable energy facilities, section 45(b)(4)(A) requires the amount in effect under section 45(a)(1) (before rounding to the nearest 0.1 cent) to be reduced by one-half. Under the calculation required by section 45(b)(2), the credit for renewable electricity production for calendar year 2022 under section 45(a) is 2.7 cents per kilowatt hour on the sale of electricity produced from the qualified energy resources of wind, closed-loop biomass, and geothermal energy, and 1.4 cents per kilowatt hour on the sale of electricity produced in open-loop biomass facilities, landfill gas facilities, trash facilities, qualified hydropower facilities, and marine and hydrokinetic renewable energy facilities.

(Authority: 45(e)(2)(A) (26 U.S.C. 45(e)(2)(A)) of the Internal Revenue Code.)

Christopher T. Kelley,

Special Counsel to the Associate Chief Counsel, (Passthroughs and Special Industries).

[FR Doc. 2022–07967 Filed 4–13–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Solicitation of Nominations for Membership on the Treasury Advisory Committee on Racial Equity

AGENCY: Department of the Treasury.

ACTION: The extension of the application due date for the solicitation of nominations for membership of the Treasury Advisory Committee on Racial Equity.

SUMMARY: The Treasury Department is soliciting nominations for membership on the Treasury Advisory Committee on Racial Equity (TACRE). The TACRE is composed of up to 25 members who will provide information, advice and recommendations to the Department of the Treasury on matters relating to the advancement of racial equity. This notice extends the process for applying for membership on the Committee until April 25th, 2022.

DATES: Applications are due on or before April 25, 2022.

FOR FURTHER INFORMATION CONTACT: Janis Bowdler, Counselor for Racial Equity, Department of Treasury, (202) 622–3002, *Equity@Treasury.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. app., as amended), the Department of the Treasury (''Department'') has established the Treasury Advisory Committee on Racial Equity (''Committee''). The Department has determined that establishing this committee is necessary and in the public interest in order to carry out the provisions of Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government.*

Committee Membership

In order to achieve a fairly balanced membership, the Committee shall include representatives from a wide range of views, such as the Federal government, financial services industry, state regulatory authorities, consumer or public advocacy organizations, community-based groups, academia, philanthropic organizations, as well as others focused on the advancement of equity priorities within the United States. Membership balance will not be static and may change, depending on the work of the Committee. The number of Committee members shall not exceed twenty-five. The Committee shall meet at such intervals as are necessary to carry out its duties. It is estimated that the Committee will generally meet four times per year, virtually or in person. Generally, Committee meetings are open to the public.

Background

Objectives and Duties

The purpose of the Committee is to provide advice and recommendations to the Department of the Treasury to assist

the Offices of the Secretary and Deputy Secretary in carrying out their duties and authorities towards advancing racial equity and addressing acute disparities for communities of color who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.

The Committee will provide an opportunity for experts to offer their advice and recommendations to the Office of the Secretary on a regular basis on aspects of the domestic economy that have directly and indirectly resulted in unfavorable conditions for Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color. Topics to be addressed by the Committee may include, but are not limited to, financial inclusion, capital access, housing stability, federal government supplier diversity and economic development.

The duties of the Committee shall be solely advisory and shall extend only to the submission of advice and recommendations to the Offices of the Secretary and Deputy Secretary, which shall be non-binding to the Department. No determination of fact or policy shall be made by the Committee. Membership appointments are for a duration of two years. Members will not receive compensation, other than reimbursement for travel, if required.

Application Process for Advisory Committee Appointment

Applicants are required to submit the following documents specifically referencing the objectives and duties outlined above:

- A one (1) page cover letter detailing their qualifications and areas of expertise as they relate to the key issues before the committee; and
- A two (2) page resume/curriculum vitae, which should clearly highlight relevant experience that addresses the focus areas of TACRE

Nominations may be submitted by the candidate him- or herself or by the person/organization recommending the candidate.

Some members of the Committee may be required to adhere to the conflict of interest rules applicable to Special Government Employees, as such employees are defined in 18 U.S.C. 202(a). These rules include relevant provisions in 18 U.S.C. related to criminal activity, Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), and Executive Order 12674 (as modified by Executive Order 12731).

In accordance with Department of Treasury Directive 21–03, a clearance process includes fingerprints, tax checks, and a Federal Bureau of Investigation criminal check. *Applicants must state in their application that they agree to submit to these pre-appointment checks.*

The application period for interested candidates will extend to the date outlined above. Applications should be submitted in sufficient time to be received by the close of business on the closing date and should be sent to *Equity@treasury.gov.*

William Fields,

Senior Advisor to the Secretary.

[FR Doc. 2022–08016 Filed 4–13–22; 8:45 am]

BILLING CODE 4810–AK–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Education, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2., that the Veterans' Advisory Committee on Education (the Committee) will meet virtually using Microsoft Teams May 24, 2022–May 26, 2022, from 10:00 a.m. to 5:00 p.m., EST. The meeting sessions are open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on the administration of education and training programs for Veterans, Servicepersons, Reservists, and Dependents of Veterans including programs under Chapters 30, 32, 33, 35, and 36 of title 38, and Chapter 1606 of title 10, United States Code.

The purpose of the meeting is for the Committee to hear briefings on topics of interest to its three subcommittees (Modernization, OJT/Apprenticeship and Distance Learning) and to obtain updates based on its report and recommendations to VA submitted in December 2021.

Interested persons may attend. The meeting will be conducted using Microsoft Teams. Please email *EDUSTAENG.VBAVACO@va.gov* for an invitation link prior to May 24, 2022 or dial-in by phone (for audio only) 1–872–701–0185 United States, Chicago (Toll), Conference ID: 464 437 245#.

Although no time will be allotted for receiving oral presentations from the public, individuals wishing to share information with the Committee may submit written statements for the Committee's review to Mr. Joseph Maltby, Designated Federal Official, Department of Veterans Affairs, by email at *EDUSTAENG.VBAVACO@va.gov*. Comments will be accepted until close of business on Monday, May 23, 2022. In the communication, the writers must identify themselves and state the organization or association they represent for inclusion in the official record. Any member of the public wishing to participate or seeking additional information should contact Joseph Maltby at *EDUSTAENG.VBAVACO@va.gov* not later than May 23, 2022.

Dated: April 11, 2022.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–08023 Filed 4–13–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the Advisory Committee on Former Prisoners of War

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is seeking nominations of qualified candidates to be considered for appointment to the Advisory Committee (Committee) on Former Prisoners of War (FPOW).

DATES: Nominations for membership on the Committee must be received no later than 5:00 p.m. EDT on June 2, 2022.

ADDRESSES: All nominations should be mailed to Outreach, Transition and Economic Development (OTED), Veterans Benefits Administration (VBA), Department of Veterans Affairs, 1800 G St. NW, Washington, DC 20006 or emailed to *julian.wright2@va.gov.*

FOR FURTHER INFORMATION CONTACT: Julian Wright, Designated Federal Officer (DFO), OTED, Department of Veterans Affairs, 1800 G St. NW, Washington, DC 20006, telephone (202) 302–8629.

SUPPLEMENTARY INFORMATION: In carrying out the duties set forth, the activities of the Committee include, but are not limited to:

(1) Advising the Secretary on how VA can assist and represent FPOWs', including recommendations regarding expanding services and benefits to FPOWs' and related policy. Administrative, legislative, and/or regulatory actions;

(2) Advising the Secretary on incorporating lessons learned from current, and previous, successful family research and outreach efforts that

measure the impact of provided care and benefits services on FPOWs;

(3) Advising the Secretary on collaborating with family support programs within VA and engaging with other VA and non-VA advisory committees focused on specific demographics of FPOWs;

(4) Advising the Secretary on working with interagency, intergovernmental, private/non-profit, community, and Veteran service organizations to identify and address gaps in services for FPOWs;

(5) Providing such reports as the Committee deems necessary, but not less than one report per year, to the Secretary, through the DFO/VBA to describe the Committee's activities, deliberations, and findings, which may include but are not limited to: (1) Identification of current challenges and recommendations for remediation related to access to care and benefits services of FPOWs; and (2) identification of current best practices in care and benefits delivery to FPOWs, and the impact of such best practices.

Authority: The Committee is authorized by statute (5 U.S.C. 541) and operates under the provisions of the Federal Advisory Committee Act (FACA). The Committee advises the Secretary on the following:

(1) The administration of benefits for Veterans who are FPOW, in the areas of service-connected compensation, dependency and indemnity compensation, health care, and rehabilitation.

(2) The use of VA care and benefits services by FPOWs, and possible adjustments to such care and benefits services;

(3) Factors that influence access to, quality of, and accountability for services and benefits for FPOWs.

Membership Criteria and Qualifications: VA is seeking nominations for Committee membership. The Committee is composed of up to 12 members and several ex-officio members.

The members of the Committee are appointed by the Secretary of Veteran Affairs from the general public, from various sectors and organizations, including but not limited to:

(1) Veterans who are FPOWs.

(2) Appropriate representatives of Veterans who are former prisoners of war;

(3) Individuals who are recognized authorities in fields pertinent to disabilities prevalent among former prisoners of war, including authorities in epidemiology, mental health, nutrition, geriatrics and internal medicine; and

(4) Appropriate representatives of disabled Veterans.

In accordance with the Committee Charter, the Secretary shall determine the number, terms of service, and pay and allowances of Committee members. The term of service for any member may not exceed three years. The Secretary may reappoint any Committee member for additional terms of service.

To the extent possible, the Secretary seeks members who have diverse professional and personal qualifications including but not limited to subject matter experts in the areas described above. We ask that nominations include any relevant experience information so that VA can ensure diverse Committee membership.

Requirements for Nomination Submission: Nominations should be typed (one nomination per nominator). Nomination package should include:

(1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee indicating the willingness to serve as a member of the Committee;

(2) The nominee's contact information, including name, mailing address, telephone numbers, and email address;

(3) The nominee's resume; and

(4) A summary of the nominee's experience and qualifications relative to the membership considerations described above.

Individuals selected for appointment to the Committee shall be invited to serve a two-year term. Committee members will receive a stipend for attending Committee meetings, including per diem and reimbursement for eligible travel expenses incurred.

The Department makes every effort to ensure that the membership of VA Federal advisory committees are diverse in terms of points of view represented and the committee's capabilities. Appointments to this Committee shall be made without discrimination because of a person's race, color, religion, sex, sexual orientation, gender identify, national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: April 11, 2022.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–07997 Filed 4–13–22; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 87 Thursday,

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 422

Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS–4190–FC4]

RIN 0938–AT97

Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period (FC) will finalize the two remaining proposals from the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' which appeared in the **Federal Register** on February 18, 2020 (February 2020 proposed rule). The two proposals being finalized here from the February 2020 proposed rule include the maximum out-of-pocket (MOOP) limits for Medicare Parts A and B services and cost sharing limits for Medicare Parts A and B services, including service category cost sharing limits and per member per month actuarial equivalence cost sharing. In addition, CMS is requesting comments in section III of this FC on new or different ways to update and change cost sharing limits in future years for service categories subject to the regulations, including mental health services.

DATES:

Effective date: These regulations are effective on June 13, 2022.

Applicability date: The provisions in this rule will apply to coverage beginning January 1, 2023.

Comment date: To be assured consideration, comments on section III. of this FC must be received at one of the addresses provided below, by July 13, 2022.

ADDRESSES: In commenting, please refer to file code CMS–4190–FC4.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4190–FC4, P.O. Box 8013, Baltimore, MD 21244–8013.

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–4190–FC4, 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: Cali Diehl, (410) 786–4053 or *Cali.Diehl@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

This final rule with comment period (FC) makes policy changes in alignment with federal laws related to the Medicare Advantage (MA or Part C) program from the 21st Century Cures Act (Pub. L. 114–255). The rule also includes regulatory changes to strengthen and improve the Part C program by codifying in regulation several CMS policies previously adopted through the annual Call Letter and other guidance documents to interpret and implement rules regarding benefits in MA plans.

In this FC, we are addressing the two remaining proposals from the February 2020 proposed rule that were not addressed in the June 2020 final rule (85 FR 33796) and the January 2021 final rule (86 FR 5864): (1) Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101); and (2) Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113). The changes to the proposals we are finalizing in this FC range from minor edits, reorganizations, corrections, and clarifications to substantive modifications based on the comments received, operational considerations (such as, changes stemming from the timing of this FC), and additional implementation of antidiscrimination requirements (such as, to support equitable access to plans for beneficiaries with high health needs). In

so doing, this FC addresses the following needs for federal regulatory action:

- The provisions relating to MOOP and cost sharing limits improve the operation of the MA program by making updates to reflect changes in Medicare FFS data projections (thereby ensuring the government program does not use outdated data) and clarifying existing policies (thereby answering questions regulated parties may have). Given the context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.
- The provisions also codify subregulatory guidance, which is an improvement in that regulated parties and CMS will have greater clarity regarding the application of these policies as a rule. Given the context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.

2. Summary of the Major Provisions

a. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. In a 2010 final rule, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits set by CMS (75 FR 19709 and 19711). Setting MOOP limits is an important step to ensure plan designs are not discriminatory and protect beneficiaries from significant changes in out-of-pocket costs regardless of the MA plan they choose. MA EGWPs must follow all relevant MA regulations and guidance unless CMS has specifically waived a requirement using its statutory authority under section 1857(i) of the Act. Section 1858(b)(2) of the Act requires a limit on in-network and out-of-pocket expenses for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. MA Local PPO (LPPO) plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also called catastrophic limits) calculated by CMS annually, including—(1) an in-network limit; and (2) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. Relying on the same statutory authority, we proposed amendments to the regulations at § 422.100(f)(4) and (5) and § 422.101(d)(2) and (3) to specify how these MOOP limits will be set for 2022 and subsequent years. In addition, our proposals made adjustments to current policy based on statutory changes that are relevant to how CMS calculates benefit category cost sharing limits.

We proposed to codify our current practices for setting MOOP limits with some revisions, including explicitly addressing authority to set up to three different MOOP limits. In addition, we proposed to conduct a multiyear transition of end-stage renal disease (ESRD) costs into the methodology for setting MOOP limits. Section 1851(a)(3) of the Act, as amended by section 17006 of the 21st Century Cures Act, amended the Medicare statute to permit Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beyond the previous enrollment limitations, beginning in contract year 2021. Enrollment impacts from section 17006 of the Cures Act are addressed in sections III.A., VII.B.3., and VIII.D.1. of the June 2020 final rule (85 FR 33796). Before the amendments made by the Cures Act were effective for contract year 2021, individuals diagnosed with ESRD could not enroll in a MA plan, subject to limited exceptions. Generally, those exceptions included the following circumstances: An individual that developed ESRD while enrolled in a MA plan could remain in that plan; an ESRD individual enrolled in a plan which was terminated or discontinued had a one-time opportunity to join another plan; or, an individual could enroll in a special needs plan that had obtained a waiver to enroll individuals with ESRD. We explained that the data we use to calculate the MOOP limits should also incorporate the out-of-pocket expenditures of beneficiaries with diagnoses of ESRD, which we are referring to in this FC as ''ESRD costs,'' to reflect this statutory change. Finally, we proposed safeguards to protect against excessive changes in the MOOP limit during and after the ESRD cost transition.

We are finalizing these MOOP proposals generally as proposed with changes to apply the provisions beginning in contract year 2023 rather than 2022, make modifications to be responsive to comments (including adoption of a transition schedule), and improve and clarify the methodology. A complete discussion of changes from the February 2020 proposed rule is available in section II.A. of this FC.

b. Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

Section 1852 of the Act imposes a number of requirements that apply to the cost sharing and benefit design of MA plans. First, section 1852(a)(1)(B) of the Act specifies that MA plans may not charge enrollees higher cost sharing than is charged under original Medicare for chemotherapy administration services (which we have implemented as including Part B—chemotherapy/radiation drugs integral to the treatment regimen), skilled nursing care, and renal dialysis services. This provision is currently reflected in §§ 417.454(e) (for cost plans) and 422.100(j) (for MA plans). We proposed to restructure paragraph (j) and codify additional cost sharing limits for other services. We did not propose to change cost plan cost sharing standards. In addition, after publication of the February 2020 proposed rule, the Families First Coronavirus Response Act (Pub. L. 116–127) amended section 1852 of the Act to prohibit MA plans from charging enrollees higher cost sharing than is charged under original Medicare for COVID–19 testing and testing-related services identified in section 1833(cc)(1) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2) during the period from March 18, 2020 through to the end of the emergency period described in section 1135(g)(1)(B) (namely, the COVID–19 public health emergency). The Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136) amended section 1852(a)(1)(B) to require MA plans have cost sharing that does not exceed cost sharing in Original Medicare for a COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

Second, section 1852(a)(1)(B)(i) of the Act provides that the MA organization must cover, subject to limited exclusions, the benefits under Parts A and B (that is, basic benefits as defined in § 422.100(c)) with cost sharing that does not exceed or is at least actuarially equivalent to cost sharing in original Medicare in the aggregate; this is repeated in a bid requirement under

section 1854(e)(4) of the Act. We have addressed and implemented this requirement in several regulations, including §§ 422.101(e), 422.102(a)(4), and 422.254(b)(4).

Third, section 1852(a)(1)(B)(iv) of the Act authorizes CMS to add to the list of items and services for which MA cost sharing may not exceed the cost sharing levels in original Medicare.

Fourth, section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. The requirements under § 422.100(f)(4) and (5) that impose MOOP limits on MA plans are based on this anti-discrimination provision by requiring MA local plans to have limits on out of pocket spending by enrollees in order to ensure that beneficiaries with high health needs are not dissuaded from enrolling in an MA plan; while the requirements under § 422.101(d)(2) and (3) implement the statutory catastrophic limits imposed on regional MA plans under section 1858(b) of the Act, those limits similarly protect enrollees with high health needs and avoid discouraging them from enrollment in MA plans. Paragraph (f)(6) provides that cost sharing must not be discriminatory by imposing cost sharing limits. Imposing limits on cost sharing for covered services is an important way to ensure that the cost sharing aspect of an MA plan design does not discriminate against or discourage enrollment of beneficiaries who have high health care needs and who need specific services. CMS issued annual limits on cost sharing for covered services and guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letter (prior to 2020) and in bidding instructions. In addition, Chapter 4 of the Medicare Managed Care Manual (MMCM) has contained long-standing polices regarding discriminatory cost sharing based on the requirements under paragraphs (f)(4) and (5).

We proposed to codify our current and longstanding practice and methodology for interpreting and applying the limits on MA cost sharing, with some modifications. Our cost sharing proposal as a whole, in combination with the MOOP limit proposal in section VI.A. of the February 2020 proposed rule, aimed to provide MA organizations incentives to offer plans with favorable benefit designs for beneficiaries. As noted in the February 2020 proposed rule, organizations must also comply with applicable Federal civil rights laws that prohibit discrimination, including those that prohibit discrimination on the basis of race, color, national origin, sex (including sexual orientation and gender identity), age, and disability, such as section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. None of the proposals in the February 2020 proposed rule limited application of such anti-discrimination requirements. Overall, our proposal aimed to clarify how we use the most relevant and appropriate information to determine whether specific cost sharing is discriminatory and to calculate standards and thresholds above which we believe cost sharing is discriminatory. We shared our intent to communicate, similar to our current practice prior to bid submission, how we apply the proposed methodologies each year, such as through HPMS memoranda, as appropriate. We solicited comment on the following cost sharing proposals:

- Codifying a long-standing interpretation of the current anti-discrimination provision of section 1852(b)(1) that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who need those services;
- Establishing a range of cost sharing limits for basic benefits furnished on an in-network basis based on the MOOP type established by the MA plan;
- Codifying the methodology used to calculate the limits for MA cost sharing for inpatient hospital acute and psychiatric services and incorporate ESRD costs into that methodology;
- Updating the cost sharing limits for emergency and post-stabilization services and codifying a new rule for cost sharing limits for urgently needed services;
- Codifying and adding specific benefits for which MA plans may not charge enrollees higher cost sharing than is charged under original Medicare; and
- Codifying our existing policy regarding the specific benefit categories for which an MA plan must not exceed the cost sharing in original Medicare on a PMPM actuarially equivalent basis.

The changes to the cost sharing proposals we are finalizing in this FC range from minor edits, corrections, and clarifications to substantive modifications based on the comments received, operational considerations (such as, changes stemming from the timing of this FC), and improvements to the methodology. CMS's goal in finalizing the cost sharing proposals as described in this FC is to adopt standards and require compliance that further antidiscriminatory requirements (such as, by supporting equitable access to plans for beneficiaries with high health needs). A complete discussion of changes from the February 2020 proposed rule is available in section II.B. of this FC.

3. Summary of Costs and Benefits

BILLING CODE 4120–01–P

Provision	Description	Primary Impact to MA Organizations, Enrollees, and Medicare Trust Fund (as applicable)
a. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)	CMS is finalizing policies (with some modifications and changes in implementation schedule) to: • Codify the approximate Medicare FFS percentiles which are used to determine the mandatory and lower MOOP limits and calculate an intermediate MOOP limit representing the numeric midpoint between mandatory and lower limits. • Incorporate costs related to beneficiaries with diagnoses of End-Stage Renal Disease (ESRD) into the methodology to calculate MOOP limits, because of the eligibility changes permitting broader enrollment in MA plans by beneficiaries with ESRD beginning in contract year 2021. • Establish guardrails to mitigate disruptive changes in MOOP limits, including a cap on how much MOOP limits can increase from year to year. • Adopt a provision regarding the release of annual guidance that identifies the MOOP and cost sharing limits and includes a description of how the regulation standards are applied. • Clarify the use of generally accepted actuarial principles and practices for the projections and calculations used for the MOOP and cost sharing limits, including specific principles for how discretion in applying the actuarial standards will be used. • Codify additional standards for combined/catastrophic MOOP limits, updating the ESRD cost transition based on comments and operational considerations stemming from the timing of this FC, adopting a simpler methodology than proposed to protect against disruptive annual changes in MOOP limits, clarifying the methodology CMS uses to calculate MOOP limits, and making additional clarifications. • Sets the specific MOOP limits for contract year 2023 using the methodology and standards in §§ 422.100(f) and 422.101(d) in addition to adopting the rules for 2024 and subsequent years.	While individual or groups of beneficiaries using specific categories of services and items may have possibly significant savings or losses, there is no aggregate cost impact to either the government or MA organizations for two reasons: (1) there is a statutory requirement for submitted bids to be actuarially equivalent to original Medicare, implying that plans can shift costs, but not create additional costs (that is, even if submitted bids proposed shifts in cost sharing of particular service categories there will be no dollar impact in the aggregate); and (2) to the extent that provisions of this FC codify existing practice, we are certain of no cost impact because of the annual review of bids which confirms compliance.

Provision	Description	Primary Impact to MA Organizations, Enrollees, and Medicare Trust Fund (as applicable)
b. Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)	CMS is finalizing policies (with some modifications and changes in implementation schedule) to: • Codify the long-standing CMS policy that enrollee cost sharing greater than 50 percent of the total MA plan financial liability or Medicare FFS allowed amount in the plan service area for Parts A and B benefits is discriminatory. • Set cost sharing limits for seven inpatient length of stay scenarios based on a percentage of estimated Medicare FFS cost sharing projected for the applicable contract year, including applying a transition schedule to incorporate costs incurred by beneficiaries with diagnoses of ESRD. • Revise long-standing CMS policy that limits cost sharing for several professional services to be no greater than 50 percent of the plan's financial liability regardless of the type of MOOP limit by updating the standard to: 50 percent coinsurance for lower MOOP limit, 40 percent for intermediate MOOP limit, and 30 percent for mandatory MOOP limit. • Increase the maximum per visit cost sharing for emergency care ($90 to $115 for a mandatory MOOP and $120 to $150 for a lower MOOP) based on 15 and 20 percent of the Medicare FFS median allowed amount for emergency services and establish a $130 cost sharing limit for an intermediate MOOP limit. • Adopt a requirement that MA plans must use cost sharing that does not exceed cost sharing in original Medicare for home health services, durable medical equipment for plans with a mandatory MOOP amount, and Part B drugs other than chemotherapy, in addition to the current limit for chemotherapy administration services, skilled nursing care (that is, SNF), and renal dialysis services. • Codify CMS's long-standing policy of evaluating cost sharing limits on a PMPM actuarially equivalent basis for the following service categories: Inpatient hospital, SNF, DME, and Part B drugs. • Transition the contract year 2022 cost sharing standards for professional service categories, emergency services, and benefits for which cost sharing may not exceed original Medicare to the cost sharing limits established using the methodology adopted by this FC. • Clarify current policies for cost sharing, such as scope of the emergency services cost sharing limit. For example, CMS is not including post-stabilization inpatient acute care services for purposes of setting the cost sharing limits for emergency services. • Sets the specific cost sharing limits for contract year 2023 using the methodology and standards in §§ 422.100(f) and (j) and 422.113(b) in addition to adopting the rules for 2024 and subsequent years.	While individual or groups of beneficiaries using specific categories of services and items may have possibly significant savings or losses, there is no aggregate cost impact to either the government or MA organizations for two reasons: (1) there is a statutory requirement for submitted bids to be actuarially equivalent to original Medicare, implying that plans can shift costs, but not create additional costs (that is, even if submitted bids proposed shifts in cost sharing of particular service categories there will be no dollar impact in the aggregate); and (2) to the extent that provisions of this FC codify existing practice, we are certain of no cost impact because of the annual review of bids which confirms compliance.

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B. Background

We received approximately 44 timely pieces of correspondence containing multiple comments for the provisions implemented in this FC from the February 2020 proposed rule. Comments were submitted by health plans, provider associations, beneficiary and other advocacy organizations, and pharmaceutical companies.

We are finalizing the policies from the February 2020 proposed rule in more than one final rule. The first final rule

titled ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program'' appeared in the **Federal Register** on June 2, 2020 (85 FR 33796) (June 2020 final rule), and contained a subset of regulatory changes that impacted MA organizations and Part D sponsors more immediately. The second final rule titled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) (January 2021 final rule), and contained the majority of the remaining provisions from the February 2020 proposed rule. This FC addresses the two remaining provisions from the February 2020 proposed rule.

The changes to the proposals we are finalizing in this FC range from minor edits, reorganizations, corrections, and clarifications to substantive modifications based on the comments received, operational considerations (such as, changes stemming from the timing of this FC), and improvements to the methodology. CMS's goal in finalizing the cost sharing proposals as described in this FC is to adopt standards and require compliance that further antidiscriminatory requirements (such as, by supporting equitable access to plans for beneficiaries with high health needs). Summaries of the public comments received and our responses to those public comments are set forth in the various sections of this FC under the appropriate headings. We also note that some of the public comments received for the provisions implemented in this FC were outside of the scope of the February 2020 proposed rule. Summaries of the out-of-scope public comments made in relation to the provisions in this FC are provided in the various sections of this FC under the appropriate headings.

The Code of Federal Regulations (CFR) will be updated consistent with the respective effective date of each provision. Because CMS is finalizing these regulations as applicable for the contract year and coverage beginning January 1, 2023, the requirements in this FC will apply to MA bid submissions occurring in calendar year 2022 for contracts effective January 1, 2023.

II. Codifying Existing Part C and D Program Policy

A. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. Under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits established by CMS (75 FR 19709 through 19711). MA EGWPs must follow all relevant MA regulations and guidance unless CMS has specifically waived a requirement under its section 1857(i) of the Act statutory authority. Section 1858(b)(2) of the Act requires a limit on in-network and out-of-pocket expenses for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. In addition, MA Local PPO (LPPO) plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also called catastrophic limits) established by CMS annually, including (a) an in-network and (b) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. Relying on the same authority, we proposed amendments to the regulations at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to specify how these MOOP limits (''MOOP amounts'' when referring to the limit established by an MA plan) will be set for 2022 and subsequent years. In addition, our proposals considered statutory changes that are relevant to how CMS sets cost sharing limits.

Under our current policy, MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee (that is, cost sharing includes deductibles, coinsurance, and copayments, pursuant to § 422.2) and to alert enrollees and contracted providers when the MOOP limit is reached. Health Maintenance Organization-Point of Service (POS) plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP limit or to a combined in- and out-of-network MOOP limit. Although the MOOP limits apply to Parts A and B benefits, an MA organization can apply the MOOP limit to supplemental benefits as well.

As discussed in the February 2020 proposed rule, CMS currently sets MOOP limits based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare Fee-for-Service (FFS). The CMS Office of the Actuary (OACT) conducts an annual analysis to determine the MOOP limits using the most recent Medicare FFS data and by projecting cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and original Medicare. The OACT bases its projections on actual claims data for Parts A and B benefits from the National Claims History files. MOOP limits for 2020, 2021 and 2022 were set under the current regulation text at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) that authorizes CMS to set MOOP limits that strike a balance between limiting costs (meaning cost sharing and premiums) to enrollees and changes in benefits, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. The mandatory MOOP limit represents approximately the 95th percentile of projected Medicare FFS beneficiary out-of-pocket spending for the year to which the MOOP limit will apply. Stated differently, using the contract year 2020 MOOP limits as examples, 5 percent of Medicare FFS beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments, and coinsurance; the voluntary MOOP limit of $3,400 represents approximately the 85th percentile of projected Medicare FFS out-of-pocket costs.

A strict application of the thresholds at the 95th and 85th percentile to set the MOOP limits, since adoption of the MOOP regulations for 2011, would have resulted in MOOP limits for MA LPPO and RPPO plans fluctuating from year-to-year. Therefore, CMS exercised discretion in order to maintain stable MOOP limits from year-to-year, when the established MOOP limits were approximately equal to the appropriate percentile. CMS took this approach in an effort to avoid enrollee confusion (which may result from annual MOOP fluctuations year over year), allow MA plans to provide stable benefit packages year over year, and not discourage MA

organizations from adopting the lower voluntary MOOP limit because of year to year fluctuations in the MOOP limits set by CMS.

MA plans may establish MOOP amounts that are lower than the CMS-established maximum limits. As discussed in the February 2020 proposed rule, for 2020, we considered any MOOP amount within the $0–$3,400 range as a voluntary MOOP limit and any MOOP amount within the $3,401–$6,700 range as a mandatory MOOP limit. These amounts were updated to $0–$3,450 for the voluntary MOOP and $3,451–$7,550 for coverage in 2021 and 2022.[1] The in-network MOOP limit dictates the combined MOOP range for PPOs (that is, PPOs are not permitted to offer a combined MOOP amount within the mandatory range, while having an in-network MOOP amount within the voluntary range). The combined MOOP limit for PPOs is calculated by multiplying the respective in-network MOOP limits by 1.5 for the relevant year and rounding, if necessary, similar to what we proposed at § 422.100(f)(4)(iii).[2] For example, the voluntary combined MOOP limit for PPOs in contract year 2020 was calculated as $3,400 × 1.5 = $5,100 (that is, an MA plan that establishes a dollar limit within the $0–$5,100 range is using a lower, voluntary combined MOOP limit). Similarly, the mandatory combined MOOP limit for PPOs in contract year 2020 was calculated as $6,700 × 1.5 = $10,050, rounded down to the nearest $100 ($10,000) and MA plans that establish a dollar amount within the $5,101–$10,000 range are using a mandatory combined MOOP limit.

As noted in the February 2020 proposed rule, CMS affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP amount (including PPO plans with a combined MOOP limit in the voluntary range) than is available to plans that adopt the higher, mandatory MOOP amount. The percentage of MA plans (excluding employer, dual eligible special needs plans (D–SNPs), and Medicare Medical Savings Accounts plans (MSAs)) offering a voluntary MOOP limit and the proportion of total enrollees in a plan with a voluntary MOOP limit (at or below $3,400) have decreased considerably from contract year 2011 to contract year 2020. Based on plan data from March 2021, this trend has continued through contract year 2021 with approximately 18.5 percent of plans (21.5 percent of enrollees) having an in-network MOOP amount within the range of the prior voluntary MOOP limit (at or below $3,400), as shown in Table 1. This percentage access to the voluntary MOOP increases to approximately 23.3 percent of plans (24.8 percent of enrollees) for contract year 2021 after taking into consideration the increase to the voluntary MOOP limit for that year (at or below $3,450).

TABLE 1: PERCENT ACCESS TO MA PLANS (EXCLUDING EMPLOYER, D-SNP, AND MSA PLANS) WITH VOLUNTARY/LOWER MOOP AMOUNTS FROM 2011 TO 2021 BASED ON MARCH 2021 PLAN DATA

Year[1]	Percent of MA plans with Voluntary/Lower MOOP Amounts	Percent of Enrollees in an MA Plan with a Voluntary/Lower MOOP Amount
2011	51.9%	51.2%
2012	48.4%	48.9%
2013	46.4%	43.8%
2014	38.0%	32.3%
2015	31.0%	25.6%
2016	25.2%	22.3%
2017	20.6%	20.7%
2018	20.1%	22.8%
2019	23.1%	26.0%
2020	24.7%	26.4%
2021[2]	23.3%	24.8%

[1]The voluntary MOOP limit was $3,400 for contract years 2011 through 2020; in contract year 2021 the amount increased to $3,450 based on incorporating a percentage of the costs incurred by beneficiaries with diagnoses of ESRD.

[2] These values reflect the percent access to a MOOP limit at or below $3,450. Access to a MOOP limit at or below $3,400 in 2021 is approximately 18.5 percent of plans (21.5 percent of enrollees).

[1] See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021 and the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

[2] CMS. ''Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011'' (2010). Retrieved from *https://www.cms.gov/Medicare/Health-Plans/HealthPlans/downloads/dfb_policymemo041610final.pdf.*

CMS explained in the February 2020 proposed rule that we intend to continue using more than one MOOP limit with a goal of encouraging plan offerings that result in favorable benefit designs for beneficiaries. In addition, we explained that by codifying the methodology for how these MOOP limits will be set, we aimed to increase the level of transparency for the MOOP and cost sharing policies, and provide more stability and predictability to the MA program. For example, CMS expects implementing more than two levels of MOOP and cost sharing limits may increase beneficiary access to plans with MOOP limits below the mandatory MOOP limit or with lower cost sharing. CMS also discussed in the February 2020 proposed rule how section 17006 of the 21st Century Cures Act amended section 1851(a)(3) of the Act to allow Medicare eligible beneficiaries with diagnoses of end-stage renal disease (ESRD) to choose a MA plan for Medicare coverage starting January 1, 2021, without the restrictions on such enrollment that previously applied. Based on these prior enrollment restrictions, we explained how the data historically used by CMS to set the MOOP limits excluded the projected out-of-pocket spending for beneficiaries with diagnoses of ESRD, which we are referring to also in this FC as ''ESRD costs,'' but that we believed the data used to set the MOOP limits for future years should align with this change in eligibility for the MA program. The February 2020 proposed rule also identified CMS authority for its proposal related to MOOP limits for MA plans as flowing from sections 1852(b)(1)(A), 1856(b)(1), 1857(e)(1), and 1858(b) of the Act. We proposed to codify our current practice, with some revisions, substantially revising and restructuring §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) as described in the following subsections.

We are finalizing, for 2023 and subsequent years, the majority of our MOOP proposals with some changes. The changes include:

- Codifying explicit ranges used to determine if a MA plan's in-network (catastrophic) and combined (total catastrophic) MOOP limits are a mandatory, intermediate, or lower MOOP limit for purposes of § 422.100(f)(6) and (j) and §§ 422.101(d) and 422.113(b)(2)(v).
- Improving clarity in the regulations regarding how CMS will set the MOOP limits for 2023 and subsequent years, including how we will use actuarial principles and practices in making the projections required by the methodology to set MOOP limits and calculate the intermediate MOOP limit.
- Modifying the transition schedule for incorporating ESRD costs (that is, the out-of-pocket spending for beneficiaries with diagnoses of ESRD) into the methodology CMS uses to set MOOP limits.
- Simplifying the maximum threshold of the guardrails which was proposed to protect MA enrollees from potentially significant changes in out of pocket costs resulting from changes to the plan's MOOP amount (during and after the ESRD cost transition is completed).
- Removing the proposed requirement of a 3-year trend to update the MOOP limits, after the ESRD cost transition is completed, to avoid duplicating the OACT practice of trending years of data to project costs for an applicable year (which will ensure MOOP limits are updated to reflect changes in Medicare FFS costs in future years).
- Adopting explicit procedures for annually announcing the MOOP limits with a process for notice and comment by the public beginning for contract year 2024.

These changes are discussed in detail in section II.A.4. of this FC. This FC sets the specific MOOP limits for contract year 2023 using the methodology and standards in §§ 422.100(f) and 422.101(d) in addition to adopting the rules for 2024 and subsequent years.

1. Authorize Setting Up to Three MOOP Limits on Basic Benefits (§§ 422.100(f)(4) and (5) and § 422.101(d)(2) and (3))

CMS proposed to codify our current practices for setting MOOP limits with some revisions, including explicitly addressing authority to set up to three MOOP limits. In addition to the proposals specific to the methodology for setting the MOOP limits and how to incorporate ESRD costs into that methodology, we proposed specific rules for the MOOP limits. These proposals were to do all of the following:

- Use the term ''basic benefits'' instead of referring to Medicare Part A and B benefits in our proposed revisions to the regulations at §§ 422.100(f)(4) and (5) and § 422.101(d)(2) and (3) because the term ''basic benefits'' is now defined in § 422.100(c).
- Amend § 422.100(f)(4) to state the general rule that, except as provided in paragraph (f)(5), MA local plans must establish MOOP limits for basic benefits; as in the current regulation, proposed paragraph (f)(5) addressed how the MOOP limits apply to the out-of-network coverage provided by local PPO plans.
- Codify the rules for PPOs in establishing in-network and combined (or catastrophic) MOOP limits for basic benefits furnished in-network and out-of-network in §§ 422.100(f)(5) and 422.101(d)(2) and (d)(3).
- Add cross-references to codify the same limits under both § 422.100(f)(5) (for MA local PPOs) and § 422.101(d)(3) (for MA regional plans) for combined MOOP limits that apply to in-network and out-of-network cost sharing and to codify the same MOOP limit under § 422.100 (f)(4) (for MA local plans) and § 422.101(d)(2) (for in-network MA regional plans) to avoid repetitive regulation text.
- Codify in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) the responsibility MA organizations have to track enrolled beneficiaries' out-of-pocket spending and to alert enrollees and contracted providers when the MOOP limit is reached. This is implicit in how a MOOP limit works, but we believe codifying these responsibilities emphasizes for MA organizations that these requirements are integral to the administration of basic benefits.
- Amend § 422.100(f)(4) to authorize CMS, for 2022 and subsequent years, to set up to three MOOP limits using projections of beneficiary spending that are based on the most recent, complete Medicare FFS data, including the current mandatory and voluntary MOOP limits and a third, intermediate MOOP limit. CMS proposed to use these terms (lower, intermediate, and mandatory) in referencing MOOP limits instead of only ''voluntary'' and ''mandatory'' MOOP limits.
- Codify the current rule for using ranges to identify the type of MOOP amount an MA plan has established and applying that rule to the three proposed types of MOOP limits: The mandatory MOOP limit, the intermediate MOOP limit, and the lower MOOP limit in § 422.100(f)(4)(ii). Specifically, establishing that: (1) The mandatory MOOP limit is any dollar limit that is above the intermediate MOOP limit and at or below the mandatory MOOP limit threshold established each year; (2) the intermediate MOOP limit is any dollar limit that is above the lower MOOP limit and at or below the intermediate MOOP limit threshold established each year; and (3) the lower MOOP limit is any dollar limit that is between $0.00 and up to and including the lower MOOP limit threshold established each year.
- Codify specific cost sharing limits and flexibilities tied to using the intermediate and lower (previously

''voluntary'') MOOP limits by MA plans (see section II.B. of this FC for the specific proposals).

2. Codify the Methodology for the Three MOOP Limits for 2022 and Subsequent Years (§ 422.100(f)(4))

CMS proposed to codify generally our current methodology for how we set MOOP limits with several revisions at § 422.100(f)(4) and to use cross-references in §§ 422.100(f)(5), 422.101(d)(2) and 422.101(d)(3) to establish how MOOP limits are set for local and regional plans. These proposals were to do all of the following:

- Amend § 422.100(f)(4) to impose general rules for setting the MOOP limits and codify the current practice of setting the MOOP limits based on a percentile of projected Medicare FFS beneficiary out-of-pocket spending, which would be developed based on the most recent, complete Medicare FFS data.
- Codify rounding each MOOP limit to the nearest whole $50 increment, or the lower $50 increment in cases where the MOOP limit is projected to be exactly in between two $50 increments, in § 422.100(f)(4)(iii).
- Codify our current policy of setting the combined MOOP limits (that is, the MOOP limits that cover both in-network and out-of-network benefits) by multiplying the respective in-network MOOP limits by 1.5 for the relevant year with rounding, if necessary, for MA regional plans in § 422.101(d)(3) and using a cross-reference to that rule for MA local PPOs in § 422.100(f)(5)(i).
- Establish the rules for setting the MOOP limits for contract years 2022, 2023, 2024, 2025, and subsequent years in § 422.100(f)(4)(iv), (v), and (vi). The proposal was, in effect, that the MOOP limits for contract year 2022 would be a recalibration of the MA MOOP limits by using a methodology adjusted from current practice. For contract year 2022, we proposed to set the MOOP limits as follows:
- The mandatory MOOP limit is set at the 95th percentile of projected Medicare FFS beneficiary out-of-pocket spending.
- The intermediate MOOP is set at the numeric midpoint of mandatory and lower MOOP limits.
- The lower MOOP limit is set at the 85th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

These MOOP limits would be set subject to the rounding rules at § 422.100(f)(4)(iii). CMS proposed to use projections for the applicable contract year of out-of-pocket expenditures for Medicare FFS beneficiaries that are based on the most recent, complete Medicare FFS data that incorporates a percentage of the costs incurred by beneficiaries with diagnoses of ESRD (called ''ESRD costs'' in this FC), using the ESRD cost transition schedule proposed in paragraph (f)(4)(vii). In the following subsection, II.A.3. of this FC, we summarize that transition schedule and the data we proposed to use for setting MOOP limits.

For future contract years, we proposed to set the MOOP limits using a methodology that considers the amount of change from the prior year's MOOP limits to minimize disruption and change for enrollees and plans. Our proposed methodology was designed to allow MA plans to provide stable benefit packages year over year by minimizing MOOP limit fluctuations unless a consistent pattern of increases or decreases in beneficiary out-of-pocket costs emerges over time. Again, we proposed that these MOOP limits would be set subject to the rounding rules and using projections based on the most recent, complete Medicare FFS data that incorporates a percentage of the costs incurred by beneficiaries with diagnoses of ESRD, using the transition schedule at § 422.100(f)(4)(vii). In addition, the proposed methodology for MOOP limits for years 2023 until the end of this transition schedule was designed to balance the incorporation of increased costs incurred by beneficiaries with diagnoses of ESRD into the Medicare FFS data projections used to calculate the MOOP limits with the goal of providing stability in the MOOP limits. For example, we proposed to delay the ESRD cost transition in years where the change in the MOOP limit might otherwise be too significant, specifically when projections for the upcoming contract year were outside the range of two percentiles above, or below, the applicable percentile of Medicare FFS beneficiary out-of-pocket spending (including costs incurred by Medicare FFS beneficiaries with and without diagnoses of ESRD) from the prior year. Similarly, the proposed methodology for establishing MOOP limits for the years following the completion of the transition schedule was intended to provide stability in the MOOP limits by placing a cap on how much limits can increase from one year to the next when certain conditions are met.

To set the mandatory and lower MOOP limits for contract years 2023 and 2024 or, if later, until the end of the ESRD cost transition, we explained that under our proposal, CMS would—

- Review OACT projections of out-of-pocket spending for the applicable year that is based on updated Medicare FFS data, including all spending regardless of ESRD diagnoses;
- Compare the applicable year's projection of the 95th percentile and 85th percentile to the prior year's projections;
- Determine if the prior year's projections for the 95th percentile and 85th percentile are within a range, above or below, of two percentiles of the applicable percentile in that updated projection. For example, for the contract year 2023 mandatory MOOP limit, we would determine if the contract year 2022 95th percentile projection is between or equal to the 93rd and 97th percentiles of the projections for 2023 out-of-pocket expenditures;
- If the prior year's 95th and 85th percentile projections are between or equal to the two percentile ranges above or below, we would continue the ESRD cost transition schedule proposed at § 422.100(f)(4)(vii) for one or both of the MOOP limits;
- If one or both of the prior year's 95th and 85th percentile projections are not within the two percentile ranges above or below, we would increase or decrease one or both of the MOOP limits up to 10 percent of the prior year's MOOP limit annually until the MOOP limit reaches the projected 95th percentile for the applicable year, subject to the rounding rules as proposed at § 422.100 (f)(4)(iii). For example, if the dollar amount that needs to be transitioned represents 15 percent, then 10 percent would be addressed during the upcoming contract year, while any remaining amount would be addressed during the following contract year (if applicable based on updated data projections from the OACT). During this period of time, we would delay implementation of the next step in the ESRD cost transition schedule proposed in paragraph (f)(4)(vii). The ESRD cost transition schedule would resume at the rate that was scheduled to occur once the prior year's projected 95th and 85th percentile remains within the range of two percentiles above or below the projected 95th percentile for the upcoming contract year. For example, for the contract year 2023 mandatory MOOP limit, if the 2023 projected 95th percentile corresponds to the projected 98th percentile for contract year 2022 out-of-pocket expenditures, we would set the contract year 2023 mandatory MOOP by increasing the contract year 2022 mandatory MOOP limit by up to 10 percent and rounding as proposed at paragraph (f)(4)(iii); and
- The intermediate MOOP limit would be set by either maintaining it as the prior year's intermediate MOOP

limit (if the mandatory and lower MOOP limits are not changed), or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounding as proposed at § 422.100(f)(4)(iii).

We proposed regulation text to implement this process for setting the mandatory, intermediate, and lower MOOP limits at § 422.100(f)(4)(v), with paragraphs (f)(4)(v)(A), (B) and (C) addressing the mandatory, intermediate, and lower MOOP limits respectively.

For contract year 2025 (or the year following the conclusion of the ESRD cost transition schedule proposed at § 422.100(f)(4)(vii)) and for subsequent years, we proposed to include in the methodology a process to consider trends that are consistent for 3 years. The proposed regulation text included ''or following the ESRD cost transition'' to clarify that the ESRD cost transition schedule may end in 2025 or extend longer due to how we proposed to handle any sudden increases or decreases in costs. For example, if for contract year 2023, the projected 95th percentile amount represents the 98th percentile from the prior year's (contract year 2022) projections, then we would only increase the MOOP limit for contract year 2023 by up to 10 percent of the prior year's MOOP amount and extend the ESRD cost transition schedule past 2025 by the number of years it takes until the upcoming year's projected 95th percentile amount was within two percentiles above or below the prior year's projection of the 95th percentile. We also proposed the methodology for the mandatory and lower MOOP limits for contract year 2025 or following the ESRD cost transition schedule. Specifically, CMS proposed that the prior year's corresponding MOOP limit is maintained for the upcoming contract year if: (1) The prior year's MOOP limit amount is within the range of two percentiles above or below the projected 95th or 85th percentile of Medicare FFS beneficiary out-of-pocket spending incurred by beneficiaries with and without diagnoses of ESRD; and (2) the projected 95th or 85th percentile did not increase or decrease for 3 consecutive years in a row. If the prior year's corresponding MOOP limit is not maintained because either (1) or (2) occur, CMS would increase or decrease the MOOP limit by up to 10 percent of the prior year's MOOP limit amount annually until the MOOP limit reaches the projected applicable percentile for the applicable year, based on the most recent, complete Medicare FFS data projections from the OACT. The intermediate MOOP limit would be set by either maintaining it as the prior year's intermediate MOOP limit (if the mandatory and lower MOOPs are not changed), or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounding as proposed in paragraph (f)(4)(iii). We proposed regulation text to implement this process for setting the mandatory, intermediate, and lower MOOP limits for contract year 2025 or following the data transition schedule and subsequent years at paragraph (f)(4)(vi), with paragraphs (f)(4)(vi)(A), (B), and (C) addressing the mandatory, intermediate, and lower MOOP limits respectively.

We explained that the principal goals of our proposal were to outline clearly the methodology for establishing the MOOP limits, to provide stability in MOOP limits and benefit packages, minimize fluctuations in the MOOP limits from year-to-year, and to minimize the potential for enrollee confusion that may result from fluctuations from year-to-year in the MOOP limit. We solicited comment on whether the February 2020 proposed rule would accomplish those things.

3. Multiyear Transition of ESRD Costs Into the Methodology for MOOP Limits (§ 422.100(f)(4))

Section 1851(a)(3) of the Act, as amended by section 17006 of the 21st Century Cures Act, permits Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beyond the previous enrollment limitations, beginning in contract year 2021. As discussed in the February 2020 proposed rule, CMS expected this change will result in Medicare beneficiaries with diagnoses of ESRD to begin transitioning to or choosing MA plans in greater numbers than previously. Specifically, the OACT expected ESRD enrollment in MA plans to increase by 83,000 beneficiaries as a result of the 21st Century Cures Act provision. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021. Based on actual 2021 enrollment data, the OACT continues to project that 83,000 beneficiaries with diagnoses of ESRD will enroll in the MA program over 6 years. We explained that the data we use to set the MOOP limits should also incorporate the out-of-pocket expenditures of beneficiaries with diagnoses of ESRD to reflect this statutory change.

For 2020 and prior years, CMS set MOOP limits using projected Medicare FFS beneficiary out-of-pocket spending for the year, based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare FFS and excluding all costs for beneficiaries with ESRD. For example, for contract year 2020 MOOP limits, we used projected out-of-pocket costs for Medicare FFS beneficiaries (excluding out-of-pocket costs from beneficiaries with diagnoses of ESRD) prepared by the OACT, based on the most recent Medicare FFS data (from 2014 to 2018). We excluded the costs for individuals with diagnoses of ESRD because of the limits on when and how a Medicare beneficiary with diagnoses of ESRD could enroll in an MA plan under section 1851(a) of the Act. In the February 2020 proposed rule we stated that in contract year 2018, 0.6 percent of the MA enrollee population, or approximately 121,000 beneficiaries, have diagnoses of ESRD. This statistic was based on the statutory definition of ESRD and CMS data. Using more recent enrollment data, the number of beneficiaries enrolled in MA in contract year 2018 with diagnoses of ESRD is lower than previously stated, approximately 120,100 (which does not impact the 0.6 percent of the MA enrollee population figure).[3] For 2021 and 2022, CMS set the voluntary and mandatory MOOP limits by applying the standard in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). Because of the expected changes in enrollment in MA plans by beneficiaries with diagnoses of ESRD beginning in 2021, we incorporated 40 percent of the ESRD cost differential (the difference between projected out-of-pocket costs for Medicare FFS beneficiaries with and without diagnoses of ESRD and only those without diagnoses of ESRD) for 2021 which increased both types of MOOP limits from 2020. These MOOP limits were maintained for contract year 2022.[4]

CMS developed the approach to conduct a multiyear transition of ESRD costs into the methodology for how CMS establishes MOOP limits with input from the OACT. CMS did not

[3] The Fiscal Year President's Budgets may be accessed at *https://www.govinfo.gov/app/collection/BUDGET/* and the annual Advance Notice and Rate Announcements may be accessed at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents*. In addition, see page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf*.

[4] See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021. See the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

expect that those Medicare beneficiaries with diagnoses of ESRD that were expected to switch from FFS to MA would enroll in the MA program immediately after the enrollment limitations were lifted and as such, CMS did not propose to integrate all of the costs associated with all beneficiaries with diagnoses of ESRD within one contract year.

As part of developing the proposal, CMS looked at the impact of factoring in 100 percent of the costs of beneficiaries with ESRD into the data used to set MA MOOP limits. Using the most recent Medicare FFS data available at the time of the February 2020 proposed rule (2015 to 2019 data, with 2018 being the most heavily weighted), the OACT projected the out-of-pocket costs for Medicare FFS beneficiaries. Based on this data, we compared the 95th and 85th percentiles of the projected out-of-pocket costs for all Medicare FFS beneficiaries for the 2021 contract year to the $7,175 and $3,360 dollar amounts (calculated using the 95th and 85th percentiles of the projections without ESRD costs) to calculate the cost difference, which we consistently refer to as an ESRD cost differential. CMS calculated the $999 95th percentile ESRD cost differential by comparing the $7,175 to $8,174 with related ESRD costs, a difference of $999.

As discussed in the February 2020 proposed rule, our goal is to strike a balance between potential increases in plan costs and enrollee costs (meaning cost sharing and premiums) by scheduling adjustments to the MOOP limits (that is, adjustments to include data about the costs incurred by beneficiaries with diagnoses of ESRD into the data used to set the MOOP limits) to reflect a reasonable transition of ESRD beneficiaries into the MA program. Accordingly, our proposed revisions to the current methodology for setting MOOP limits included a scheduled transition for incorporating ESRD costs to allow MA organizations to plan for the change and mitigate sudden changes in MOOP limits, benefit designs, and premiums that could be disruptive to enrollees and MA organizations. To accomplish this, we proposed to do all of the following:

- Codify at § 422.100(f)(4)(vii) a multiyear transition schedule from our current practice of excluding all costs incurred by beneficiaries with diagnoses of ESRD to including all related costs into the Medicare FFS data that is used to set the MOOP limits.
- Add § 422.100(f)(4)(vii) to define the term ''ESRD cost differential'' to refer to the difference between: (1) Projected out-of-pocket costs for beneficiaries using Medicare FFS data excluding the costs incurred by beneficiaries with ESRD diagnoses for contract year 2021 and (2) the projected out-of-pocket costs for all beneficiaries using Medicare FFS data (including the costs incurred by beneficiaries with ESRD diagnoses) for each year of the ESRD cost transition.
- Identify the specific dollar amounts in the regulation text defining the ESRD cost differential at § 422.100(f)(4)(vii), as $7,175 for the 95th percentile and $3,360 for the 85th percentile based on the projected costs incurred by beneficiaries without ESRD diagnoses for the 2021 contract year.
- Add § 422.100(f)(4)(vii)(A), (f)(4)(vii)(B), and (f)(4)(vii)(C) to establish a specific schedule for factoring in an increasing percentage of the ESRD cost differential annually until 2024 or, if later, the final year of the transition and beyond.
- Begin the regulatory ESRD cost transition with the 2022 contract year, factoring in 60 percent of the ESRD cost differential and increasing that percentage by 20 percentage points for each successive year of the transition, as follows:

—For 2023 (or the next year of the transition), factor in 80 percent of the ESRD cost differential.

—For 2024 (or the final year of the transition), factor in 100 percent of the ESRD cost differential.

While we proposed to factor in the ESRD cost differential for contract year 2022 through contract year 2024, CMS initially started incorporating ESRD costs into the MOOP limits for contract year 2021. Specifically, CMS calculated the MOOP limits for contract year 2021, under the current regulations, using projections of Medicare FFS cost data from 2015 to 2019 for beneficiaries without diagnoses of ESRD. The OACT determined the Medicare FFS percentiles for 2021 by applying Medicare FFS cost sharing trends (consistent with the 2019 Medicare Trustees Report) to project contract year 2021 costs. CMS then added in 40 percent of the ESRD cost differential to the projected Medicare FFS percentiles. A more complete discussion on how CMS set MOOP limits for contract year 2021 is available in the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020. In the February 2020 proposed rule, CMS also proposed a methodology to prevent excessive changes in the MOOP limit. Taking into consideration both the 2021 MOOP limits and our proposal for contract years 2022 through 2024, CMS's proposed policy would have effectively used a 4-year period to transition to full incorporation of ESRD costs.

CMS included in the February 2020 proposed rule two tables (Table 4, ''Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections'' and Table 5, ''Illustrative Example of Combined MOOP Limits for LPPO and Catastrophic (MOOP) Limits for RPPO Plans Based on Most Recent Medicare FFS Data Projections'') to show the potential impact of incorporating the out-of-pocket costs of Medicare FFS beneficiaries with diagnoses of ESRD into the methodology for the MOOP limits proposed at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) (85 FR 9077). These tables were developed to project 2021 costs using Medicare FFS data from 2015–2019, which was the most recent Medicare FFS data available at the time of the February 2020 proposed rule. In developing Tables 4 and 5 from the February 2020 proposed rule, we applied the proposed methodology, including not only the multiyear transition for incorporating the ESRD cost differential but also the rounding rules, and illustrated the ranges for the three MOOP limits. We explained that the tables were only illustrative MOOP limits for contract years 2022 through 2024 based on the most, recent complete Medicare FFS data at the time the February 2020 proposed rule was developed. As a result, we noted actual MOOP limits for these contract years may be different from the illustrative limits based on updated Medicare FFS data and projections. As part of our proposal, we explained that we would apply the methodology as codified and publish the resulting MOOP limits for each year on a timely basis, such as through an HPMS memorandum, with a description of how the regulation standard was applied, but we did not propose to codify the timeframe or a requirement for that publication.

In conclusion, we proposed to amend §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) as described to allow plans to provide stable benefit packages year over year by minimizing MOOP limit fluctuations unless a consistent pattern of increases or decreases in costs emerges over time. We solicited comment on this approach in light of our goal of avoiding enrollee confusion and maintaining stable benefit packages. We also solicited comments whether our proposed regulation text adequately and clearly specified the methodology that would be used to set the MOOP limits each

year. We noted our intention to issue annual guidance applying these rules, in advance of the bid deadline so that MA organizations know and understand the MOOP limits for the upcoming year.

4. Comments Received and Responses for All MOOP Limit Provisions

We received feedback from 27 commenters on this proposal. The majority of comments were from health plans, provider associations, beneficiary and other advocacy organizations, and pharmaceutical companies. A summary of the comments (generally by issue) and our responses follows:

Comment: Several commenters supported CMS's proposals related to MOOP limits overall and some additional commenters supported codifying longstanding policies in regulation, including the Medicare FFS percentiles used to determine the MOOP limits. A few commenters that supported codifying longstanding policies in regulation noted that the standardization, transparency, and predictability of formal rulemaking provides program stability. A few other commenters specifically appreciated the additional transparency in how CMS sets the MOOP limits. A commenter was supportive of the MOOP limit proposal to codify the methodology CMS uses to set the MOOP limits and the addition of the third intermediate MOOP limit for the flexibility it would provide for MA organizations to innovate, improve available benefit offerings, and provide beneficiaries with affordable MA plans tailored to their unique healthcare needs and financial situation. Another commenter appreciated the opportunity to provide feedback to guide implementation processes.

Response: We thank commenters for their support. CMS believes codifying these flexibilities in regulation will encourage MA organizations to develop plan designs to take advantage of the flexibilities as well as provide transparency and stability for the MA program. In addition, we expect MA organizations will have a greater understanding about how the MOOP limits are calculated and be better prepared to anticipate changes in MOOP limits in future years as a result of this provision. As we discussed in the February 2020 proposed rule and in more detail in our responses to comments, the goals of this rulemaking touch on several issues and we believe that this FC will result in positive outcomes for the MA program.

The changes to the proposals we are finalizing in this FC range from minor edits, reorganizations, corrections, and clarifications to substantive modifications based on the comments received, operational considerations (such as, changes stemming from the timing of this FC), and improvements to the methodology. Our goal in finalizing the cost sharing proposals as described in this FC is to adopt standards and require compliance that further antidiscriminatory requirements (such as, by supporting equitable access to plans for beneficiaries with high health needs). Because of the timing of this FC, operational considerations, and to help ensure that MA organizations have sufficient implementation time, the provisions in this FC will be applicable for coverage beginning January 1, 2023. This reflects a one-year delay from the proposed implementation schedule. When MA bids for contract year 2023 are submitted for review and approval by the statutory deadline (June 6, 2022 for contract year 2023), the regulations and final MOOP and cost sharing limits in this FC will be used to evaluate those bids for approval as well as applying to the coverage provided beginning January 1, 2023. Several modifications to the proposed regulation text (for example, changing a reference from January 1, 2022 to January 1, 2023 in § 422.100(f)(4)) are because of this change in the implementation of the MOOP provisions. Therefore, to avoid repetitive text in responses to comments in this section II.A. of this FC, we explain here that the proposed regulation text in §§ 422.100 and 422.101 was modified to change implementation by 1 year. Changes to the implementation of the proposed policies that are more nuanced are explained in detail (for example, section II.A.4.c. of this FC addresses the multi-year transition schedule of ESRD costs into MOOP limits). For the same reason, to avoid repetitive text, where there is no distinction made about the Medicare FFS data projections used, CMS means the data includes out-of-pocket costs from beneficiaries with and without diagnoses of ESRD. Specifically, the term ''Medicare FFS data projections'' is used as defined in § 422.100(f)(4)(i).

We take this opportunity to clarify, in addition to the discussion in the February 2020 proposed rule, which costs are tracked and accumulate toward the MOOP limit. As discussed in the final rule titled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' that appeared in the **Federal Register** on April 15, 2011 (76 FR 21431) (April 2011 final rule), the in-network (catastrophic) and combined (total catastrophic) MOOP limits consider only the enrollee's actual out-of-pocket spending for purposes of tracking out of pocket spending relative to its MOOP limit. This approach also applies to D–SNPs. Thus, for any D–SNP enrollee, MA plans are only required to count those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost sharing toward the MOOP limit rather than the cost sharing amounts for services the plan has established in its plan benefit package (PBP). (MA plans are permitted to count toward the MOOP any cost sharing that is exempted from collection because the enrollee is dually eligible for Medicare and Medicaid or that has been paid by Medicaid, but are not required to do so.) We did not propose in the February 2020 proposed rule to change the policy adopted in the April 2011 final rule regarding which cost sharing amounts must be counted toward the MOOP limit. We are finalizing the amended regulations at § 422.100(f)(4) and (f)(5) using the phrase ''incurred by the enrollee'' to be consistent with current § 422.101(d)(4), which refers to costs ''incurred by'' the enrollee in describing the MOOP limit. In the proposed rule titled, ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' that appeared in the **Federal Register** on January 12, 2022 (87 FR 1842) (January 2022 proposed rule), CMS is proposing that the MOOP limit in an MA plan (after which the plan pays 100 percent of MA costs for Part A and Part B services) be applied based on the accrual of all cost-sharing in the plan benefit, regardless of whether that cost sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost-sharing. Throughout this FC and in the various regulations adopted here, we use ''incurred by'' in referring to out-of-pocket costs of an MA enrollee that are counted toward accumulation of the MA plan's MOOP amount to avoid suggesting this FC adopts an unproposed change in the policy from the April 2011 final rule or distinction in the data we use regarding out-of-pocket costs in the Medicare FFS program. In light of the January 2022 proposed rule, we note that the amendments regarding the phrase ''incurred by the enrollee'' described in this response may be subject to change if a final rule for the MOOP attainment proposal is published. However, other

than in the specific cases related to an MA organization's obligation to track the MOOP limit for enrollees, the term is used in a more general sense that does not specifically incorporate this aspect of the current regulations for MOOP limits as applied to dually eligible individuals.

Under this FC, MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the applicable MOOP amount is reached (for § 422.100(f)(4) the in-network MOOP; for paragraph (f)(5)(iii) the combined MOOP). In addition, we are not finalizing the regulations at § 422.101(d)(2)(ii) and (d)(3)(iii) as proposed (which substantively addressed the same requirement for the catastrophic (in-network) MOOP and the total catastrophic (combined) MOOP) to avoid repeating text that is in paragraph (d)(4). Existing § 422.101(d)(4) requires MA regional plans to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) based on incurred out-of-pocket beneficiary costs for original Medicare covered services and to notify members and health care providers when the deductible (if any) or a limit has been reached; we are not making any revisions to that specific provision. As finalized, the regulations at § 422.100(f)(4) and (f)(5)(iii) require MA organizations to track out-of-pocket spending incurred by the enrollee in a local MA plan and alert enrollees and contracted providers when the applicable MOOP amount (in-network, combined, catastrophic, or total catastrophic) is reached. This FC maintains the ability for D–SNPs to establish zero cost sharing for enrollees who are dually enrolled in both Medicare and Medicaid. For example, in a Zero-Dollar Cost Sharing D–SNP, Medicare inpatient hospital stays and doctor visits are available at no cost to the enrollee. A Medicare Non-Zero Dollar Cost Sharing D–SNP is a D–SNP under which the cost sharing for Medicare Part A and B services varies depending on the enrollee's category of Medicaid eligibility.

Comment: A few commenters requested that CMS educate beneficiaries with diagnoses of ESRD about their costs and plan choices in the MA program. Related to this topic, another commenter noted that dialysis providers may make special efforts to educate their patients about the option to enroll in a MA plan, so that the beneficiary may benefit from potential reductions in out-of-pocket costs because of the MOOP limit and the value of supplemental benefits in addition to the dialysis provider potentially being paid higher than Medicare FFS rates due to provider concentration and network adequacy requirements in the MA program.

Response: We agree with the commenters in that all beneficiaries should have access to the information they need to make informed decisions about what health plan best fits their needs. Enrollment of beneficiaries with diagnoses of ESRD in MA increased in the years prior to 2021 while the limitations on enrollment were in place. This suggests that this patient population is knowledgeable about Medicare plan choices. In addition, MA organizations, providers, and other stakeholders have been aware of the program change to allow (beyond the previous enrollment exceptions) Medicare beneficiaries with diagnoses of ESRD to enroll in MA beginning with contract year 2021 since the enactment of section 17006 of the 21st Century Cures Act in December 2016. CMS expects that MA organizations, providers, State Health Insurance Assistance Programs, and other stakeholders have and will continue to communicate information about MA plan options to all Medicare eligible beneficiaries, including those with diagnoses of ESRD. Section 422.111 requires that MA plans make materials available to existing and prospective enrollees, including provider networks, benefit coverage, and cost sharing. We believe that those requirements will also ensure that eligible beneficiaries, including those with diagnoses of ESRD, receive plan-level information they need to make an enrollment election. In addition, CMS provides a Medicare & You handbook to all beneficiaries annually which includes information about MA plan options and eligibility (including for those with diagnoses of ESRD). We agree with the comment that dialysis and other specialty providers typically involved in caring for patients with diagnoses of ESRD may choose to make special efforts to educate their patients about the MA program. (We remind MA organizations that they and their downstream entities must comply with applicable marketing and communication regulations, including the limits on MA marketing activities with healthcare providers and in healthcare settings in § 422.2266.) CMS also expects beneficiaries with diagnoses of ESRD will evaluate all available health care plan options, including MA plans.

Comment: Several commenters had general concerns about beneficiaries with diagnoses of ESRD being discouraged from enrollment or having a lack of access to MA plans due to discriminatory benefit designs. For example, some commenters noted that enrollees with diagnoses of ESRD are more expensive and will reach the MOOP amount more quickly than enrollees without diagnoses ESRD, so MA organizations may have an incentive to discourage enrollment of beneficiaries with diagnoses of ESRD. In addition, commenters suggested MA plans may tier or use different out of pocket costs based on certain conditions, or limit benefits for ESRD enrollees compared to other enrollees. A commenter noted concerns about ESRD enrollees having adequate access to MA plan options based on the MOOP limits and network adequacy time and distance requirements (another provision from the February 2020 proposed rule).

Response: MA plans may not use higher MOOP amounts or limit benefits for enrollees with diagnoses of ESRD and CMS's review of bids will evaluate for and deny benefit packages that CMS determines are designed to discourage enrollment by beneficiaries with diagnoses of ESRD. As noted in the February 2020 proposed rule, section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. In addition, as stated in section VI.B. of the February 2020 proposed rule (page 9079), MA organizations must comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex (including sexual orientation and gender identity), age, disability, including section 1557 of the Affordable Care Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. The regulation at § 422.110 provides that an MA organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status. MA organizations discouraging or preventing enrollment in an MA plan by beneficiaries on the basis of their ESRD diagnoses after January 1, 2021, would be prohibited by § 422.110. CMS relies on the MA anti-discrimination provision, the agency's authority under

section 1856(b) of the Act to adopt standards for MA organizations, and the agency's authority under section 1857(e) of the Act to add terms and conditions that are necessary, appropriate, and not inconsistent with the Medicare statute in setting the requirements under § 422.100(f)(4) and (5) that impose MOOP limits on local MA plans in alignment with the statutory catastrophic limits imposed on regional MA plans under section 1858(b) of the Act. We believe that requiring the inclusion of a MOOP limit in plan benefit design is necessary in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act). None of the provisions in this FC limit application of other anti-discrimination requirements.

As we discussed in the CY 2019 Call Letter [5] and April 2018 final rule (83 FR 16440), the flexibility we have adopted for how MA plans must offer uniform benefits is premised on MA plans furnishing additional benefits to improve treatment and outcomes for a specific health condition; that flexibility may not be used to lower or restrict benefits based on health status (83 FR 16480 through 16481). Therefore, the flexibility to offer additional supplemental benefits based on a connection with a particular health condition may not be used as a means to discourage enrollment by or discriminate against beneficiaries with diagnoses of ESRD. We encourage beneficiaries and other stakeholders to bring to our attention marketing and communications materials or other activities that may indicate that an MA organization is violating the anti-discrimination requirements applicable in the Medicare Advantage program by contacting 1–800–MEDICARE or by submitting a Medicare Complaint Form online.[6]

a. Authorize Setting Three MOOP Limits on Basic Benefits (§§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3))

Comment: Several commenters supported CMS's proposal to add a third, intermediate MOOP limit. Commenters who supported the proposal noted that an intermediate MOOP limit will provide MA organizations the flexibility to innovate, improve benefit designs to offer high-value plan options to beneficiaries, and provide beneficiaries with affordable MA plans tailored for their unique healthcare needs and financial situation. A commenter stated this flexibility is increasingly important, as CMS has allowed MA organizations to develop specialized plans designed to address beneficiaries with chronic conditions. Another commenter was supportive and stated lower MOOP limits provide critical affordability protection for MA beneficiaries as actuarial firm modeling has shown that the voluntary MOOP limit provides substantial value to MA enrollees without driving higher member premiums.[7] Several commenters supported CMS monitoring over time whether changes from the provisions in this FC result in beneficiaries having access to plan offerings with MOOP limits below the mandatory MOOP limit or lower cost sharing. A commenter noted that this monitoring is critically important to ensuring that CMS can effectively enforce the anti-discrimination provision of the statute.

Response: We appreciate the support. By implementing more than two types of MOOP limits and providing increased flexibility in the cost sharing limits for MA organizations with a lower MOOP amount, we expect to encourage MA plan offerings with favorable benefit designs so that beneficiaries can choose plans that meet their needs. CMS compared the percentage of contract year 2021 plans with MOOP amounts within the final dollar range of each MOOP type for contract year 2023 (as calculated using the methodology set through this FC) to determine the proportion of plans that established a MOOP amount that would be considered one of the three MOOP types we are finalizing for use beginning in contract year 2023. Based on plan data from March 2021 (excluding employer, D–SNPs, and MSA plans), the percentage of contract year 2021 plans (and enrollees) with an in-network MOOP amount within the final dollar range of each MOOP type for contract year 2023 (as shown in Table 5, which incorporates ESRD costs as discussed in section II.A.4.c. of this FC) is approximately:

- 24.9 percent of plans (25.8 percent of enrollees) have an in-network MOOP amount between $0 and $3,650 (the contract year 2023 lower MOOP limit);
- 36.9 percent of plans (41.7 percent of enrollees) have an in-network MOOP amount between $3,651 and $6,000 (the contract year 2023 intermediate MOOP limit); and
- 38.2 percent of plans (32.6 percent of enrollees) have an in-network MOOP amount between $6,001 (the lowest range amount for the contract year 2023 mandatory MOOP limit) and $7,550 (the highest allowable contract year 2021 mandatory MOOP amount).

This distribution shows that the smallest proportion of contract year 2021 plans established a MOOP amount that would qualify for a lower MOOP type in contract year 2023 (see Table 5 for the final contract year 2023 MOOP limits). A contributing factor to this distribution may be how most cost sharing standards for professional services have been historically set at the same amount regardless of the MOOP type (mandatory or lower, previously ''voluntary'' MOOP limit) established by the MA plan. In section VI.B. of the February 2020 proposed rule, we proposed differentiating cost sharing limits for highly utilized services (for example, primary care physician and physician specialist PBP service categories) and various other cost sharing services categories by the MOOP type, with lower MOOP limits receiving the most cost sharing flexibility. By establishing the maximum permitted cost sharing limit at different amounts (that is, by using a range of differentiated cost sharing limits for most services) across the three MOOP types, this FC is expected to promote greater differences between plans and provide MA organizations with meaningful cost sharing flexibilities if they choose to use the lower MOOP limits in their benefit design.

As discussed further in section II.B. of this FC, plan designs with mandatory MOOP types will have less flexibility in cost sharing and therefore less ability to use cost sharing as a means to incentivize enrollee behavior and manage medical costs beginning in contract year 2023. For example, MA organizations that establish a mandatory MOOP type for contract year 2026 will be subject to a 30 percent coinsurance limit for certain professional services and those that establish an intermediate MOOP type will be subject to a 40 percent coinsurance limit (as finalized in section II.B. of this FC). As discussed in the February 2020 proposed rule, the 30 percent coinsurance amount is most closely related to the cost sharing limit amounts stated in the CY 2020 Call Letter. Stated another way, we expect

[5] Available at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[6] The online Medicare Compliant Form may be accessed and submitted at: *https://www.medicare.gov/medicarecomplaintform/home.aspx.*

[7] Julia M. Friedman, Brett L. Swanson, Mary G. Yeh, and Jordan Cates, Milliman Inc., ''State of the 2020 Medicare Advantage industry: As strong as ever.'' February 14, 2020 *https://at.milliman.com/en/insight/state-of-the-2020--medicare-advantage-industry-as-strong-as-ever.*

MA plans that establish a mandatory MOOP type will have lower or comparable copayment amounts when compared to existing benefit packages because the copayment limits set by CMS in past years for MA plans were, based on 2015 through 2019 Medicare FFS data projections available at the time of the February 2020 proposed rule, close to the 30 percent limit being set in this FC for several professional standards. In addition, by offering the intermediate MOOP type, we will be providing a mid-level MOOP option which is currently projected (for contract year 2023) to represent approximately 37 percent of plan in-network MOOP amounts in contract year 2021. We expect the combination of the three MOOP types and proportional cost sharing flexibilities for each type will encourage plans to adopt lower or intermediate MOOP amounts and adopt cost sharing that is lower or comparable when compared to existing benefit packages. Without the intermediate MOOP type as an option, plans may be more likely to adopt higher MOOP limits as a result of being afforded less cost sharing flexibility. Plans could design their plan benefits in ways that also meet enrollee needs by focusing on other benefit features, such as, zero premium and supplemental benefits, rather than lower MOOP amounts.

CMS will monitor whether changes from this FC result in beneficiaries having access to MA plan offerings with lower or intermediate MOOP types and cost sharing that is lower or comparable when compared to existing benefit packages over time. Specifically, we will conduct these analyses annually and communicate concerns through the subregulatory process finalized at § 422.100(f)(7)(iii) and may consider whether changes are necessary in future rulemaking based on the results of these analyses.

Comment: A commenter had concerns about the potential beneficiary impact of having up to three MOOP limits for local and regional plans, such as the possibility of MA plans varying costs by beneficiary health status and tiering or targeting higher MOOP limits towards beneficiaries with diagnoses of ESRD. The commenter explained that if MA plans tiered or targeted higher MOOP limits that it would create a significant financial burden for beneficiaries with diagnoses of ESRD. In addition, the commenter believed these increased costs and benefit designs would discourage beneficiaries with diagnoses of ESRD and other chronic illnesses from enrolling in the MA program and ultimately result in the de facto elimination (or lack of access to meaningful coverage options) of MA plans, contrary to the intent of Congress. The commenter requested CMS clarify that MA plans may not target higher MOOP limits to only ESRD patients. This commenter also noted that the strong protections CMS applies for all other beneficiaries that prohibit discrimination on the basis of health status, should be applied fairly to beneficiaries with diagnoses of ESRD to prevent MA plans from discriminating against and discouraging beneficiaries with diagnoses of ESRD from enrolling in the MA program.

Response: We disagree that adding a third, intermediate MOOP limit will allow MA organizations to design plans that discriminate against beneficiaries with diagnoses of ESRD or other chronic conditions and discourage them from enrolling in the MA program. Nothing in the MOOP regulations, as proposed or finalized, permits an MA plan to have higher MOOP amounts for certain enrollees in the plan based on health status. Specifically, MA plans are not permitted to create tiered MOOP amounts based on chronic conditions, such as kidney failure or the need for dialysis services, and if a MA organization submitted a plan bid with tiered MOOP amounts based on chronic conditions, that benefit design would not be approved. MOOP limits are and must be applied uniformly to all plan enrollees and our proposal to add a third, intermediate MOOP limit did not change this requirement. In addition, MA plans are required to provide all medically necessary Medicare Parts A and B services to enrollees. We reiterate that the benefits for all enrollees in an MA plan must be uniform, subject to the waiver of uniformity that may be provided for an MA plan to target specific Special Supplemental Benefits for the Chronically Ill (SSBCI) under § 422.102(f) and how optional supplemental benefits are only provided for enrollees who elect to pay the extra premium for that coverage under § 422.101(c)(2). The ability to offer supplemental benefits that have a connection with a specific health condition is permitted only for reductions in cost sharing and additional benefits, not for decreasing benefits, and requires the supplemental benefit to be available to all similarly situated enrollees. Therefore, MOOP amounts are applied uniformly to all plan enrollees, while MA plans are allowed to offer different additional supplemental benefits, including additional reductions in cost sharing, for similarly situated individuals based on disease state or chronic health condition as part of a uniform benefit package. As proposed and finalized, the MOOP limits cannot be applied so that enrollees with diagnoses of ESRD have a higher or otherwise different MOOP amount. In addition, a more complete discussion about the statutes and regulations preventing MA plans from discriminating against beneficiaries with diagnoses of ESRD or other chronic conditions is provided in section II.A.4. of this FC in response to other similar concerns about discrimination.

Finally, CMS will also continue evaluations based on enforcement of the current authority prohibiting plans from misleading beneficiaries in their marketing and communication materials and continue efforts to improve plan comparison tools and resources (for example, Medicare Plan Finder, Medicare & You, and 1–800–MEDICARE) in order to monitor whether plan communications give the impression that MOOP amounts are not applied uniformly for all enrollees. We encourage beneficiaries and other stakeholders to bring to our attention marketing and communication materials or other activities that may indicate that an MA organization is violating the anti-discrimination requirements applicable in the MA program, by contacting 1–800–MEDICARE or by submitting a Medicare Complaint Form online.[8]

Comment: A commenter believed a third MOOP limit may create choice confusion for new and existing enrollees when evaluating their plan options.

Response: We disagree that adding a third, intermediate MOOP limit will confuse beneficiaries when they are evaluating their plan options. CMS expects that all beneficiaries reviewing their plan options for the upcoming contract year will continue to consider a number of factors when choosing an MA plan, such as plan type, benefits, per-service cost sharing, provider network, and the MOOP amount. This information will continue to be available to beneficiaries in Medicare Plan Finder and MA plan communication materials. We also expect that MA organizations, providers, State Health Insurance Assistance Programs, and other stakeholders have and will continue to communicate information about MA plan options to all Medicare eligible beneficiaries. Although beneficiaries make their plan choice based on a number of factors, such as the MOOP

[8] The online Medicare Compliant Form may be accessed and submitted at: *https://www.medicare.gov/medicarecomplaintform/home.aspx.*

amount and premium, they are typically not aware if the plan's MOOP amount qualifies as a lower, intermediate, or mandatory MOOP limit based on MA regulations.

Comment: A commenter opposed a third, intermediate MOOP limit because it may result in higher MOOP limits for all MA beneficiaries.

Response: While there may be more variation in the MOOP amounts and cost sharing structures used by MA plans as a result of this FC, we believe that beneficiaries have the tools and resources to evaluate their expected out-of-pocket costs, compare cost sharing amounts charged by different MA plans, and determine whether a particular plan design would benefit them. For example, these comparisons may be assisted by using Medicare Plan Finder and communications materials. We expect the MOOP limit and cost sharing flexibilities finalized in this FC will allow MA organizations to design benefits that encourage positive enrollee decision-making about their health care needs and manage medical costs more effectively without producing plan options that are confusing for beneficiaries.

Under section 1854(a)(5)(C)(ii) of the Act, CMS is authorized to deny a plan bid if the bid proposes significant increases in enrollee costs or decrease in benefits from one plan year to the next. A plan's Total Beneficiary Cost (TBC) is the sum of the plan-specific Part B premium, plan premium, and estimated beneficiary out-of-pocket costs. CMS uses a standardized TBC evaluation for each bid to evaluate year over year changes when bids are submitted for the upcoming contract year. The TBC standard is applied at the plan level to ensure enrollees in each applicable plan are not subject to too significant an increase in costs or decrease in benefits from one plan year to the next. CMS has observed that MA organizations tend to reduce their profit margins, rather than substantially change their benefit package from one year to the next. We believe this tendency may be to ensure that a bid does not exceed the TBC threshold and also due to marketing and competitive forces; for example, an MA plan with fewer or less generous supplemental benefits, even for one year, may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it may be advantageous for the MA organization to temporarily reduce its margin, rather than reduce benefits. MA organizations have a range of cost sharing flexibilities for a few service categories now (such as, inpatient hospital acute and psychiatric length of stay scenarios) and typically do not establish the highest allowable cost sharing for the MOOP amount used by the MA plan. In fact, CMS has found that MA organizations typically offer benefits with lower cost sharing amounts than the maximum cost sharing limits for the vast majority of service categories we have permitted in past years (such as primary care physician). While we do not have definitive data, we believe this is due to multiple factors, including the principles and incentives inherent in managed care, effective negotiations between MA organizations and providers, and competition. Further, MA plan must, at a minimum, offer plan designs where the cost sharing for basic benefits is at least actuarially equivalent to the cost sharing in the original Medicare program. In addition, we expect beneficiary choice will continue to act as an incentive for MA organizations to offer favorable benefit designs. Considering these factors, CMS expects that differentiating cost sharing standards by the three MOOP types, and in some cases limiting the cost sharing flexibility for MA plans that establish a mandatory MOOP type, will encourage MA organizations to establish a lower MOOP type (that is, lower or intermediate) and/or lower cost sharing amounts for enrollees in order to maintain a competitive position in the market.

Comment: A commenter opposing the proposal was concerned that a third, intermediate MOOP limit would not provide a strong actuarial incentive for more MA plans to establish lower MOOP limits and that MA organizations may find it difficult to determine which MOOP limit offers the best value.

Response: We disagree with the comment that MA organizations may find it difficult to determine which MOOP amount offers the best value for their purposes as a result of this provision. CMS expects MA organizations have, and will use, business tools and actuarial resources to effectively structure benefit designs, including MOOP amounts.

Comment: A commenter opposing the proposal to add a third, intermediate MOOP limit suggested CMS encourage MA organizations to offer plans with lower MOOP limits through alternative means. The commenter suggested some alternative ways to incentivize MA plans to establish a voluntary, lower MOOP limit including that CMS: (1) Raise the 85th percentile that determines the voluntary MOOP limit to the 87th or 88th percentile while maintaining the 95th percentile for the mandatory MOOP limit; or (2) provide higher ratings in the Part C and D Star Rating program for MA plans that establish the lower, voluntary MOOP limit. The commenter's rationale for increasing the percentile that determines the lower, voluntary MOOP limit was that MA plans could increase their cost sharing over time while the voluntary MOOP limit increases simultaneously, which would not encourage MA plans to switch to the mandatory MOOP limit.

Response: We appreciate the suggestions of other options to incentivize MA organizations to offer plans with lower MOOP amounts. While the commenter's suggestion to raise the percentile that we use to calculate the lower, voluntary MOOP limit might produce some incentive for MA plans to choose a lower MOOP type, it may also likely mean that enrollees face increased cost responsibility with the lower MOOP options than they would under our proposal and this FC. We believe maintaining the lower (previously ''voluntary'') MOOP limit at the 85th percentile is beneficial to enrollees and provides incentive to MA plans to offer lower MOOP amounts when the cost sharing flexibilities unique to each MOOP type are considered. The cost sharing provisions, addressed in section II.B. of this FC, provide incentives for MA organizations to offer lower MOOP amounts by permitting higher cost sharing when a lower (or intermediate) MOOP type is used. For example, CMS's longstanding policy has been to allow MA plans to establish up to 50 percent coinsurance for most in-network professional services (subject to exceptions, such as for inpatient hospital acute and psychiatric services, skilled nursing facility, chemotherapy administration including chemotherapy drugs and radiation therapy, and renal dialysis), regardless of the MOOP limit. In this FC, we limit this degree of flexibility of having up to 50 percent coinsurance for in-network professional services, beginning in contract year 2023, to MA plans that establish lower MOOP amounts (40 percent coinsurance for intermediate MOOP amounts and 30 percent coinsurance for mandatory MOOP amounts after the transition period). The cost sharing flexibilities adopted in this rule apply to highly utilized services (for example, professional and inpatient hospital service categories) and, thus, afford the most flexibility to MA plans that have lower MOOP amounts. As a result, this flexibility will encourage MA organizations to establish MOOP amounts at or below the lower MOOP limit because they will have more

flexibility in establishing cost sharing. Overall, we aim to prevent discriminatory benefit designs with the adoption of the methodologies and rules for setting MOOP and cost sharing limits and by capping the amount of financial responsibility the MA organization can transfer to enrollees. Limits on out-of-pocket costs prevent plan designs that deter or discourage enrollment by beneficiaries that are high utilizers of health care services or that have higher-cost medical needs.

In regard to a commenter's suggestion to provide additional star rating value for MA plans offering the lower voluntary MOOP amount, we believe this request is outside of the scope of our proposal. Our Star Ratings proposals did not include adding a quality measure or a quality rating methodological change tied to MOOP type and were finalized in section IV.D. of the January 2021 final rule (86 FR 5864).

We are finalizing our proposal for three MOOP limits. We take this opportunity to explain the use of terminology in this FC and the regulations; we use consistent language when referring to MOOP limits (calculated by CMS by applying the methodologies finalized here), MOOP amounts (established by MA organizations), and MOOP types (lower, intermediate, and mandatory) in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). We are also finalizing the regulations at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) with slight changes from the February 2020 proposed rule to be clearer that: (1) § 422.100(f)(4) applies to an in-network MOOP limit for local MA plans and, consistent with our current policy and practice, that in-network MOOP limit applies to private fee-for-service (PFFS) plans; (2) § 422.100(f)(5) applies to a combined MOOP limit (for basic benefits that are provided in-network and out-of-network) for MA local PPO plans; (3) § 422.101(d)(2) applies to a catastrophic limit (in-network MOOP limit) for regional MA plans; and (4) § 422.101(d)(3) applies to a total catastrophic limit (combined MOOP) for regional MA plans. In addition, we made edits throughout these provisions to ensure clarity and consistency in referencing in-network, combined, catastrophic, and total catastrophic MOOP limits, amounts, or types. For example, in § 422.101(d)(3)(i) we clarify that the total catastrophic limit may not be used to increase the catastrophic limit described in paragraph (d)(2).

CMS is finalizing § 422.100(f)(4) with a clearer statement that MA local plans must have an enrollee in-network MOOP amount for basic benefits that is no greater than the annual limit calculated by CMS using Medicare FFS data projections (as defined in paragraph (f)(4)(i)). We believe this change clarifies a point from the February 2020 proposed rule that HMO–POS plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP amount or to a combined in- and out-of-network MOOP amount. Currently, and with the change proposed and finalized in this rule, paragraph (f)(5) requires MA local PPO plans to have a combined MOOP amount for basic benefits that are provided in network and out-of-network. This change compared to our proposed text for paragraph (f)(4) also improves the regulation text by making the requirement to not exceed MOOP limits calculated by CMS more definitive and transparent than the general reference to paragraph (f)(4) in the February 2020 proposed rule. In addition, we added a statement to paragraph (f)(4) to codify CMS's longstanding policy (since 2012) that PFFS plans must use the in-network MOOP limit for all covered basic benefits, regardless of whether the provider is contracted with the PFFS plan or whether the PFFS plan has a partial or full provider network. Specifically, PFFS plans have been subject to the in-network MOOP limits for in- and out-of-network benefits because of the complexities of their provider network designs and ability to use balance billing. We also modified paragraph (f)(4)(i) to clarify that CMS will calculate three in-network MOOP limits. Additional changes to paragraph (f)(4)(i) (namely, defining a consistent term that describes the data CMS uses in the methodology to calculate MOOP limits and specifying the dollar ranges for each MOOP type) are discussed more completely in section II.A.4.b. of this FC.

We thank commenters for all of their input. In this FC, we are finalizing the proposed addition of a third, intermediate MOOP type at §§ 422.100(f)(4) and (f)(5) and 422.101(d)(2) and (d)(3). The three MOOP types will apply to MA local and regional plans and to in-network and, for PPO plans, out-of-network basic benefits. The methodology for calculating the MOOP limits, including that the calculations are subject to the rounding rules in paragraph (f)(4)(iii) and the ESRD cost transition schedule in paragraph (f)(4)(vii), is discussed in sections II.A.4.b. and c. of this FC. Among the modifications we are finalizing are a change in the scope of data used to calculate the MOOP and cost sharing limits (discussed in section II.A.4.b. of this FC) and a change in the transition schedule for the ESRD cost differential (discussed in section II.A.4.c. of this FC). Further, we are finalizing the addition of descriptive headings to § 422.100(f)(1)—(9) to orient the reader to the content in each paragraph. While we did not propose updates to paragraphs (f)(1)–(3), the addition of headings will improve the clarity of the regulations, does not change the substance of the regulations, and results in a consistent approach for paragraph (f). Paragraph (f)(6) and new paragraphs (f)(7)–(9) are discussed in detail in section II.B. of this FC.

b. Codify the Methodology for the Three MOOP Limits for 2023 and Subsequent Years (§ 422.100(f)(4))

Comment: A few commenters responded to the solicitation from the February 2020 proposed rule on whether a specific rule requiring CMS to issue subregulatory guidance applying the methodology in these regulations by a specific date each year should be codified. The commenters requested CMS provide guidance well in advance of the upcoming plan year that the MOOP limit changes are effective. A commenter requested CMS release annual guidance no later than 60 days prior to the first Monday in April with a minimum 30-day comment period to align with the Advance Notice of Methodological Changes for the upcoming Calendar Year for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies.

Response: CMS will apply the finalized regulations each year to calculate the MOOP limits for contract year 2023 and future years using the methodology adopted in this FC and the most recent Medicare FFS data projections. The final contract year 2023 MOOP limits in Table 5 are calculated using the methodology and formulas in § 422.100(f)(4). These calculations using contract year 2023 Medicare FFS data projections (based on 2017 to 2021 Medicare FFS data) are provided in Tables 2 through 4. We are adopting at § 422.100(f)(7)(iii) a provision regarding the release of annual subregulatory guidance beginning for contract year 2024. The guidance will identify the contract year MOOP limits that are set and calculated using the methodology and standards in §§ 422.100(f) and 422.101(d). This guidance may include a description of how CMS calculated the ESRD cost differential to set the MOOP limits. This annual guidance will be

issued prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. We expect this date will typically be by the first Monday in April, which aligns with the deadline for the Rate Announcement for MA rates and the risk adjustment factors under section 1853(b) of the Act and § 422.312. Coordinating these MOOP and other cost sharing limit changes with the announcement of MA payment policies for the year is important to CMS and means that the final annual guidance of how the regulations we are adopting in this FC will be applied with updated data is unlikely to be issued prior to the first Monday in April. However, we are not adopting this date as a deadline for the final issuance of annual guidance specifying the MOOP limits and cost sharing standards as CMS may not always be able to meet this timeline as competing priorities, particularly those with statutory deadlines such as the Rate Announcement, may take precedence. For contract year 2024, we expect to issue the final MOOP limits and cost sharing standards sometime in April, 2023. As finalized in § 422.100(f)(7)(iii), CMS will provide a public notice and comment period on the projected MOOP limits and cost sharing limits for the upcoming contract year unless a public comment period is impracticable, unnecessary, or contrary to the public interest. We believe these situations will be rare and intend to solicit comment annually, but believe that aligning the availability of prior notice and an opportunity to comment with rulemaking standards, which include authority to waive prior notice and a comment period when it is impracticable, unnecessary, or contrary to the public interest, is appropriate. To the extent necessary and appropriate, CMS may solicit and consider public comment on actuarial approaches before releasing the final MOOP limits and cost sharing standards as required in paragraph (f)(7)(iii). The exercise of actuarial judgment by the OACT may be a topic on which the public, or MA organizations, wish to comment when reviewing how CMS has applied the regulations adopted in this FC to calculate the benefit parameters for MA plans. As appropriate, we will consider such comments and may revise the decisions made in developing the projections and calculations of the MOOP and other cost sharing limits. In addition to using set departmental methods of posting guidance (for example, the HHS guidance repository), CMS may also release this annual subregulatory guidance through communication vehicles CMS has used in the past to deliver certain guidance, such as HPMS memoranda.[9] We believe stakeholders are used to annual guidance for the MA program being released through these additional avenues and continuing this practice will encourage comment submissions as received in prior years.

We did not codify a deadline or a specific minimum time frame for the comment period on the MOOP and cost sharing standards for the upcoming contract year to ensure flexibility when necessary in future situations. As highlighted by the COVID–19 pandemic, maintaining a certain level of flexibility in regulation can be beneficial for the agency to better serve our stakeholders. For example, we may consider a comment period less than 30 days in the event of delays from external variables (such as, public health emergencies) when it is necessary in order to release final MOOP and cost sharing limits on a timeframe that is sufficient for MA organizations to prepare and submit plan bids. This approach will support the release of subregulatory guidance that addresses MOOP limits and cost sharing standards in advance of the upcoming plan year.

We are finalizing the proposal that the three MOOP types will be calculated using the 95th and 85th percentiles of projected Medicare FFS beneficiary out-of-pocket spending and the mid-point between those with the specific provisions as provided in § 422.100(f)(4). In addition, we are finalizing additional changes in the codification of the methodology that CMS uses to calculate MOOP limits in paragraph (f)(4). First, the ESRD cost transition (which was proposed in paragraph (f)(4)(vii)) is finalized in paragraph (f)(4)(vi) with changes from the proposal and we are finalizing the rules for calculating the in-network MOOP limits for 2023 in § 422.100(f)(4)(iv) and for 2024 and subsequent years in § 422.100(f)(4)(v) (as more completely addressed in section II.A.4.c. of this FC).

Second, we are not finalizing the term ''complete'' in various provisions that describe the data used to develop the cost projections that are the basis for calculating the MOOP limits to more accurately reflect current practice in calculating MOOP limits and cost sharing limits. The February 2020 proposed rule stated that the OACT uses the most recent, complete Medicare FFS data to project costs for the applicable year. Upon reflection, CMS realizes that the word ''complete'' may be subject to different interpretations. For example, ''complete'' could be interpreted as meaning that the data for that year being used to project costs is missing no information or that only one year of data would be used by the OACT to project costs. To ensure clarity in the regulation text on this point, we are removing the reference of ''complete'' and explaining here how the OACT approaches developing the projections to be used in calculating cost sharing limits. In developing the projections that CMS uses to determine cost sharing limits, the OACT uses several years of Medicare data (generally 99 percent complete) that apply trend factors (consistent with the most recent Medicare Trustees Report). The trend factors give the most weight to the more recent calendar years of data. Projections are then modified using actuarial judgement. This is considered an actuarially acceptable approach in determining and projecting Medicare FFS percentiles and is consistent with longstanding policy. As a result, we are updating the references to the data CMS uses to calculate MOOP and cost sharing limits throughout the regulations at §§ 422.100(f) and (j) and 422.101(d). Specifically, in paragraph (f)(4)(i) we are defining the term, ''Medicare FFS data projections'' as meaning the projections of beneficiary out-of-pocket costs for the applicable contract year, based on recent Medicare FFS data, including data for beneficiaries with and without diagnoses of ESRD, that are consistent with generally accepted actuarial principles and practices as outlined in paragraph (f)(7)(i) (discussed subsequently in this response). The Medicare FFS data and resulting Medicare FFS data projections necessarily include cost and utilization data associated with the projected out-of-pocket costs. As defined and used throughout the regulations, the term ''Medicare FFS data projections'' concisely and consistently describes the data CMS uses to calculate MOOP and cost sharing limits. In addition, we believe using the term ''Medicare FFS data projections'' in describing the data is consistent with past practice and our intent for this aspect of the methodology (that is, data are from calendar years but the data are not fully complete, data from more than one calendar year may be used, trend factors are used, and projections are made to the contract year for which the MOOP limits are set). Based on the definition and how we have used the term, the Medicare FFS

[9] Individuals and organizations may request placement on the HPMS listserv at *https://hpms.cms.gov/app/ng/home/*.

data projections reflect full incorporation of the ESRD cost differential.

Third, we are finalizing the substance of proposed § 422.100(f)(4)(ii)(A) through (C) in paragraphs (f)(4)(i)(A) through (C) with clarification. Specifically, we are clarifying in paragraphs (f)(4)(i)(A) and (B), consistent with Table 4 (Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections) in the February 2020 proposed rule, that the ranges determining in a plan's MOOP amount is considered a mandatory or intermediate MOOP type are as follows:

- Mandatory MOOP limit: One dollar above the intermediate MOOP limit and up to and including the mandatory MOOP limit.
- Intermediate MOOP limit: One dollar above the lower MOOP limit and up to and including the intermediate MOOP limit.

We are finalizing the description of the range for the lower MOOP limit in paragraph (f)(4)(i)(C) as proposed (in paragraph (f)(4)(ii)(C)) as we believe the proposed regulation text is sufficiently clear.

Next, we are finalizing § 422.100(f)(4)(ii) with a more complete list of the regulations which use the terms ''mandatory MOOP limit,'' ''intermediate MOOP limit,'' and ''lower MOOP limit.'' These terms encompass a MOOP amount that varies from the specific highest allowable dollar figure announced by CMS for each MOOP type when the plan's MOOP amount is within the ranges specified in § 422.100(f)(4)(i)(A) through (C). We proposed to refer to paragraphs (f)(6) and (j) of § 422.100, but are finalizing references to paragraphs (f) and (j) of § 422.100, § 422.101(d), and § 422.113(b)(2)(v). This change better reflects the cost sharing requirements finalized in section II.B. of this FC. Referring to § 422.101(d) is consistent with how the types of in-network MOOP limits referenced in § 422.100(f)(4)(i)(A), (B), and (C) will be used, beginning for contract year 2023, to calculate the catastrophic and total catastrophic (combined MOOP) limits that apply to regional plans under § 422.101(d)(2) and (3).

To better reflect how finalized § 422.100(f)(4) applies to catastrophic and total catastrophic (combined MOOP) limits, increase clarity in the regulations, and make necessary corrections from the February 2020 proposed rule to codify the range CMS has applied in calculating and evaluating compliance with these MOOP limits, we are also finalizing changes in § 422.101(d)(2) and (3). We are consolidating proposed § 422.101(d)(2) to clearly require MA regional plans to: (1) Establish a catastrophic enrollee MOOP for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4); and (2) have the same MOOP type (lower, intermediate, or mandatory) for the catastrophic (in-network MOOP) limit and total catastrophic (combined in-network and out-of-network expenditures) limit under § 422.101(d)(3).

In addition, we are adding new paragraphs (d)(3)(ii)(A), (B), and (C) in § 422.101. New paragraphs (d)(3)(ii)(A), (B), and (C) specify the ranges to determine if a plan's total catastrophic (combined MOOP) amount is considered a mandatory, intermediate, or lower MOOP type for purposes of §§ 422.100 and 422.101. These correspond to the ranges in § 422.100(f)(4)(i)(A) through (C) but are specific to the total catastrophic (combined MOOP) limits. Including these ranges for total catastrophic (combined MOOP) limits improves the regulation overall by providing more specificity in our codification of longstanding policy. As finalized in new § 422.101(d)(3)(ii)(A), (B), and (C), the ranges that define the type of total catastrophic (combined MOOP) limit (mandatory, intermediate, and lower) are as follows:

- Mandatory MOOP limit: One dollar above the in-network intermediate MOOP limit and up to and including the total catastrophic mandatory MOOP limit.
- Intermediate MOOP limit: One dollar above the in-network lower MOOP limit and up to and including the total catastrophic intermediate MOOP limit.
- Lower MOOP limit: Between $0.00 and up to and including the total catastrophic lower MOOP limit.

This addition adds clarity to the regulation text and the ranges now codified in § 422.101(d)(3)(ii)(A) and (B) are consistent with our current practice for setting the lower and upper ranges of the total catastrophic MOOP limits.

Finalizing regulation text with these ranges explicitly described reflects a necessary correction to the proposed rule. Specifically, the approach in § 422.101(d)(3)(iii)(A) through (C) of having total catastrophic (combined MOOP) limits set one dollar above the in-network lower and intermediate MOOP limit amounts (for the total catastrophic (combined) intermediate and mandatory MOOP limits, respectively) is consistent with longstanding practice and reflects our current policy for how MA plans must have the same type of in-network and total catastrophic (combined MOOP) amount (mandatory, intermediate, or lower). In the illustrative MOOP limits from Table 5 (Illustrative Example of Combined MOOP Limits for LPPO And Catastrophic (MOOP) Limits for RPPO Plans Based on Most Recent Medicare FFS Data Projections) in the February 2020 proposed rule, the lower range of the illustrative combined intermediate and mandatory MOOP types did not correctly reflect our intention to continue our current policy. For example, based on the illustrative in-network and combined MOOP limits for contract year 2022 provided in Tables 4 and 5 in section VI.A. of the February 2020 proposed rule, an MA plan that established an in-network intermediate MOOP of $3,451 would have to establish a combined intermediate MOOP between $5,151 and $8,400, even if a plan wanted to establish a combined MOOP amount of $4,000. Requiring an MA plan with an in-network MOOP amount to establish a combined MOOP amount that is one dollar above the combined lower MOOP limit (as shown in Table 5 from the February 2020 proposed rule) unnecessarily raises the combined MOOP amount rather than tying the lower range of the amount to the type of in-network MOOP amount chosen. As a result, the contract year 2023 in-network and total catastrophic (combined MOOP) limits in Table 5 reflect this finalized policy (as well as other changes more completely discussed in this section to apply the proposed rounding rules in § 422.100(f)(4)(iii), clarify how the application of the 10 percent cap on increases to the MOOP limits applies, and changes to the proposed ESRD cost transition discussed in section II.A.4.c. of this FC.). No changes in the approach to calculating the lower range of the combined lower MOOP limit are needed as the MOOP limits were shown to correctly reflect current practice by beginning at zero dollars in Table 5 from the February 2020 proposed rule. In summary, CMS will continue our longstanding approach by codifying the ranges finalized in §§ 422.100(f)(4)(i) and 422.101(d)(3)(ii) to determine if an MA organization is compliant with the finalized requirement in § 422.101(d)(2)(ii) (proposed in paragraph (d)(2)(i)) that the MA plan has the same type of in-network and total catastrophic (combined MOOP) limit (mandatory, intermediate, or lower).

We are finalizing at § 422.100(f)(4)(iii) the rounding rules CMS uses for the MOOP limits generally as proposed but

we are also finalizing new text to clarify and correct how the rounding rules at § 422.100(f)(4)(iii) are applied in calculating the in-network intermediate MOOP limit and all types of the catastrophic MOOP limits. In order to avoid applying the rounding rules in paragraph (f)(4)(iii) twice to calculate the in-network intermediate MOOP limit and to ensure that the resulting intermediate MOOP limit most closely reflects a numeric midpoint between the final mandatory and lower MOOP limits, we are finalizing a modification to paragraphs (f)(4)(iv)(B) and (v)(B). First, CMS will identify the unrounded mandatory and lower MOOP limits and apply the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year (as discussed in section II.A.4.c. in this FC). Second, CMS will identify the numeric midpoint of those two figures. Third, CMS will apply the rounding rules in paragraph (f)(4)(iii) to that numeric midpoint. The resulting figure is the intermediate MOOP limit. This process of calculating the intermediate MOOP limit is illustrated in Table 3. Specifically, Table 3 shows the calculations to set the contract year 2023 in-network intermediate MOOP limit following the methodology finalized in this FC. By basing the intermediate MOOP limit on the non-rounded, capped amounts used to calculate the final mandatory and lower MOOP limits, we are still calculating the intermediate MOOP limit as the numeric midpoint between the two MOOP limits as proposed. We are not finalizing any reference to the rounding rules in § 422.101(d)(2) because this modification to the provisions in § 422.100(f)(4) will apply to the catastrophic MOOP limits for in-network basic benefits for regional MA plans calculated under § 422.101(d)(2) because of how § 422.101(d)(2) cross-references § 422.100(f)(4). In addition, we are finalizing § 422.101(d)(3)(ii) with clarifying language about when the rounding rules are applied in order to avoid applying the rounding rules twice in calculating the total catastrophic MOOP limits for regional MA plans for contract year 2023 and subsequent years. We are also finalizing clarifying language about applying the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year when calculating the total catastrophic MOOP limits. Specifically, for contract year 2023 and subsequent years, we will calculate the total catastrophic (combined MOOP) limits for regional MA plans by multiplying the respective non-rounded in-network MOOP limits (after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in § 422.100(f)(4)(iv) and (v)) by 1.5 and then applying the rounding rules to that figure. The rounded number will be the final upper range amount for the catastrophic limit for MA regional plans for combined in-network and out-of-network expenditures for basic benefits.

We believe these modifications to § 422.100(f)(4)(iv)(B) and (v)(B), and to § 422.101(d)(3)(ii) will result in more precise in-network intermediate MOOP limits and total catastrophic (combined MOOP) limits for future years. CMS completed the calculations of the in-network intermediate and total catastrophic (combined MOOP) limits for contract year 2023 following this methodology as shown in Tables 3 and 4. The final contract year 2023 in-network intermediate MOOP limits and total catastrophic (combined MOOP) limits in Table 5 reflect these updates (as well as the other changes for calculating MOOP limits finalized in this FC). MA plans must comply with the resulting final MOOP limits included in Table 5 for contract year 2023.

We are also finalizing additional and revised text in § 422.101(d)(2) and (d)(3) to clarify the scope of the regional MA plan MOOP amounts and the specific services to which the different MOOP limits apply: The catastrophic limit calculated under paragraph (d)(2) applies to in-network basic benefits and the total catastrophic limit calculated under paragraph (d)(3) applies to in-network and out-of-network basic benefits. We are finalizing a new paragraph (d)(3)(iii) to clearly require an MA organization to establish the total catastrophic MOOP amount (mandatory, intermediate, or lower) within the dollar range specified in paragraphs (d)(3)(ii)(A) through (C) and the type of MOOP limit will be used for purposes of §§ 422.100(f)(6), (j)(1), 422.101(d), and 422.113(b)(2)(v).

In large part the proposal was to describe and codify the methodology used for MOOP limits under CMS's policies first developed in a 2011 rulemaking for adopting MOOP limits beginning in 2012. As described in the February 2020 proposed rule, the OACT performs the data projections used for setting MOOP limits. Taking the most recent Medicare FFS data and developing projections for the contract year for which we will be calculating the MOOP limits necessarily involves informed judgment and the making of actuarial assumptions. CMS and the OACT have been guided by generally accepted actuarial principles and practices in developing the projections used for calculating the MOOP limits. The proposal implicitly acknowledged this in its description of how the OACT analyzes the relevant data to develop the projections in the preamble of the February 2020 proposed rule. Specifically, the February 2020 proposed rule discussed how the OACT conducted necessary analyses and projections in the past and made clear that the OACT would be involved in applying the methodologies to calculate the MOOP limits we were proposing. CMS will continue to use generally accepted actuarial principles and practices in finalizing the projections of beneficiary out-of-pocket costs that form the basis of the methodology to calculate MOOP limits. As a result, we are also finalizing new § 422.100(f)(7) to ensure that this FC provides more detail regarding the actuarial nature of how Medicare costs are projected which we believe is better stated in the regulation text. These principles permit discretion and the exercise of actuarial judgment; as a result, different actuaries and analysts may come to different, equally appropriate, projections. Actuaries often consider different methodologies and assumptions to project the effect of uncertain events.[10] Generally, data from full calendar years would be used (and may be full data or samples based on full data), but specific trends and/or utilization patterns from more recent periods may be considered even if the Medicare FFS program and/or more recent utilization information from MA encounter data are from incomplete years. The projections of the percentiles that determine MOOP limits may be affected in limited situations by changes in legislation (such as, changes in Medicare benefits), payment policy changes, significant region-specific events (such as, natural disasters), or other emergency situations. As the OACT determines their projections, trend factors are applied (consistent with the most recent Medicare Trustees Report). For example, the OACT will apply trend factors that reflect the expected volatility and impact of COVID–19 on Medicare FFS utilization data from prior years in order to determine the Medicare FFS data projections for 2023 and subsequent years that CMS will use in calculating MOOP limits for those years. This approach is consistent with accepted actuarial standards of practice in that actuaries may use their professional judgment when selecting methods and assumptions, conducting an analysis, and reaching a conclusion. We reiterate

[10] *http://www.actuarialstandardsboard.org/profcounts/asop-no-1-and-professional-judgment/.*

that this is an example and that CMS and the OACT may exercise actuarial judgment in other matters as appropriate based on the regulatory standard being finalized at paragraph (f)(7)(i). CMS may explain the significant, professional actuarial judgments the OACT considered and solicit comment from stakeholders through the subregulatory process finalized in paragraph (f)(7)(iii) prior to final issuance of the MOOP limits and cost sharing standards for a future contract year. CMS may also describe how the OACT reached the projections used to calculate MOOP limits, if applicable and appropriate. For contract year 2023, the Medicare FFS data projections of the 95th and 85th percentiles included in row D of Table 2 reflect the OACT's actuarial judgements of expected costs in contract year 2023, including considerations of the impact from COVID–19. In summary, we are finalizing paragraph (f)(7)(i) to ensure transparency about the standards applied in developing the projections used in the methodologies for calculating the MOOP limits in §§ 422.100(f)(4) and (f)(5), and 422.101(d)(2) and (d)(3) will be applied using generally accepted actuarial principles and practices.

As discussed in more detail in section II.B of this FC, new § 422.100(f)(7) will also apply to how cost sharing standards in paragraph (f)(6) and (j) are calculated and evaluated using the methodologies adopted in this FC. Accordingly, we also discuss this new regulatory paragraph as it relates to cost sharing standards in section II.B. of this FC. Next, we address comments received on the ESRD cost transition schedule, explain how CMS's calculations of MOOP limits are impacted by ESRD costs, and more specifically address how the MOOP limits will be set for 2023 and future years in section II.A.4.c. of this FC.

c. Multiyear Transition of ESRD Costs Into the Methodology for MOOP Limits and Post-Transition Changes in the MOOP Limits (§ 422.100(f)(4)(iv) Through (vi))

CMS proposed to conduct a multiyear transition of ESRD costs into the methodology for how we calculate MOOP limits. Section 1851(a)(3) of the Act, as amended by section 17006 of the 21st Century Cures Act, amended the Medicare statute to permit Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beyond the previous enrollment limitations, beginning in contract year 2021. Before these amendments were effective for contract year 2021, individuals diagnosed with ESRD could not enroll in a MA plan, subject to limited exceptions. In the proposed rule, we explained that the data CMS uses to calculate the MOOP limits should also incorporate the out-of-pocket expenditures of beneficiaries with diagnoses of ESRD, which we are referring to in this FC as ''ESRD costs,'' to reflect this statutory change. We also proposed safeguards to protect against excessive changes in the MOOP limit during and after the ESRD cost transition. Since the February 2020 proposed rule, OACT studied the impact of expanded ESRD enrollment eligibility for the MA program on MA benefits using 2021 Medicare data and has estimated the impact to be $ − 0.45 PMPM which is the weighted average for all MA plans.

Comment: A commenter noted that the February 2020 proposed rule did not include Table 11, to which CMS referred (85 FR 9076) to illustrate how the transition of ESRD costs into the MOOP limit calculations would work.

Response: The references to Table 11 in the February 2020 proposed rule preamble (85 FR 9076) were incorrect. We should have referenced Table 4, titled ''Table 4—Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections.'' As indicated in the context of the February 2020 proposed rule and the table title, Table 4 illustrated the transition of the ESRD cost differential into the MOOP limit calculations using projections of Medicare FFS cost based on 2015 to 2019 Medicare FFS data (85 FR 9077).

Comment: Many commenters were generally concerned about the potential effects from enrollee subsidization of ESRD costs and believed passing the financial burden of ESRD care on to enrollees is not an appropriate solution. The commenters noted non-ESRD enrollee subsidization of ESRD costs may produce negative downstream effects on MA enrollment, plan options, premiums, supplemental benefits (including SSBCI), care coordination services, and access to lower MOOP and cost sharing limits. A commenter that opposed the transition of ESRD costs into MOOP limits acknowledged that some increase may be justified but stated that the incorporation of ESRD costs simply raises costs for all beneficiaries and was similarly concerned about non-ESRD enrollees subsidizing costs associated with enrollees with diagnoses of ESRD.

A commenter, in referencing a Wakely actuarial consulting firm study,[11] suggested MA organizations may raise enrollee premiums by as much as $18 per member per month, or reduce benefits by a similar magnitude, or limit plan options, to cover the increase in plan expenses due to covering enrollees with diagnoses of ESRD. Another commenter mentioned that MA organizations may redirect MA rebate dollars, normally used for benefit enhancements such as reduced cost sharing and mandatory supplemental benefits, to instead cover the additional ESRD costs. A commenter noted that while some cost subsidization across all MA enrollees is inherent to the design of the MA program, the commenter did not believe that increasing the cost burden for all MA enrollees is a sustainable solution for higher costs caused by an increased number of ESRD beneficiaries in the MA program. Another commenter urged CMS to give equal consideration to containing out-of-pocket costs for all Medicare beneficiaries.

Response: We believe conducting a multiyear transition of ESRD costs into our methodology for setting MOOP limits is an important and necessary step to ensure plan designs are not discriminatory and protect beneficiaries from significant changes in out-of-pocket costs regardless of the MA plan they choose. As the MOOP limits will apply to enrollees with and without diagnoses of ESRD, the data CMS uses to calculate the MOOP limits should include out-of-pocket expenses from beneficiaries with and without diagnoses of ESRD similar to how costs for other high cost health conditions are included in the Medicare FFS data used to calculate MOOP limits.

We appreciate that some MA plans anticipate increased costs associated with covering the cost of care for individuals with diagnoses of ESRD. An analysis conducted by the OACT demonstrates that the ESRD open enrollment opportunities beginning in 2021 are expected to have a limited impact on both the financial outcomes of MA organizations and the corresponding benefits and premiums of the MA program. The primary reasons for the relatively small effect are that the increase in projected MA ESRD enrollment will represent a small fraction of membership in MA plans and that any financial effects will be diluted across existing plan membership. For the base data for this analysis, the OACT used the 2019 ESRD experience submitted by MA

[11] Tim Courtney and Rachel Stewart, Wakely Consulting Group. ''2021 Medicare Advantage Advance Notice,'' March 4, 2020 *https://www.ahip.org/2021-medicare-advantage-advance-notice/.*

organizations as part of their 2021 bids. Increases in MA enrollment of beneficiaries with ESRD due to the expanded ESRD enrollment eligibility were estimated based on prior baselines that did not include this expansion. The expectations are that the projected movement of beneficiaries with ESRD into the MA program will result in slightly decreased MA margins. The Medical Loss Ratio (MLR) for ESRD enrollees is projected to be higher than the MLR for non-ESRD enrollees. The MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care, rather than for such other items as administrative expenses or profit. In general terms, the MLR is inversely correlated with margins; higher MLRs are normally associated with lower margins. The impact of the MA margin change on MA benefits was estimated based on the assumption that MA organizations will recoup the losses (gains) stemming from increased ESRD enrollment through a reduction (increase) in the margin represented in the MA bid. Using the revised bid margin assumption, we recalculated the key bid values, including the plan bid, MA rebate, and MA basic premium, if applicable. Combining these assumptions, the enrollment-weighted average estimated change in net MA benefits resulting from the ESRD enrollment expansion is −$0.45 PMPM for contract year 2021.

As provided in section 1853(a)(1)(H) of the Act, CMS establishes separate rates of payment to MA organizations for ESRD beneficiaries enrolled in MA plans. See also §§ 422.254 and 422.304 through 422.308. The rates used for enrollees in dialysis or transplant status are based on statewide average Medicare FFS costs for ESRD beneficiaries in dialysis status. For enrollees with functioning graft status, the MA county benchmark rates are the payment rates. The rates for those in dialysis, transplant, and functioning graft status are also adjusted using a risk adjustment methodology that is specific to the health care costs for beneficiaries with ESRD in dialysis, transplant or functioning graft status. The proposal being finalized here was about how the MOOP limits should be calculated, including the data used and the percentiles of Medicare FFS data projections that should be used in those calculations.

We proposed to transition the out-of-pocket costs for beneficiaries who have diagnoses of ESRD into the methodology CMS uses to calculate MOOP limits over multiple years to avoid sudden and significant changes, which would be disruptive to enrollees. A sudden and significant shift in the MOOP limits—which would happen if the MOOP limits were increased by 100 percent of the ESRD cost difference in one year—is not consistent with protecting enrollees from disruptive year over year benefit or cost sharing changes. In this manner, we believe our approach gives equitable consideration to containing out-of-pocket costs for all current and potential MA enrollees.

CMS acknowledges and understands that some plans may adopt a mandatory MOOP type. However, we expect MA organizations will continue to offer favorable benefit designs that meet beneficiary needs, are competitive, and are attractive to beneficiaries. In addition, MA organizations have multiple strategies to manage care and costs through provider contracting, care coordination, case management, plan benefit designs, and benefit flexibilities including SSBCI and MA uniformity flexibility. As such, CMS believes MA organizations have the opportunity to design affordable benefit packages that are tailored to beneficiary needs. CMS does not expect the potential negative downstream effects on MA enrollment, plan options, premiums, supplemental benefits (including SSBCI), care coordination services, and access to lower MOOP limits, referenced by the commenters, to come to fruition solely due to the provisions in this FC.

Comment: A few commenters were concerned that the ESRD cost transition and the resulting MOOP limits would promote adverse selection of certain MA plans by enrollees with diagnoses of ESRD. These commenters noted that the nature of the needed medical care to manage ESRD is ongoing, complex, and will consistently produce annual health care costs that significantly exceed the projected lower MOOP limit. Commenters believe these factors will result in beneficiaries with diagnoses of ESRD being disproportionately attracted to and enrolling in MA plans with lower MOOP limits. A commenter noted that this would place a heavier cost burden on MA plans that endeavor to keep costs low for beneficiaries than for plans who maintain higher MOOP limits.

Response: We understand the concern about potential adverse selection that may result when MA plans establish a lower MOOP type for beneficiaries that generally have higher health care costs, including beneficiaries with diagnoses of ESRD. While some MA organizations have experience in managing the health care services for beneficiaries with diagnoses of ESRD, under the prior enrollment policy, the proposals on MOOP limits and cost sharing standards, which we are finalizing with some modifications, provide incentives in the form of cost sharing flexibilities to MA organizations that adopt MOOP amounts below the mandatory level. Further, MA plans can utilize effective risk mitigation strategies, contracting arrangements, and care management policies in conjunction with the addition of the cost sharing flexibilities. For example, the People-to-People Health Foundation reported MA SNP enrollees had lower mortality and lower rates of utilization across the care continuum in comparison to Medicare FFS beneficiaries and stated that SNPs may be an effective alternative care financing and delivery model for patients with diagnoses of ESRD.[12] Unlike past years, MA plans adopting a mandatory MOOP type in the future will have limited cost sharing flexibility for most service category standards compared to other MOOP limits (for example, the cost sharing limit will be reduced from 50 percent coinsurance in 2022 to 30 percent by contract year 2026 for most professional standards). CMS establishes separate rates of payment to MA organizations for ESRD beneficiaries enrolled in MA plans; the rates used for enrollees in dialysis or transplant status are based on statewide average FFS Medicare costs for ESRD beneficiaries in dialysis status and are subject to risk adjustment. Therefore, as the MA ESRD rates are based on FFS costs, higher costs of covering medically necessary benefits for beneficiaries with ESRD are factored into setting the payments to MA plans for enrollees with ESRD. As a result, we do not believe that the concern about adverse selection is as significant as it might otherwise be.

Further, we did not propose or discuss increasing MOOP limits or plan premiums for only beneficiaries with diagnoses of ESRD. Consistent with sections 1852(d) and 1854(c) of the Act, MA regulations at §§ 422.100(d), 422.254(b), and 422.262(c) require benefits, cost sharing, and premiums for enrollees to be uniform. Our interpretation of uniformity may permit an MA plan to reduce, not increase, cost sharing for similarly situated enrollees in order to address specific health needs of the enrollees (such as, lower cost sharing for enrollees with diabetes to see an endocrinologist). Section 422.100(d), which was finalized in section V.C. of the January 2021 final

[12] Powers, et al. ''The Beneficial Effects Of Medicare Advantage Special Needs Plans For Patients With End-Stage Renal Disease'' September 2020 *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.01793?journalCode=hlthaff.*

rule to codify our interpretation of uniformity, does not authorize lower cost sharing or increased benefits for healthier enrollees. The requirement for uniform benefits is also subject to the waiver of uniformity that may be provided for an MA plan to target specific Special Supplemental Benefits for the Chronically Ill (SSBCI) under § 422.102(f) and how optional supplemental benefits are only provided for enrollees who elect to pay the extra premium for that coverage under § 422.101(c)(2). The ability to offer supplemental benefits that have a connection with a specific health condition is permitted only for reductions in cost sharing and additional benefits, not for decreasing benefits, and requires the supplemental benefit to be available to all similarly situated enrollees. We did not propose to permit an MA plan to apply MOOP amounts (or other cost sharing standards) in a non-uniform manner and are not finalizing any authority for that. CMS's proposal discussed calculating MOOP limits that are applied uniformly to all MA plan enrollees to cap the MOOP costs for enrollees, protect beneficiaries, and prevent discrimination against enrollees with significant health care needs. Our proposal necessarily encompassed projected future increases to the MOOP limits but those increases are also to be uniformly applied. In addition, plan premiums are applied uniformly across plan enrollees (except for EGWPs that use a waiver of the requirement for uniform premiums) and cannot be targeted to specific beneficiaries or those with certain health conditions. Because of these uniformity considerations, we do not believe that the methodology for calculating the MOOP limits or the incorporation of the ESRD cost differential into the data that is used to calculate the MOOP limits will result in adverse selection or discrimination against beneficiaries with diagnoses of ESRD.

Comment: A commenter believed the proposal to transition the out-of-pocket costs for beneficiaries with diagnoses of ESRD into the data used to set MOOP limits would result in an increased MOOP limit only for enrollees with diagnoses of ESRD and stated that an $850 increase in the mandatory MOOP limit is insufficient for MA organizations to cover the ESRD-related costs for this population.

Response: We reiterate that as proposed and finalized, the MOOP limits may not be applied so that enrollees with diagnoses of ESRD have a higher MOOP amount than enrollees without these health conditions. A more complete discussion of the uniformity aspects of CMS's MOOP limits proposal is available in section II.A.4.a. of this FC and in a previous response to comment in this section. Although the commenter stated that initial increases to MOOP limits proposed for contract year 2022 (in essence, the first year we proposed to apply the changes) were insufficient to cover the increased costs that are projected for enrollees with diagnoses of ESRD, the MOOP limits are projected to further increase in future years based on our proposal to incorporate more of the ESRD cost differential.

As discussed in greater detail subsequently in this section, CMS will limit the potential increase in MOOP limits to a cap of 10 percent compared to the MOOP limits set for the prior year (beginning with contract year 2023). As illustrated in Tables 2 and 3 and reflected in the final MOOP limits for contract year 2023, the in-network contract year 2023 mandatory MOOP limit has been capped at a 10 percent increase based on the contract year 2022 mandatory MOOP limit. This means the mandatory MOOP limit for contract year 2023 does not fully reflect the 95th percentile of Medicare FFS data projections as doing so would result in an increase greater than 10 percent compared to the contract year 2022 mandatory MOOP limit. Applying this cap on the amount of potential increase each year to the MOOP limits is an important beneficiary protection and consistent with how we have previously balanced the goal of limiting enrollee costs (to avoid plan designs that discourage enrollment by sicker beneficiaries) and ensuring continued access to affordable and sustainable benefit packages when setting MOOP limits.

Comment: A few commenters who were opposed to the ESRD cost transition generally encouraged CMS to explore alternative solutions to account for the approximately $6,300 difference between the existing mandatory MOOP limit ($6,700) and the average annual out-of-pocket costs for beneficiaries with ESRD in Medicare FFS ($13,042 [13] based on data from 2015–2017) rather than raising the MOOP limit (as projected from incorporating the ESRD cost differential into the out-of-pocket costs used to establish the MOOP and cost sharing limits). Some of these commenters referenced data analyses completed by MedPAC [14] and the Kaiser Family Foundation (KFF) [15] that found that the average cost of covering Medicare beneficiaries with ESRD is significantly more than the healthcare costs of an average MA beneficiary. Another commenter also referred to the research finding that applying the mandatory MOOP limit to ESRD beneficiary spending results in increased MA costs by an estimated 8 to 9 percent on average when compared to Medicare FFS spending.[16] A commenter described this data from the perspective that every ESRD enrollee effectively represents an outlier compared to the current average costs of care for other beneficiaries. Another commenter was concerned about the possibility of MA plans discriminating against and discouraging beneficiaries with diagnoses of ESRD from enrolling in the MA program.

In a related note, a few commenters encouraged CMS to consider how coverage costs for ESRD patients can be significantly above or below the overall state average in certain locales, such as metropolitan areas in California, Florida, Ohio, and Texas. A commenter referenced the Avalere Health analysis of 2018 Medicare FFS claims data that found 10 of the top 15 metropolitan statistical areas with the most ESRD patients had costs that exceeded the MA payment rate.[17] Given the research, a few commenters suggested that most, if not all, enrollees with diagnoses of ESRD will surpass the highest allowable, mandatory MOOP limit despite projected increases from the proposed ESRD cost transition.

Response: We appreciate the commenters' feedback and requests to consider alternatives to raising the MOOP limits to protect beneficiaries from increases in their out-of-pocket

[13] Health Management Associates. ''End-Stage Renal Disease and Medicare Advantage.'' February 12, 2019. The most recent report is available online at: *https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf.*

[14] MedPAC. June 2019. Section 2: Medicare Beneficiary Demographics. June 2019 Data Book: Health Care Spending and the Medicare Program. The most recent version of MedPAC's annual data book may be retrieved from: *https://www.medpac.gov/document-type/data-book.*

[15] KFF, ''Medicare Beneficiaries With End-Stage-Renal Disease (ESRD),'' 2019 *https://www.kff.org/medicare/state-indicator/enrollees-with-esrd/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[16] Health Management Associates. ''End-Stage Renal Disease and Medicare Advantage.'' February 12, 2019. The most recent report is available online at: *https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf.*

[17] Kazan et al, Avalere Health, ''Medicare Advantage Plans May Be Paid Below Actual ESRD Patients' Costs in Large Metropolitan Areas in 2021'' December 2019 *https://avalere.com/insights/medicare-advantage-plans-may-be-paid-below-actual-esrd-patients-costs-in-large-metropolitan-areas-in-2021.*

costs. Under the current regulation, MA MOOP limits have been based on stable percentiles of Medicare FFS spending. This approach supports our goal of ensuring that all eligible beneficiaries have access to affordable and sustainable benefit packages. Our approach to incorporate costs of beneficiaries with diagnoses of ESRD in setting MOOP limits is consistent with the approach CMS has historically used of spreading the burden of medical costs across all potential MA enrollees uniformly through the continued use of the 95th and 85th percentiles of out-of-pocket spending for the population that is eligible to enroll in an MA plan. Historically, CMS has tried to balance between limiting beneficiaries' maximum out-of-pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. This practice avoids discriminating against beneficiaries with diagnoses of ESRD—or any group of beneficiaries with a particular high cost condition or health status—that would result if there were higher premiums, cost sharing, or MOOP amounts applicable only to those individuals with a certain chronic condition. Excluding the out-of-pocket costs for beneficiaries with diagnoses of ESRD from the data used to calculate the MOOP limits might serve to keep the out-of-pocket expenses borne by MA enrollees lower, but would not be consistent with ensuring access to affordable and sustainable benefit packages for all eligible beneficiaries because it would result in a significant increase in the costs that exceed the MOOP limit and therefore are borne by the MA organization. Increasing the coverage costs for MA organizations could lead to other increases in premiums or decreases in benefits. Further, calculating the MOOP limits at a level that is significantly less than the 85th and 95th percentiles of beneficiary out-of-pocket spending is not as consistent with the underlying purpose for adopting the MOOP: Ensuring that beneficiaries that are most likely to be discriminated against—those beneficiaries who have much higher health care needs—are not discouraged from enrolling in an MA plan.

We acknowledge that as beneficiaries with diagnoses of ESRD enroll in greater numbers into the MA program, MA organizations will more often than before have to cover the costs associated with that chronic condition when these enrollees meet the plan's MOOP amount and incur more costs past the MOOP than enrollees without diagnoses of ESRD are projected to do, on average. CMS uses historical FFS reimbursement and enrollment data for beneficiaries with diagnoses of ESRD to develop the rates used to pay MA organizations for these enrollees, which are generally higher than the rates paid to MA organizations for enrollees without diagnoses of ESRD.[18] CMS believes without incorporating ESRD costs into the MOOP limits, MA plans may have a greater likelihood of increasing premiums for all enrollees or reducing benefits to address the expected increased costs associated with additional enrollment of beneficiaries with diagnoses of ESRD. Guarding against those outcomes is consistent with the standard CMS uses to calculate the MOOP limit under current §§ 422.100(f) and 422.101(d) and part of our rationale for incorporating the ESRD cost differential. We believe that it is important for the MOOP limits to be calculated using data regarding the out-of-pocket expenses of beneficiaries with and without diagnoses of ESRD because the MOOP limits will apply to enrollees with and without diagnoses of ESRD.

MA organizations serve different geographic areas and ESRD enrollment and spending may vary across metropolitan areas and states. It would be overly complex to set MOOP limits by geographic area. For example, some complicating factors include: Medical economics in different geographic areas; how to reasonably define geographic areas; varying negotiating leverage of MA organizations and resources; and potential resulting complexities for beneficiaries in evaluating plan options. Also, it would be difficult to incorporate the remainder of the ESRD cost differential at a rate that was consistent with the enrollment rate of beneficiaries with diagnoses of ESRD in specific geographic areas. Finally, setting geographically specific MOOP limits was not proposed.

Comment: Some commenters requested CMS modify the ESRD cost transition schedule to match projected enrollment changes or actual enrollment of beneficiaries with diagnoses of ESRD. For example, a commenter requested CMS delay finalizing the complete ESRD cost transition schedule until the actual year-1 penetration rate of beneficiaries with diagnoses of ESRD in the MA program can be assessed. In addition, this commenter requested (if the actual penetration rates were not used) that CMS match the ESRD cost transition rate to OACT's projected rate of transition of beneficiaries with diagnoses of ESRD into the MA program.

Response: CMS endeavors to calculate and issue these MOOP limit and cost sharing standards sufficiently in advance of the bid deadlines (typically by the first Monday in April, as discussed in section II.A.4.b. of this FC, when capitation rates and payment policies are announced for the upcoming year) to provide MA organizations with sufficient time to develop their bids. In addition, we did not propose to set the schedule for transitioning ESRD costs into MOOP limits based upon OACT's projection of ESRD enrollment because actual ESRD enrollment per plan may vary and OACT's analysis reflects expectations for the MA program as a whole. Using the penetration and enrollment rates from the prior year to transition the ESRD cost differential would not truly address the issue raised by the commenter (that is, the amount of the ESRD cost differential used in calculating the MOOP limit for a year is not the same as the MA enrollment rate of beneficiaries with diagnoses of ESRD for that year). The time lag between: (1) The enrollment information we have available at the time we calculate the MOOP limits; and (2) the contract year for which the MOOP limits are applied would mean that there would always be a disconnect between the enrollment numbers and the MOOP limit. In addition, as previously summarized in this section, it would be overly complex to set MOOP limits by geographic area and incorporate the remainder of the ESRD cost differential at a rate that was consistent with the enrollment rate of beneficiaries with diagnoses of ESRD in specific geographic areas.

While we appreciate the commenter's suggestion to align the ESRD cost transition schedule with the OACT's projected rate of ESRD enrollment, we believe this would add another layer of complexity and further delay the transition process. As discussed in the February 2020 proposed rule, the OACT expected ESRD enrollment in MA plans to increase by 83,000 beneficiaries as a result of the 21st Century Cures Act provision. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021; the remaining 41,500 additional beneficiaries were expected to enroll in MA plans during the years 2022 to 2026 under the assumption that the number of additional enrollees who have diagnoses of ESRD will continue to increase during that time frame though

[18] The Calendar Year 2021 and 2022 Rate Announcements may be accessed at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

at a decreasing rate in later years. Based on actual 2021 enrollment data, the OACT continues to project that 83,000 beneficiaries with diagnoses of ESRD will enroll in the MA program over 6 years. If CMS were to match the transition of incorporating ESRD costs to that of OACT's enrollment projections, we would be forced to delay the full transition of ESRD costs until 2026. After publication of the February 2020 proposed rule, CMS announced that it would take the Medicare FFS costs of beneficiaries with diagnoses ESRD into account in developing MOOP and cost sharing limits for 2021.[19] The contract year 2021 MOOP limits (which encompassed 40 percent of the ESRD cost differential) were maintained for contract year 2022 while enrollment of beneficiaries with diagnoses of ESRD is projected to increase.[20] As a result, CMS believes any further delays to the ESRD cost transition would not be beneficial as only 40 percent of the ESRD cost differential has been incorporated up to contract year 2022, the year the OACT projected total enrollment of beneficiaries with diagnoses of ESRD into the MA program to exceed 50 percent. In addition, when developing our proposed ESRD cost transition schedule, we considered how OACT's aggregate projections may not reflect the experiences in all geographic locations, which could have different rates of transition and changes in expenditures for providing care to beneficiaries with diagnoses of ESRD.

Comment: As summarized in this section, CMS received many comments relevant to the solicitation in the February 2020 proposed rule on whether the ESRD cost transition schedule proposed at § 422.100(f)(4)(vii) aligns with the goals of providing predictable and transparent MOOP limits and cost sharing standards, minimizing significant new costs for MA plans or enrollees, and providing flexibility if the ESRD cost differential transition needs to be adjusted. Most commenters supported a multi-year transition of ESRD costs into the MOOP limits, but recommended changes to accelerate or simplify the transition. Some commenters who were supportive of the proposed transition schedule, or who did not solely tie their concerns to the proposed schedule of transitioning ESRD costs into the methodology for setting MOOP limits at paragraph (f)(4)(vii), shared concerns addressed in previous comment summaries in this section (namely, negative effects from costs associated with enrollees with diagnoses of ESRD being subsidized by other enrollees without these diagnoses; adverse selection of MA plans by enrollees with diagnoses of ESRD; and the possibility of MA plans discriminating against and discouraging beneficiaries with diagnoses of ESRD from enrolling in the MA program). A commenter who supported the transition noted that the projected MOOP limit increases over time would allow flexibility for MA organizations to adjust to the costs of covering enrollees with diagnoses of ESRD and that the gradual implementation of higher MOOP limits will minimize impacts (such as, additional cost sharing or increased premiums) on enrollees. Another commenter supported the ESRD cost transition schedule as proposed.

Several commenters recommended accelerating or simplifying the ESRD cost transition because: (1) A lengthy, complex or confusing transition would be difficult for MA organizations to plan and execute; (2) a longer transition would not support MA plans managing the higher ESRD costs quickly enough; and (3) delaying the transition may require premium increases to fully cover or subsidize ESRD member costs. A commenter requested CMS complete the transition over 3 years, instead of 4 years, by incorporating 25 percent of the ESRD cost differential each year as follows: 50 percent in 2021, 75 percent in 2022, and 100 percent of all ESRD costs incorporated in 2023. In addition, a few commenters were concerned that the OACT's projections of beneficiaries with diagnoses of ESRD that will enroll in an MA plan during the next several years is understated. A commenter explained that even if only a small number of beneficiaries with diagnoses of ESRD migrate from Medicare FFS to the MA program, MA organizations will face significantly increased medical care costs. This commenter also stated that CMS's phase-in proposal for the ESRD cost differential was understating the speed at which beneficiaries with ESRD will transition to MA plans. A commenter that wanted to accelerate the transition was also concerned that as beneficiaries with diagnoses of ESRD migrate to MA and fewer remain in Medicare FFS, CMS's methodology of calculating MOOP limits using both non-ESRD and ESRD costs would result in MOOP limits being set too low and would fail to achieve an actuarially equivalent level of cost sharing. Specifically, this commenter noted that the substantial financial benefits of the MOOP limit for ESRD members would result in the ultimate blending (of out-of-pocket costs for all beneficiaries) being insufficient if the penetration rate of ESRD members in MA plans ends up exceeding that of non-ESRD members.

Response: In response to the comments we received (summarized in this section) and given the timing of this FC, we are finalizing some changes to the schedule for incorporating the ESRD cost differential into the Medicare FFS cost data used in the methodology for calculating the MOOP limits each year (and also used in the methodology for calculating inpatient hospital acute and psychiatric cost sharing limits, as discussed in section II.B. of this FC). The transition schedule was proposed as follows: 60 percent in 2022; 80 percent in 2023 or next year; and 100 percent in 2024 or the final year of transition. This was proposed in the context of the 2021 MOOP limits being based on Medicare FFS data projections that incorporated 40 percent of the ESRD cost differential. In addition, we proposed guardrails to pause the incorporation of the ESRD cost differential and cap the annual maximum change in MOOP limits to a 10 percent increase or decrease in the limits from the prior year, if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs increased or decreased by a difference of more than two percentiles above or below the 85th and 95th percentile from the prior year. The combination of the transition and guardrails was designed to strike a balance of providing plan benefit design stability while also protecting beneficiaries from rapid premium or cost sharing changes. We respond to general concerns regarding potential beneficiary discrimination tied to the MOOP limit methodology in section II.A.4. of this FC and to concerns related to enrollee subsidization of ESRD costs and potential adverse selection in previous responses in this section.

We appreciate the recommendations about the timing to incorporate ESRD costs into the data used to calculate MOOP limits (and inpatient hospital acute and psychiatric cost sharing limits). In this FC, we are finalizing the use of a transition schedule combined with guardrails on overall increases with some modifications compared to the proposal. We are finalizing the definition and use of the ESRD cost differential as a specific way to measure ESRD costs and factor them into the data (and the methodology CMS uses to calculate annual MOOP limits) with

[19] See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020 for information on MOOP limits for contract year 2021.

[20] See the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021 for information on MOOP limits for contract year 2022.

moderate modifications based on commenter feedback. We are finalizing a modification to the ESRD cost differential definition at § 422.100(f)(4)(vi) (proposed in paragraph (f)(4)(vii)) to clarify that this value is the difference between, first, for the mandatory MOOP limit, $7,175 and for the lower MOOP limit, $3,360 and second, for the mandatory MOOP limit, the 95th percentile and, for the lower MOOP limit, the 85th percentile of the Medicare FFS data projections for each year between 2023 and 2024. The proposed definition mistakenly referred only to using costs incurred by beneficiaries with ESRD and did not fully clarify the specific comparisons being made for the mandatory and lower MOOP types. We note using the ''Medicare FFS data projections'' term as defined in paragraph (f)(4)(i) ensures that the ESRD cost differential compares the 95th and 85th percentiles of the projected out-of-pocket costs for Medicare FFS beneficiaries with and without diagnoses of ESRD for the upcoming year to the $7,175 and $3,360 dollar amounts in order to calculate the ESRD cost differential for that year (as discussed in the February 2020 proposed rule). We believe that clarification on these points improves the regulation text. We also added language to paragraph (f)(4)(vi) to clarify that the ESRD cost differential is used in the ESRD cost transition finalized throughout paragraph (f)(4). Because the Medicare FFS data projections will be updated each year with more recent data, references to different projections in this FC include the contract year that the projections are for and the years of data that those projections are based on. For example, contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017 to 2021) reflect the amounts CMS used to calculate the MOOP and cost sharing limits for contract year 2023.

As discussed in section V.H.1. of this FC, CMS considered several alternatives to implementing the proposed ESRD cost transition schedule into the methodology CMS uses to calculate MOOP limits based on public comments, the timing of this FC, potential for enrollee disruption, and impacts of further delays in integrating ESRD costs. After consideration of those alternatives, we believe finalizing a modified transition schedule would be beneficial and address the concerns and interests raised by the comments. The delay in finalizing this provision resulted in no increased ESRD cost adjustment for contract year 2022 MOOP limits (rather, the ESRD cost differential remained the same as 2021) while ESRD enrollment in MA is projected to increase in 2022. Specifically, CMS maintained the contract year 2021 MOOP limits for contract year 2022. Therefore, we are not finalizing a provision to address the incorporation of the ESRD cost differential for contract year 2022 (proposed at paragraph (f)(4)(vii)(A)) and are organizing the regulation text as necessary.

As a result, we are finalizing at § 422.100(f)(4)(vi)(A) and (B) that the ESRD cost differential will be factored into the Medicare FFS data projections used to calculate the MOOP limits as follows: For 2023, 70 percent and for 2024, 100 percent.

In finalizing use of 70 percent of the ESRD cost differential for 2023, we aim to strike a balance among curbing potential disruptive changes in MOOP limits from contract year 2022 to contract year 2023, avoiding the concerns with a lengthy transition identified by commenters, and ensuring MA organizations can continue offering all plan enrollees, regardless of their ESRD status, quality care and service while keeping premiums and cost sharing at non-discriminatory levels. As finalized, § 422.100(f)(4)(iv) through (vi) reflects the updated timing for the finalized transition and includes some minor clarifications and edits to use consistent terminology. We expect these changes will help ensure that MA plans are able to both expand their membership to beneficiaries with diagnoses of ESRD and continue offering all enrollees, regardless of their ESRD status, high-quality health care and service while keeping premiums and out-of-pocket costs at reasonable levels for all enrollees.

The modified schedule we are finalizing to transition ESRD costs was used to update the MOOP limits from the illustrative figures provided in Tables 4 and 5 (Table 4, ''Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections'' and Table 5, ''Illustrative Example of Combined MOOP Limits for LPPO and Catastrophic (MOOP) Limits for RPPO Plans Based on Most Recent Medicare FFS Data Projections'') in the February 2020 proposed rule. In this FC, Table 5 contains the final MOOP limits for contract year 2023 and Table 9 contains illustrative MOOP limits for contract year 2024 for comparison purposes to Tables 4 and 5 from the February 2020 proposed rule. The calculations to reach the MOOP limits in Tables 5 and 9 are provided in Tables 2–4 and Tables 6–8. In addition, Tables 4, 5, 8, and 9 include a correction in the calculation of the lower ranges to the total catastrophic (combined MOOP) limits per § 422.100(d)(3)(iii), as discussed in section II.A.4.b. of this FC. CMS took public comments on the MOOP limit proposal from the February 2020 proposed rule into consideration regarding the use of a subregulatory notice and comment process before finalizing the MOOP and cost sharing limits each year and as discussed in sections II.A.4.b. and II.B.5. of this FC, we are adopting that process for the future. However, as this FC is not being published early enough to provide time for CMS to solicit comment and release subregulatory guidance before the contract year 2023 bid deadline, the MOOP limits contained in Table 5 are final. These limits were calculated applying the rules finalized in this FC. CMS intends to update the illustrative contract year 2024 MOOP limits using contract year 2024 Medicare FFS data projections (based on Medicare FFS data from 2018 to 2022) when available and have a separate public comment period (based on § 422.100(f)(7)(iii)) before releasing the final contract year 2024 MOOP limits.

Using the 95th percentile of contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017–2021), the projected percent increase to the mandatory MOOP limit for contract year 2023 would be greater than 10 percent in comparison to the mandatory MOOP limit set for contract year 2022. Table 2 compares the unrounded contract year 2023 in-network mandatory MOOP limit before application of the 10 percent cap ($8,530.20) to the mandatory MOOP limit set for contract year 2022 ($7,550.00); this increase equates to approximately 13 percent (after accounting for the rounding rules which would raise the MOOP limit amount to $8,550.00). As a result, Tables 2 through 5 illustrate application of the 10 percent guardrail for the mandatory MOOP limit in contract year 2023 to limit the increase to 9.9 percent after application of the rounding rules. Conversely, the percent increase of 5.8 percent to the lower MOOP limit for contract year 2023 is less than 10 percent in comparison to the voluntary MOOP limit set for contract year 2022. Similarly, comparing the highest allowable in-network mandatory and lower MOOP limits for contract year 2023 to the corresponding illustrative in-network MOOP limits for contract year 2024 is less than 10 percent. For example, the final contract year 2023 in-network mandatory MOOP limit

($8,300.00) compared to the illustrative unrounded contract year 2024 in-network mandatory MOOP limit ($9,111.00) reflects an approximate 9.8 percent increase (and an approximate 3.3 percent increase for the illustrative lower MOOP limits). As a result, Tables 2 through 9 illustrate application of the 10 percent guardrails finalized in paragraphs (f)(4)(iv)(A) and (C) and (f)(4)(v)(A) when the increase threshold is met. These guardrails are also discussed more completely in a subsequent response to comment in this section.

Under § 422.100(f)(4)(vi), the ESRD cost differential for contract year 2023 is the difference between, first, for the mandatory MOOP limit, $7,175 and for the lower MOOP limit, $3,360 and second, for the mandatory MOOP limit, the 95th percentile ($9,111.00) and for the lower MOOP limit, the 85th percentile ($3,772.00) of the contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017 to 2021). As shown in Tables 2 through 5, modifying the ESRD cost transition from the proposed 80 percent to 70 percent of the ESRD cost differential in contract year 2023 and completing the calculations using projections of Medicare FFS data from 2017–2021 (compared to the 2015–2019 Medicare FFS data available at the time of the February 2020 proposed rule), produced a moderate increase from the illustrative amounts contained in the February 2020 proposed rule. For example, the highest allowable (and illustrative) in-network mandatory MOOP limit was listed as $7,950 for contract year 2023 in the February 2020 proposed rule. In comparison, as shown in Table 5, the final contract year 2023 highest allowable in-network mandatory MOOP limit is $8,300 (an increase of $350).

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TABLE 2: CMS CALCULATIONS OF FINAL CONTRACT YEAR 2023 IN-NETWORK MANDATORY AND LOWER MOOP LIMITS USING PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

Row Reference	Description	Mandatory MOOP Limit	Lower MOOP Limit
A	Contract year 2022 MOOP limit	$7,550.00	$3,450.00
B	Maximum contract year 2023 MOOP limit per § 422.100(f)(4)(iv) (110% of row A)	$8,305.00	$3,795.00
C	Medicare FFS percentile in § 422.100(f)(4)	95th	85th
D	Unrounded contract year 2023 Medicare FFS data projections for the applicable percentile in row C[1]	$9,111.00	$3,772.00
E	Baseline MOOP amount in § 422.100(f)(4)(iv)	$7,175.00	$3,360.00
F	Contract year 2023 ESRD Cost Differential per § 422.100(f)(4)(vi) (difference between row D and row E)	$1,936.00	$412.00
G	70% of the contract year 2023 ESRD Cost Differential per § 422.100(f)(4)(vi)(A) (row F multiplied by 0.7)	$1,355.20	$288.40
H	Unrounded contract year 2023 MOOP limit prior to applying 10% cap on increases per § 422.100(f)(4)(iv) and (vi)(A) (row E plus row G)	$8,530.20	$3,648.40
I	Unrounded contract year 2023 MOOP limit with 10% cap on increases applied (the lesser value comparing row B and row H)	$8,305.00	$3,648.40
J	Rounded contract year 2023 MOOP limit per § 422.100(f)(4)(iii) and (iv) (row I rounded)	$8,300.00	$3,650.00
K	Lowest dollar range of the contract year 2023 MOOP limit per § 422.100(f)(4)(i)	$6,001.00[2]	$0.00[3]
L	Final contract year 2023 MOOP limit dollar ranges per § 422.100(f)(4)(i) through (iv) and (vi)	$6,001.00 to $8,300.00	$0.00 to $3,650.00

[1]The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7)).

[2]The in-network mandatory MOOP limit dollar range begins at the value of the in-network intermediate MOOP limit from row D in Table 3 plus $1.00 per § 422.100(f)(4)(i)(A).

[3]The in-network lower MOOP limit dollar range begins at $0.00 per § 422.100(f)(4)(i)(C).

TABLE 3: CMS CALCULATIONS OF FINAL CONTRACT YEAR 2023 IN-NETWORK INTERMEDIATE MOOP LIMIT PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

Row Reference	Description	Intermediate MOOP Limit
A	Unrounded contract year 2023 mandatory MOOP limit with 10% cap on increases applied (row I, mandatory MOOP limit column in Table 2)	$8,305.00
B	Unrounded contract year 2023 lower MOOP limit with 10% cap on increases applied (row I, lower MOOP limit column in Table 2)	$3,648.40
C	Unrounded contract year 2023 intermediate MOOP limit per § 422.100(f)(4)(iv) (numeric midpoint between row A and row B)	$5,976.70
D	Rounded contract year 2023 intermediate MOOP limit (row C rounded per § 422.100(f)(4)(iii))	$6,000.00
E	Lowest dollar range of the contract year 2023 MOOP limit per § 422.100(f)(4)(i)(B)	$3,651.00*
F	Final contract year 2023 intermediate MOOP limit dollar range per § 422.100(f)(4)(i) through (iv) and (vi)	$3,651.00 to $6,000.00

*The in-network intermediate MOOP limit dollar range begins at the value of the in-network lower MOOP limit from row J in Table 2 plus $1.00 per § 422.100(f)(4)(i)(B).

TABLE 4: CMS CALCULATIONS OF FINAL CONTRACT YEAR 2023 COMBINED MOOP LIMITS FOR LPPO AND TOTAL CATASTROPHIC MOOP LIMITS FOR RPPO PLANS USING PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

Row Reference	Description	Mandatory MOOP Limit	Intermediate MOOP Limit	Lower MOOP Limit
A	Corresponding unrounded in-network MOOP type with 10% cap on increases applied (values from row I in Table 2 and row C in Table 3)	$8,305.00	$5,976.70	$3,648.40
B	Unrounded contract year 2023 combined and total catastrophic MOOP limit per § 422.101(d)(3)(ii) (row A multiplied by 1.5)	$12,457.50	$8,965.05	$5,472.60
C	Rounded contract year 2023 combined and total catastrophic MOOP limit (row B rounded per § 422.100(f)(4)(iii))	$12,450.00	$8,950.00	$5,450.00
D	Lowest dollar range of the contract year 2023 MOOP limit per § 422.101(d)(3)(ii)	$6,001.00[1]	$3,651.00[2]	$0.00[3]
E	Final contract year 2023 combined and total catastrophic MOOP limit dollar ranges per § 422.101(d)(3)(ii)	$6,001.00 to $12,450.00	$3,651.00 to $8,950.00	$0.00 to $5,450.00

[1]The combined and total catastrophic mandatory MOOP limit dollar range begins at the value of the in-network intermediate MOOP limit from row D in Table 3 plus $1.00 per § 422.101(d)(3)(ii)(A).
[2]The combined and total catastrophic intermediate MOOP limit dollar range begins at the value of the in-network lower MOOP limit from row J in Table 2 plus $1.00 per § 422.101(d)(3)(ii)(B).
[3]The combined and total catastrophic lower MOOP limit dollar range begins at $0.00 per § 422.101(d)(3)(ii)(C).

TABLE 5: FINAL CONTRACT YEAR 2023 MOOP LIMITS BY PLAN TYPE

Plan Type	Lower MOOP Limit	Intermediate MOOP Limit	Mandatory MOOP Limit
HMO	$0 - $3,650	$3,651 to $6,000	$6,001 - $8,300
HMO POS	$0 - $3,650 In-network	$3,651 to $6,000	$6,001 - $8,300 In-network
Local PPO	$0 - $3,650 In-network and $0 - $5,450 Combined	$3,651 to $6,000 In-network and $3,651 - $8,950 Combined	$6,001 - $8,300 In-network and $6,001 - $12,450 Combined
Regional PPO	$0 - $3,650 In-network and $0 - $5,450 Combined	$3,651 to $6,000 In-network and $3,651 - $8,950 Combined	$6,001 - $8,300 In-network and $6,001 - $12,450 Combined
PFFS (full network)	$0 - $3,650	$3,651 to $6,000	$6,001 - $8,300
PFFS (partial network)	$0 - $3,650	$3,651 to $6,000	$6,001 - $8,300
PFFS (non-network)	$0 - $3,650	$3,651 to $6,000	$6,001 - $8,300

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In summary, we are finalizing § 422.100(f)(4)(vi) (proposed in paragraph (f)(4)(vii)) with changes in the transition schedule to calculate annual in-network MOOP limits and modifications to paragraph (f)(4) addressed in this section and section II.A.4. of this FC.

CMS will monitor the penetration rate of beneficiaries with diagnoses of ESRD in MA plans and if the penetration rate ends up being significantly different from Medicare FFS, we will consider future rulemaking to alter the methodology CMS uses to set MOOP limits if there are significant unforeseen impacts or negative consequences that need to be addressed. We also would consider whether additional changes would outweigh the interests of maintaining a settled methodology for the MOOP limits and sufficiently protect enrollees from substantial changes in cost sharing and benefits from one year to the next. Finally, we note that MA organizations can still design a PBP with cost sharing that is actuarially equivalent to cost sharing in Medicare FFS while complying with the MOOP and cost sharing limits in this FC.

Comment: A few commenters made specific requests on how CMS should simplify or otherwise modify the proposed transition of ESRD costs into MOOP limits. A commenter requested CMS enforce the schedule to transition ESRD costs into MOOP limits regardless of any year-over-year changes to the 95th and 85th percentiles for the following reasons: (1) ESRD migration is happening separately from any changes to non-ESRD costs in setting the MOOP limits; and (2) potential delays in the ESRD phase-in schedule could require additional member premium increases for non-ESRD members in order to subsidize ESRD member costs. Another commenter noted that simplifying the methodology for incorporating the ESRD cost differential would increase transparency and predictability.

Response: Regarding the request to enforce the ESRD cost transition schedule year-over-year regardless of any other considerations, we believe the commenter was specifically referring to the guardrails at proposed § 422.100(f)(4)(v)(A) and (C) that we proposed to prevent sudden, significant changes to MOOP limits for contract year 2023 and 2024 (or until the end of the ESRD cost transition) if the projections of the 85th or 95th percentile were to shift more than two percentiles within 1 year. We proposed that if the dollar value at the 85th or 95th percentile shifted more than two percentiles during the ESRD cost transition, the MOOP limits would only increase or decrease by 10 percent. The 97th and 93rd percentiles of the contract year 2021 Medicare FFS data projections (based on Medicare FFS data from 2015–2019) were $11,485 and $6,391 respectively, in comparison to the 95th percentile of $8,174. The 97th percentile was approximately 40 percent higher than the 95th percentile and the 93rd percentile was approximately 22 percent lower than that the 95th percentile for contract year 2021. In addition, the 87th and 83rd percentiles of the contract year 2021 Medicare FFS data projections (based on Medicare FFS data from 2015–2019) were $3,993 and $3,162 respectively, in comparison to the 85th percentile of $3,537. The 87th percentile was approximately 13 percent higher than the 85th percentile and the 83rd percentile was approximately 11 percent lower than that the 85th percentile for contract year 2021. Our proposed guardrails were intended to protect MA enrollees from being potentially subject to a MOOP amount that is substantially different compared to the prior contract year. However, based on historical trends, we do not expect a shift in one year that is outside of the range created by these percentiles. We believe that the guardrails can be simplified while protecting enrollees as intended.

We are modifying the proposed guardrails to use only a 10 percent cap on increases to MOOP limits from the prior year and will apply this guardrail for contract year 2023 and subsequent years at § 422.100(f)(4)(iv) and (v). In essence, we are not finalizing the condition that the projections of the 85th or 95th percentile must shift more than two percentiles within one year in order to apply a 10 percent change cap to the mandatory and lower MOOP limits. We are also not finalizing the proposal to toll or delay the incorporation of the ESRD cost differential as part of the limits on changes to MOOP limits from year to year. We are finalizing the 10 percent guardrail in paragraphs (f)(4)(iv) and (v) and will apply it during and after the ESRD cost transition. To simplify the regulation text for how CMS calculates the MOOP limits for contract year 2024 and subsequent years, we are also consolidating into one paragraph ((f)(4)(v)(A)) rather than two (proposed paragraphs (f)(4)(v)(A) and (C)) the methodology that will apply consistently to both the mandatory and lower MOOP types (with the only difference being the percentile that determines the type of limit). This makes the regulation simpler while providing stability and a measure of predictability for enrollees and MA organizations about the degree of change that may occur in MOOP limits from year to year. As finalized, paragraphs (f)(4)(iv) and (f)(4)(v) provide that the mandatory and lower MOOP limits may only increase by 10 percent; the intermediate MOOP limit will be calculated as the numeric midpoint between the mandatory and lower MOOP limits after application of the 10 percent cap on increases, subject to the clarified rounding rules. By finalizing

only the 10 percent cap on increases, we are making the guardrails more definitive and more likely to limit dramatic shifts in annual Medicare FFS data projections that do not quite reach a change that is more than two percentiles from the 95th and 85th percentiles. We believe this is appropriate as the 95th percentile of contract year 2023 Medicare FFS data projections with full incorporation of the ESRD cost differential (based on Medicare FFS data from 2017–2021) is $9,111 and does not reflect a change that is more than two percentiles different than the projected amounts for the prior contract year. Specifically, based on Medicare FFS data from 2016–2020, the projected contract year 2022 95th percentile was $8,468, the 97th percentile was $11,837, and the 93rd percentile was $6,631. Using the proposed two percentile requirement, these projections would not trigger CMS to apply the 10 percent cap to calculate the contract year 2023 mandatory MOOP limit because $9,111 does not exceed $11,837. Using the $9,111 amount without applying the cap on increases would produce a contract year 2023 mandatory MOOP limit of $8,550, which is approximately 13 percent higher than the contract year 2022 mandatory MOOP limit ($7,550) after applying the rounding rules and incorporating 70 percent of the ESRD cost differential. In addition, this would increase the intermediate MOOP limit as it is calculated using the numeric midpoint between the mandatory and lower MOOP limits and the total catastrophic (combined) MOOP limits as they are calculated at 1.5 times the in-network amounts. It is likely that significant increases in costs occurring within two percentiles of the prior year's Medicare FFS data projections would circumvent the purpose of our proposed guardrail to provide stability and predictability of MOOP limits from one year to the next. In such a situation, MA enrollees would not be protected from potentially significant increases in MOOP amounts for that contract year. In order to better protect MA enrollees from significant increases in costs for contract year 2023 and future years, we are finalizing the 10 percent cap on increases without the two percentile requirement; application of the 10 percent cap is shown in Tables 2 through 9. In summary, this removal of the two percentile requirement results in a contract year 2023 mandatory MOOP limit that is $8,300 rather than $8,550 and an intermediate MOOP limit that is $6,000 rather than $6,100. In addition, the increases to the total catastrophic (combined) MOOP mandatory and intermediate MOOP types for contract year 2023 were tempered through application of the final 10 percent cap requirement, with the mandatory limit set at $12,450 rather than $12,800 and the intermediate MOOP limit set at $8,950 rather than $9,150. With regard to the lower MOOP limit, the contract year 2023 limit compared to the prior contract year reflects an increase less than 10 percent. In addition, the contract year 2023 85th percentile ($3,772) did not exceed the prior year's 87th percentile ($4,153), so there is no effect in removing the two-percentile requirement for the lower in-network and total catastrophic (combined) MOOP type for contract year 2023. As shown in Tables 6 through 9, we currently project that the contract year 2024 mandatory MOOP limit will incorporate any remaining difference, to the lower of $9,130 (a 10 percent increase) or the value at the 95th percentile as projected using the annually updated Medicare FFS data projections.

Regarding the comments about potential increases in MA premiums associated with our proposals to limit increases in the MOOP limits from year to year and to phase-in the ESRD cost differential over a period of time, only 40 percent of the ESRD cost differential was incorporated into the MOOP limits set for contract year 2021 (and maintained for contract year 2022) which is a one year delay in incorporating additional ESRD costs (in comparison to the schedule proposed). Despite this delay and the limited increase in MOOP limits for these contract years during which enrollment of beneficiaries with diagnoses of ESRD continued to increase into the MA program, the weighted average monthly plan premium is continuing to decrease from prior years and the percent of plans offering supplemental benefits or other benefit flexibilities (such as, SSBCI) continues to increase (based on plan bid information for contract year 2022). This suggests that increases in plan premiums or supplemental benefit changes are not occurring on an aggregate level in response to a 1 year delay of incorporating additional ESRD costs into the methodology CMS uses to calculate MOOP limits. We expect this may be a result of market forces and competition. Therefore, we believe that finalizing a 10 percent cap on increases to the MOOP limits from the prior year and its application for the mandatory and intermediate MOOP limits (in-network and combined) using contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017–2021) will not immediately result in MA plans increasing premiums or reducing benefits. We are finalizing guardrails at § 422.100(f)(4)(iv) and (v) that use this 10 percent cap on increases in the mandatory and lower MOOP limits; this cap will necessarily limit increases in the intermediate MOOP limit and the total catastrophic (combined) MOOP limits as well based on the methodology to calculate those limits.

Therefore, subject to the rounding rules in § 422.100(f)(4)(iii) and the ESRD cost transition schedule in § 422.100(f)(4)(vi), the MOOP limits for 2023 and subsequent years will be calculated as follows:

For contract year 2023 (applying both § 422.100(f)(4)(iv) and (vi)(A)):

- The mandatory MOOP limit is calculated as $7,175 (the 95th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: the resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the mandatory MOOP limit from the prior year, in which case CMS caps the increase to the mandatory MOOP limit by 10 percent of the prior year's MOOP limit.
- The intermediate MOOP limit is calculated as the numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in § 422.100(f)(4)(iii) and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraphs (f)(4)(iv)(A) and (C)).
- The lower MOOP limit is calculated as $3,360 (the 85th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: The resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the voluntary MOOP limit from the prior year, in which case CMS caps the increase to the lower MOOP limit by 10 percent of the prior year's MOOP limit.

The MOOP limits for contract year 2024 and subsequent years will be calculated, subject to the rounding rules in paragraph (f)(4)(iii), as follows:

- The mandatory and lower MOOP limits are calculated as the 95th and

85th percentiles of the Medicare FFS data projections if the resulting MOOP limits reflect a decrease or an increase equal to or less than 10 percent compared to each of the prior year's corresponding MOOP limits. If the MOOP limits are not calculated as the 95th and 85th percentiles of the Medicare FFS data projections, CMS increases the prior year's mandatory and lower MOOP limits by 10 percent annually until the MOOP limits are calculated at the applicable percentile (95th percentile for the mandatory MOOP limit and 85th percentile for the lower MOOP limit) of Medicare FFS data projections. This policy is finalized in paragraph (f)(4)(v)(A).

- The intermediate MOOP type is either maintained at the prior year's limit or if either the mandatory or lower MOOP limit changes from the prior year, updated to the new numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraph (f)(4)(v)(A)). This policy is finalized in paragraph (f)(4)(v)(B).

As a result, CMS will distribute significant (that is, more than 10 percent) increases to the mandatory and lower MOOP types over multiple years in order to avoid potential disruption to beneficiaries and plan designs for contract year 2023 and subsequent years. This is generally consistent with our approach in the February 2020 proposed rule of limiting changes in the MOOP limit but, we believe, is a more direct and simpler approach. Based on the contract year 2021 Medicare FFS data projections (based on Medicare FFS data from 2015–2019) available at the time of the February 2020 proposed rule, a comparison of 95th percentile data reflected an approximate 14 percent difference ($8,174 with and without ESRD costs compared to $7,175 with only non-ESRD costs, respectively). As discussed in the February 2020 proposed rule, distributing a difference in projected costs of this magnitude over multiple years is necessary in order to avoid disruption to beneficiaries. By applying the 10 percent cap, we will ensure changes of a similar magnitude are limited. For example, if the value at the 95th percentile of Medicare FFS data is $10,049 (meaning a MOOP limit of $10,050 after application of the rounding rules in paragraph (f)(4)(iii)), and the next year the value at the 95th percentile is projected to be $11,219 (a rounded MOOP value of $11,200), there would have been a potential increase of $1,150 or approximately 11 percent. Under the rules finalized here, the MOOP limit would be increased by only 10 percent, resulting in a mandatory MOOP limit of $11,050 in the second year. In the third year, the mandatory MOOP limit would incorporate any remaining difference, to the lower of $12,150 (a 10 percent increase) or the value at the 95th percentile as projected using the annually updated Medicare FFS data projections. If the 95th percentile for the third year is projected to be $11,603 (an increase of approximately 5 percent over the prior year), the MOOP limit for that third year would be $11,600 after application of the rounding rules. By applying the 10 percent cap, we will ensure increases of a similar magnitude are limited. However, the projections for 2024 and subsequent years would be made using annually updated Medicare FFS data projections that are based on data for beneficiaries with and without diagnoses of ESRD.

This 10 percent cap on increases to the MOOP limits provision in § 422.100(f)(4)(iv) and (v) will make sure that, if the projected 95th or 85th percentile substantially increases from one year to the next for contract year 2023 and subsequent years, enrollees are not subject to potentially significant increases in MOOP amounts for that contract year. In addition, by consistently applying the 10 percent guardrail and ESRD cost transition to both the mandatory and lower MOOP limits (which, in turn, determine the intermediate MOOP limit and the total catastrophic MOOP limits), there will be a level of stability and predictability for MA organizations and better protection for MA enrollees. Codifying this rule provides transparency in how CMS will address significant changes in Medicare FFS data projections for contract year 2023 and subsequent years. In addition to these substantive changes, this FC includes clarifying edits. By generally maintaining the proposed limit of a 10 percent increase in comparison to the prior year's MOOP limit amount, we are essentially continuing the ESRD cost transition, but in a limited fashion in order to protect enrollees from potentially significant changes in out-of-pocket costs. As a result, we do not believe these guardrails will directly result in increases in premiums or decreases to supplemental benefits. However, we will consider future rulemaking if there are significant unforeseen changes.

CMS proposed a similar but separate methodology to maintain or update MOOP limits for contract year 2025 or after completion of the ESRD cost transition at proposed § 422.100(f)(4)(vi). Since we are applying the simplified guardrails in paragraph (f)(4)(v) to contract year 2024 and subsequent years, we are not finalizing paragraph (f)(4)(vi) as proposed. Our proposal included similar guardrails for during the ESRD cost transition and after the completion of the ESRD cost transition to protect against potentially disruptive changes to the MOOP limits during and after the ESRD cost transition; this FC is generally consistent with that. In addition, we are not finalizing the requirement that there must be a consistent trend of changes over 3 years of the 85th and 95th percentiles to update the mandatory and lower MOOP limits after the ESRD cost transition is completed (proposed in paragraphs (f)(4)(vi)(A)*(2)* and (f)(4)(vi)(C)*(2)*). In the February 2020 proposed rule, we noted that the OACT uses the most recent complete Medicare FFS data to project costs for the applicable year. Specifically, the OACT applies actuarial judgement to create trend factors (that are consistent with the Medicare Trustees Report) to project expected costs (or savings) for the applicable future year, taking into consideration current laws, regulations, and several years of Medicare data in order to determine the cost projections CMS proposed to use to calculate MOOP limits. As a result, the requirement to meet a 3-year trend as proposed is duplicative of the trend factors to an extent and may unnecessarily delay updates to the MOOP limits. In proposing use of a 3-year trend, we intended to base changes in the MOOP limits on a material change. To achieve the goal of updating the MOOP limits when there are material changes to the Medicare FFS data projections, as intended by the February 2020 proposed rule, CMS will instead annually update the MOOP limits to reflect the applicable percentile of Medicare FFS data projections. Small fluctuations in the MOOP limits are likely to be eliminated by application of the rounding rule, so changes in the MOOP limit from year to year will be within these ranges:

- Decreases of $50 or more, in $50 increments; or
- Increases of at least $50 and in increments of $50 but less than a 10 percent increase.

In summary, § 422.100(f)(4)(iv) and (v) reflect final CMS policies in this FC for 2023 and for subsequent years. We expect that applying the standardized update, as detailed in paragraphs (f)(4)(iv) and (v), will result in MOOP

limits that better guard against potentially disruptive annual changes. Therefore, we are finalizing this more streamlined approach, which includes aspects of our proposal, to calculate the mandatory and lower MOOP limits for contract year 2023 and subsequent years.

CMS will annually update the mandatory and lower MOOP limits for the upcoming contract year (subject to the rounding rules at paragraph § 422.100(f)(4)(iii)) to reflect the Medicare FFS data projections of the 85th and 95th percentiles unless either of the resulting MOOP limits reflect an increase greater than 10 percent compared to the same type of MOOP limit from the prior year. If there is a 10 percent or more increase in the dollar value at the applicable percentile, we would cap the increase of the applicable MOOP limit(s) at 10 percent of the prior year's MOOP limit annually, until the MOOP limit(s) reflects the applicable percentile(s). In addition, under finalized paragraph (f)(4)(iv)(B) and (f)(4)(vi)(B), for 2023 and for subsequent years, the intermediate MOOP limit will either be maintained at the prior year's limit, or, if the mandatory or lower MOOP limit changes from the prior year, we will update the intermediate MOOP limit to the new numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraphs (f)(4)(iv) and (v)). Application of this methodology for calculating and setting contract year 2023 MOOP limits is reflected in Tables 2 through 5, as described previously in this section.

We included Tables 6 through 9 to illustrate how contract year 2024 MOOP limits would be set using the methodology described in § 422.100(f)(4)(v) and applying the ESRD cost transition and the 10 percent cap on increases to the MOOP limits. Specifically, Tables 6 through 9 illustrate how CMS would calculate contract year 2024 MOOP limits using contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017–2021) because contract year 2024 projections were not available at the time of this FC. For example, the illustrative contract year 2024 in-network mandatory and lower MOOP limits in Table 6 reflect 100 percent of the ESRD cost differential based on finalized § 422.100(f)(4)(vi)(B). However, other potential outcomes are possible and we expect the final contract year 2024 MOOP limits will be different than the illustrative amounts in Table 9 after updating the calculations to use contract year 2024 Medicare FFS data projections (based on Medicare FFS data from 2018–2022).

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TABLE 6: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 IN-NETWORK MANDATORY AND LOWER MOOP LIMITS USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Mandatory MOOP Limit	Lower MOOP Limit
A	Contract year 2023 MOOP limit (values from row J in Table 2)	$8,300.00	$3,650.00
B	Maximum contract year 2024 MOOP limit per § 422.100(f)(4)(v) (110% of row A)	$9,130.00	$4,015.00
C	Medicare FFS percentile in § 422.100(f)(4)	95th	85th
D	Unrounded contract year 2024 MOOP limit prior to applying 10% cap on increases per § 422.100(f)(4)(v) and (vi)(B)[1]	$9,111.00	$3,772.00
E	Unrounded contract year 2024 MOOP limit with 10% cap on increases applied (the lesser value comparing row B and row D)	$9,111.00	$3,772.00
F	Rounded contract year 2024 MOOP limit per § 422.100(f)(4)(iii) and (v) (row E rounded)	$9,100.00	$3,750.00
G	Lowest dollar range of the contract year 2024 MOOP limit per § 422.100(f)(4)(i)	$6,451.00[2]	$0.00[3]
H	Illustrative contract year 2024 MOOP limit dollar ranges per § 422.100(f)(4)(i) through (iii) and (v) through (vi)	$6,451.00 to $9,100.00	$0.00 to $3,750.00

[1]These amounts are for illustrative purposes only and are the values for contract year 2023 from row D in Table 2 (the unrounded Medicare FFS data projections for the applicable percentile in row C). The projected percentile amounts CMS will use to calculate the final contract year 2024 MOOP limits will be based on Medicare FFS data from 2018 – 2022 and reflect 100 percent of the ESRD Cost Differential per § 422.100(f)(4)(vi)(B).

[2]The in-network mandatory MOOP limit dollar range begins at the value of the in-network intermediate MOOP limit from row D in Table 7 plus $1.00 per § 422.100(f)(4)(i)(A).

[3]The in-network lower MOOP limit dollar range begins at $0.00 per § 422.100(f)(4)(i)(C).

TABLE 7: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 IN-NETWORK INTERMEDIATE MOOP LIMIT USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Intermediate MOOP Limit
A	Unrounded contract year 2024 mandatory MOOP limit with 10% cap on increases applied (row E, mandatory MOOP limit column in Table 6)	$9,111.00
B	Unrounded contract year 2024 lower MOOP limit with 10% cap on increases applied (row E, lower MOOP limit column in Table 6)	$3,772.00
C	Unrounded contract year 2024 intermediate MOOP limit per § 422.100(f)(4)(v) (numeric midpoint between row A and row B)	$6,441.50
D	Rounded contract year 2023 intermediate MOOP limit (row C rounded per § 422.100(f)(4)(iii))	$6,450.00
E	Lowest dollar range of the contract year 2024 MOOP limit per § 422.100(f)(4)(i)(B)	$3,751.00*
F	Illustrative contract year 2024 intermediate MOOP limit dollar range per § 422.100(f)(4)(i) through (iii) and (v) through (vi)	$3,751.00 to $6,450.00

*The in-network intermediate MOOP limit dollar range begins at the value of the in-network lower MOOP limit from row F in Table 6 plus $1.00 per § 422.100(f)(4)(i)(B).

TABLE 8: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 COMBINED MOOP LIMITS FOR LPPO AND TOTAL CATASTROPHIC MOOP LIMITS FOR RPPO PLANS USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Mandatory MOOP Limit	Intermediate MOOP Limit	Lower MOOP Limit
A	Corresponding unrounded in-network MOOP type with 10% cap on increases applied (values from row E in Table 6 and row C in Table 7)	$9,111.00	$6,441.50	$3,772.00
B	Unrounded contract year 2024 combined and total catastrophic MOOP limit per § 422.101(d)(3)(ii) (row A multiplied by 1.5)	$13,666.50	$9,662.25	$5,658.00
C	Rounded contract year 2024 combined and total catastrophic MOOP limit (row B rounded per § 422.100(f)(4)(iii))	$13,650.00	$9,650.00	$5,650.00
D	Lowest dollar range of the contract year 2024 MOOP limit per § 422.101(d)(3)(ii)	$6,451.00[1]	$3,751.00[2]	$0.00[3]
E	Illustrative contract year 2024 combined and total catastrophic MOOP limit dollar ranges per § 422.101(d)(3)(ii)	$6,451.00 to $13,650.00	$3,751.00 to $9,650.00	$0.00 to $5,650.00

[1]The combined and total catastrophic mandatory MOOP limit dollar range begins at the value of the in-network intermediate MOOP limit from row D in Table 7 plus $1.00 per § 422.101(d)(3)(ii)(A).
[2]The combined and total catastrophic intermediate MOOP limit dollar range begins at the value of the in-network lower MOOP limit from row F in Table 6 plus $1.00 per § 422.101(d)(3)(ii)(B).
[3]The combined and total catastrophic lower MOOP limit dollar range begins at $0.00 per § 422.101(d)(3)(ii)(C).

TABLE 9: ILLUSTRATIVE CONTRACT YEAR 2024 MOOP LIMITS BY PLAN TYPE

Plan Type	Lower MOOP Limit	Intermediate MOOP Limit	Mandatory MOOP Limit
HMO	$0 - $3,750	$3,751 to $6,450	$6,451 - $9,100
HMO POS	$0 - $3,750 In-network	$3,751 to $6,450	$6,451 - $9,100 In-network
Local PPO	$0 - $3,750 In-network and $0 - $5,650 Combined	$3,751 to $6,450 In-network and $3,751 - $9,650 Combined	$6,451 - $9,100 In-network and $6,451 - $13,650 Combined
Regional PPO	$0 - $3,750 In-network and $0 - $5,650 Combined	$3,751 to $6,450 In-network and $3,751 - $9,650 Combined	$6,451 - $9,100 In-network and $6,451 - $13,650 Combined
PFFS (full network)	$0 - $3,750	$3,751 to $6,450	$6,451 - $9,100
PFFS (partial network)	$0 - $3,750	$3,751 to $6,450	$6,451 - $9,100
PFFS (non-network)	$0 - $3,750	$3,751 to $6,450	$6,451 - $9,100

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Some other potential outcomes of how CMS may annually update MOOP limits for 2024 and for subsequent years, subject to the rounding rules in paragraph (f)(4)(iii) and the ESRD cost transition in paragraph (f)(4)(vi), may include:

- Maintaining the contract year 2024 MOOP limits for contract year 2025 if the 95th and 85th percentiles of contract year 2025 Medicare FFS data projections result in values equivalent to the MOOP limits in effect for the prior contract year after applying the rounding rules at § 422.100(f)(4)(iii).
- Calculating updated MOOP limits for contract year 2026 (after the contract year 2024 MOOP limits were maintained for contract year 2025) if the 95th and 85th percentiles of contract year 2026 Medicare FFS data projections result in increases of 3 percent and 5 percent, respectively, from the MOOP limits in effect for the prior contract year.
- Increasing the prior year's mandatory MOOP limit by 10 percent and increasing the prior year's lower MOOP limit by 8 percent (and calculating the intermediate MOOP limit per the regulation text) for contract year 2025 if the 95th and 85th percentiles of contract year 2025 Medicare FFS data projections result in increases of 16 and 8 percent, respectively, from the MOOP limits in effect for the prior contract year.

We reiterate that, as finalized in § 422.100(f)(7)(i), CMS will use generally accepted actuarial principles and practices in projecting the beneficiary out of pocket costs using updated Medicare FFS data each year to calculate MOOP limits in accordance with paragraph (f)(4) and (5) and § 422.101(d)(2) and (d)(3). In addition, we may explain the calculations CMS made to apply the regulations through the subregulatory process finalized in paragraph (f)(7)(iii). Tables 2 through 4 illustrate how the methodology for setting the MOOP limits for has been applied for contract year 2023 MOOP limits. Because this FC is adopting the specific MOOP limits for contract year 2023, as shown in Table 5, the requirement for a subregulatory notice and comment process will begin with the calculation of the 2024 MOOP limits under the rules finalized in §§ 422.100(f)(4) and (f)(5) and 422.101(d)(2) and (d)(3).

Comment: A few commenters were concerned that MA provider network instability or weak dialysis networks in combination with higher MOOP limits would discourage beneficiaries with diagnoses of ESRD from enrolling in MA plans. Concerns about the number of dialysis providers in an MA plan network appear tied to the MA and cost plan network adequacy proposal from the February 2020 proposed rule that was finalized in the June 2020 final rule. Similarly, another commenter was concerned about the combination of ESRD payment rates, MOOP limits, and network adequacy standards creating disincentives for beneficiaries with diagnoses of ESRD from enrolling in MA plans. In addition, a commenter requested that CMS ensure beneficiaries with diagnoses of ESRD are properly informed about the adequacy of MA plan networks (in addition to out-of-pocket costs as discussed in section II.A.4. of this FC) to assist them in making health care coverage choices.

Response: We do not believe that CMS's network adequacy requirements and ESRD payment rates by themselves or in combination with the MOOP limit provision will discourage beneficiaries with diagnoses of ESRD from enrolling in MA plans. We direct commenters to the Calendar Year 2021 and 2022 Rate Announcements at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents* for finalized policies on ESRD payment for contract year 2021 and 2022. As mentioned in the Calendar Year 2021 Rate Announcement, we will continue to analyze and consider whether, consistent with the statutory provisions for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the methodology may be warranted in future years. We also direct commenters to the June 2020 final rule (85 FR 33796) for how CMS finalized policies related to network adequacy (section V.A. of the June 2020 final rule) and note that MA plans and cost plans are required to provide medically necessary services for all enrollees and that the regulations regarding network adequacy standards do not limit application of this requirement. In addition, MA organizations must maintain a network of contracted providers that is sufficient to provide adequate access to covered services to meet the needs of the population served and is consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered per § 422.112. Importantly, the regulations at § 422.112(a) provide a critical beneficiary protection (including when a provider or facility specialty type is not subject to the network evaluation standards in § 422.116) that access to providers at in-network cost sharing must be provided by the MA organization if the MA plan's network providers are unavailable or inadequate to furnish medically necessary benefits for an enrollee. This critical beneficiary protection ensures that MA enrollees have similar reasonable access to providers and facilities for covered benefits as beneficiaries in Medicare FFS. Therefore, we believe that MA plans will continue to provide adequate access to dialysis providers and the network adequacy requirements will not discourage beneficiaries with diagnoses of ESRD from enrolling in MA plans. The ESRD payment rates, CMS's

network adequacy requirements, and the MOOP limit do not provide an incentive for MA organizations to discriminate against beneficiaries with chronic conditions, including diagnoses of ESRD.

If beneficiaries believe that an MA organization is not providing adequate access to services, complaints may be submitted online or by calling 1–800–MEDICARE. CMS monitors and investigates complaints related to plan coverage and CMS caseworkers assist in the resolution of issues with the MA organizations. CMS may take compliance or enforcement actions against an MA organization for failing to meet any contract or regulatory requirements, such as providing adequate access to medically necessary services, as warranted. In addition, enrollees who have complaints about their plan have the right to file a grievance under § 422.564 and, if they believe that benefits have been improperly denied, file an appeal under the appeal rules in §§ 422.562 through 422.619.

In addition, we believe provider networks and the plan's established MOOP amount are not the only factors beneficiaries consider when choosing a health plan. Enrollees may continue to consider a number of factors in relation to their unique healthcare needs and financial situation, such as perception of brand, premium, plan type, benefits, cost sharing, quality ratings, provider network, and the MOOP amount when choosing a health care plan [21]. This information will continue to be available to beneficiaries as they review their MA plan options for the upcoming contract year. Beneficiaries can use Medicare Plan Finder (MPF), provider network information, and other communications materials in determining which plan options available to them (such as the MA program, Medicare FFS, and Medigap) best meet their healthcare needs and financial situation.

d. Out-of-Scope Comments

Comment: Many commenters also provided a wide range of feedback that was outside of the scope of the changes proposed to §§ 422.100(f) and 422.101(d) for the MOOP limits, including requests for CMS to change ESRD payments for MA plans in addition to, or in place of, transitioning ESRD costs into MOOP limits; commenters stated these payment changes would mitigate the costs for MA plans and keep MA program costs low for beneficiaries. These commenters were concerned that payment changes were needed in order to ensure MA plans and ultimately providers have the resources needed to treat this population of chronically ill patients, support MA plans in covering the higher medical costs for beneficiaries with diagnoses of ESRD, and prevent detrimental changes to the number and scope of plans offered, premiums, cost sharing, and supplemental benefits. A commenter was concerned the ESRD payment amounts might limit MA plan options. Similarly, some commenters suggested that we adjust MA payment rates for ESRD beneficiaries receiving dialysis to reflect the impact of MOOP limits.

In addition, a few commenters were concerned that the estimate of kidney acquisition costs, which are carved out of MA payment rates, was inflated and tied that to the proposed MOOP limits. A commenter was specifically concerned that an inflated estimate of kidney acquisition costs, combined with the proposed MOOP limits, could lead to reductions in benefits and result in adverse selection for plans that may attract higher numbers of enrollees with diagnoses of ESRD (such as through lower MOOP limits and cost sharing structures). Other out-of-scope comments included suggestions to modify the MOOP limit to include the Part D prescription drug program and to change the total beneficiary cost (TBC) evaluation that CMS uses (under § 422.256(a)) each year to identify MA bids that include potentially significant increases in enrollee costs or decreases in enrollee benefits.

Response: While we appreciate the comments, ensuring payments to MA plans capture the cost of enrollees with diagnoses of ESRD and the development of MA capitation rates (which must exclude kidney acquisition costs pursuant to section 1853(k) and (n) of the Act) is not within the scope of the proposal to adopt a methodology for calculating MOOP limits. Further, we do not find the specific suggestions to modify MA payments (including adjusting payment rates for beneficiaries receiving dialysis to reflect the impact of MOOP limits as well as rate adjustments to be made instead of factoring in the ESRD cost differential) to be consistent with our interpretation of section 1853 of the Act as a whole, which is that CMS should more closely align MA payment rates with FFS costs. We also do not find the suggestions consistent with the statutory provisions for ESRD payment policies. In accordance with section 1853(b) of the Act, CMS addresses the methodology for developing the MA (including ESRD) capitation rates and payment policies in the Advance Notice and Rate Announcement for each contract year.[22] Comments were submitted and addressed in the CY 2021 and CY 2022 Rate Announcements. Similar to comments regarding the accuracy in calculating the kidney acquisition cost, the methodology used by CMS and the amount of payment to MA plans are addressed by CMS in the annual Rate Announcement. We direct readers to the annual Advance Notice and Rate Announcement documents for a more detailed discussion of these issues. We also direct commenters to the June 2020 final rule (85 FR 33796) for how CMS finalized policies related to kidney acquisition costs (sections III.B. and III.C. of the June 2020 final rule) and ESRD enrollment (section III.A. of the June 2020 final rule). To the extent that consideration of how enrollees with diagnoses of ESRD will incur more costs, including out-of-pocket expenses, is related to calculating the MOOP limits, we have addressed those issues in section II.A.4.c. of this FC in response to other comments.

Finally, the MOOP limit is one of a number of factors that CMS takes under consideration in setting the TBC standard on an annual basis. For example, we also consider benefit and payment policies and technical out-of-pocket cost (OOPC) model changes. The TBC evaluation process is distinct and separate from calculating MOOP and cost sharing limits. We direct commenters to the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020, for TBC requirements finalized for contract year 2021 and the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021, for TBC requirements finalized for contract year 2022.[23] CMS released an HPMS memorandum titled ''Preliminary Contract Year 2023 Part C Benefits Review and Evaluation'' on March 3, 2022 (with a comment period) that includes potential changes to the TBC threshold for contract year 2023. CMS will also consider soliciting comment

[21] Adam Barnhart, Julia M. Friedman, and Peter T. Kissinger, Milliman, ''Star Rating Changes: How Medicare Advantage Plans React,'' October 2020 *https://us.milliman.com/en/insight/Star-rating-changes-How-Medicare-Advantage-plans-react.*

[22] Advance Notice and Rate Announcement documents are available at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[23] These HPMS memoranda may be accessed through the HHS guidance repository at: HHS Guidance Submissions | Guidance Portal and individuals and organizations may request placement on the HPMS listserv at *https://hpms.cms.gov/app/ng/home/.*

on how CMS sets the TBC threshold for contract year 2024 and future years, if necessary.

5. Final Decision

CMS received feedback from 27 commenters pertaining to the MOOP limit proposal, with the majority reflecting support for, or requests for modifications to, the proposed amendments at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to: (1) Calculate three in-network and out-of-network MOOP limits for local and regional MA plans; (2) transition the ESRD cost differential (that is, data regarding the out-of-pocket costs of beneficiaries who have diagnoses of ESRD) into the Medicare FFS data used to calculate MOOP limits; and (3) calculate MOOP limits during and after completion of the transition schedule. We thank commenters for their feedback and helping to inform our final policy concerning MOOP limits. CMS intends to track several measures of plan benefit design to monitor the potential impact of the polices adopted in this FC, such as: (1) Percent of plans offering lower MOOP limits; (2) percent of plans that use copayments rather than coinsurance in their plan designs; (3) percent of plans that establish the highest allowable cost sharing for each service category (and/or the average or median cost sharing for each service category as a direct year over year comparison); (4) percent of plans with zero premium; and (5) the average number of plan options. CMS may consider additional changes to the methodology for calculating MOOP limits in future rulemaking if this FC results in unforeseen negative consequences, does not encourage favorable benefit designs for enrollees, or does not increase access to plan offerings with lower or intermediate MOOP amounts and cost sharing that is lower or comparable when compared to existing benefit packages.

After careful consideration of all the comments we received, and for the reasons set forth in the February 2020 proposed rule and in our responses to the related comments discussed previously, we are finalizing amendments §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) as proposed, with some modification. These new MOOP provisions are applicable for coverage beginning January 1, 2023 and later. We will therefore use these rules and the final contract year 2023 MOOP limits in Table 5 to evaluate MA bids submissions due the first Monday in June (June 6, 2022) for the 2023 contract year. We will also use these rules to evaluate MA bid submissions for subsequent contract years going forward. In summary, the proposed changes are finalized substantially as proposed but with the following modifications from the proposal:

- Adding descriptive headings to § 422.100(f)(1)–(9) to orient the reader to the content in each paragraph.
- Applying the methodology in the amendments to §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) beginning on or after January 1, 2023 instead of January 1, 2022.
- Revisions in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to use consistent language in regulation text when referring to: (1) Plan MOOP amounts established by MA organizations and MOOP limits calculated by CMS; (2) in-network, combined, catastrophic, and total catastrophic MOOP limits, amounts, or types; and (3) the Medicare FFS data projections CMS uses in calculating MOOP and cost sharing limits.
- Revising introductory language in § 422.100(f)(4) for clarity and to: (1) Retain how MA local plans, as defined in § 422.2, must have an enrollee in-network maximum out-of-pocket amount for basic benefits before January 1, 2023 that is no greater than the annual limit calculated by CMS using Medicare FFS data projections; and (2) codify current policy that the in-network MOOP limits apply to PFFS plans for all covered basic benefits.
- Revising § 422.100(f)(4)(i) to address: (1) That CMS will calculate three MOOP limits; (2) the addition of a definition for the term ''Medicare FFS data projections''; and (3) how the MOOP limits are based on the Medicare FFS data projections.
- Adding § 422.100(f)(4)(i)(A)–(C) to specify: (1) The dollar ranges of the three in-network MOOP types; (2) the range of the mandatory MOOP limit begins one dollar above the intermediate MOOP limit; and (3) the range of the intermediate MOOP limit begins one dollar above the lower MOOP limit.
- Revisions in § 422.100(f)(4)(ii) to: (1) Clarify that the ranges specified in paragraphs (f)(4)(i)(A) through (C) are dollar ranges for each MOOP type; and (2) add references to §§ 422.101(d) and 422.113 because the MOOP types are referenced in those sections.
- Removing § 422.100(f)(4)(ii)(A)–(C), as this information is finalized with clarifications in paragraphs (f)(4)(i)(A)–(C).
- Revisions in § 422.100(f)(4)(iv) to: (1) Address how CMS will calculate MOOP limits for 2023, including incorporation of 70 percent of the ESRD cost differential in the data used for calculating the MOOP limits; and (2) apply a 10 percent cap on increases to the MOOP limits from the prior year.
- Revisions in § 422.100(f)(4)(iv)(B) to provide that the numeric midpoint is calculated from the mandatory and lower MOOP limits before rounding and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year.
- Revisions in § 422.100(f)(4)(v) to: (1) Update the applicable dates (to 2024 and subsequent years); and (2) update the reference to the ESRD cost transition to paragraph (f)(4)(vi)(B).
- Revisions in § 422.100(f)(4)(v)(A) to: (1) Apply that paragraph to calculate both the mandatory and lower MOOP limits to make the regulation text concise and ensure consistency in the methodology; (2) replace the two-percentile guardrail with a 10 percent cap on increases to the MOOP limits from the prior year; and (3) to include clarifying edits because the proposal to delay the ESRD cost differential transition is not being finalized.
- Revisions in § 422.100(f)(4)(v)(B) to: (1) Clarify that the numeric midpoint is calculated between the mandatory and lower MOOP limits if either limit changes from the prior year; (2) avoid double rounding in the calculations of the intermediate MOOP limit; and (3) calculate the numeric midpoint after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year.
- Removing § 422.100(f)(4)(v)(C) as the methodology CMS will use to calculate the lower MOOP limit for contract year 2024 and subsequent years is addressed in paragraph (f)(4)(v)(A).
- Removing proposed § 422.100(f)(4)(vi) as the methodology for how CMS calculates MOOP limits for 2025 and subsequent years is now addressed in paragraph (f)(4)(v).
- Finalizing the proposed ESRD cost differential transition (proposed at § 422.100(f)(4)(vii)) in paragraph (f)(4)(vi) with revisions to: (1) Clarify that the definition of ''ESRD cost differential'' is used for purposes of the ESRD cost transition methodology to calculate annual MOOP limits; (2) correct and update the definition of the ESRD cost differential by using the new defined term of Medicare FFS data projections and identifying the specific Medicare FFS percentiles that CMS will use for each MOOP type; (3) decrease the percentage of ESRD cost differential to incorporate for 2023 (70 percent instead of 80 percent); and (4) finalize the substance of proposed paragraph (f)(4)(vii)(C) in paragraph (f)(4)(vi)(B) and apply it to 2024 and subsequent years.

• Revisions in § 422.100(f)(5) to clarify that the MOOP limits specified in paragraph (f)(4) apply to in-network providers.

• Revisions in § 422.100(f)(5)(i) to: (1) Clarify that the combined MOOP is applied to MA enrollees (rather than beneficiaries); and (2) refer to § 422.101(d)(3) to encompass the addition of dollar ranges for the total catastrophic (MOOP) limits.

• Revisions in § 422.100(f)(5)(iii) to clarify that the MA organization's responsibility to track out-of-pocket spending applies to the combined MOOP amount.

• Finalizing new § 422.100(f)(7)(i) to: (1) Clarify that CMS will use generally accepted actuarial principles and practices in making the projections and calculations used in the methodologies described in §§ 422.100(f)(4), (f)(5), (f)(6), (f)(7)(ii), (f)(8), and (j) and 422.101(d)(2) and (d)(3) to calculate the MOOP limits; and (2) provide examples of the types of approaches and data CMS may consider. This provision and paragraphs (f)(7)(i)(B)–(C) are also applicable to the cost sharing standards addressed in paragraph (f)(6) and (j) and a more complete discussion of these applications is available in section II.B. of this FC.

• Finalizing new § 422.100(f)(7)(iii) to: (1) Codify a specific rule, beginning with contract year 2024, requiring CMS to issue subregulatory guidance prior to bid submission that specifies the MOOP limits and cost sharing standards CMS sets for the upcoming year to allow sufficient time for MA organizations to prepare and submit plan bids; and (2) provide a public comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year, unless a public comment period is impracticable, unnecessary, or contrary to the public interest.

• Revisions in § 422.101(d)(2) to specify the requirements related to establishing a catastrophic MOOP amount for MA regional plans.

• Revisions in § 422.101(d)(2)(i) to require MA regional plans to establish a catastrophic enrollee MOOP amount for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4).

• Revisions in § 422.101(d)(2)(ii) to: (1) Remove repetitive references to the requirement that MA organizations are required to track out-of-pocket spending and alert enrollees and contracted providers when the MOOP amount is reached; and (2) clarify that MA regional plans must have the same MOOP type for the catastrophic MOOP (in-network) limit and total catastrophic (combined in-network and out-of-network expenditures) limit.

• Revisions in the introductory language of § 422.101(d)(3) to clarify that the total catastrophic MOOP amount encompasses the combined in-network and out-of-network expenditures and that this MOOP amount is applied to MA enrollees.

• Revisions in § 422.101(d)(3)(i) to: (1) Avoid repetitive text in the regulation; and (2) clarify the reference to paragraph (d)(2) applies to the catastrophic limit.

• Revisions in § 422.101(d)(3)(ii) to: (1) Avoid double rounding in the calculations of the total catastrophic MOOP limits; (2) calculate the total catastrophic MOOP limits using the mandatory and lower MOOP limits after application of the 10 percent cap on increases from the prior year; and (3) add new paragraphs (d)(3)(ii)(A), (B), and (C) to provide the dollar ranges for each type of total catastrophic MOOP limit (mandatory, intermediate, and lower) for purposes of paragraph (d) and § 422.100(f) and (j).

• Removing proposed § 422.101(d)(3)(iii) and revising to: (1) Remove repetitive references to the requirement that MA organizations are required to track out-of-pocket spending and alert enrollees and contracted providers when the MOOP is reached; and (2) reference the total catastrophic MOOP dollar ranges specified in paragraph (d)(3)(ii) for purposes of paragraph (d) and §§ 422.100(f)(6), (j)(1), and 422.113(b)(2)(v) as those sections apply certain flexibilities depending on the MOOP type established.

• Adding various minor technical and grammatical changes from the proposed regulation text at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to ensure clarity and avoid repetitive text in the regulations.

Finally, in addition to the authority outlined in the February 2020 proposed rule for these MOOP limits, section 1854(a)(5) and (6) of the Act provide that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. Under section 1854(a)(5)(C)(ii) of the Act, CMS is authorized to deny a plan bid if the bid proposes too significant an increase in enrollee costs or decrease in benefits from one plan year to the next. While the rules adopted here do not limit our negotiation authority (§ 422.256), they provide minimum standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids in addition to establishing important protections to ensure that enrollees with high health care costs are not discouraged from enrolling in MA plans.

B. Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

Section 1852 of the Act imposes a number of requirements that apply to the cost sharing and benefit design of MA plans. First, section 1852(a)(1)(B)(i) of the Act provides that the MA organization must cover, subject to limited exclusions, the benefits under Parts A and B (that is, basic benefits as defined in § 422.100(c)) with cost sharing that does not exceed or is at least actuarially equivalent to cost sharing in original Medicare; this is repeated in a bid requirement under section 1854(e)(4) of the Act. We have addressed and implemented that requirement in several regulations, including §§ 422.101(e)(2), 422.102(a)(4), and 422.254(b)(4). Second, section 1852(a)(1)(B)(iii) and (iv) of the Act also imposes particular constraints on the cost sharing for specific benefits, which have been implemented in § 422.100(j) for MA plans and extended to cost plans under § 417.454(e); the statute authorizes CMS to add to the list of items and services for which MA cost sharing may not exceed the cost sharing levels in original Medicare. Relatedly, we have codified a requirement in § 422.100(k) that MA plans must cover original Medicare-covered preventive services (as defined in § 410.152(l)) without cost sharing when the services are provided in-network; the same restriction is applied to cost plans under § 417.454(d). Third, section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. The requirements under §§ 422.100(f)(4) and (5) that impose Maximum Out-of-Pocket (MOOP) limits on MA local plans are based on this anti-discrimination provision and designed to prohibit discrimination against or discouragement of enrollment by beneficiaries with high health care needs. In addition, the MOOP requirements under §§ 422.101(d)(2) and (3) implement the statutory catastrophic limits imposed on regional MA plans under section 1858(b) of the Act. Section 422.100(f)(6) provides that cost sharing must not be discriminatory. Calculating limits on cost sharing for covered services is an important way to

ensure that the cost sharing aspect of an MA plan design does not discriminate against or discourage enrollment of beneficiaries who have high health care needs. CMS issued annual limits on cost sharing for covered services and guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letters issued prior to 2020 [24] and in bidding instructions. In addition, Chapter 4 [25] of the Medicare Managed Care Manual (MMCM) has contained long-standing polices regarding discriminatory cost sharing based on the requirements under § 422.100(f).

Currently, CMS annually analyzes Medicare program data to interpret and apply the various cost sharing limits from these authorities and to publish guidance on MA cost sharing limits. The relevant Medicare data included in this analysis are the most recent Medicare fee-for-service (FFS) data, including cost and utilization data, and MA patient utilization information from MA encounter data. CMS sets cost sharing limits based on analyses of and projections from this data and then reviews cost sharing established by MA organizations to determine compliance with the cost sharing limits and requirements established in the statute and regulations, as interpreted and implemented in sub-regulatory guidance, including Chapter 4 from the MMCM. The cost sharing limits set by CMS reflect a combination of outpatient and professional visits and inpatient utilization scenarios based on the lengths of stays typically used by average to sicker Medicare patients. CMS uses multiple inpatient utilization scenarios to guard against MA organizations setting inpatient cost sharing amounts in a manner that is potentially discriminatory. CMS also sets review parameters for frequently used Medicare professional services, such as primary and specialty care services.

CMS proposed to codify our current and longstanding practice and methodology for interpreting and applying the limits on MA cost sharing, with some modifications. In addition, CMS proposed to add categories of services to the regulation requiring MA cost sharing be no greater than that in original Medicare. Our proposal as a whole, in combination with the MOOP proposal in section VI.A. of the February 2020 proposed rule, aimed to provide MA organizations incentives to offer plans with favorable benefit designs for beneficiaries. As noted in the February 2020 proposed rule, organizations must also comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex (sexual orientation and gender identity), age, disability, including section 1557 of the Affordable Care Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. None of the proposals in the February 2020 proposed rule limited application of such anti-discrimination requirements.

In the February 2020 proposed rule, CMS explained that in developing and applying the reviews of MA cost sharing for 2020 and prior years,[26] we exclude the costs for individuals with diagnoses of ESRD from the Medicare FFS data used. We explained the exclusion of costs for these individuals is because of the pre-2021 restrictions on when and how Medicare beneficiaries with diagnoses of ESRD could enroll in an MA plan under section 1851(a) of the Act. In the February 2020 proposed rule, we stated that in contract year 2018, 0.6 percent of the MA enrollee population, or approximately 121,000 beneficiaries, have diagnoses of ESRD. This statistic was based on the statutory definition of ESRD and CMS data. Using more recent enrollment data, the number of beneficiaries enrolled in MA in contract year 2018 with diagnoses of ESRD is lower than previously stated, approximately 120,100 (which does not impact the 0.6 percent of the MA enrollee population figure).[27] As discussed in more detail in section III.A. of the June 2020 final rule (85 FR 33796), section 17006 of the 21st Century Cures Act amended the Medicare statute to allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beginning in contract year 2021. CMS expected this change would result in Medicare beneficiaries with diagnoses of ESRD beginning to transition to, or choosing, MA plans in greater numbers than they did before contract year 2021. As discussed in the February 2020 proposed rule, the OACT expected ESRD enrollment in MA plans to increase by 83,000 as a result of the 21st Century Cures Act provision. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021. Given the potential increase in enrollment of beneficiaries with diagnoses of ESRD in MA plans, the OACT has conducted another analysis to determine the impact of including all costs incurred by beneficiaries with diagnoses of ESRD into the Medicare FFS data CMS uses to project future out-of-pocket expenditures to calculate cost sharing standards and limits. Based on the most recent analyses and projections, adding in ESRD costs (that is, projected out-of-pocket costs for beneficiaries with diagnoses of ESRD) affects MA cost sharing limits for inpatient hospital acute length of stay scenarios, with the longer length of stay scenarios being the most affected. As discussed in section VI.A. of the February 2020 proposed rule, CMS proposed a schedule for incorporating use of the most recent, complete Medicare FFS data for beneficiaries with diagnoses of ESRD into the data used to set MOOP limits. (Section II.A. of this FC addresses that proposal.) CMS made a similar proposal to codify, with some updates and changes, the current process for calculating non-discriminatory cost sharing limits and to incorporate out-of-pocket expenditures for beneficiaries with diagnoses of ESRD. CMS also proposed to codify the methodology used to set the standards for MA cost sharing for professional services and for inpatient hospital acute and psychiatric services at § 422.100(f)(6) and to require MA plans to have cost sharing that does not exceed the standards set each year using the methodology in paragraph (f)(6). As explained in the February 2020 proposed rule (and reflected in the proposed regulation text), the limits in proposed § 422.100(f)(6) would be in

[24] See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021 and the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

[25] Chapter 4 of the MMMCM can be accessed at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

[26] After publication of the February 2020 proposed rule, CMS announced that it would take the Medicare FFS costs of beneficiaries with diagnoses of ESRD into account in developing MOOP limits and cost sharing limits for 2021 and 2022. See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021 and HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

[27] The Fiscal Year President's Budgets may be accessed at *https://www.govinfo.gov/app/collection/BUDGET/* and the annual Advance Notice and Rate Announcements may be accessed at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.* In addition, see page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

addition to other limits on cost sharing that apply to MA plans. CMS also proposed, at § 422.100(j), that MA plans must not impose cost sharing that exceeds original Medicare for certain specific benefits and for certain categories of benefits on a per member per month actuarially equivalent basis. The proposal also included specific cost sharing requirements for emergency/post-stabilization services and urgently needed services, proposed in § 422.113(b)(2)(v) and (vi).

We explained in the February 2020 proposed rule how CMS is committed to encouraging plan offerings with favorable MOOP and cost sharing limits. Based on that, CMS proposed to modify the regulations at §§ 422.100(f)(6) and 422.113(b)(2)(v) and (vi) to establish a range of cost sharing limits for basic benefits furnished on an in-network basis based on the MOOP limit established by the MA plan. We explained that providing MA organizations with greater flexibility to set cost sharing based on different MOOP limits should incentivize MA organizations to create favorable benefit designs for MA enrollees.

In addition, CMS proposed amending §§ 422.100(f)(6) and (j) and 422.113(b)(2) to implement safeguards to ensure MA enrollees are not subject to discriminatory benefits or discriminatory costs for basic benefits. These proposed safeguards included codifying a long-standing interpretation of the current anti-discrimination provision of section 1852(b)(1) that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who need those services. Specifically, CMS proposed to codify in § 422.100(f)(6)(i)(A) that MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established, for basic benefits that are provided in-network and out-of-network that are not explicitly addressed in the cost sharing standards at paragraph (f)(6). We noted in the February 2020 proposed rule that, under current policy and guidance,[28] copayments are expected to reflect specific benefits identified within the plan benefit package (PBP) service category or a reasonable group of benefits or services. Organizations may design their plan benefits as they see fit so long as they satisfy Medicare coverage requirements, including applicable MA regulations. MA organizations typically offer benefits with lower cost sharing amounts than the annual limits published by CMS; we believe this is due to multiple factors, including the principles and incentives inherent in managed care, effective negotiations between organizations and providers, and market competition.

1. General Non-Discriminatory Cost Sharing Limits (§ 422.100(f)(6))

CMS proposed to codify in § 422.100(f)(6) a set of general rules for cost sharing for basic benefits. The term ''basic benefits,'' as defined in § 422.100(c), means items and services (other than hospice care and, beginning 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare and including additional telehealth benefits offered consistent with the requirements at § 422.135. We proposed that the rules in paragraph (f)(6) must be followed by MA plans in addition to other regulatory and statutory requirements for cost sharing. MA organizations have the option to charge either coinsurance or a copayment for most service categories, which we aimed to make clear in the proposed regulation text. Under our proposal, the MA plan would be prohibited from exceeding the coinsurance or copayment limit for service category standards set by CMS using the various rules in paragraph (f)(6) and (j). In addition, after publication of the February 2020 proposed rule, the Families First Coronavirus Response Act (Pub. L. 116–127) amended section 1852 of the Act to prohibit MA plans from charging enrollees higher cost sharing than is charged under original Medicare for COVID–19 testing and testing-related services identified in section 1833(cc)(1) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2) during the period from March 18, 2020, through to the end of the emergency period described in section 1135(g)(1)(B) (namely, the COVID–19 public health emergency). The Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136) amended section 1852(a)(1)(B) to require MA plans have cost sharing that does not exceed cost sharing in Original Medicare for a COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

CMS proposed to codify our long-standing interpretation and implementation of the anti-discrimination provisions (including section 1852(b)(1) of the Act) that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who have significant health care needs and discourages enrollment in the plan by such beneficiaries. We stated how we recognize that it is difficult to set a cost sharing limit for every possible benefit and that this catch-all rule, which has been long-standing policy used in our review of bids, is an important beneficiary protection. We proposed that this rule would apply regardless of the MOOP limit established and regardless of whether the basic benefit is furnished in-network or out-of-network, to protect beneficiaries regardless of the MA plan they choose. As used in the proposed regulation text, the term ''total MA plan financial liability'' meant the total payment paid and includes both the enrollee cost sharing and the amount paid by the MA organization. Specifically, CMS proposed to codify at § 422.100(f)(6)(i) that MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established, for in-network benefits and out-of-network benefits for which a cost sharing limit is not otherwise specified in proposed paragraph (f)(6), inclusive of basic benefits. In order to clarify this policy, we also proposed in paragraphs (f)(6)(i)(B) and (C) how this rule would apply when coinsurance or copayment structures are used: (1) If the MA plan uses copayments, the copayment for an out-of-network benefit cannot exceed 50 percent of the average Medicare FFS allowable amount for that service area and the copayment for in-network benefits cannot exceed 50 percent of the average contracted rate of that benefit (that is, the PBP service category level or for a reasonable group of benefits or services covered under the plan); and (2) if the MA plan uses coinsurance, then the coinsurance cannot exceed 50 percent.

CMS also proposed general rules to govern how CMS would set copayment limits. This included proposed § 422.100(f)(6)(ii)(A) which provided that CMS rounds amounts to the nearest whole $5 increment for professional services copayments and nearest whole $1 for inpatient acute and psychiatric and skilled nursing facility copayments. Our proposal at paragraph (f)(6)(ii)(B) provided that for all cases in which the copayment limit is projected to be exactly between two increments, CMS rounds to the lower dollar amount. This rounding rule would codify, for the most part, current policy, but with slight modification to protect beneficiaries from higher increases in costs by rounding down whenever possible.

[28] See page 180 in the 2020 Rate Notice and Final Call Letter, retrieved from *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

In proposed § 422.100(f)(6)(iii), CMS proposed to codify rules to give MA plans flexibility in setting cost sharing for professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services. The proposed flexibility is, in many respects, the same as the flexibility we currently provide for MA plans that use the lower, voluntary MOOP limit, but with modifications to account for our proposal in section VI.A. of the February 2020 proposed rule which proposed the setting of three MOOP limits each year. This included new paragraph (f)(6)(iii)(A) to provide that an MA plan may not establish cost sharing amounts that exceed the limits under paragraph (f)(6)(iii) for basic benefits that are professional services furnished in-network (that is, by contracted providers). In addition, CMS proposed new paragraph (f)(6)(iii)(B) to specify the data that CMS would use in applying the methodology in paragraph (f)(6)(iii) to set the cost sharing limits for professional services. As proposed, the specific data would be projections of out-of-pocket costs representing beneficiaries with and without diagnoses of ESRD based on the most recent, complete Medicare FFS data. Finally, CMS proposed new paragraph (f)(6)(iii)(C) to outline the method for setting the cost sharing limits for professional services each year and to clarify that the resulting limits (specified as dollar amounts) are subject to the rounding rules in paragraph (f)(6)(ii). CMS explained the cost sharing limits would vary based on the type of MOOP limit used by the MA plan as follows:

- *Mandatory MOOP limit:* 30 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 70 percent of the total MA plan financial liability.
- *Intermediate MOOP limit:* 40 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 60 percent of the total MA plan financial liability.
- *Lower MOOP limit:* 50 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 50 percent of the total MA plan financial liability.

Under the proposal, an MA plan must pay no less than a specific percentage of the total financial liability for professional services to align with the range of flexibility each MOOP limit provides. We explained that our proposal was intended to ensure that there is a clear increase in an MA organization's financial responsibility for professional services if the MA plan uses a mandatory MOOP limit, rather than a lower or intermediate MOOP limit. We arrived at the specified percentages by assigning the highest coinsurance amount that was not discriminatory (50 percent) to the lowest MOOP limit, and assigning 30 percent coinsurance (which is most closely related to copayment limits from prior contract years) to the mandatory MOOP limit, to balance the incentives for each type of MOOP limit. We proposed the midpoint (40 percent) for the intermediate MOOP limit. We explained that these coinsurance percentages would result in reasonable differences between expected copayment limits for each of the MOOP limits. Overall, our proposal aimed to prevent discrimination against the enrollees with high health needs for the covered services by setting these cost sharing limits to cap the amount of financial responsibility for professional services the MA organization can transfer to enrollees. To set the actuarially equivalent values for the copayment limits based on the regulation text each year, we stated that CMS would calculate copayment limits that are approximately equal to the identified coinsurance percentage limit based on the OACT's projections of the most recent, complete Medicare FFS data that includes 100 percent of the out-of-pocket costs representing all beneficiaries with and without diagnoses of ESRD.

CMS proposed to base the approximate actuarially equivalent copayment limits for primary care, physician specialties, mental health specialty services, and physical and speech therapy on the most recent, complete Medicare FFS average cost data (including 100 percent of the out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD), weighted by utilization for the applicable provider specialty types for each service category. We stated that using an average that is weighted by specialty type utilization is consistent with developing an actuarially equivalent copayment for the coinsurance percentage specified in proposed § 422.100(f)(6)(iii). We solicited comment on whether our regulation text should be further revised on this point. In the preamble of the February 2020 proposed rule, we listed the applicable provider specialty types we would use in this analysis:

- *Primary Care:* Family Practice; General Practice; Internal Medicine
- *Physician Specialties:* Cardiology; Geriatrics; Gastroenterology; Nephrology; Otolaryngology (ENT)
- *Mental Health Specialty Services:* Clinical Psychologist; Licensed Clinical Social Worker; Psychiatry
- *Physical and Speech Therapy:* Physical Medicine and Rehabilitation; Speech-language Pathologists

In addition to these categories, we proposed to base the approximate actuarially equivalent copayment limits for psychiatric services, occupational therapy, and chiropractic care on the most recent, complete Medicare FFS cost data from a single, most applicable provider specialty: respectively, Psychiatry, Occupational Therapist, and Chiropractor. We solicited comment on whether other provider specialty types should inform our proposed actuarially equivalent copayment limits for the various professional services. Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule (85 FR 9086–9087) provided an illustration of potential cost sharing limits for contract year 2022 based on projections of the Medicare FFS cost data from 2015–2019 for professional services, emergency/post-stabilization services, and urgently needed services.

We also solicited comment on whether to require additional regulation text to address combining or bundling of cost sharing. CMS has previously issued guidance in Chapter 4, section 50.1, ''Guidance on Acceptable Cost-sharing,'' [29] of the MMCM that cost sharing should appear to MA enrollees consistent with MA disclosure requirements at § 422.111(b)(2). Section 422.111(b)(2) requires MA plans to clearly and accurately disclose benefits and cost sharing. We explained in the February 2020 proposed rule that MA plans must identify (and charge) the enrollee's entire cost sharing responsibility as a single copay (if using copayment rather than coinsurance) even if the MA plan has differential cost sharing that varies by facility setting or contracted arrangements that involve separate payments to facilities (or settings) and other providers. As discussed in the February 2020 proposed rule, we are aware that a facility or another health care delivery setting may charge an amount separate from that charged by the health care provider who actually furnishes covered services. In the February 2020 proposed rule, we clarified that those separate fees should be combined (bundled) into the cost sharing amount for that

[29] Chapter 4, Section 50.1 of the MMMCM can be accessed at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

particular place of service and be clearly reflected as a total copayment in beneficiary communication and marketing materials. We noted that we believe this current guidance is an appropriate interpretation of § 422.111, but solicited comment on codifying it.

2. Cost Sharing Limits for Inpatient Hospital Acute and Psychiatric Services (§ 422.100(f)(6)(iv))

As discussed in the February 2020 proposed rule, since contract year 2011, CMS has set cost sharing limits for certain inpatient length of stay scenarios based on a percentage of estimated Medicare FFS cost sharing projected to the applicable contract year. We explained the current process and proposed to codify continued use of it with some modifications.

We stated in the February 2020 proposed rule that the OACT conducts an annual analysis of the most recent, complete Medicare FFS data, and uses that data to project costs for the Part A deductible and Part B costs based on the length of stay scenarios and the setting of the inpatient stay (acute or psychiatric), to help determine the inpatient hospital acute and psychiatric cost sharing limit amounts. CMS compares the cost sharing for an MA enrollee, under the plan design for each bid, to the projected Medicare FFS cost sharing in each scenario; for MA plans with the mandatory MOOP limit, the cost sharing limit is 100 percent of the Medicare FFS cost sharing for the applicable scenario and for MA plans using the lower, voluntary MOOP limit, it is 125 percent of the Medicare FFS cost sharing. If an MA plan's cost sharing exceeds the applicable limit for any of the length of stay scenarios, CMS considers the MA plan's cost sharing as discriminatory under current § 422.100 and does not approve that plan benefit package. CMS proposed new § 422.100(f)(6)(iv)(A) through (D) to codify this long-standing policy for the cost sharing established by an MA plan for inpatient acute and psychiatric services, with modifications to incorporate cost sharing expenditures for beneficiaries with diagnoses of ESRD in setting the limits and to set a limit for MA plans that use the intermediate MOOP limit. Proposed paragraph (f)(6)(iv)(A) required an MA plan to have cost sharing for inpatient hospital acute and psychiatric benefits that does not exceed the limits set in paragraph (f)(6)(iv). Our proposal aimed to provide transparency on how CMS will set the cost sharing thresholds with which MA organizations must comply for inpatient hospital acute and psychiatric benefits. We proposed that during our review of bids, we would evaluate the MA cost sharing included in plan bids to determine compliance with the cost sharing limits adopted in the regulation.

We proposed to add a 3-day length of stay scenario for acute stays and an 8-day length of stay scenario for psychiatric care to those used under our current policy; these proposed scenarios were based on Medicare FFS data and informed by patient utilization information from MA encounter data. As a result, proposed § 422.100(f)(6)(iv)(B) specified the seven inpatient stay scenarios (current and new) for which cost sharing would apply under original Medicare and that would be used to set the MA cost sharing limits. The inpatient hospital acute stay scenarios are for 3 days, 6 days, 10 days, and 60 days and the psychiatric inpatient hospital stay scenarios are for 8 days, 15 days, and 60 days. Many of these same scenarios were described in the contract year 2020 Call Letter and in previous years.

Under our proposal, cost sharing limits for each of the seven inpatient hospital length of stay scenarios would incorporate the projected Medicare FFS inpatient Part A deductible and Part B professional costs. We explained that under our proposal, plans could vary cost sharing for different admitting health conditions, providers, or services provided, but overall benefit cost sharing must satisfy the limits established by CMS. Proposed § 422.100(f)(6)(iv)(C) described the data CMS would use for calculating the Medicare FFS out-of-pocket costs for each scenario. Under the proposal, CMS would use projected out-of-pocket costs and utilization data based on the most recent Medicare FFS data that factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD on the transition schedule we proposed in paragraph (f)(4)(vii)(A) through (D) and could also use patient utilization information from MA encounter data. In addition, for purposes of setting these cost sharing limits, the February 2020 proposed rule provided that the Medicare FFS data that factors in the ESRD cost differential would not include the exceptions for tolling the scheduled transition that were proposed for the MOOP limit calculations (in proposed paragraphs (f)(4)(v)(A) and (C)).

As discussed in the February 2020 proposed rule, the OACT conducted an analysis to help determine the impact of including all costs incurred by beneficiaries with diagnoses of ESRD into the most recent Medicare FFS data projections used to calculate cost sharing standards. This analysis found adding in related ESRD costs affects inpatient hospital acute cost sharing limits but that adding in those costs did not impact inpatient hospital psychiatric standards based on projections of Medicare FFS data available at the time of writing the February 2020 proposed rule. Based on this, we proposed to update the methodology to consider ESRD costs in setting all inpatient hospital acute and psychiatric standards. Specifically, CMS proposed to integrate approximately 60 percent of the difference between Medicare FFS costs incurred by all beneficiaries (including those with diagnoses of ESRD) and the costs excluding beneficiaries with diagnoses of ESRD into the data used to set the inpatient hospital acute and psychiatric cost sharing limits for contract year 2022. After contract year 2022, CMS proposed to incorporate an additional 20 percent of costs incurred by beneficiaries with diagnoses of ESRD each year until contract year 2024, when CMS would integrate 100 percent of the costs incurred by beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data that is used to determine inpatient hospital acute and psychiatric cost sharing limits. This was the same schedule proposed to transition ESRD costs into MOOP limit calculations so we used a cross-reference in the proposed regulation text to avoid repetitive regulation text.

Finally, at § 422.100(f)(6)(iv)(D), CMS proposed specific cost sharing limits for inpatient acute and psychiatric stays that are tied to the type of MOOP limit used by the MA plan. The proposed limits were stated as percentages of the FFS costs for each length of stay scenario (based on original Medicare cost sharing for a new benefit period):

- *Mandatory MOOP limit:* Cost sharing must not exceed 100 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs.
- *Intermediate MOOP limit:* Cost sharing must not exceed the numeric mid-point between the cost sharing limits for the mandatory and lower MOOP limits.
- *Lower MOOP limit:* Cost sharing must not exceed 125 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs. For inpatient acute 60-day length of stays, we proposed that MA plans that establish a lower MOOP limit would have the flexibility to set cost sharing above 125 percent of estimated Medicare Fee-for-Service cost sharing as long as the total cost sharing for the inpatient benefit does not exceed the MOOP limit or cost

sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

We proposed to use the same percentage of estimated Medicare FFS cost sharing for the mandatory and lower MOOP limits (100 percent and 125 percent respectively) as under current policy to determine inpatient hospital acute and psychiatric cost sharing limits. Using the rule proposed in § 422.100(f)(6)(ii)(A), all inpatient hospital acute and psychiatric cost sharing limits would be rounded to the nearest or lower whole $1 increment. As discussed in the February 2020 proposed rule, our proposal for limits on the cost sharing for inpatient acute and psychiatric services aligned with our current practice (with some modifications, as discussed). We explained that would provide benefit design stability for MA plans.

The February 2020 proposed rule stated that CMS would continue to publish acceptable inpatient hospital acute and psychiatric cost sharing limits and a description of how the regulation standard is applied (that is, the methodology used) through subregulatory means, such as a Health Plan Management System (HPMS) memoranda, issued prior to bid submission each year. We solicited comment on whether to include additional regulation text to establish when information would be published for plans.

The February 2020 proposed rule included Table 4 (Illustrative Example of Cost Sharing Limits Based on Current Medicare FFS Data for Inpatient Hospital Acute 10-Day Length of Stay Scenario), to provide an illustrative example of the cost sharing limits for the 10-day length of stay scenario (an inpatient hospital acute stay); the illustration was developed using 2015–2019 data projected to contract years 2022 through 2024 (85 FR 9082). We explained that the limits were illustrations and that the actual cost sharing limits set for future years could change, based on updated projections and Medicare FFS cost sharing requirements. We also explained in more detail how the proposed methodology was applied to illustrate a contract year 2022 cost sharing amount in Table 4.

We also included Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule to illustrate the potential impact of our proposals for other in-network service categories (85 FR 9086 through 9087). The February 2020 proposed rule Table 5 included projections of potential inpatient hospital acute and psychiatric cost sharing limits based on the methodology we proposed in § 422.100(f)(6)(iv). As explained in the February 2020 proposed rule, we expect the cost sharing limits for inpatient services for future years would be different from the illustrations in the February 2020 proposed rule due to updated projections using Medicare FFS data.

CMS requested comments and suggestions on its proposed cost sharing standards. We also requested comment on whether additional regulation text or restructuring of § 422.100(f)(6)(iv) was needed to achieve CMS's goal of providing additional transparency on how CMS will: (1) Develop the seven length of stay scenarios for inpatient hospital acute and psychiatric services; (2) transition ESRD costs into inpatient hospital acute and psychiatric limit calculations; and (3) calculate inpatient hospital acute and psychiatric limits after the ESRD cost transition is complete.

3. Basic Benefits for Skilled Nursing Facilities (SNFs), Outpatient, and Professional Services Subject to Cost Sharing Limits (§ 422.100(j))

CMS proposed to codify and adopt specific cost sharing limits for certain benefits (by service and by category of services) that are based on a comparison to the cost sharing applicable in the Medicare FFS program. We relied on both section 1852(a)(1)(B)(iv)(VII) [30] and section 1852(b) of the Act to propose codifying the current policy and adding new limits. Section 1852(a)(1)(B)(iv)(VII) of the Act explicitly authorizes the Secretary to identify services that the Secretary determines appropriate (including services that the Secretary determines require a high level of predictability and transparency for beneficiaries) to be subject to a cost sharing limit that is tied to the cost sharing imposed for those services under original Medicare. In addition, we have relied on how higher cost sharing for these benefits discriminates against the enrollees who need these services in setting additional cost sharing limits in the past. We believe that charging higher cost sharing for specific services discriminates against and discourages enrollment by beneficiaries with a health status that requires those services. We further rely on sections 1856(b) and 1857(e) of the Act, which authorize CMS to set implementing standards for Part C and adopt additional requirements as necessary, appropriate and not inconsistent with Part C, to the extent necessary to set these additional cost sharing protections for enrollees. As discussed extensively in this FC, setting standards for cost sharing limits and codifying the methodology serves important program purposes and goals for the MA program.

a. Range of Cost Sharing Limits for Certain Outpatient and Professional Services (§ 422.100(f)(6)(iii))

CMS proposed to modify the regulation at § 422.100(f)(6) to establish a range of cost sharing limits based upon the MOOP limit established by the MA plan for basic benefits (as defined in § 422.100(c)(1)) offered on an in-network basis. The proposal was intended to provide MA organizations with benefit design flexibilities while balancing the incentives for each MOOP type. As discussed in the February 2020 proposed rule, this proposal aligned with the long-standing policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing when the MA plan adopts a lower, voluntary MOOP amount.

CMS proposed to add § 422.100(f)(6)(iii) to specify that for basic benefits that are for professional services furnished in-network, MA plans may have greater flexibility in setting cost sharing based on the MOOP limit they establish. This proposal addressed the type of data used to set cost sharing limits for those professional services and proposed paragraphs (f)(6)(iii)(C)*(1), (2),* and *(3)* specified the maximum cost sharing limit based on the MOOP limit established by the MA plan. In addition to those cost sharing limits, CMS proposed to amend § 422.100(j) to impose cost sharing limits for specific benefits and specific categories of benefits that are based on the cost sharing used in original Medicare. Our proposal for paragraph (j) also considered the MOOP type used by an MA plan to grant additional cost sharing flexibility to MA plans with regard to specific services. As a whole, our proposal would apply multiple standards to the cost sharing for professional services and outpatient benefits. In the February 2020 proposed rule, Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) illustrated the application of the proposed copayment limits to in-network cost sharing for basic benefits, using the most recent

[30] Section 1852(a)(1)(B)(iv)(IV), as cited in the February 2020 proposed rule, was re-designated to section (a)(1)(B)(iv)(VII) pursuant to amendments to section 1852 of the Act made by the Families First Coronavirus Response Act (Pub. L. 116–127) and the CARES Act (Pub. L. 116–136) regarding coverage of COVID–19 testing, testing-related services, and vaccination.

Medicare FFS data projections available at the time of the February 2020 proposed rule (that is, 2015–2019 data) (85 FR 9086 through 9087).

As discussed in the February 2020 proposed rule, CMS will monitor copayment amounts and coinsurance percentages during our annual review of plan cost sharing. Copayments are for specific benefits identified within the PBP service category or a reasonable group of benefits or services covered by the plan. Some PBP service categories may identify specific benefits for which a unique copayment would apply (for example, PBP service category 7a includes ''primary care services''), while other categories may include a variety of services with different levels of costs which may reasonably have a range of copayments based on groups of similar services (for example, PBP service category 15 includes ''Part B drugs—other'' which covers a wide range of products and costs). We noted that MA plans may establish one cost sharing amount for multiple visits provided during an episode of care (for example, several sessions of cardiac rehabilitation) as long as the overall (or total) cost sharing amount satisfies CMS standards. Based on the amendments CMS proposed for §§ 422.100(f)(6), 422.100(j), and 422.113(b)(2)(v) and (vi), we clarified that if finalized, bids for the upcoming year to which the proposed rules would apply must reflect enrollee cost sharing for in-network services no greater than the coinsurance levels set in or the copayments amounts calculated using those regulations. We confirmed that, under our proposal, MA organizations would still have the option to charge either coinsurance or a copayment for most service category benefits. We also noted that although MA plans have the flexibility to establish cost sharing amounts as copayments or coinsurance, MA plans should keep in mind, when designing their cost sharing, that enrollees generally find copayment amounts more predictable and less confusing than coinsurance.[31]

b. Emergency/Post-Stabilization Services and Urgently Needed Services (§ 422.113(b)(2)(v) and (vi))

Currently, § 422.113(b)(2)(v) requires MA plans to charge cost sharing for emergency department services that does not exceed the lesser of: (1) An amount CMS sets annually; or (2) the plan's cost sharing for the services if they were obtained through the MA plan's network. After explaining that applying a specific dollar limit for cost sharing for emergency and post-stabilization services would be more appropriate than a methodology for changing the cost sharing limit for those services, we proposed to revise the existing rules for the cost sharing limits for emergency and post-stabilization services and to codify a new rule for cost sharing limits for urgently needed services. CMS proposed, at paragraph (b)(2)(v), that the MA organization is financially responsible for emergency and urgently needed services with a dollar limit on emergency/post-stabilization services costs for enrollees that is the lower of—

- The cost sharing established by the MA plan if the emergency/post-stabilization services were provided through the MA organization; or
- A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:
  - $115 for MA plans with a mandatory MOOP limit.
  - $130 for MA plans with an intermediate MOOP limit.
  - $150 for MA plans with a lower MOOP limit.

As discussed in the February 2020 proposed rule, the proposed limits were based on analyses of Medicare FFS costs that showed shifts in payment trends that may affect emergency/post-stabilization services costs more so than urgently needed services. The proposed dollar limits were based on the projected median total allowed amount for emergency services (including visit and related procedure costs) using the most recent Medicare FFS data available at the time, which included 100 percent of the out-of-pocket costs incurred by all beneficiaries, both with and without diagnoses of ESRD. We arrived at the proposed cost sharing limits for an MA plan with a mandatory MOOP limit and an MA plan with a lower MOOP limit by taking the dollar figures that are 15 percent and 20 percent of that median cost, rounded to the nearest whole $5 increment. The proposed maximum cost sharing limits for MA plans with an intermediate MOOP limit was based on the numeric midpoint of the related cost sharing limits for MA plans with mandatory and lower MOOP limits, rounded to the nearest whole $5 increment. In addition, CMS proposed clarifying updates to the language at § 422.113(b)(2)(v) to note that the cost sharing limits for emergency services include post-stabilization service costs. For urgently needed services, CMS proposed that the same cost sharing limits for professional services under § 422.100 apply to urgently needed services, regardless whether those urgently needed services are furnished in-network or out-of-network. We did not propose any changes to § 422.113 regarding the MA organization's obligations to cover and pay for emergency/post-stabilization services and urgently needed services but only to codify specific cost sharing limits for those services. As noted in the February 2020 proposed rule, CMS intends to monitor trends and consider updating cost sharing limits for both urgently needed services and emergency/post-stabilization services in future rulemaking based on emerging trends.

c. Services No Greater Than Original Medicare (§ 422.100(j)(1))

Section 1852(a)(1)(B) of the Act specifies that MA plans may not charge enrollees higher cost sharing than is charged under original Medicare for chemotherapy administration services (which we have implemented as including Part B—chemotherapy/radiation drugs integral to the treatment regimen), skilled nursing care, and renal dialysis services. This provision is currently reflected in §§ 417.454(e) (for cost plans) and 422.100(j) (for MA plans). The statute provides authority for CMS to require cost sharing that does not exceed cost sharing in the FFS Medicare program for additional Medicare-covered services. As noted elsewhere, section 1852(b) of the Act also prohibits plan designs that have the effect of discriminating against or discouraging enrollment by beneficiaries based on their health needs; we rely on this authority and sections 1856(b) and 1857(e) of the Act, which authorize CMS to set implementing standards for Part C and adopt additional requirements as necessary, appropriate and not inconsistent with Part C, to the extent necessary to set these additional cost sharing protections for enrollees. CMS proposed to restructure paragraph (j) and codify additional cost sharing limits for other services. We clarified that under our proposal cost sharing standards for cost plans will remain the same.

In our current interpretation and application of this requirement for skilled nursing care, MA plans that establish the higher, mandatory MOOP limit must establish $0 per-day cost sharing for the first 20 days of a SNF stay and the per-day cost sharing for days 21 through 100 must not be greater than the original Medicare SNF amount.

[31] Loewenstein G, Friedman JY, McGill B, Ahmad S, Linck S, Sinkula S, Beshears J, J.Choi J, Kolstad J, Laibson D, Madrian BC, List JA, Volpp KG. ''Consumers' misunderstanding of health insurance''. Journal of Health Economics 2013;32(5):850–862. Retrieved from: *https://scholar.harvard.edu/laibson/publications/consumers-misunderstanding-health-insurance.*

We proposed at § 422.100(j)(1)(iii) that, beginning in contract year 2022, the current rule for MA plans that use the higher, mandatory MOOP limit would remain the same and that limited cost sharing for the first 20 days of SNF would be permitted for MA plans that establish either the lower or intermediate MOOP limit.

In addition, CMS proposed to add the following services to the requirement that cost sharing charged by an MA plan may not exceed cost sharing required under original Medicare: (1) Home health services (as defined in section 1861(m) of the Act) for MA plans that establish a mandatory or intermediate MOOP limit; and (2) durable medical equipment (DME). For home health services, we also proposed that when the MA plan establishes the lower MOOP limit, the MA plan may have cost sharing up to 20 percent, or an actuarially equivalent copayment, of the total MA plan financial liability. Our proposal would prohibit the DME per-item or service cost sharing from being greater than original Medicare cost sharing for MA plans that establish a mandatory MOOP limit. For MA plans that establish a lower or intermediate MOOP limit, our proposal was that total cost sharing for all DME PBP service categories combined would be required to be equal or less than original Medicare cost sharing on a per member per month actuarially equivalent basis, but such MA plans would be permitted to establish cost sharing for specific service categories of DME that exceed the cost sharing under original Medicare as long as it complies with other CMS cost sharing requirements. In order to codify these changes at § 422.100(j), we proposed to reorganize that paragraph with new text at paragraph (j)(1) to provide that for the basic benefits specified, an MA plan may not establish in-network cost sharing that exceeds the cost sharing required under original Medicare.

d. In-Network Service Category Cost Sharing Requirements

We included Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule to provide examples of cost sharing limits for contract year 2022 based on projections of the most recent Medicare FFS data available at the time of the February 2020 proposed rule (2015–2019 data) and using the proposed methodology to set the various cost sharing limits specified as proposed §§ 422.100(f)(6), 422.100(j) and 422.113(b)(2)(v) and (vi). We noted these were only projections of potential cost sharing limits for contract year 2022 to illustrate the impact of the methodology. We stated that our proposed standards and cost sharing limits would continue to be inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. We proposed to update the cost sharing limits on an annual basis based on the final regulations. We noted our intention to apply the revised regulations each year to calculate the amounts that would be the copayment limits unless otherwise stated and that we would publish the annual limits with a description of how the regulation standard is applied (that is, the methodology used) prior to bid submission each year, such as through HPMS memoranda. We proposed to use projections of the most recent, complete Medicare FFS data that include 100 percent of ESRD costs to set the amounts for copayment limits, that is the actuarially equivalent amount of the coinsurance limits proposed in paragraph (f)(6), versus a transition of ESRD costs over time; there were no significant differences in the resulting cost sharing amounts when including ESRD for any of the physician specialties based on projections of the most recent Medicare FFS from the OACT.

In the February 2020 proposed rule, Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) did not include approximate actuarially equivalent copayment limits for some services: cardiac rehabilitation, intensive cardiac rehabilitation, pulmonary rehabilitation, supervised exercise therapy (SET) for symptomatic peripheral artery disease (PAD), partial hospitalization, home health, therapeutic radiological services, DME, dialysis, Part B Drugs Chemotherapy/Radiation Drugs, and ''Part B Drugs—Other''. As discussed in the February 2020 proposed rule, we found these categories are subject to a higher variation in cost or unique provider contracting arrangements, which would potentially make using Medicare FFS average or median cost data less suitable for developing a standardized actuarially equivalent copayment value at this time. Accordingly, in order to monitor and enforce compliance with these cost sharing requirements when the copayment is based on an analysis of the contracted rates the MA plan uses for in-network services, CMS noted that MA organizations may be required to provide information to CMS demonstrating how plan cost sharing complies with the regulation standards proposed in § 422.100(f)(6). We solicited comment whether an explicit regulatory provision should be added to require MA organizations to demonstrate compliance with these standards upon request by CMS; such demonstration would include providing CMS with information substantiating the contracted rates for basic benefits that are professional services for which CMS has not calculated an approximate actuarially equivalent copayment limit, and illustrating how the MA organization determined its cost sharing amounts.

As discussed in the February 2020 proposed rule, MA organizations with plan benefit designs that use a coinsurance or copayment amount for which we did not propose to publish a specific cost sharing threshold (for example, coinsurance for inpatient or copayment for durable medical equipment), must maintain documentation that clearly demonstrates how the coinsurance or copayment amount satisfies the regulatory requirements for each applicable plan. This is consistent with existing MA program monitoring and oversight for MA organizations to be able to demonstrate compliance with applicable program requirements. Cost sharing and other plan design elements remain subject to § 422.100(f)(2), which prohibits MA plans from designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. This documentation may be used by CMS during bid review as well as to address issues concerning beneficiary appeals, complaints, and/or to conduct general oversight activities. In addition, MA plans are required to attest when they submit their bid(s) that their benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations.

4. Per Member per Month Actuarial Equivalent (AE) Cost Sharing Limits for Basic Benefits (§ 422.100(j)(2))

As discussed in the February 2020 proposed rule, under the statute and regulations, an MA plan's total cost sharing for Parts A and B services (excluding hospice services and kidney acquisition costs and including additional telehealth benefits) must not exceed cost sharing for those services in Medicare FFS on an actuarially equivalent basis and must not be discriminatory. In order to ensure that cost sharing is consistent with both §§ 422.254(b)(4), 422.100(f)(2), and

current 422.100(f)(6), CMS has also historically evaluated cost sharing limits on a per member per month actuarially equivalent basis for the following service categories: Inpatient hospital, SNF, DME, and Part B drugs.

Proposed § 422.100(j)(2) required that total cost sharing for all basic benefits covered by an MA plan, excluding out-of-network benefits covered by a regional MA plan, not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. We explained that the provision implements section 1852(a)(1)(B) of the Act and the carve out of out-of-network benefits covered by a regional MA plan is to be consistent with section 1852(a)(1)(B)(ii) of the Act. As noted elsewhere, section 1852(b) of the Act also prohibits plan designs that have the effect of discriminating against or discouraging enrollment by beneficiaries based on their health needs. We explained in the February 2020 proposed rule that our proposals were based on this authority and sections 1856(b) and 1857(e) of the Act, which authorize CMS to set implementing standards for Part C and adopt additional requirements as appropriate and not inconsistent with Part C, to the extent necessary. CMS also proposed to codify, in § 422.100(j)(2)(i), our existing policy regarding the specific service categories for which an MA plan must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis. The services we proposed for this rule are consistent with long-standing policy and were: (1) Inpatient hospital acute and psychiatric services, defined as services provided during a covered stay in an inpatient facility during the period for which cost sharing would apply under original Medicare; (2) DME; (3) drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs and other drugs covered under Part B); and (4) skilled nursing care, defined as services provided during a covered stay in a SNF during the period for which cost sharing would apply under original Medicare.

As discussed in the February 2020 proposed rule, we believe our proposals would ensure that MA plans that have greater cost sharing flexibility in these categories are not designing benefits in a way that discriminates against enrollees with health status factors and conditions that require the services in § 422.100(j)(2)(i). Further, we noted that limiting cost sharing in this way will ensure that enrollees with certain conditions, or who are high utilizers of these basic benefits, are not discouraged from enrolling in MA plans because of higher cost sharing on necessary services. We noted that setting copayment limits through quantitative formulas (such as those used for our inpatient hospital acute and psychiatric standards) may be less appropriate for some categories, like DME and Part B drugs, and that it may be better to evaluate cost sharing for these service categories on an aggregate service category basis to determine whether they are discriminatory. These categories include items or services that significantly vary in cost or may be subject to provider contracting arrangements that make it difficult for CMS to calculate a specific copayment amount for the category as a whole, as opposed to specific items and benefits.

CMS also proposed, at § 422.100(j)(2)(ii), to extend flexibility for MA plans when evaluating actuarial equivalent cost sharing limits for those service categories to the extent that the per member per month cost sharing limit is actuarially justifiable based on generally accepted actuarial principles and supporting documentation included in the bid, provided that the cost sharing for specific services otherwise satisfies published cost sharing standards. The proposed exception would apply in limited situations, such as when the MA plan uses capitated arrangements with provider groups, when the MA organization operates its own facilities, or other unique arrangements. This flexibility would be consistent with long-standing policy and practice.

Overall, our proposal was aimed to describe how CMS would determine whether specific cost sharing is discriminatory and to set standards and thresholds above which CMS believes cost sharing is discriminatory as well as to implement specific statutory authority regarding cost sharing for basic benefits in an MA plan as compared to original Medicare. Similar to our current practice prior to bid submission, CMS shared our intent to communicate application of the regulation for future years, such as through HPMS memoranda, as appropriate. We solicited comment on our various cost sharing limit proposals.

5. Comments Received and Responses for All Cost Sharing Provisions

We received feedback from 17 commenters on our proposal for codifying the methodology for setting certain cost sharing standards each year. The majority of comments were from health plans, provider associations, beneficiary and other advocacy organizations, and pharmaceutical companies. A summary of the comments (generally by issue) and our responses follows:

Comment: Several commenters generally supported proposals to codify long-standing policies and increase transparency, including the methodology CMS uses to determine cost sharing limits described in section VI.B. of the February 2020 proposed rule. A commenter supported transitioning from subregulatory guidance to rulemaking and believed that the standardization, transparency, and predictability of formal rulemaking makes it a more appropriate vehicle for most provisions that make significant changes to the Medicare program. Another commenter appreciated the opportunity to provide feedback to guide implementation processes.

Response: We thank commenters for their support and feedback. CMS's goals for this proposal, in combination with section II.A. of this FC, include addressing potential stakeholder concerns about the impact of the MA eligibility changes for Medicare beneficiaries with diagnoses of ESRD on the methodology used for cost sharing limits and providing MA organizations with cost sharing flexibilities as an incentive to encourage favorable benefit designs for beneficiaries. Our aim is to provide transparency and predictability in how CMS calculates cost sharing thresholds for MA plans and evaluates MA organization compliance with cost sharing standards. We also intend this FC to encourage and facilitate stability in plan benefit design for beneficiaries. Proposing and codifying these flexibilities in regulation in advance of the years to which they will apply will encourage MA organizations to develop plan designs to take advantage of the flexibilities, as well as provide a measure of transparency and stability for the MA program. In addition, based on this rulemaking, MA organizations should have greater knowledge about how MA cost sharing limits are calculated and an ability to anticipate cost sharing limits in future years.

Consistent with our long-standing policy, most of the cost sharing standards we proposed and are finalizing apply only to in-network Parts A and B services and exceptions to that (where limits will apply to out-of-network benefits) are explicitly stated. In-network service category cost sharing standards are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan-level deductibles (for example, deductibles that include several service categories). In addition,

as finalized, CMS will use Medicare FFS data projections (the definition is codified in § 422.100(f)(4)(i) as discussed in section II.A. of this FC) to calculate cost sharing limits for service categories subject to § 422.100(f)(6) and (j)(1); this is explicitly addressed in § 422.100(f)(7)(ii) and discussed in more detail in section II.B.5.a. of this FC. This means that unless otherwise stated, CMS will use projections of beneficiary out-of-pocket costs for the applicable contract year, based on recent Medicare FFS data (including data for beneficiaries with and without diagnoses of ESRD) that are consistent with generally accepted actuarial principles and practices as outlined in paragraph (f)(7)(i) to calculate cost sharing limits. As a result, the Medicare FFS data projections used in calculating MA MOOP and cost sharing limits will encompass all original Medicare requirements, such as coverage restrictions and cost sharing limits. For emergency services (service category clarified as discussed in section II.B.5.e. of this FC.) and urgently needed services, the cost sharing limit applies whether the services are received inside or outside the MA organization's contracted network of providers and facilities (§ 422.113(b)(2)(i)), which is consistent with current policy and the obligation on all MA plans to cover such services both in-network and out-of-network without imposing any prior authorization limits. These considerations are generally aligned with our proposal to use the most recent Medicare FFS data projections to calculate MOOP and cost sharing limits and our longstanding practice of applying original Medicare rules to ensure MA plans are using cost sharing that is overall at least actuarially equivalent to Medicare FFS. In addition, this FC maintains the ability for D–SNPs to establish zero cost sharing for enrollees who are dually enrolled in both Medicare and Medicaid. For example, in a Zero-Dollar Cost Sharing D–SNP, Medicare inpatient hospital stays and doctor visits are available at no cost to the enrollee. A Medicare Non-Zero Dollar Cost Sharing D–SNP is a D–SNP under which the cost sharing for Medicare Part A and B services varies depending on the enrollee's category of Medicaid eligibility.

The changes to the proposals we are finalizing in this FC range from minor edits, reorganizations, corrections, and clarifications to substantive modifications based on the comments received, operational considerations, and additional implementation of antidiscriminatory requirements (such as, to support equitable access to plans for beneficiaries with high health needs). Due to operational considerations and to help ensure that MA organizations have sufficient implementation time, the provisions in this FC will not be applicable until January 1, 2023. This reflects a one-year delay from the proposed implementation schedule. When MA bids for contract year 2023 are submitted for review and approval by the statutory deadline (June 6, 2022, for contract year 2023), the regulations in this FC will be used to evaluate those bids for approval. This change means that the dates in the proposed regulation text in §§ 422.100(f)(6), 422.100(j), and 422.113 have been updated from the February 2020 proposed rule (for example, changing a reference from January 1, 2022 to January 1, 2023) and we do not discuss those edits in much detail in our responses to comments and description of the final regulations. Changes to the implementation of the proposed policies that are more nuanced are explained (for example, section II.B.5.c. of this FC addresses the multi-year transition schedule of ESRD costs into inpatient hospital cost sharing limits). Further, we are adding descriptive headings to paragraphs (f)(6) introductory text and (f)(6)(i) through (iv) to identify the scope of the content in each paragraph. Additional changes to paragraphs (f)(6) introductory text and (f)(6)(i) through (iv) are discussed in sections II.B.5.a., b., and c. of this FC. Similarly, in our reorganization of proposed (j)(1) discussed in section II.B.5.e. of this FC, we are adding descriptive headings to paragraphs (j)(1)(i) and (ii). These headings are not substantive changes.

As discussed in section II.A. of this FC, the MOOP limits and cost sharing standards for contract year 2024 and future years will be communicated annually through a subregulatory process, which we are finalizing at § 422.100(f)(7)(iii). This FC adopts the MOOP limits and specific cost sharing limits for contract year 2023 by applying the rules being finalized. As finalized in § 422.100(f)(7)(iii), beginning with contract year 2024, CMS will issue annual subregulatory guidance that specifies the MOOP limits and cost sharing standards that are set and calculated using the rules adopted in this FC; that guidance will be released prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. We expect this date will typically be by the first Monday in April. In addition, CMS will provide a public notice and comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year unless a public comment period is impracticable, unnecessary, or contrary to the public interest. We believe these situations will be rare and intend to solicit comment annually, but believe that aligning the availability of prior notice and an opportunity to comment with rulemaking standards, which include authority to waive prior notice and a comment period when it is impracticable, unnecessary, or contrary to the public interest, is appropriate. For example, CMS may solicit and consider public comment on actuarial approaches before releasing the final MOOP limits and cost sharing standards. The exercise of actuarial judgment by the OACT may be a topic on which the public, or MA organizations, wish to comment when reviewing how CMS has applied the regulations adopted in this FC to calculate the benefit parameters for MA plans. As appropriate, we will consider such comments and may revise the decisions made in developing the projections and calculations of the MOOP and other cost sharing limits. To set the final contract year 2023 cost sharing limits following the methodology in this FC, CMS is using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data) which reflect the OACT's actuarial judgements of expected costs in contract year 2023, including considerations of the impact from COVID–19. We did not codify the first Monday in April as a deadline to release the final MOOP limit and cost sharing standards or a specific minimum time frame for the comment period so CMS can remain flexible to potential future situations. The regulation provides for the release of subregulatory guidance that addresses MOOP limits and cost sharing standards in advance of the upcoming plan year with sufficient time for MA organizations to prepare bids. For contract year 2023, we are releasing the final MOOP and cost sharing limits in this FC, in Tables 5 and 28. In addition, the final cost sharing limits for contract year 2023 through 2026 and future years for emergency services are provided in Table 24. Descriptions of the calculations CMS completed to reach these final contract year 2023 MOOP and cost sharing limits following the regulations finalized in this FC are available in section II.A.4. and II.B.5. of this FC.

February 2020 Proposed Rule Comment Solicitation for Bundled Copayments

In the February 2020 Proposed Rule, CMS solicited comment on whether to codify the current guidance regarding bundled copayments. Our current guidance [32] requires MA organizations to disclose and charge a single, bundled copayment in order to ensure that enrollees are provided accurate information about their potential financial liability (prior to and following enrollment in a plan) and to avoid confusion. Specifically, in situations where a facility or setting charges a separate amount from the health care provider that actually furnishes covered services, such as an emergency department fee and a fee for the emergency room physician, our guidance has been that those fees be combined (bundled) into the cost sharing amount for that particular place of service and be clearly reflected as a total copayment in appropriate materials distributed to beneficiaries. This longstanding guidance reflects CMS's interpretation of § 422.111 that enrollees be provided clear information about benefits and cost sharing that is not confusing. CMS received no comments regarding whether to codify this guidance.

CMS strives to make sure that plan cost sharing is transparent to MA enrollees and Medicare beneficiaries who are considering enrolling in MA. To ensure the MA regulations are sufficiently clear on these points, we are finalizing additional regulation text, at § 422.100(f)(9), to require that cost sharing (copayments and coinsurance) reflect the enrollee's entire cost sharing responsibility, inclusive of professional, facility, or provider setting charges, by combining (or bundling) all applicable fees into the cost sharing amount for that particular service(s) and setting(s) and be clearly reflected as a single, total cost sharing amount in appropriate materials distributed to beneficiaries. MA enrollees must receive the plan's Evidence of Coverage (EOC) document and other applicable plan materials that clearly disclose their total cost sharing responsibility for particular benefits. By requiring MA plans to clearly disclose and apply cost sharing this way, this FC will ensure that beneficiaries receive information about their financial responsibility for covered benefits through an MA plan and when comparing MA plans. We are finalizing this provision at § 422.100(f)(9) instead of in § 422.111 because it is about cost sharing and related to the cost sharing rules we are codifying in paragraph (f) even if the underlying purpose of the existing guidance and adequate information is provided to beneficiaries. Finally, this requirement about bundling cost sharing into one copayment amount applies to cost sharing for basic benefits.

a. General Non-Discriminatory Cost Sharing Limits (§ 422.100(f)(6))

Comment: CMS received mixed comments on the proposal to codify the long-standing policy, used in CMS's review of bids, that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who need those services at § 422.100(f)(6)(i). A few commenters opposed CMS's proposal to allow MA plans with lower MOOP limits to establish cost sharing up to a 50 percent coinsurance, based on beneficiary discrimination concerns, and suggested that lower cost sharing would better protect beneficiaries who need higher-cost services. These beneficiary concerns were shared by other commenters generally or in relation to other specific cost sharing proposals and are also addressed, more comprehensively, in section II.B.5.b. of this FC.

A few commenters were generally supportive and requested clarifications or technical modifications. For example, a commenter requested CMS confirm that it did not intend to require MA plans to measure financial liability at the individual item or service level or use the average allowable amount when calculating the copayment applicable to a specific transaction; the commenter noted that measuring financial liability at the ''individual item or service level'' would make the use of copayments very difficult, and would not correspond with other parts of the February 2020 proposed rule that indicated copayments are preferred over coinsurance. In addition, the commenter noted that MA plans may not have the average Medicare FFS allowed amount for each claim (which was referred to in the February 2020 proposed rule), but would have the plan's allowable amount for each particular provider to calculate a cost sharing threshold. Similarly, another commenter requested CMS allow the average contracted rate to be calculated at the parent organization level for purposes of determining compliance with the 50 percent total MA plan financial liability limit. This commenter noted that this approach would allow MA organizations the ability to consider credibility when setting cost sharing limits to help create year over year cost sharing stability for beneficiaries. CMS believes the commenter was referencing claims credibility for pricing purposes in their comment.

Response: We appreciate the support and questions from commenters seeking guidance on how to implement and demonstrate compliance with our proposal to codify the longstanding policy for out-of-network basic benefits and in-network basic benefits that are in service categories for which CMS has not otherwise established a cost sharing standard. The requirement that MA organizations must pay at least 50 percent of the total MA plan financial liability for the benefit protects beneficiaries with high health needs and ensures an equitable plan design that balances overall costs between the MA plan and enrollees. In addition to addressing these concerns, we take this opportunity to explain the changes we are finalizing to § 422.100(f)(6), (f)(6)(i), and new paragraph (f)(7) that are related to the overall policies being adopted for calculating MA cost sharing limits. In brief, paragraph (f)(7) codifies how CMS will utilize generally accepted actuarial principles and practices, Medicare FFS payment data, Medicare FFS and MA utilization data, and other factors as part of calculating the copayment limits for the cost sharing standards in this FC. We explain how these clarifications, modifications and new paragraphs apply to service categories subject to paragraph (f)(6)(i), as well as cost sharing limits set under other paragraphs. The method by which an MA organization identifies estimated total MA plan financial liability for purposes of ensuring that its cost sharing does not exceed 50 percent of that amount is similar to the process an MA organization would use to ensure that MA cost sharing complies with the other limits we proposed and are finalizing in § 422.100(f)(6). We believe addressing these changes first in this response will provide context and clarity regarding how MA organizations may implement and demonstrate compliance with the rules finalized in § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1). The specific cost sharing standards finalized at § 422.100(f)(6)(iii) and (j)(1) are explained in more detail in section II.B.5.b and II.B.5.e. of this FC.

MA organizations previously and currently have flexibility to establish cost sharing up to 50 percent coinsurance for many benefits, but generally do not establish cost sharing amounts at the maximum allowable cost sharing limit for most service categories. MA organizations typically offer

[32] As referenced in Chapter 4, section 50.1 and the CY 2017 Final Call Letter; both documents may be accessed in the HHS Guidance Repository at: *https://www.hhs.gov/guidance/.*

benefits with lower cost sharing amounts than the permitted maximum cost sharing limits for the vast majority of service categories (such as primary care physician). While we do not have definitive data, we believe this is due to multiple factors, including the principles and incentives inherent in managed care, effective negotiations between MA organizations and providers, and market competition. Further, the requirement that cost sharing for basic benefits overall must be actuarially equivalent to cost sharing in original Medicare, with the ability to reduce cost sharing as a supplemental benefit, discourages MA plans from using extremely high cost sharing. In addition, we expect beneficiary preferences will continue to act as an incentive for MA organizations to offer favorable benefit designs. Also, several professional service category cost sharing standards calculated in this FC for intermediate and mandatory MOOP types (as discussed in section II.B.5.b. of this FC) are lower than what would be allowable under CMS's longstanding policy that cost sharing not exceed 50 percent of the estimated total MA plan financial liability for the benefit. Considering these factors, CMS expects that codifying this longstanding policy will not result in significant increases in cost sharing amounts for enrollees compared to prior contract years as MA organizations have incentive to maintain a competitive position in the market.

Our rule explicitly addresses both copayment and coinsurance structures. We proposed (at § 422.100(f)(6)(i)(A), (B), and (C)) that coinsurance cannot exceed 50 percent of the total MA plan financial liability and specific rules for setting copayments based on that percentage limit. We are finalizing similar, but not identical requirements, at paragraph (f)(6)(i) to consolidate and simplify the regulation. We did not intend by our proposal at paragraph (f)(6)(i) that copayments would be required to vary with each specific encounter (that is, that the copayment amount for a particular item or service would vary based on the payment rate to a specific provider for that service). To ensure clarity in the regulations on this point, we are finalizing the introductory language in paragraph (f)(6) with a revision to explicitly provide that cost sharing may be a coinsurance or copayment for a plan benefit package service category or for a reasonable group of benefits covered under the plan. This means that copayments are not required to vary by specific provider, item, or service, based on the provider's payment amount but rather must be set at a dollar amount that applies to visits of the identified service category of benefits. This reflects CMS's intent to codify the less burdensome, longstanding policies that are familiar to MA stakeholders. In tandem with this modification to paragraph (f)(6), we are not finalizing the proposed regulation text in paragraph (f)(6)(i)(C) about using the MA organization's average contracted rate of that benefit (item or service) to calculate the copayment dollar amount for out-of-network benefits. Rather, we are finalizing rules in paragraph (f)(6)(i) to require that MA plans must not establish a cost sharing amount that exceeds 50 percent coinsurance or an actuarially equivalent copayment value for the service category or for a reasonable group of benefits in the PBP. This includes finalizing rules for the data used by the MA organization to determine an amount that is actuarially equivalent to 50 percent coinsurance, including authority to use the average Medicare FFS allowable amount (as proposed in paragraph (f)(6)(i)(C)). CMS will monitor copayment amounts and coinsurance percentages as part of our annual bid review process during which we examine plan cost sharing. In addition, MA organizations may use the estimated total MA plan financial liability for the service category or for a reasonable group of benefits in the PBP for that contract year to determine the actuarially equivalent value to 50 percent coinsurance. With this approach, we intend to permit the MA organization to use aggregate payment data about the service category, or for the reasonable group of benefits, to which the cost sharing applies when determining the dollar figure that is actuarially equivalent to 50 percent coinsurance. That dollar figure would be the maximum permissible copayment amount for the service category or group of benefits. In addition, we are adopting a provision that an MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s). We believe that this important enrollee protection is necessary and a corollary of our proposal that MA plans be responsible for at least 50 percent of total MA plan liability for basic benefits, whether furnished in-network or out-of-network. As this FC clarifies that our cost sharing limits apply at the service category level (or a reasonable group of benefits), we are finalizing regulation text to explicitly protect enrollees from paying more cost sharing than the estimated total MA plan financial liability for the covered service(s).

When CMS evaluates compliance, either through reviewing bids or other oversight activities, it may not examine in detail a plan's compliance with cost sharing standards for every service category. Also, CMS might not calculate and publish actuarially equivalent copayment values for every service category or situation. Nevertheless, the regulations we are finalizing here will continue to apply to all MA cost sharing charged for basic benefits. Sections II.B.5.b. through II.B.5.f. of this FC finalize specific cost sharing requirements for some in-network benefits in addition to the rule in paragraph (f)(6)(i) for all other in-network and out-of-network benefits (for example, certain categories of benefits in § 422.100(f)(6)(iii) and (iv) and specific services and categories in § 422.100(j)(1)). Section II.B.5.d. of this FC also finalizes specific cost sharing limits for emergency and urgently needed services in § 422.113(b)(2). MA plans (at the segment-level, if applicable) must comply with all of these requirements. To ensure clarity on this point, the introductory text in paragraph (f)(6) requires that an MA organization must establish cost sharing for basic benefits that complies with the standards in §§ 422.100(f)(6) and (j) and 422.113(b)(2) and codifies longstanding policy of how CMS completes cost sharing evaluations at the plan (or segment) level. These standards include coinsurance and specific copayment limits specified in the regulations or copayment limits calculated by CMS using the methodology identified in those regulations. As proposed and finalized with clarifying edits and additions, § 422.100(f)(6) states that these requirements are in addition to other limits and rules applicable to MA cost sharing, such as the requirement that the overall MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing (that is, the PMPM actuarial equivalence evaluation in § 422.254(b)(4) and as finalized in paragraph (j)(2)). In situations where CMS does not calculate a copayment limit for a particular service category specified in these regulations, then the copayment amount that the MA organization sets for that service must not exceed the actuarially equivalent value limit of the applicable coinsurance for the MOOP limit of the plan. Consistent with this, we are generally maintaining the current language in paragraph (f)(6) regarding how cost sharing for basic benefits specified by CMS must not exceed

levels annually determined by CMS to be discriminatory for such services. This is consistent with how, currently, MA organizations establish copayment amounts that do not exceed maximum coinsurance limits in those instances where CMS does not calculate a specific copayment limit. We are also finalizing rules for the data to be used in calculating the actuarially equivalent values that would be used in CMS's calculation of copayment limits and evaluation of MA plan copayments.

We are finalizing at § 422.100(f)(6)(i) with a rule prohibiting MA plans from paying less than 50 percent of the estimated total MA plan financial liability for that contract year or the average Medicare FFS allowable amount for the plan service area for the benefit, which is generally what we proposed in paragraph (f)(6)(i)(A) with additions for clarity that remain consistent with our longstanding policy. For example, as discussed in more detail subsequently in this response, the addition of ''estimated'' to the term ''total MA plan financial liability'' in paragraph (f)(6)(i) recognizes that MA organizations may not have the data necessary to determine the final total MA plan financial liability for the benefit sufficiently in advance of the bid submission deadline. In addition, instead of stating the rule as how much an MA plan must pay, we are finalizing the rule as a limit on the cost sharing that an MA plan may impose on enrollees. As proposed, this rule regarding the 50 percent limit on cost sharing applies to all out-of-network basic benefits. While the proposed paragraph (f)(6)(i)(A) referred to paragraph (f)(6)(i), this FC clarifies that the 50 percent coinsurance limit applies to service categories that are not subject to other specific cost sharing standards set under §§ 422.100(f)(6) and (j)(1) and 422.113(b)(2). While we proposed (and are finalizing in sections II.B.5.b. through II.B.5.e. of this FC.) separate cost sharing standards and requirements for professional services, inpatient hospital service categories, emergency services, and a prohibition on cost sharing for certain specific benefits that exceeds the cost sharing under original Medicare, we believe that additional clarity on this point improves the regulation.

Setting limits on cost sharing for covered services and ensuring MA organizations comply with these limits are important ways to ensure that the cost sharing aspect of a plan design does not discriminate against or discourage enrollment in an MA plan by beneficiaries who have high health care needs. CMS has historically evaluated bid and market data to identify areas of concern and conduct research, and has added new service category cost sharing limits based on these analyses. For example, prior to contract year 2017, CMS did not set a copayment limit for cardiac rehabilitation. In the CY 2017 Call Letter,[33] we noted that cardiac rehabilitation (a professional service that will be subject to the cost sharing limits in § 422.100(f)(6)(iii)) was an area of concern and, as part of reviewing bids for contract year 2017 through 2019, we asked MA organizations to justify cost sharing above $50 for cardiac rehabilitation services. Then, for contract year 2020 we added specific cost sharing standards for cardiac rehabilitation services that MA plans could not exceed. As a result, the services for which we announce cost sharing limits and how CMS evaluates an MA plan's cost sharing have operationally varied in past years to be responsive to changes to market conditions and Medicare FFS payment policy. We intend to continue this approach to how CMS expends its resources in calculating copayment values under this FC, in general oversight activities, and in evaluating bid submissions. For example, we have not previously set a specific copayment limit for each specific category of DME but since the February 2020 proposed rule we have reviewed contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data) to calculate a contract year 2023 copayment limit for the ''DME—shoes or inserts'' and ''DME—diabetes monitoring supplies'' service categories for MA plans that establish a lower or intermediate MOOP limit. This copayment limit is actuarially equivalent to the longstanding 50 percent coinsurance limit, which will continue to apply to these categories per § 422.100(f)(6)(i). The calculations of the final contract year 2023 copayment limits for those DME service categories using the rules in paragraph (f)(6)(i) are included subsequently in this response. In addition, the complete list of final contract year 2023 cost sharing limits for in-network services are summarized in Table 28. While not applicable for contract year 2023, we are evaluating Medicare FFS data projections and considering future copayment limits for other categories that are subject to paragraph (f)(6)(i) that are not included in Table 28, such as ambulance services. If we determine that it is appropriate to apply the rules in § 422.100(f)(6)(i) to calculate a copayment value that is actuarially equivalent to the mandatory 50 percent coinsurance limit, we may announce that copayment limit using the guidance issued under § 422.100(f)(7)(iii) for contract year 2024 or another future year.

As MA organizations may continue to establish coinsurance up to 50 percent, we do not believe that CMS retaining flexibility to calculate a copayment limit that equates to that coinsurance level reflects a change from current practice. Nor does the manner by which CMS calculates the copayment limits under this FC represent a drastic change. When CMS calculates an actuarially equivalent copayment limit for a service category subject to § 422.100(f)(6)(i), the administrative burden for MA plans may be reduced. In the past, when CMS did not set a copayment limit, MA organizations that use copayments instead of coinsurance generally had to submit supporting documentation to show how the MA plan's copayment met the 50 percent coinsurance standard. While, going forward, we may not require documentation demonstrating the calculation of every copayment used by an MA plan, documentation or justifications may be necessary in some cases to demonstrate compliance with the regulation. For service categories where we calculate a copayment that is actuarially equivalent to 50 percent coinsurance (such as ''DME—diabetic shoes or inserts'' as shown in Table 28), MA organizations will not need to provide supporting documentation if the MA plan's copayments are below the values calculated and issued by CMS under § 422.100(f)(6).

We are including information in Table 28 to illustrate how the 50 percent cap on cost sharing for basic benefits that are not addressed by other regulations will interact with the other regulations specifying cost sharing limits. Table 28 identifies 50 percent coinsurance as the cost sharing limit for all the DME service categories for MA plans that establish a lower or intermediate MOOP limit. This is a clarifying update from the ''N/A'' designations for the same service categories and types of MOOP limits in the February 2020 proposed rule's Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) and from subregulatory guidance in prior contract years for MA plans that established a voluntary MOOP limit.[34] Other services not

[33] Call Letters communicating CMS policy for contract years prior to 2021 may be accessed here: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[34] See Table 5: CY 2021 In-Network Service Category Cost Sharing Requirements from the

included on the chart continue to be subject to paragraph § 422.100(f)(6)(i), such as ambulance services (50 percent coinsurance limit regardless of MOOP type). We believe these clarifications will increase understanding and transparency in how § 422.100(f)(6)(i) applies.

As finalized, § 422.100(f)(6)(i) imposes limits on the cost sharing that may be charged to enrollees for out-of-network and in-network basic benefits for which another regulation has not otherwise calculated a cost sharing standard. This rule provides flexibility for CMS to calculate the value for copayment limits for new categories of basic benefits when CMS determines it is appropriate. This flexibility and how we intend to use it are consistent with CMS's prior practice for calculating copayment limits. For benefits subject to § 422.100(f)(6)(i), the enrollee coinsurance cannot exceed 50 percent and the copayment must be no greater than an actuarially equivalent value for that coinsurance regardless of the type of MOOP limit established by the plan (with one exception for the DME service categories for the mandatory MOOP limit, as discussed in section II.B.5.e. of this FC). Similarly, as proposed at § 422.100(f)(6)(iii)(C) (finalized with clarifying additions at § 422.100(f)(6)(iii)(C)–(F)), an MA plan must pay at least a specified percentage of the estimated total MA plan financial liability for the covered benefit for that contract year. As discussed in a subsequent response to comment in this section, the cost sharing limits imposed by § 422.100(f)(6)(i), like other cost sharing limits finalized in this FC, are also subject to the rounding rules finalized in paragraph (f)(6)(ii).

As also discussed in section II.A. of this FC, calculation of the MOOP and cost sharing limits using the methodologies and standards finalized in §§ 422.100(f) and (j) and 422.101(d) requires the exercise of actuarial judgment and the use of generally accepted actuarial principles and practices. Our proposal in the February 2020 proposed rule implicitly acknowledged the use of these principles and practices as a longstanding part of how CMS calculates cost sharing limits and it is inherent in how the OACT performs many of the projections and calculations. Specifically, the February 2020 proposed rule discussed how the OACT conducted necessary analyses and projections in the past and made clear that the OACT would be involved in applying the methodologies to calculate the MOOP and cost sharing limits we were proposing. As a result, while not explicitly proposed, CMS is finalizing a new regulation at § 422.100(f)(7)(i) that addresses use of generally accepted actuarial principles and practices by CMS and MA organizations to ensure that this FC provides more detail regarding the actuarial nature of how costs are projected (which we believe is better stated in the regulation text). This new provision describes how generally accepted actuarial principles and practices will be used in: (1) Developing the beneficiary cost sharing projections used to calculate the MOOP limits in § 422.100(f)(4) and (f)(5) and § 422.101(d)(2) and (d)(3) and the inpatient hospital acute and psychiatric service category cost sharing limits in § 422.100(f)(6)(iv); (2) calculating the copayment values that are actuarially equivalent to the coinsurance limits set for service categories in § 422.100(f)(6)(i), for professional services in § 422.100(f)(6)(iii), and for the benefits for which MA cost sharing may not exceed cost sharing under original Medicare in § 422.100(j)(1); (3) evaluating MA organization compliance with §§ 422.100(f)(6) and (j); and (4) developing the projections and calculations used in applying § 422.100(f)(8) for transitioning current (contract year 2022) copayment limits to the copayment limits produced by the methodology adopted in § 422.100(f)(6)(iii), (f)(7)(ii), and (j)(1), as discussed in more detail in section II.B.5.b. and e. of this FC. Under § 422.100(f)(7)(i), CMS and MA organizations must use generally accepted actuarial principles and practices for these purposes. As a result, in paragraph (f)(6)(i) we refer to paragraph (f)(7) as applying when CMS calculates copayment limits that are at an actuarially equivalent value to 50 percent coinsurance for service categories representing in-network basic benefits that are not otherwise addressed in paragraph (f)(6), (j)(1), or in § 422.113(b)(2).

CMS's longstanding practice in developing and setting MOOP and cost sharing limits has been to use generally accepted actuarial principles and practices in developing the projections of beneficiary costs. In projecting out-of-pocket costs and utilization based on the Medicare FFS data projections (as defined in § 422.100(f)(4)(i)) for CMS to use in calculating MOOP and cost sharing limits for contract year 2023 and future years, the OACT will continue to use generally accepted actuarial principles and practices. In the past, we have considered all or some of the following information when setting copayment limits: (1) Projected median or average total Medicare FFS allowed amounts (occasionally weighted by utilization, including place of service and/or provider type, as applicable); and (2) a Medicare FFS claims cost distribution. In continuing this practice under the rules adopted in paragraph (f)(7)(i)(A) when calculating cost sharing limits, we may take into account the number of visits or sessions a beneficiary typically receives in order to reach an actuarially equivalent copayment amount for a service category that is subject to a wide-range of costs. For example, as discussed in the February 2020 proposed rule, we calculated the illustrative copayment limit for the ''mental health specialty services'' service category in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule by weighting the average Medicare FFS allowed amount by the utilization of specific relevant provider specialty types (clinical psychologist, licensed clinical social worker, and psychiatry). As discussed in section II.B.5.b., the contract year 2023 actuarially equivalent copayment value for the ''mental health specialty services'' service category is calculated by weighting the average Medicare FFS allowed amount by the utilization of the same provider specialty types using updated Medicare FFS data projections. We will also consider the purpose of the cost sharing limits and their role in the MA program when deciding among different approaches and, if it is appropriate, to take additional data into consideration in making projections and calculating cost sharing and MOOP limits using generally accepted actuarial principles and practices. As codified in paragraph (f)(7)(i)(A), information such as changes in legislation (such as, changes in Medicare benefits), Medicare payment policy, trends over several years of data, and external variables (such as public health emergencies) may be taken into account when performing the calculations and projections used to set the MOOP limits and cost sharing limits. The OACT considers these variables as they develop their projections by applying trend factors (that are consistent with the most recent Medicare Trustees Report). In addition, future impacts of laws and regulations are factored into OACT's projections. Specifically, actuaries use their professional judgment when selecting

HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020.

methods and assumptions, conducting an analysis, and reaching a conclusion which is consistent with generally accepted actuarial standards and principles.[35] For example, the OACT is applying trend factors that reflect the expected volatility and impact of COVID–19 on the Medicare FFS utilization data from prior years in order to determine the Medicare FFS data projections for 2023 and subsequent years that CMS will use to calculate the MOOP and cost sharing limits for those future years. This is an example of how external variables may be taken into account. Actuarial judgment will be exercised in other matters as appropriate in applying the regulatory standards. When MA organizations use and apply generally accepted actuarial principles and practices to calculate actuarially equivalent copayment values when required under this FC, we anticipate that, MA organizations will take similar considerations into account. In addition, paragraph (f)(7)(i)(B) codifies that MA organizations must also use generally accepted actuarial principles and practices in complying with the regulations in paragraphs (f)(6) and (j) of this section. Finally, paragraph (f)(7)(i)(C) requires the same principles and practices to be used by CMS in evaluating MA plan compliance with paragraphs (f)(6) and (j). In summary, the approach allowing for actuarial professional judgments in making the projections and calculations used in applying the methodologies to set and comply with the cost sharing limits from this FC is adopted in paragraph (f)(7)(i), to clarify our intent and to be consistent with prior practice.

In addition to complying with § 422.100(f)(7)(i), we will follow the same process and apply the same considerations in calculating the values needed for copayment limits that are actuarially equivalent to the coinsurance percentages specified in the regulation text in § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1). Rather than repeat those standards in each regulation, we are codifying them in a new provision at § 422.100(f)(7)(ii). As discussed previously, CMS may not calculate a specific copayment limit for every service category; if we do, it will be in compliance with paragraph (f)(7). New paragraph (f)(7)(ii) provides that CMS calculates copayment limits as feasible and appropriate to carry out program purposes and paragraphs (f)(7)(ii)(A) through (E) outline the process and standards for that. Paragraphs (f)(7)(ii)(A) and (B) address the data CMS will use in calculating copayment limits. As referenced in the February 2020 proposed rule, CMS has annually analyzed Medicare program data to set the various cost sharing limits under current law and to publish guidance on MA cost sharing limits. The relevant Medicare data has included the most recent Medicare FFS data, including cost and utilization data and, in some cases, MA patient utilization information from MA encounter data. For example, CMS has used patient utilization from MA encounter data to inform inpatient hospital acute and psychiatric length of stay scenarios used in identifying MA plan cost sharing standards that are not discriminatory. Paragraph (f)(7)(ii)(A) codifies how CMS will use Medicare FFS data projections (as defined in paragraph (f)(4)(i)) for the applicable year and service category in order to calculate copayment limits for service categories subject to paragraph (f)(6)(i), (iii), and (j)(1). Development of the Medicare FFS data projections are based on Medicare FFS cost and utilization data for specific services and service categories. If available and where appropriate to consider utilization differences between Medicare FFS beneficiaries and MA enrollees to reach a value that most closely reflects an actuarially equivalent copayment for the benefit and beneficiary population, paragraph (f)(7)(ii)(B) codifies how CMS may also use patient utilization information from MA encounter data in our calculations. For example, if the utilization of different settings of service (such as, outpatient hospital compared to physician office) were available, comparable, and significantly different between Medicare FFS and MA encounter data, we may weight Medicare FFS cost data projections by MA encounter utilization of the relevant facility and provider types in order to calculate a cost sharing limit that is most closely actuarially equivalent to what MA enrollees may typically experience. In many cases, we may determine that MA encounter data is sufficiently available and recent for the relevant service category in order to apply analyses of MA utilization encounter data in our copayment limit calculations. CMS will complete accuracy checks in determining whether and when to use MA encounter data when paragraphs (f)(6)(iv) and (f)(7)(ii) permit use of that data. (See section II.B.5.c. of this FC for discussion of § 422.100(f)(6)(iv).) As a result, we clarify here that the use of MA encounter data is not mandatory under paragraph (f)(7)(ii)(B) for calculating cost sharing limits. Rather, use of MA encounter data may be informative for CMS and the OACT to consider in making decisions about the actuarial approach to apply to the Medicare FFS data projections.

Consistent with prior practice and as finalized in new § 422.100(f)(7)(ii)(C), CMS will be guided by what is appropriate to carry out program purposes when deciding how to calculate copayment limits for a service category identified in these regulations using the data described in paragraphs (f)(7)(ii)(A) and (B). Program purposes include such considerations as setting copayment limits that most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protecting against discriminatory cost sharing, and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries. These considerations will guide how judgement is exercised when generally accepted actuarial principles and practices provide choices and discretion. In situations where there are multiple or a range of actuarially equivalent copayment values for a service category, CMS will select a particular approach to calculate an actuarially equivalent copayment value in order to carry out those program purposes. For example, CMS may choose the methodology that results in the lowest possible increase or change in cost sharing for enrollees from the prior year, if there are multiple methodologies that are actuarially acceptable in calculating an actuarially equivalent copayment value. This approach is consistent with the stated goal in the February 2020 proposed rule to protect enrollees from increases in cost sharing when possible and including it in the regulation text provides additional transparency for stakeholders. In addition, in a situation where there are multiple approaches resulting in multiple actuarially equivalent values, CMS may choose the actuarial approach that is most consistent with trends and patterns in MA utilization and costs, if such information is available. For example, in the February 2020 proposed rule we explained that CMS proposed to add new cost sharing limits for an inpatient hospital acute 3-day length of stay scenario because it represented the median length of stay based on separate analyses of Medicare FFS and MA encounter data (for the same time

[35] See Actuarial Standards Board, Actuarial Standard of Practice No. 1, adopted March 2013, Sections 2.9 and 3.1.4 *https://www.actuarialstandardsboard.org/wp-content/uploads/2013/10/asop001_170.pdf*) and *http://www.actuarialstandardsboard.org/profcounts/asop-no-1-and-professional-judgment/*.

period). A similar comparison may be completed if MA encounter data is also available related to a service category subject to paragraph (f)(6)(i), (f)(6)(iii), or (j)(1). While helpful for comparison purposes and to inform which measure of central tendency CMS should use, MA encounter cost data will not be used to calculate the copayment limits. This approach further protects beneficiaries and plan designs from potentially disruptive changes to cost sharing.

As discussed in section II.B.5.b. and e. of this FC, we are finalizing at § 422.100(f)(8) a transition for copayment limits calculated under this FC. New paragraph (f)(7)(ii)(D) provides that actuarially equivalent copayment limits will be consistent with that transition. The actuarially equivalent copayment transition finalized at § 422.100(f)(8) is only applicable to service categories subject to paragraphs (f)(6)(iii) and (j)(1). Similarly, as discussed in section II.A. and II.B.5.c. of this FC, the transition of ESRD costs (finalized in paragraph (f)(4)(vi)) is only applicable for the methodology CMS uses to calculate MOOP and inpatient hospital cost sharing limits. Specifically, service categories subject to paragraph (f)(6)(i) are not subject to paragraph (f)(4)(vi) (the ESRD cost transition) or paragraph (f)(8) (the transition to actuarially equivalent copayments) because CMS has not historically calculated copayment limits in addition to the 50 percent coinsurance limit for most of these benefits in prior years. Finally, § 422.100(f)(7)(ii)(E) applies the rounding rules in paragraph (f)(6)(ii) as a necessary part of the copayment limit calculations. The rounding rules are discussed in more detail in a subsequent response to comment in this section.

In summary, § 422.100(f)(7)(i) and (ii) generally codify elements of our existing practice and policy for cost sharing limits and clarifies how the necessary judgment will be used in developing actuarially sound projections of beneficiary out-of-pocket costs (to calculate MOOP limits) and actuarially equivalent copayment amounts. As in the past when calculating cost sharing limits, CMS will conduct analyses and make projections using the various data described in the regulation. Taken together, § 422.100(f)(6), (f)(6)(i), and (f)(7) require an MA plan use cost sharing that is no greater than 50 percent coinsurance or an actuarially equivalent copayment value, with that copayment value calculated and announced by CMS or, if CMS does not calculate a copayment limit, based on the average Medicare FFS allowable amount for the plan service area or the estimated total MA plan financial liability for that contract year, for in-network benefits that are not otherwise addressed in §§ 422.100(f)(6), (j)(1), or 422.113(b)(2) and for out-of-network basic benefits.

To illustrate application of the methodology and how we intend to interpret and rely on § 422.100(f)(7)(i) and (ii) for a service category subject to paragraph (f)(6)(i), we explain here the development of final contract year 2023 copayment limits for the specific service category of ''DME—diabetic shoes or inserts.'' The copayment limit must be actuarially equivalent to 50 percent coinsurance for MA plans that establish a lower or intermediate MOOP amount. (As discussed in section II.B.5.e. of this FC, MA plans that establish a mandatory MOOP amount must have cost sharing that does not exceed cost sharing in original Medicare (that is, 20 percent coinsurance) for the specific service categories of DME specified in § 422.100(j)(1)(i)(E).) We acknowledge that the February 2020 proposed rule stated that the ''DME'' service category was one of several categories identified as subject to a higher variation in cost or unique provider contracting arrangements, which makes Medicare FFS average or median cost data less suitable for developing a standardized actuarially equivalent copayment value. Since then, we have worked closely with the OACT to analyze additional and updated Medicare FFS data projections for these service categories. CMS has been able to make progress to address and apply actuarial approaches (consistent with finalized paragraphs (f)(7)(i) and (ii)) to address these concerns (such as, weighting by the number of visits or sessions a beneficiary typically receives in order to reach an actuarially equivalent copayment amount for a service category that is subject to a wide range of costs). Table 10 includes the calculations of the actuarially equivalent copayment values for both the DME ''diabetic shoes or inserts'' and ''diabetes monitoring supplies'' service categories for the lower and intermediate MOOP types using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). Table 28 illustrates the results of applying paragraphs (f)(6), (f)(7), (f)(8), and (j)(1) to set final contract year 2023 in-network service category cost sharing limits. As a result, the actuarially equivalent copayment values from row D in Table 10 are included in Table 28 as the final contract year 2023 copayment limits for those DME service categories and MOOP types. The copayment values listed in Tables 10 and 28 for a lower and intermediate MOOP limit for the ''DME—diabetic shoes or inserts'' service category are the CMS-calculated actuarial equivalent value for a 50 percent coinsurance cost sharing limit. As illustrated in Table 10, to calculate this actuarially equivalent copayment value, we started with the contract year 2023 Medicare FFS data projections from the OACT. Based on HCPCS codes from the Medicare FFS data projections, the projected weighted average total Medicare FFS allowed amount for the ''DME—diabetic shoes or inserts'' service category equals $47.51 for contract year 2023. CMS weighted this projected average Medicare FFS allowed amount by utilization of pairs of diabetic shoes, inserts, and shoe modifications. We chose to weight the relevant HCPCS codes (A5500, A5501, A5512, A5513, and A5500) by utilization as there was a relatively wide range of costs projected for 2023, approximately $30 to $220, depending on whether the item was a custom molded shoe, insert, or shoe modification. Weighting the projected average costs by utilization results in a value that more accurately represents an actuarially equivalent value to the costs the OACT projects will be experienced by Medicare FFS beneficiaries. Using 50 percent of the projected Medicare FFS weighted average amount ($23.76), and applying the rounding rules in paragraph (f)(6)(ii), we reached $25.00 as an actuarially equivalent copayment value to 50 percent coinsurance for this service category for MA plans that establish a lower or intermediate MOOP amount in contract year 2023. CMS completed similar analyses to calculate and set a final contract year 2023 copayment limit that is actuarially equivalent to 50 percent coinsurance for the ''DME—diabetes monitoring supplies'' service category in Table 28.

As CMS did not set copayment limits for service categories subject to the longstanding 50 percent coinsurance limit in prior years, the limits we are adopting in paragraph (f)(8) to transition to actuarially equivalent values are not relevant for the DME service categories for MA plans that establish a lower or intermediate MOOP. Accordingly, Table 28 reflects a final contract year 2023 $25 copayment limit for the ''DME—diabetic shoes or inserts'' service category and a $20 copayment limit for the ''DME—diabetes monitoring supplies'' service category for MA plans with a lower or intermediate MOOP limit in addition to the 50 percent coinsurance limit. As discussed in section II.B.5.e. of this FC,

the same starting figures ($47.51 and $39.48 for the DME ''diabetic shoes or inserts'' and ''diabetes monitoring supplies'' service categories, respectively) were used to calculate an actuarially equivalent copayment value to 20 percent coinsurance to reach the final contract year 2023 copayment limits for the mandatory MOOP type. Applicable MA encounter utilization data was not available at the time CMS was making these calculations, so all final contract year 2023 copayment limits in Table 28 are solely based on Medicare FFS costs and utilization (including for the DME service categories). In addition, based on the available Medicare FFS data projections, CMS (in consultation with the OACT) did not conclude that another approach would be better suited to calculate an actuarially equivalent copayment value for these DME service categories.

TABLE 10: CMS CALCULATIONS OF THE FINAL CONTRACT YEAR 2023 COPAYMENT LIMITS FOR THE DME "DIABETIC SHOES OR INSERTS" AND "DIABETES MONITORING SUPPLIES" SERVICE CATEGORIES SUBJECT TO § 422.100(f)(6)(i) FOR THE LOWER AND INTERMEDIATE MOOP TYPES USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	DME – Diabetic Shoes or Inserts	DME – Diabetes Monitoring Supplies
A	Contract year 2023 Medicare FFS projections of total weighted average cost*	$47.51	$39.48
B	Contract year 2023 coinsurance limit per § 422.100(f)(6)(i)	50%	
C	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(i) (row A multiplied by row B)	$23.76	$19.74
D	Rounded actuarially equivalent copayment value to contract year 2023 coinsurance limit (row C rounded per § 422.100(f)(6)(ii))	$25.00	$20.00

*The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7)).

Consistent with § 422.100(f)(7), we may calculate actuarially equivalent copayment limits for the other DME service categories and other categories subject to § 422.100(f)(6)(i) (such as ambulance services) in future years (as those categories do not have final contract year 2023 copayment limits in Table 28) as feasible and appropriate to carry out program purposes. Considerations include whether additional Medicare FFS data projections are available and suitable (based on paragraph (f)(7)(i)), the need for CMS to prioritize use of its resources, and whether calculating a copayment limit would assist CMS in protecting against discriminatory cost sharing and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries. These considerations and calculations of copayment limits will be completed annually based on the Medicare FFS data projections for the applicable year and service category. Conversely, there may be years where CMS does not exercise its authority to apply the methodology in these regulations to calculate a specific copayment limit for a particular basic benefit. In this case, if the MA organization wants to establish a copayment for a benefit where CMS has not calculated the actuarially equivalent copayment limit, the MA organization must apply these regulations to calculate the actuarially equivalent value of a particular coinsurance percentage for that basic benefit using the data specified in the regulations (for example, the MA plan's estimated total financial liability for that contract year). The reasons for CMS's approach each year may vary, such as that CMS resources may be better devoted to other program responsibilities or available data projections are insufficient to produce an actuarially equivalent copayment value for that year. However, preliminary analyses could indicate that there is a copayment level which clearly does not exceed the limits set in this regulation for copayments. It might be beneficial for CMS to provide that information along with an indication that CMS does not believe that scrutiny is required of copayments established by an MA plan at or below that level. In those cases, as no copayment limit has been officially issued by CMS, MA plans would need to be able to validate how a copayment established above that copayment level complies with the regulatory standards.

Under this FC, MA organizations may choose a copayment or coinsurance form of cost sharing for any in-network or out-of-network benefit. If the plan chooses to establish a copayment, the amount is limited to an actuarially equivalent value based on the applicable regulation standard. When using copayments for benefits where CMS has not calculated the value that is actuarially equivalent to the maximum coinsurance percentage value, MA organizations must also use generally accepted actuarial principles and practices and the type of data that is described in paragraphs (f)(6)(i) and (iii). We are finalizing § 422.100(f)(6) and (f)(6)(i) with changes from the proposal and finalizing new paragraph (f)(7) to provide context and clarity regarding how CMS will implement and apply the regulations and also how MA organizations may implement and demonstrate compliance with the cost sharing limitations and protections adopted in this FC.

MA organizations are not expected to experience any greater burden when demonstrating compliance with the service category cost sharing standards

in these regulations than MA organizations have had in the past when CMS reviewed MA plan benefit packages (PBPs) in the annual MA bids. Consistent with prior contract years, the PBP software includes validations to prevent an MA organization from entering cost sharing (coinsurance and copayment amounts) for a particular service category that is above the cost sharing limit. This process is expected to be maintained in future years for service categories, using the coinsurance limits in these regulations and the copayment limits that CMS calculates applying the rules in these regulations. MA organizations must submit documentation (either with their initial bid or upon request) that clearly demonstrates how the copayment amount satisfies the regulatory requirements for each applicable plan where CMS has not calculated a copayment or coinsurance limit under these regulations and programmed the PBP with that limit. Next, we address how MA plans should: (1) Generally prepare and submit supporting documentation for the service category or for a reasonable group of benefits, if necessary; (2) calculate the estimated total MA plan financial liability for that contract year; (3) calculate the average Medicare FFS allowed amount for the plan service area; (4) modify supporting documentation for different provider payment structures; and (5) address three specific components of the supporting documentation that may be used to satisfy the regulatory requirements. Further guidance on these topics will be issued by CMS, as necessary.

For service categories where CMS does not calculate the specific copayment limits, each plan bid with a copayment for that benefit would need to be prepared and evaluated in relation to the estimated total MA plan financial liability for that contract year or the average Medicare FFS allowed amount for the benefit in the plan service area. Section 422.100(f)(6)(i) permits use of either of these. As discussed in sections II.B.5.b. and II.B.5.e. of this FC, paragraph (f)(6)(iii) requires use of only the estimated total MA plan financial liability for that contract year and § 422.100(j)(1) permits use of either set of data. We may request supporting documentation from the MA organization that shows how the plan's copayment amount satisfies the cost sharing standards finalized in paragraphs (f)(6) and (j)(1) as part of our evaluation of plan bids. The data MA organizations may use to develop supporting documentation for the cost sharing included in their PBP(s) are clarified in paragraphs (f)(6)(i), (iii)(B), and (j)(1)(ii) and are more completely discussed subsequently in this response. CMS, consistent with past years, will direct MA organizations through annual guidance, such as HPMS memoranda or bid instructions, on whether supporting documentation must be submitted with their initial bid or submitted upon request depending on the service category. MA organizations must identify this documentation separately from other supporting documentation submitted as part of the BPT. MA organizations may include information for multiple plans in one set of documentation, but calculations must be presented for each plan individually (or plan segment, if applicable). The MA organization's calculations and documentation must reflect cost sharing amounts that combines the enrollee's entire cost sharing responsibility as a single, total copayment as finalized in § 422.100(f)(9), even if the MA plan has contract arrangements involving separate payments to facilities and professional providers. This is consistent with our current practice of having MA organizations submit supporting documentation with the bid. For example, under current (contract year 2022) and previous policy, if an MA organization used copayments for the ''DME—Equipment'' service category and established a mandatory MOOP amount, it would have submitted supporting documentation in order to demonstrate how the copayment satisfied the cost sharing standards because only a coinsurance limit has been traditionally provided for that service category. This approach remains the same for contract year 2023 for the ''DME—Equipment'' service category and other DME service categories without final contract year 2023 copayment limits in Table 28. In addition, MA organizations with inpatient hospital acute and psychiatric and SNF coinsurance plan benefit designs in contract year 2022 and prior years submitted supporting documentation in order to demonstrate how their coinsurance met the cost sharing standards because we do not have a coinsurance limit for those service categories. This requirement also continues to apply for contract year 2023, as CMS has not included coinsurance limits for those service categories in the final contract year 2023 cost sharing limits provided in Table 28.

The February 2020 proposed rule noted that MA organizations must maintain (and provide to CMS upon request) supporting documentation for actuarial justifications for cost sharing, including the methods used in calculating the total MA plan financial liability. We proposed that regardless of the type of cost sharing used, an MA plan must not pay less than a specified percentage of the total MA plan financial liability for in-network benefits in proposed § 422.100(f)(6)(i), (iii), and (j)(1)(iv). The February 2020 proposed rule stated that the term ''total MA plan financial liability'' means the total payment paid and includes both the enrollee cost sharing and the MA organization's payment. In this FC we modified paragraphs (f)(6)(i), (f)(6)(iii), and (j)(1)(ii) to use the term ''estimated total MA plan financial liability for that contract year'' to clarify that MA organizations may use more than one year of data to project this amount (following generally accepted actuarial principles and practices as required by paragraph (f)(7)). As a result of using this term consistently in the regulations, the mechanics of this process for calculating the copayment amount when CMS has not calculated an actuarially equivalent copayment limit are quite similar for paragraphs (f)(6)(i), (f)(6)(iii), and (j)(1). (The specified percentage of the estimated total MA plan financial liability for that contract year will vary based on the type of MOOP limit used by the plan for benefits subject to paragraph (f)(6)(iii).) For each provision, the copayment amount must be equal to, or less than, the copayment limit calculated by CMS or a dollar amount that is actuarially equivalent to a specified percentage of the estimated total MA plan financial liability for that contract year (or the average Medicare FFS allowable amount for the plan service area for benefits subject to paragraph (f)(6)(i) or (j)(1)). We are generally finalizing those polices, with some modifications as discussed throughout section II.B of this FC. As a result, in the absence of a copayment limit calculated by CMS, the MA plan must pay at least the specified percentage of the estimated total MA plan financial liability for that contract year or average Medicare FFS allowable amount (as applicable) for the service category or for a reasonable group of benefits in the PBP. We are finalizing explicit regulation text to be clear in paragraphs (f)(6)(i), (f)(6)(iii)(B), and (j)(1)(ii) what data the MA organization may use in calculating a dollar amount, if CMS does not calculate a copayment limit. It is not necessary for an MA organization to use one data source over the other (estimated total MA plan financial liability for that contract year or average Medicare FFS allowable

amount) when complying with § 422.100(f)(6)(i)(B) and (j)(1)(ii), which both provide the choice. However, as proposed and discussed in more detail in section II.B.5.b. of this FC, MA organizations must pay a minimum percentage of the estimated total MA plan financial liability for in-network basic benefits that are professional services; this necessarily means that in calculating copayment dollar amounts for service categories subject to paragraph (f)(6)(iii), the MA plans must use data about the estimated total MA plan financial liability for that contract year.

In response to the comment requesting that CMS allow the average contracted rate to be calculated at the parent organization level, we clarify here that MA organizations may use the estimated total financial liability for that contract year calculated at the MA plan level where this FC permits use of data about the MA plan's financial liability. A minority of MA organizations use segmented plans and, in those cases, the estimated total financial liability for that contract year would be calculated at the segment level (CMS will also complete the cost sharing evaluation at the segment level). However, in calculating actuarially equivalent copayment standards CMS will use aggregate (or nationally representative) projections from the OACT. In comparison, MA organizations will use aggregate payment data for their plan service area about the service category, or for a reasonable group of benefits, to which the cost sharing applies when determining the dollar figure that is actuarially equivalent to the coinsurance standard. Conducting the evaluation at the plan (or segment) level is the better policy, and the one we are finalizing here, as it: (1) Reflects the cost sharing experienced by enrollees in the plan's service area; (2) protects against possible distortions from aggregating the average payment rate calculation across a larger organizational level that may not sufficiently reflect the plan's service area; and (3) coincides with the MA organization's provider contracts that may vary geographically. MA organizations that are new may calculate the estimated total MA plan financial liability for new plans based on projections of available provider contracts and expected enrollment trends for that contract year. In addition, MA organizations that are entering a new service area may calculate the estimated total MA plan financial liability for that plan based on the total MA plan financial liability for the benefit in the organization's existing service area and also take into consideration projections of available provider contracts and expected enrollment trends in that new service area for that contract year. To address the potential that the MA organization may have insufficient data about the specific service area, CMS will implement and enforce the rules adopted in this FC to permit use of data on the MA plan financial liability that is not limited to the specific service area for new plans and new service areas.

For in-network benefits, the estimated total MA plan financial liability for that contract year is based on the provider contracting arrangements and expected enrollee utilization for the particular provider type and service. MA plans and their network providers negotiate payment arrangements without interference by CMS and may have varying enrollee utilization experience; CMS lacks information on those specifics and understands that plans may contract with providers through a variety of arrangements (such as, FFS, capitation, salary, or value-based arrangements). As a result, if CMS does not calculate a copayment limit for an in-network professional service category for a particular contract year, calculating a dollar amount that is actuarially equivalent to the coinsurance value will require analysis by the MA organization and that analysis must consider the various amounts that the MA plan expects to pay for that basic benefit in the applicable year. An MA organization may consider the various types of payment arrangements it has with network providers and aggregate this information to calculate a dollar amount that is actuarially equivalent to the applicable coinsurance limit for service categories subject to § 422.100(f)(6)(i), (iii), and (j)(1). In addition, an MA organization may weigh the aggregated data in calculating this dollar amount (that is, the actuarially equivalent value to the applicable coinsurance limit) using past utilization and variation of provider payments. For example, to comply with the requirements in paragraph (f)(6)(i) for in-network copayments, an MA organization may use their contracted payment rates for the providers that furnish the service(s) to determine the estimated total MA plan financial liability for those service(s); the estimated total MA plan financial liability for that contract year is compared to the plan's cost sharing on a percentage basis to determine if the cost sharing exceeds an actuarially equivalent copayment amount to the 50 percent cost sharing standard. This process is consistent with the supporting documentation CMS has accepted in prior years.

For covered out-of-network basic benefits, the estimated total MA plan financial liability for that contract year must necessarily be based on the average Medicare FFS allowable amount for the plan service area because MA plans are required to ensure that out-of-network providers receive the Medicare FFS payment for the basic benefit that has been furnished to the enrollee. As a result, we are clarifying that, while § 422.100(f)(6)(i) describes the use of the estimated total MA plan financial liability for that contract year and the average Medicare FFS allowable amount, to comply with the requirement in paragraph (f)(6)(i) for out-of-network benefits, the plan must use the average Medicare FFS allowable amount for these determinations because the MA plan is required to pay, at a minimum, the Medicare FFS allowable amount for these benefits. If an MA organization is using copayment amounts for out-of-network services, the plan must use the average Medicare FFS allowable amount for all providers for the applicable service category or reasonable group of services in its plan service area as the basis for their calculations of the actuarially equivalent dollar amount. In addition, an MA organization may weigh the average Medicare FFS allowable amount using the plan's past utilization (such as including the Medicare FFS payment for each applicable provider type to administer the benefit) in calculating this dollar amount (that is, the actuarially equivalent value to the 50 percent coinsurance limit for out-of-network basic benefits). MA organizations establish cost sharing at the plan-level and we reiterate here that any calculations must be done at the plan (segment, if applicable) level to reflect the benefit design. This approach may be modified as necessary to comply with generally accepted actuarial principles and standards as described in paragraph (f)(7)(i). However, an MA organization that relies on paragraph (f)(7)(i) to use data and analyses from other than the plan's estimated total financial liability and service area must explain and support such a determination.

In summary, and as required by § 422.100(f)(6) and (j)(1) as finalized in this FC, MA organizations must establish either: (1) A coinsurance level that does not exceed the coinsurance percentage in the regulation; or (2) in the absence of a specific cost sharing limit calculated by CMS, a copayment that does not exceed the value that is actuarially equivalent to the specified

percentage of the MA plan's estimated total financial liability for the benefit for that contract year (or the average Medicare FFS allowable amount for the plan service area for benefits subject to paragraph (f)(6)(i) and (j)(1)(i)). Specifically, to comply with paragraph (f)(6)(i), as well as demonstrate compliance, when CMS has not calculated a copayment limit, an MA organization must calculate the average Medicare FFS allowable amount of the plan service area or its estimated total MA plan financial liability for the service category or for a reasonable group of benefits or services covered under the plan in order to establish a maximum copayment amount (that is, dollar amount) that is actuarially equivalent to, or less than, 50 percent. If using copayments, the MA plan must use a copayment that is no greater than that maximum copayment amount. Similarly, as discussed in section II.B.5.e. of this FC, finalized paragraph (j)(1) provides that cost sharing established by the MA organization may not exceed the cost sharing required under original Medicare for the specified services; that means the cost sharing may be a copayment limit that is actuarially equivalent to the coinsurance used in original Medicare, which would be a dollar limit calculated by CMS or, if CMS did not calculate a copayment limit, a dollar limit calculated by the MA organization based on the average Medicare FFS allowable amount or the estimated total MA plan financial liability for that benefit in the plan's service area. The MA plan may have a copayment that is less than that maximum amount, but may not exceed that limit. As a result, the process MA organizations take to develop supporting documentation and to comply with paragraph (j)(1) when CMS has not calculated and issued a specific copayment limit is the same as for paragraph (f)(6)(i). The MA organization must use the average Medicare FFS allowable amount for the plan service area, or the estimated total MA plan financial liability for the benefit in order to calculate and establish a copayment amount (that is, dollar amount) that is actuarially equivalent to, or less than, the cost sharing under original Medicare for the benefit. In order to be consistent in applying this approach for benefits that cannot exceed cost sharing under original Medicare, we are not finalizing part of proposed paragraph (j)(1)(iv) (which is otherwise finalized as paragraph (j)(1)(i)(D)) related to basing a copayment on the total MA plan financial liability for home health services. The policies being finalized at § 422.100(j)(1) are more completely discussed in section II.B.5.e. of this FC. In addition, to comply with paragraph (f)(6)(iii) in situations where CMS has not calculated and issued a copayment limit for a particular service category, an MA organization must calculate an actuarially equivalent copayment amount to ensure that the MA organization does not pay less than the specified percentage of the estimated total MA plan financial liability for the applicable type of MOOP limit. This will allow MA plans to establish a copayment amount for a professional service category that is equal to or less than an actuarially equivalent value to the coinsurance limit required by paragraph (f)(6)(iii) based on the estimated total MA plan financial liability for the benefit. An MA organization is not required to ensure that every service for every enrollee meets the requirement that the MA plan pay no less than the specified percentage of the estimated total MA plan financial liability for that contract year when the MA organization is using copayment structures.

CMS's evaluations for purposes of determining compliance with § 422.100(f)(6) and (j)(1), if CMS has not published a copayment standard (or coinsurance limit for inpatient hospital standards set in paragraph (f)(6)(iv)), will align with OACT bidding guidance [36] and follow generally accepted actuarial standards of practice in accordance with paragraph (f)(7)(i). The estimated total MA plan financial liability for that contract year and Medicare FFS allowed amount should consider credibility based on OACT bidding guidance and be adjusted to meet actuarial principles and practices. In addition, copayment amounts will be calculated using the rounding rules finalized in paragraph (f)(6)(ii). This approach to develop and evaluate supporting documentation is consistent with current OACT bidding guidance, supports cost sharing stability for beneficiaries, and allows MA organizations to establish plan benefit structures that incorporate copayments. We acknowledge that MA organizations may have different provider arrangements (for example, fee-for-service and capitation) so determining that an in-network copayment amount is not more than the specified coinsurance percentage of the estimated total MA plan financial liability for the applicable service category may require plan-specific approaches; we expect to take this into account when determining if an MA plan's (or segment-level) cost sharing complies with paragraphs (f)(6)(i), (f)(6)(iii), and (j)(1). In evaluating an MA organization's supporting documentation for service categories subject to paragraphs (f)(6)(i), (iii), and (j)(1), CMS may accept information that considers the MA plan's estimated total financial liability for that contract year using these provider payment arrangements or a combination of these arrangements, as long as it is reflects the plan's service area (or the service area of a segment). For example, if upon request, the MA organization submits supporting documentation at the contract level with sufficient actuarial justification, instead of calculating at the plan level (such as, unique provider payment arrangements), CMS will take this under consideration. Likewise, if CMS were to request an MA organization to provide a justification for the copayment included in their contract year 2023 PBP for Medicare-covered podiatry (which is subject to § 422.100(f)(6)(i) and lacks a CMS set copayment limit for contract year 2023 as it is not included in Table 28), we may consider actuarial justifications that are specific to and reflect capitated payment arrangements with different providers (and different types of providers) that furnish Medicare-covered podiatry services, if applicable.

Because the analyses performed by MA organizations must use generally accepted actuarial principles and practices pursuant to § 422.100(f)(7)(i), supporting documentation must be consistent with generally accepted actuarial principles and practices. The MA organization's analysis must demonstrate how plan cost sharing complies with the regulations in § 422.100(f)(6)(i), (iii), and (j)(1). As a result, the documentation must demonstrate:

- How the MA organization calculated the plan's estimated total financial liability for the benefit for that contract year (or the average Medicare FFS allowable amount for the service area for benefits subject to § 422.100(f)(6)(i) and (j)(1));
- The percentage the copayment represents of the plan's estimated total financial liability for the benefit for that contract year (or the average Medicare FFS allowable amount for the service area for benefits subject to § 422.100(f)(6)(i) and (j)(1)); and
- How the cost sharing does not exceed, as applicable, an actuarially

[36] The annual OACT MA bidding guidance may be accessed from CMS's page on Bid Forms & Instructions from the website: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions.*

equivalent amount to the 50 percent estimated total MA plan financial liability requirement (established at § 422.100(f)(6)(i)), the range of cost sharing requirement based on the type of MOOP limit (established at paragraph (f)(6)(iii)), and cost sharing under original Medicare (established at § 422.100(j)(1) and (2)).

MA organizations must develop and maintain documentation that demonstrates how plan cost sharing satisfies the estimated total MA plan financial liability for that contract year and average Medicare FFS allowable amount requirements and other applicable cost sharing coinsurance limits for covered benefits. If CMS requests information as part of bid review or general oversight of the plan's copayment or coinsurance amounts for specific service categories, an MA organization may submit an analysis that addresses each of the three components described previously, or use a PMPM analysis that addresses multiple components simultaneously. For example, the copayment may be represented as a percentage of the estimated total MA plan financial liability for that contract year or the average Medicare FFS allowed amount for the benefit. If necessary, we expect that supporting documentation and data may include information on provider payments or costs, enrollee enrollment and utilization, and cost sharing paid by enrollees (both in terms of dollar figures and as a percentage of the estimated total MA plan financial liability for that contract year or average Medicare FFS allowable amount for the benefit) to demonstrate how the plan's cost sharing amounts satisfy requirements being finalized in this rule. We provide in Table 11 an illustration of one way an MA organization can approach developing and summarizing supporting documentation that addresses the three components described previously for some select service categories. We would expect MA organizations to also include any necessary payment, cost, and/or utilization data or assumptions. Requiring supporting documentation as described in this response protects enrollees from high cost sharing (generally and in relation to specific service categories, such as physical therapy and speech-language pathology, as summarized in section II.B.5.b. of this FC) by ensuring that MA plan copayments satisfy cost sharing requirements in various scenarios.

TABLE 11: GENERAL ILLUSTRATION OF SUMMARY OF SUPPORTING DOCUMENTATION FOR AN MA PLAN WITH A LOWER MOOP LIMIT TO EVALUATE COMPLIANCE WITH §§ 422.100(f)(6)(i), 422.100(f)(6)(iii)(C), AND 422.100(j)(1)

Plan ID	PBP Service Category	Cost Sharing Standard	Estimated Total MA Plan Financial Liability[1]	PBP Cost Sharing	Percent of Estimated Total MA Plan Financial Liability[1]	Pass/Fail Test
H0000-001-1	DME - Equipment	50%[2]	$100	$30	30%	PASS
H0000-001-2	Example Service Category A	50%[3]	$100	$75	75%	FAIL
H0000-001-3	Example Service Category B	20%[4]	$250	$45	18%	PASS

[1] The Medicare FFS allowed amount for the benefit may also be used for service categories subject to § 422.100(f)(6)(i) and (j)(1) and must be an average for the plan service area. The estimated total MA plan financial liability for that contract year and Medicare FFS allowed amount should consider credibility based on OACT bidding guidance and be adjusted to meet actuarial principles and practices.

[2] For MA plans with a lower MOOP limit, the cost sharing limit for the "DME – Equipment" service category is 50% in accordance with § 422.100(f)(6)(i) and (j)(1).

[3] For MA plans with a lower MOOP limit, the cost sharing limit for the "Example Service Category A" is 50% coinsurance in accordance with § 422.100(f)(6)(iii).

[4] The cost sharing limit for the "Example Service Category B" is 20% coinsurance in accordance with § 422.100(j)(1).

CMS intends to work with MA organizations when requesting supporting documentation to address any unique situations and ensure calculations and subsequent evaluations comply with generally accepted actuarial principles and standards. We may also provide additional information on how MA organizations should prepare their cost sharing supporting documentation and data (such as, potential formats and information to be included in documentation) through instructions, such as HPMS memoranda or bidding instructions. Individuals and organizations may request placement on the HPMS listserv at *https://hpms.cms.gov/app/ng/home/* to ensure that they receive HPMS memoranda.

Comment: A commenter requested CMS make the 50 percent total financial liability determination subject to the nearest $5 rounding rule, proposed at § 422.100(f)(6)(ii)(A), to help with year over year benefit design stability.

Response: Having MA plans apply the same rounding methodology specified in § 422.100(f)(6)(ii) does not appear to result in any harm, especially as CMS will be using those rounding rules for calculating cost sharing limits. In addition, applying the same rounding rules to calculate actuarially equivalent copayment values regardless if the calculations are completed by CMS or by an MA organization will promote consistency in determining compliance with the regulatory standards being set through this FC. Accordingly, we are finalizing here that MA organizations will use the rounding rules in paragraph (f)(6)(ii) when calculating actuarially equivalent cost sharing values for the regulatory standards in § 422.100(f)(6), (f)(7), and (j)(1). This will allow MA organizations to round to the nearest $5 increment (or lower $5 increment where the amount is exactly between two

increments) when calculating an actuarially equivalent copayment for benefits that must satisfy the 50 percent coinsurance obligation under paragraph (f)(6)(i), professional services subject to paragraph (f)(6)(iii), and benefits listed in paragraph (j)(1)(i). In addition, MA plans may round to the nearest whole $1 for out-of-network inpatient acute and psychiatric and skilled nursing facility cost sharing, also rounding down when the actuarially equivalent copayment is projected to be exactly between two increments, when calculating values that comply with paragraph (f)(6)(iv). This rounding rule for inpatient hospital cost sharing was proposed in paragraph (f)(6)(ii)(A) and is finalized generally as proposed in paragraph (f)(6)(ii)(B). As finalized, paragraph (f)(6)(ii) is clear that the rounding rules will be used in calculating copayment limits and evaluating whether an MA plan's cost sharing complies with the cost sharing limits.

Based on the changes to § 422.100(f)(6)(i) and new paragraph (f)(7), the transition schedule we are adopting in new paragraph (f)(8), and changes we are finalizing in § 422.100(j) (as discussed in section II.B.5.e. of this FC), we are finalizing proposed paragraph (f)(6)(ii) with modifications. First, as finalized, paragraph (f)(6)(ii)(A) will apply the $5 rounding rules proposed for professional service categories and benefits that are subject to § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1)(i). As a result, in calculating copayment limits and in evaluating an MA plan's compliance with paragraphs (f)(6)(i), (f)(6)(iii), and (j)(1), CMS will round to the nearest whole $5 increment. The exception to this is copayments for inpatient hospital acute and psychiatric and SNF services, where paragraph (f)(6)(ii)(B) explicitly provides that the $1 rounding rule applies. In addition, MA plans that calculate actuarially equivalent copayments values because CMS has not calculated a copayment limit will round to the nearest whole $5 increment for service categories for which paragraph (f)(6)(ii)(A) applies. For cases in which the copayment limit is projected to be exactly between two increments, the final actuarially equivalent copayment value is rounded (by CMS and by MA plans) to the lower dollar amount. Consistent with current practice, this application of the rounding rules does not prevent an MA plan from establishing a copayment that is not a $5 increment. For example, if CMS does not set a copayment limit for a service category subject to paragraph (f)(6)(iii), an MA organization may choose to establish a $13 copayment if, in following the rules in paragraph (f)(6)(ii) and (f)(6)(iii), the calculations of an actuarially equivalent value to the applicable coinsurance standard equaled $12.52, rounded to $15. This ensures consistency in how actuarially equivalent copayment values are calculated using the rounding rules while maintaining flexibility for MA organizations to establish copayments below the actuarially equivalent value. In comparison, if CMS had the same result in calculating an actuarially equivalent copayment for a service category subject to paragraph (f)(6)(iii), $12.52, rounded to $15, we would issue the copayment limit at the $5 increment, or $15. Second, we added references to paragraphs (f)(6)(iv) and (j)(1)(i)(C) to paragraph (f)(6)(ii)(B) to clarify which regulations are subject to the inpatient hospital cost sharing rounding rules. Third, in making these changes we added introductory language to paragraph (f)(6)(ii) and reorganized (f)(6)(ii) for clarity. As a result, the proposed requirement in paragraph (f)(6)(ii)(B) that the actuarially equivalent copayment value is rounded down to the lower dollar amount is finalized generally as proposed in paragraph (f)(6)(ii)(C). Fourth, as discussed in a prior response to comment in this section, new paragraph (f)(7) codifies the use of actuarial principles and practices and the requirements to calculate actuarially equivalent copayment limits. To ensure these requirements are applied consistently with the proposed rounding rules, § 422.100(f)(7)(ii)(E) refers to paragraph (f)(6)(ii) as part of the steps for CMS calculation of copayment limits. Fifth, as discussed in section II.B.5.b. of this FC, we are adopting a transition schedule for certain cost sharing standards; we are finalizing a reference to that schedule (which is in paragraph (f)(8)) in paragraph (f)(6)(ii) to clarify that the rounding rules will be used for those transitional copayment limits as well.

Comment: A commenter encouraged CMS to codify an explicit requirement for MA organizations to demonstrate compliance with the regulation standards proposed at § 422.100(f)(6) by providing CMS with information substantiating their contracted rates for professional services and their cost sharing limits for basic benefits.

Response: CMS thanks the commenter for their feedback. In this FC, we are not adopting an explicit regulatory provision to require MA organizations to demonstrate compliance with the regulation standards in § 422.100(f)(6), as we believe that CMS's bid review processes will generally address this and that CMS's oversight and monitoring authority would support any requests for information and necessary documentation from MA organizations. Compliance program, record keeping, audit and access requirements in §§ 422.503 and 422.504, in conjunction with longstanding bid review policy, adequately establish CMS's authority to investigate compliance with the MA program and benefit requirements adopted in this FC. In addition, the regulation at § 422.254(b)(5), (c)(5), and (c)(6) requires that MA organization bid submissions for coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and for MA private fee-for-service plans must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles and must include the actuarial bases of the bid, a description of cost sharing applicable under the plan, and the actuarial value of the cost sharing. If we find, through future bid review or general oversight activities, that greater clarification in regulatory text in needed, we will pursue future rulemaking.

In general, MA organizations are required to provide CMS with information that demonstrates how their bid and plan design (including coinsurance or copayment amounts) satisfy the regulatory requirements, if necessary as part of CMS's bid review process or at any time during the year for general oversight activities. For example, for MA plans that choose to establish a coinsurance cost sharing for inpatient hospital scenarios or SNF service categories, CMS will typically use plan information to evaluate, consistent with current practice, whether the coinsurance exceeds the applicable copayment dollar amounts calculated and issued for that contract year. This evaluation is based on actuarial information and analyses.

b. Range of Cost Sharing Limits for Certain Outpatient and Professional Services (§ 422.100(f)(6)(iii) and (f)(8))

Comment: Comments were mixed regarding CMS's proposal to codify the methodology used to set the MA cost sharing standards for professional services and to establish a range of cost sharing limits for benefits furnished on an in-network basis, based upon the type of MOOP limit established by the MA plan. A commenter supported differentiating cost sharing limits based on the plan's MOOP limit and requested CMS better differentiate the maximum

copayment limits between the voluntary and mandatory MOOP limits for primary care physician (PCP), physician specialist, emergency/post-stabilization services, and home health services. The commenter stated that currently, the maximum copayments for the ''PCP'' and ''physician specialist'' service categories are the same under the voluntary and mandatory MOOP limits set by CMS. The commenter stated that CMS should make greater differentiation in the cost sharing levels for service categories for the various MOOP limits, especially for those services that have higher utilization rates (which will increase the actuarial value of the copayments). The commenter stated that these changes would make it more likely that an MA plan would choose to offer the voluntary MOOP limit.

Response: We appreciate the commenters' feedback on our proposal at § 422.100(f)(6)(iii). We do not believe that it is necessary to finalize a more significant difference between the cost sharing levels permitted for each MOOP type in paragraph (f)(6)(iii). We proposed a 10-percentage point difference between the coinsurance levels based on the type of MOOP limit and thus sufficiently differentiated cost sharing limits for these categories without creating potentially discriminatory cost sharing for beneficiaries. As discussed in the February 2020 proposed rule, we arrived at the specified percentages of 30 percent, 40 percent, and 50 percent for the underlying benefit, tied to use of the mandatory (highest), intermediate, and lower MOOP limits, by assigning the highest coinsurance amount that we believe is not discriminatory (50 percent) to the lowest MOOP limit; and 30 percent coinsurance (which is most closely related to copayment limits from prior contract years) to the mandatory MOOP limit, to balance the MA plan's incentives to use each type of MOOP limit. Then, we established the midpoint (40 percent) for the intermediate MOOP limit. By establishing these limits to range from the highest amount, we will permit cost sharing amounts the MA market is used to from prior contract years for several service categories. Our intention is to balance several goals: (1) Protect beneficiaries from discriminatory cost sharing amounts; (2) avoid disruptive changes in MA plan designs; and (3) create cost sharing standards that would result in a clear increase in MA organization financial responsibility for professional services if the MA plan establishes a mandatory MOOP limit rather than a lower or intermediate MOOP limit.

We agree with the commenter that increasing the number of service categories for which cost sharing limits can be differentiated by the type of MOOP limit from prior contract years may be an incentive for MA organizations to offer lower MOOP limits. We also believe differentiating these cost sharing limits may encourage innovative plan designs, such as those that are trying to improve health care outcomes. This may include changing cost sharing for certain service categories to encourage enrollees to seek preventive health care or high-value services. CMS supports value-based insurance design and expects that providing increased flexibility in plan designs, within non-discriminatory cost sharing ranges, will encourage competition and innovation by MA plans. However, we do not believe that a greater number of differentiated service categories would necessarily increase the actuarial value of cost sharing for that plan's benefit design. The actuarial value of the plan's cost sharing depends on the given benefit compared to other benefits. If a service type with a lower amount of cost sharing has a high rate of utilization, then that would likely lower the plan's actuarial value of cost sharing. For example, if an MA plan establishes a mandatory MOOP limit which has lower cost sharing standard amounts compared to prior contract years across a number of service categories then the plan may have a lower actuarial value of cost sharing. Finally, MA organizations establish cost sharing amounts based on a number of factors such as competition, provider contracts, and needs of beneficiaries in their service area. While CMS can set cost sharing requirements to discourage discrimination against beneficiaries with high health care needs and encourage MA plans to lower the financial burden on enrollees, we do not believe CMS should dictate identical cost sharing for all basic benefits for all MA plans and we did not propose to do so in this rulemaking.

Comment: A commenter stated doctors of optometry may be considered a ''physician specialty'' or a ''primary care physician'' for the purpose of the cost sharing limits set in this FC, but noted their preference was the primary care category to ensure the lower cost sharing limit would apply to prevent financial barriers hindering beneficiary access to needed eye care. This commenter explained that doctors of optometry play an important role in patient care with respect to general health and the management of systemic diseases with ocular manifestations and as such, provide primary care.

Response: For purposes of the PBP, the longstanding practice has grouped doctors of optometry (namely, specialties of ophthalmology and optometry) with physician specialties and CMS expects to maintain this approach in future years. In addition, applying the copayment limits calculated for the ''physician specialist'' service category to doctors of optometry is consistent with the current network adequacy requirements (in that doctors of optometry are not used to determine if a plan's provider network for primary care services is sufficient). As a result, we are not implementing the recommendation that we characterize optometry services as primary care services in this FC for purposes of applying § 422.100(f)(6)(iii). We note the current (and longstanding) service category description of primary care services in the PBP is as follows:

> Internal Medicine, General Practice, or Family Practice Services provided by a medical doctor or a doctor of osteopathy: General Physicians' services are the professional services performed by a physician for a patient including diagnosis, therapy, surgery, consultation, and care plan oversight. The services must be rendered by the physician or incident to physician's services. A service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. Direct visualization would be possible by means of X-rays, electrocardiogram and electroencephalogram tapes, tissue samples, telecommunications, etc. References: 42 CFR 410.10 and 410.26 and the Medicare Benefit Policy Manual, Chapter 15.

Original Medicare does not currently cover eye exams furnished by optometrists. However, original Medicare does cover some other services that may be provided by optometrists, such as screening for glaucoma.

We may change the list of provider specialties that are used to calculate actuarially equivalent copayments in future years and would generally describe such a change in the annual guidance required by § 422.100(f)(7)(iii). For example, in this FC, we are modifying the data used to calculate the final contract year 2023 copayment limits for the ''primary care physician'' and ''physician specialist'' service categories to better align the applicable provider specialties for these categories with network adequacy standards and typical standards of care. In the February 2020 proposed rule, we

described using the following provider specialty types to calculate a copayment limit for the ''physician specialist'' and ''primary care physician'' service categories:

- *Physician Specialist:* Cardiology; Geriatrics; Gastroenterology; Nephrology; and Otolaryngology (ENT)
- *Primary Care Physician:* Family Practice; General Practice; and Internal Medicine

These groupings of provider specialties do not exactly match the list of provider specialties that are used to determine provider network adequacy for the same professional service categories. Currently, network adequacy requirements only allow MA plans to list credentialed providers for the following specialties to count towards meeting our standards for primary care providers: General Practice, Family Practice, Internal Medicine, and Geriatrics.[37] Considering how provider or facility-specialty types may change for a network adequacy evaluation annually (as discussed in the January 2021 Final Rule and codified in § 422.116(b)(3)), we believe maintaining a certain level of flexibility to add or remove a provider specialty type in the calculations of actuarially equivalent copayment limits will ensure copayment limits reflect the providers the cost sharing is applied to. CMS's current position is that the geriatrics provider type furnishes services that we would consider as primary care rather than a specialist and geriatricians are responsible for the whole patient. Usually, specialists treat a limited disease area, often with a limited patient population. In addition, provider specialists often have equipment and perform procedures that support diagnoses in the disease domain in which they specialize. In general, provider specialists are not responsible for general preventive services and screening. As a result of these considerations, we are using the following provider specialty types to calculate the final contract year 2023 copayment limits for the ''physician specialist'' and ''primary care physician'' service categories in this FC:

- *Physician Specialist:* Cardiology; Gastroenterology; Nephrology; Otolaryngology (ENT)
- *Primary Care Physician:* Family Practice; General Practice; Internal Medicine; Geriatrics

Although we are including flexibility to use a slightly modified list of provider specialties, the rules in this FC for the process and methodology for calculation of the actuarially equivalent copayment limits, which are generally as proposed, will continue to apply in future years. The final contract year 2023 in-network copayment limits for the ''primary care physician'' and ''physician specialist'' service categories in Table 28 reflect this update as well as the changes in implementing the range of cost sharing limits proposed, as discussed in a subsequent response to comment in this section, and use of contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). Finally, moving the ''geriatrics'' provider specialty to inform the calculations of an actuarially equivalent copayment for the ''primary care physician'' service category did not, in itself, produce significant changes in comparison to the illustrative copayment limits for both of the ''primary care physician'' and ''physician specialist'' service categories from the February 2020 proposed rule. If we had used these different lists of provider specialties to calculate the illustrative copayment limits provided in Table 5 in the February 2020 proposed rule, the only difference in those copayment amounts would have been the illustrative copayment for the ''physician specialist'' service category for the lower MOOP limit; using this different list of provider specialties, the actuarially equivalent copayment value to 50 percent coinsurance for the lower MOOP limit would have increased from $80 to $85 after application of the proposed rounding rules in that table.

Comment: A commenter requested that CMS implement the proposal of establishing a range of cost sharing limits for professional services (in § 422.100(f)(6)(iii)) over several years to reduce disruption in the market and for beneficiaries. This commenter noted that because MA plans are still going to be required to satisfy the Total Beneficiary Cost (TBC) standard, requiring plans with a mandatory MOOP limit to meet these new cost sharing standards in a single year could prove to be very disruptive. The commenter stated that MA plans will be forced to make drastic changes on short notice, which, in some cases, would cause some plans to be non-renewed. In addition, the commenter provided an example of a schedule to implement a multiyear phase-in of the policy in paragraph (f)(6)(iii). This example, illustrating a multiyear transition to reach the proposed range of cost sharing by the type of MOOP limit by 2025, is presented in its entirety as Table 12, ''Example of a Multiyear Phase-in for Cost Sharing Limits Based on the MOOP Type.'' In the commenter's example, the lower MOOP retains the 50 percent cost sharing limit we currently use (and proposed for MA plans that use the lower MOOP limit) while the cost sharing limit tied to the mandatory MOOP limit decreases from the current level of 50 percent by 5 percentage points annually until it reaches 30 percent; under this example, the cost sharing limit tied to the intermediate MOOP limit is calculated as the percentage that is the mid-point of the other two MOOP limits, which is consistent with our proposed approach for MA plans that use the intermediate MOOP limit.

As referenced in other comment summaries in this section and in sections II.B.5.d and e. of this FC, several commenters were also concerned about the proposed level of allowable cost sharing overall or for specific service categories (including the ''dialysis services'' and ''physical therapy and speech-language pathology'' service categories). For the ''physical therapy and speech-language pathology'' service category, a commenter on that topic was similarly concerned about the projected increase in the copayment limit from contract year 2021 limits being unreasonably high for enrollees.

[37] See the HSD reference file for the: *https://www.cms.gov/medicare/medicare-advantage/medicareadvantageapps.* In the June 2020 final rule (85 FR 33853), CMS identified the types of providers considered primary care providers by reference to the HSD reference file as well.

TABLE 12: EXAMPLE OF A MULTIYEAR PHASE-IN FOR COST SHARING LIMTS BASED ON THE MOOP TYPE

MOOP Level	2021	2022	2023	2024	2025
Lower	50%	50%	50%	50%	50%
Intermediate		47.5%	45%	42.5%	40%
Mandatory	50%	45%	40%	35%	30%

Response: We appreciate the concerns about providing time for MA organizations to adjust to the new cost sharing limits to minimize potential market and beneficiary disruption and agree that a transition over several years to the new cost sharing limits is appropriate. In this response we explain the changes CMS is making to address the commenter's concerns and additional changes that impact our proposals in § 422.100(f)(6)(iii) in order to comprehensively present the finalized requirements. As discussed in section II.B.5.a. of this FC in relation to new § 422.100(f)(7), we are consolidating and clarifying the data and requirements CMS uses to calculate copayment limits for service categories subject to § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1). As a result, we are finalizing proposed paragraph (f)(6)(iii) with modifications to incorporate references to paragraph (f)(7) as well to include new transition provisions.

We proposed and are finalizing that the cost sharing for in-network basic benefits that are professional services must not exceed specific coinsurance thresholds and actuarially equivalent copayment values, with those cost sharing thresholds tied to the type of MOOP limit used by the MA plan; in addition, the MA plan must not pay less than an identified percentage of the estimated total MA plan financial liability for these basic benefits for that contract year. We are finalizing a schedule for implementing the use of the 30 percent, 40 percent, and 50 percent cost sharing limits for use of the mandatory, intermediate and lower MOOP limits; that transition will be from 2023 through 2026 and is finalized in paragraphs (f)(6)(iii)(C) through (F). We are also finalizing an additional provision in new paragraph (f)(8) to limit increases to copayment limits calculated by CMS over the same transition period from 2023 to 2026. New paragraph (f)(8) will control how CMS calculates and issues copayment limits in order to transition from contract year 2022 copayment limits to values that are actuarially equivalent to the range of coinsurance limits that are finalized in paragraph (f)(6)(iii)(F) for contract year 2026. When CMS does not calculate the copayment limit for a professional service category, MA organizations must follow the transition schedule in paragraphs (f)(6)(iii)(C) through (F) for both coinsurance and copayments. In addition, we are finalizing a provision to more clearly address in paragraphs (f)(7) and (f)(8)(ii)(D) the specific methodology CMS will apply, in using the data described in proposed paragraph (f)(6)(iii)(B), to calculate copayment limits. The new provisions provide more detail, which we believe was implicit in the descriptions in the preamble of the February 2020 proposed rule but is better stated in the regulation text. Under this FC, the cost sharing limits set in paragraph (f)(6)(iii) are subject to new paragraph (f)(7). Overall, the changes from our February 2020 proposed rule regarding the limits on cost sharing for professional services that are basic benefits are to include transition provisions (for both coinsurance limits and copayment limits) and to more explicitly address the data and standards used to calculate values for copayment limits that are actuarially equivalent to the coinsurance limits.

We are finalizing § 422.100(f)(6)(iii)(A) substantially as proposed to prohibit MA plans from having cost sharing for in-network basic benefits that exceeds the limits in paragraph (f)(6)(iii) for the MOOP limit established by the plan, with a correction to reference paragraph (f)(6)(iii) as intended. We note this change does not affect how the rounding rules in paragraph (f)(6)(ii) will be applied to copayments for professional services. (Section II.B.5.a. of this FC discusses how the rounding rules are being finalized substantially as proposed.) Proposed paragraph (f)(6)(iii)(B) identified the data that CMS would use when calculating the cost sharing limits for in-network basic benefits that are professional services but as finalized specifies the rules for calculating copayment limits. In revising paragraph (f)(6)(iii)(B) to be subject to paragraph (f)(7), the standard for the data that CMS may use is now addressed in paragraphs (f)(7)(ii)(A) and (B). Specifically, CMS will use Medicare FFS data projections (as defined in paragraph (f)(4)(i) and discussed in detail in section II.A.4.b. of this FC) which includes cost and utilization data from beneficiaries with and without ESRD. In addition, CMS may use available MA encounter data if available and where appropriate (which is codified in paragraph (f)(7)(ii)(B)). While we only proposed use of MA encounter data in calculating cost sharing for inpatient services, we believe that it is appropriate to also permit use of MA encounter data for calculating other cost sharing in order to consider utilization differences between Medicare FFS beneficiaries and MA enrollees; these utilization differences may be useful to reach an amount that most closely reflects an actuarially equivalent copayment to the applicable coinsurance percentage for the service category and beneficiary population. For example, if the utilization of different physician types (such as, physical therapists compared to speech-language pathologists) was significantly different between Medicare FFS and MA encounter data, we may consider weighting Medicare FFS cost data by utilization reflected in available MA encounter data for the relevant facility and provider types in order to reach a copayment value that is most closely actuarially equivalent to what MA enrollees may typically experience at the applicable coinsurance level for the type of MOOP limit. CMS did not apply any MA encounter utilization data in our calculations to reach the final contract year 2023 copayment limits shown in Table 28. However, we believe that this is an important flexibility for ensuring that copayment limits are actuarially equivalent to the maximum coinsurance percentages set in the regulation. In addition, using MA encounter utilization data in this manner may be one of the topics on which we could solicit comment through the subregulatory process finalized in paragraph (f)(7)(iii) for contract year 2024 and future years. Finally, use of MA encounter data will also be limited to the encounter data

that is available at the time of the necessary analyses and projections and appropriate for that use. Per § 422.310(g), MA organizations generally have until the January 2 years after the year in which an encounter occurred to submit all encounter data. As a result, this timeframe means that CMS does not always have complete years of MA encounter data that is as recent as the Medicare FFS claims data CMS will use in calculating MOOP and cost sharing limits. We will consider factors like this when deciding whether and when it is appropriate to use MA encounter data and whether sufficient MA encounter data is available to be used in calculating copayment limits under this FC.

CMS is also modifying the cost sharing regulations to clarify that the cost sharing limits may be a coinsurance limit or a copayment limit that is an actuarially equivalent dollar amount to the applicable coinsurance limit (subject to § 422.100(f)(7) and (8)) and clarify that the copayment limits may be calculated by CMS, or, if CMS does not calculate a copayment limit, the MA plan must establish a copayment that does not exceed the actuarially equivalent dollar amount to the applicable coinsurance limit. This is also discussed in section II.B.5.a. of this FC in relation to finalized paragraph (f)(6)(i). To be clear on this point in relation to cost sharing limits for professional services, we are finalizing new text in paragraph (f)(6)(iii)(B). We also clarify that where CMS does not calculate a copayment limit, finalized paragraph (f)(6)(iii)(B) nonetheless requires that the copayment amount used by the MA plan not exceed the actuarial equivalent of the coinsurance percentage, based on the estimated total MA plan financial liability for that benefit and contract year. While the proposed regulation text stated an absolute requirement in paragraphs (f)(6)(iii)(C)*(1)* through *(3)* that MA plans must pay not less than the specified percentage, we believe that additional clarity on this point improves the regulation. Under this FC, the copayment limits calculated by CMS take precedence but CMS does not intend to calculate and issue copayment limits for every imaginable benefit covered by Parts A and B. As discussed in section II.B.5.a. of this FC, new paragraphs (f)(7)(i) and (ii) codify how CMS uses Medicare FFS data projections in accordance with generally accepted actuarial principles and practices when calculating actuarially equivalent copayment values when multiple approaches are available. Referencing paragraph (f)(7) in paragraph (f)(6)(iii)(B) makes clear in the regulation that: (1) These standards apply to the copayment limits CMS calculates for professional services for contract year 2023 and subsequent years; and (2) the copayment limits will be updated annually based on the Medicare FFS data projections. In addition, the reference to paragraph (f)(8) in paragraph (f)(6)(iii)(B) applies the limit on increases to copayment limits and the copayment transition for how CMS calculates copayment limits for these professional services (discussed in more detail subsequently in this response). Paragraphs (f)(4)(i), (f)(6)(iii)(B), (f)(7), and (f)(8) together describe the Medicare FFS data projections and the process CMS uses in calculating cost sharing limits for professional services. Further, the process of identifying the data to be used will be subject to new paragraph (f)(7)(i) and its requirement to use actuarial principles and practices in calculating copayment limits under paragraphs (f) and (j).

As discussed in section II.B.5.a. of this FC, in relation to new § 422.100(f)(7)(i) and (ii), CMS intends to only issue and maintain copayment limits for service categories subject to § 422.100(f)(6) and (j)(1) when: (1) An actuarially equivalent copayment can be calculated using Medicare FFS data projections available to CMS and using generally accepted actuarial principles and practices; and (2) CMS believes calculating such a copayment limit is appropriate to carry out program purposes, including setting copayment limits that most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protecting against discriminatory cost sharing, and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries. Where CMS does not calculate the copayment limit, MA organizations must establish copayment amounts that comply with paragraph (f)(6)(iii) based on their estimated total MA plan financial liability for the benefit for that contract year. In doing so, MA organizations may use their data about cost and utilization of the relevant services in the plan (or segment, if applicable) and must also use generally accepted actuarial principles and practices. A decision by CMS not to calculate a copayment limit applying the rules in paragraphs (f)(6), (7), and (8) for a particular year will not prevent CMS from calculating and issuing the copayment limit in future years. Because paragraph (f)(6)(iii) purposefully does not include a complete list of professional services that are basic benefits, but is rather representative of examples of professional services, CMS may need to request supportive documentation from MA organizations regarding various covered services in cases where an MA plan has calculated an actuarially equivalent value to establish the copayment for a particular service. We note instructional guidance is provided in section II.B.5.a. of this FC on how MA organizations can prepare supporting documentation for copayments subject to paragraph (f)(6)(iii). Next, we discuss the commenter's specific recommendation to conduct a multiyear transition to reach the proposed range of cost sharing by the type of MOOP limit by contract year 2025.

We agree with the commenters that CMS should minimize potential market and beneficiary disruption as we shift away from cost sharing limits that have not been updated in recent years to the cost sharing limits we proposed and are finalizing. In addition, as we considered our proposal to make annual changes to the copayment limits for professional services based on updated Medicare FFS data projections, we examined how other policies proposed and finalized in § 422.100(f)(4) through (f)(6) include protections to guard against volatility and significant changes from one year to the next. For example, we structured the proposals in sections VI.A. and B. of the February 2020 proposed rule to transition changes, such as the proposed multiyear incorporation of ESRD costs into the methodology that CMS uses to calculate MOOP and inpatient hospital cost sharing limits. We also proposed, and are finalizing with modifications (as discussed in section II.A. of this FC), guardrails in paragraph (f)(4)(iv) and (f)(4)(v) to limit the amount of change from one year to the next in the MOOP limits. CMS's goal is to provide MA organizations the flexibility to design stable benefit structures from 1 year to the next as well as ensure that enrollee cost sharing does not discriminate against beneficiaries with high health care needs. We believe that having MOOP and cost sharing standards that are predictable and stable from 1 year to the next supports this goal. To ensure that this goal is met in connection with the cost sharing polices as well, we must also take into account the change from the current (contract years 2021 and 2022) cost sharing limits, particularly copayment limits, to cost sharing limits that will be set under this rule.

We developed our proposal to create reasonable differences (which took into

consideration the effect of the $5 increment rounding proposal for professional service categories) in the cost sharing permitted for different types of MOOP limit in order to create meaningful incentives for MA organizations to offer plans with lower MOOP limits. However, some of the contract year 2022 copayment limits have been in place for a number of years and were set to prohibit discriminatory cost sharing by striking a balance between limiting beneficiary out-of-pocket costs and the potential impact to plan design and costs, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. In the February 2020 proposed rule, we noted that we chose to assign actuarially equivalent copayments to 30 percent coinsurance for MA plans that establish a mandatory MOOP limit in order to be closer to the limits in the CY 2020 Call Letter for professional services. While MA plans (regardless of the type of MOOP limit) could have established a coinsurance up to 50 percent for professional services in contract year 2020, the copayment limits for the same professional service categories were approximately equal to 30 percent coinsurance for several of the professional service categories (based on the Medicare FFS data projections available at the time of the February 2020 proposed rule). As a result, while our proposal was designed to keep some copayment limits aligned with prior years by using a copayment limit that would be actuarially equivalent to 30 percent coinsurance, changing the coinsurance limit from 50 percent to 30 percent in one year represented a more significant change for MA plans that establish a mandatory MOOP limit. While MA plans may consider establishing lower MOOP limits based on the cost sharing flexibilities (which maintain a 50 percent coinsurance limit from prior years), we recognize that most plans currently utilize a mandatory MOOP limit and organizations may need time to modify provider contracts and their plan designs to accommodate a lower MOOP limit or a 20 percent increase in MA plan financial liability across several professional service categories.

Our proposed methodology to calculate copayment limits based on coinsurance percentages that are unique to the plan's MOOP limit type and the most recent Medicare FFS data projections available was, in effect, a proposal to recalibrate and update current copayment limits, using a methodology based on long-standing CMS policy with some changes. As a result, some of the illustrative copayment limits in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule represented substantial shifts from the 2020 and 2021 contract years. For example, as referenced by some commenters, the illustrative $85 copayment limit in the February 2020 proposed rule for the ''physical therapy and speech-language pathology'' service category (for MA plans that establish a mandatory MOOP limit) represented an increase of $45 from the contract year 2021 copayment limit for that service category. Similarly, the illustrative $80 copayment limit for the ''physician specialist'' service category in the February 2020 proposed rule (for MA plans that establish a lower MOOP limit) reflected an increase of $50 from the copayment limit established for 2021. These illustrative copayment limits (and the updated actuarially equivalent copayment values in Tables 14A, 14B, and 15) show how some of the copayment limits from contract year 2022 represent a significantly lower actuarially equivalent value than 50 percent coinsurance based on more recent Medicare FFS data projections. Despite the increases, CMS expects annually updating, based on the most recent Medicare FFS data projections, these long-standing copayment limits to values that are actuarially equivalent to coinsurance percentages will be an improvement from prior years. If CMS maintained copayment limits at lower amounts, MA organizations would still be able to establish higher cost sharing using coinsurance structures. Adopting requirements where the cost sharing limits are more equalized for coinsurance and copayment structures will provide transparency and more uniformity into the actual costs beneficiaries may experience.

We expect updating copayment limits to align with coinsurance limits based on the most recent Medicare FFS data projections will encourage the use of copayments in MA plan designs. We anticipate that MA organizations may take advantage of the increased flexibility for copayments resulting from this FC when establishing cost sharing for these service categories in future years. As stated in Chapter 4 of the MMCM, enrollees generally find copayment amounts more predictable and less confusing than coinsurance.[38] This is the case because copayments are defined amounts while coinsurance may have a unique cost sharing amount based on the particular provider and the amount that provider has negotiated with the MA plan as payment. Specifically, beneficiaries can more easily predict potential out-of-pocket costs for their expected health care needs over the year before receiving the services if copayment designs are used. If coinsurance designs are used, beneficiaries cannot make as accurate predictions until the unique cost sharing amount for the providers and services they expect to utilize are known. Therefore, changes that encourage the use of copayments may support beneficiaries in understanding their expected out of pocket costs in MA plans. We recognize that MA organizations may need time to modify provider contracts and prepare for implementing a copayment structure if they have previously used coinsurance structures in their plan designs. Updating the copayment limits to reflect the most recently developed actuarially equivalent values will also address the advances in medical technology utilized by the professional specialties, the costs MA organizations are expected to incur in providing these services for MA enrollees, and appropriate adjustments for medical inflation since the current copayment limits were last set. The cost sharing limits set in contract year 2022 have been in place for a number of years, so we are cognizant that an immediate change to the coinsurance and copayment limits established in this FC could be disruptive for some service categories if there is not a transition period. But we still expect that a transition to actuarially equivalent values for copayment limits, calculated at the coinsurance percentages that provide a meaningful differentiation between the types of MOOP limits, will ultimately result in stable benefit packages by ensuring cost sharing limits are calculated following established actuarial methods, using the most recent Medicare FFS data projections available, and by keeping copayment limits aligned with coinsurance limits.

In an effort to minimize the risk of disruptive changes and be responsive to commenters' concerns, we are finalizing a process to transition from current practice to the range of coinsurance and actuarially equivalent copayment limits based on the type of MOOP limit proposed in § 422.100(f)(6)(iii). We expect that a multiyear implementation schedule could be helpful to: (1)

[38] Loewenstein G, Friedman JY, McGill B, Ahmad S, Linck S, Sinkula S, Beshears J, J.Choi J, Kolstad J, Laibson D, Madrian BC, List JA, Volpp KG. ''Consumers' misunderstanding of health insurance''. Journal of Health Economics 2013;32(5):850–862. Retrieved from: *https://scholar.harvard.edu/laibson/publications/consumers-misunderstanding-health-insurance.*

Mitigate potentially disruptive changes based on the substantial projected increases to certain service category copayment limits resulting from using recent Medicare FFS data projections; and (2) be responsive to commenter requests to provide time for MA organizations and enrollees to adjust to updated cost sharing limits. We thank the commenter for providing the example (reproduced in Table 12) of how CMS could conduct a multiyear phase in to implement a range of cost sharing standards by the type of MOOP limit for professional services. We believe this recommendation effectively addresses the concerns to provide time for MA organizations and enrollees to adjust to updated coinsurance limits, with edits based on the timing of this FC and to remain consistent with our rounding proposal in paragraph (f)(6)(ii). Specifically, in the commenter's example the intermediate MOOP limit equaled 47.5 percent and 42.5 percent for contract years 2022 and 2024. As we proposed general rules to govern how CMS rounds down to the lower dollar amount in cases where the copayment limit is projected to be exactly between two increments in paragraph (f)(6)(ii)(B), we believe applying this methodology to the coinsurance limits (that are applied to the same service categories as those rounded copayment limits) is appropriate to continue protecting enrollees from higher costs by rounding down whenever possible. We also believe whole percentages would be more easily understood by beneficiaries and implemented by MA plans that use coinsurance structures. In addition, incorporating decimal point differences would necessitate changes to the existing PBP software while applying the rounding rules avoids such modifications. Further, CMS is delaying applicability of this provision to begin for contract year 2023 as discussed previously in section II.B.5. of this FC based on the timing of this FC, so we are not adopting the commenter's specific recommendation as reflected in Table 12. CMS is adopting a multiyear transition similar to the commenter's recommendation, to transition coinsurance limits from the prior 50 percent coinsurance standard. The transition schedule we are finalizing in § 422.100(f)(6)(iii) is in Table 13, which includes the coinsurance limits used for contract year 2022 to provide context.

TABLE 13: FINAL MULTIYEAR PHASE-IN FOR COINSURANCE LIMTS BASED ON THE MOOP TYPE FOR SERVICE CATEGORIES SUBJECT TO § 422.100(f)(6)(iii)

MOOP Type	2022	2023	2024	2025	2026 and Future Years
Lower (Previously "voluntary")	50%	50%	50%	50%	50%
Intermediate	N/A	47%	45%	42%	40%
Mandatory	50%	45%	40%	35%	30%

To implement the multiyear transition in Table 13 to the proposed coinsurance limits, CMS is finalizing additional paragraphs at § 422.100(f)(6)(iii)(D)–(F). The substance of what was proposed at paragraph (f)(6)(iii)(C) is being finalized at paragraph (f)(6)(iii)(F) to govern the cost sharing that is permitted for MA plans using the different MOOP types beginning with coverage in 2026. Specifically, for contract year 2023, as finalized at paragraph (f)(6)(iii)(C), MA plans must not exceed the cost sharing limits for professional service categories as follows:

- Mandatory MOOP limit: 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.
- Intermediate MOOP limit: 47 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 53 percent of the estimated total MA plan financial liability for the benefit.
- Lower MOOP limit: 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

As finalized, § 422.100(f)(6)(iii)(B) directs how copayment limits calculated by CMS take precedence over amounts MA organizations may calculate and applies to paragraphs (f)(6)(iii)(C)–(F). In addition, paragraph (f)(6)(iii)(C) no longer references paragraph (f)(6)(ii)(A) to reduce repetitive references to the rounding rules. All of the rounding rules under paragraph (f)(6)(ii) are applicable to the copayments calculated under paragraph (f)(6)(iii). Paragraphs (f)(6)(iii)(D) through (F) reflect the transition after contract year 2023, as included in Table 13.

Although this transition schedule we are finalizing in § 422.100(f)(6)(iii)(C) through (F) addresses our concerns about sudden changes to the permitted level of coinsurance, it does not fully address our concerns about how the majority of copayment limits for professional service categories that apply for contract year 2022 (which are similar if not the same as copayment limits in earlier years) are roughly an actuarial equivalent value to, or less than, 30 percent coinsurance (as discussed previously in this response). We believe additional steps are necessary to smooth the transition from the copayment limits announced for contract year 2022 for MA plans that use copayment structures instead of coinsurance. For example, the contract year 2022 copayment limit for the ''primary care physician'' service category was $35 (for both the voluntary and mandatory MOOP limits) and calculating copayment limits at actuarially equivalent values to 45, 47, and 50 percent for contract year 2023 (using contract year 2023 Medicare FFS data projections based on 2017 to 2021 Medicare FFS data), would increase the copayment limits to $50, $55, and $60 for the mandatory, intermediate, and lower MOOP limits, respectively. Then, in applying the coinsurance percentages finalized for contract 2026, our projections show the limits would decrease over the subsequent years to $35, $45, and $60 (the $35 and $45 amounts are the same as the illustrative

copayment limits for this service category in Table 5: ''Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits'' in the February 2020 proposed rule, while the illustrative copayment for the lower MOOP type was $55 based on 2015–2019 Medicare FFS data projections). This is because, as we discussed previously, contract year 2022 copayment limits for most professional service categories do not reflect actuarially equivalent dollar amounts to 50 percent coinsurance that are calculated using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). In comparison, the separate methodology we are finalizing in paragraph (f)(8) to transition copayment limits does not produce this type of fluctuation. For example, using the methodology in paragraph (f)(8) results in final contract year 2023 primary care copayment limits of $35, $40, and $40 for the mandatory, intermediate, and lower MOOP limits, respectively (as shown in Table 28). We prevent potentially disruptive changes to copayment limits during the transition of coinsurance limits if we use a separate transition for copayment limits. We next address new paragraph (f)(8) and the final rule policy to apply additional steps to transition the copayment limits that are subject to paragraph (f)(6)(iii).

New § 422.100(f)(8) provides a multiyear transition for how CMS will change copayment limits from their current (contract year 2022) level to actuarially equivalent values for service categories subject to paragraph (f)(6)(iii) (and § 422.100(j)(1) as discussed in section II.B.5.e. of this FC). This transition will also be conducted over contract years 2023 through 2025, and result in CMS calculating, for contract year 2026 and subsequent years, copayment limits using actuarial equivalent values to the coinsurance percentages proposed for each MOOP type. However, this transition for (and cap on increases for) copayment limits in paragraph (f)(8) will not apply to the service categories subject to paragraph (f)(6)(i) and (f)(6)(iv). We proposed separate approaches for calculating the cost sharing limits for the services addressed in paragraph (f)(6)(i) and (f)(6)(iv). For contract year 2023, CMS calculated copayment limits for two service categories included in the PBP that are subject to paragraph (f)(6)(i) based on a review of the contract year 2023 Medicare FFS data projections and consultation with the OACT. These two service categories are the ''DME—Diabetic Shoes or Inserts'' and ''DME—Diabetes Monitoring Supplies'' service categories (for the lower MOOP type). Because CMS has not previously issued copayment limits for these service categories for MA plans that establish a lower MOOP limit, a copayment transition is not necessary for the ''DME—Diabetic Shoes or Inserts'' or the ''DME—Diabetes Monitoring Supplies'' service categories or for the other service categories subject to paragraph (f)(6)(i) that did not have a specific copayment limit for contract year 2022. Our final policy for the service categories subject to paragraph (f)(6)(i) and (f)(6)(iv) is more comprehensively addressed in sections II.B.5.a. and c. of this FC. For contract year 2026 and subsequent years, when CMS calculates copayment limits for in-network professional services that are basic benefits, it will do so using the methodology in paragraphs (f)(6)(iii), (f)(7), and (j)(1) but not paragraph (f)(8).

Section 422.100(f)(8) limits the amount of annual increase in copayment limits for a service category subject to § 422.100(f)(6)(iii) or (j)(1) during the transition. Specifically, paragraph (f)(8) requires CMS to set these copayment limits at an amount that is the lesser of: (1) An actuarially equivalent value to the applicable cost sharing standard (from paragraph (f)(6)(iii) or (j)(1)); or (2) the value resulting from the actuarially equivalent copayment transition in paragraph (f)(8)(ii) for that service category. In addition, these copayment limits are all rounded as provided in paragraph (f)(6)(ii). The copayment limits calculated using the formula in paragraph (f)(8)(ii) act as a cap on the copayment limits CMS sets following the requirements in paragraph (f)(6)(iii)(C) through (E). By ''cap'' here and in the regulation text, we mean that increases to the copayment limit will be governed by the formula in paragraph (f)(8)(ii). For example, if the value that is actuarially equivalent to 40 percent coinsurance (the coinsurance limit applicable for contract year 2024 for the mandatory MOOP type) for a given professional service category is $100 when applying paragraph (f)(6)(iii)(D)*(1)* and the value is $75 when applying the formula in paragraph (f)(8)(ii), then the copayment limit set by CMS for that professional service in 2024 for MA plans that establish a mandatory MOOP amount is $75. In applying paragraphs (f)(6)(iii) and (f)(8), coinsurance and copayment limits are simultaneously transitioned to reach the proposed cost sharing limits by contract year 2026. As a result, the cost sharing limits (coinsurance and copayments) will be equalized (or actuarially equivalent to one another) by contract year 2026.

Section 422.100(f)(8)(i) defines the main component of the formula used in paragraph (f)(8)(ii) for this transition of copayment limits: The actuarially equivalent copayment differential. The methodology under paragraph (f)(8)(ii) occurs over 4 years (beginning for contract year 2023) and is structured in a similar manner as proposed (and finalized) for ESRD costs (as discussed in sections II.A. and II.B.5.c. of this FC). Similar to the ESRD cost transition, this actuarially equivalent copayment transition factors in an increasing percentage of the difference between two values. The ''actuarially equivalent copayment differential'' is defined in paragraph (f)(8)(i) as:

- For cost sharing at the mandatory and lower MOOP limits, the difference between, first, the copayment limit set for a plan benefit package service category based on the MOOP type for 2022 and second, the projected actuarially equivalent copayment value for the same service category and MOOP type based on the coinsurance limits in §§ 422.100(f)(6)(iii) and (j)(1) that apply in 2026.
- For cost sharing at the intermediate MOOP limit, the difference between, first, the copayment limit set for a plan benefit package service category based on the mandatory MOOP type for 2022 and second, the projected actuarially equivalent copayment value for the same service category based on the coinsurance limits in §§ 422.100(f)(6)(iii) and (j)(1) that apply for the intermediate MOOP type in 2026.

Given the limited number of professional service categories in contract year 2022 that had cost sharing limits differentiated by the type of MOOP limit, the first value (for most comparisons) will be based on the same figure for each professional service category for which CMS may calculate copayment limits during the transition. The second value (the actuarially equivalent copayment to the applicable cost sharing standard) will be recalculated each year using updated Medicare FFS data projections, consistent with the standards in paragraph (f)(7). This definition of the ''actuarially equivalent copayment differential'' means that each year, for each service category subject to paragraph (f)(6)(iii) to which paragraph (f)(8)(i) applies, CMS will calculate the difference between these two figures for each service category:

- For the mandatory MOOP limit: The copayment limit set for contract year 2022 for the mandatory MOOP

limit and the copayment value that is actuarially equivalent to 30 percent (the coinsurance limit that applies in 2026) using the Medicare FFS data projections (updated each year) to reflect the costs of the contract year for which the copayment limit will apply.

• For the intermediate MOOP limit: The copayment limit set for contract year 2022 for the mandatory MOOP limit and the copayment value that is actuarially equivalent to 40 percent (the coinsurance limit that applies in 2026) using the Medicare FFS data projections (updated each year) to reflect the costs of the contract year for which the copayment limit will apply.

• For the lower MOOP limit: The copayment limit set for contract year 2022 for the voluntary MOOP limit and the copayment value that is actuarially equivalent to 50 percent (the coinsurance limit that applies in 2026) using the Medicare FFS data projections (updated each year) to reflect the costs of the contract year for which the copayment limit will apply.

In comparison, the ''actuarially equivalent copayment differential'' as defined and applied to service categories subject to § 422.100(j)(1) (as discussed in section II.B.5.e. of this FC) means that CMS will calculate, for all MOOP limits (unless otherwise specified in paragraph (j)(1)(i)), the difference between these two figures for each service category: (1) The copayment limit set for contract year 2022 and (2) the copayment value that is actuarially equivalent to cost sharing under original Medicare that applies in 2026 using the Medicare FFS data projections (updated each year) to reflect the costs of the contract year for which the copayment limit will apply. Assuming that there are no changes to cost sharing rules in original Medicare, this second figure will be an actuarially equivalent value to 20 percent coinsurance for most of the services listed in § 422.100(j)(1).

As a result, the value of the ''actuarially equivalent copayment differential'' is unique for each service category, MOOP type, and contract year. Tables 14A, 14B, and 15 illustrate how the actuarially equivalent copayment differential is calculated in row H in each table.

Section 422.100(f)(8)(ii) provides the specific formula CMS will follow to complete the actuarially equivalent copayment transition. Specifically, CMS will add a percentage of the ''actuarially equivalent copayment differential'' identified for each service category, MOOP type, and contract year to the copayment limit set for contract year 2022 for that service category. The percentage of the actuarially equivalent copayment differential that will be used each year is as follows:

• Contract Year 2023: 25 percent.
• Contract Year 2024: 50 percent.
• Contract Year 2025: 75 percent.

This means that for each year and service category subject to § 422.100(f)(6)(iii) or (j)(1) to which (f)(8)(ii) applies, CMS will calculate the transitional value under paragraph (f)(8) that will be compared to what is actuarially equivalent to the applicable coinsurance limit for that contract year to determine which is the lesser value. Each year, CMS will use the most recent Medicare FFS data projections for the contract year to calculate these figures. Specifically, for contract year 2023, the formula to calculate the transitional value is as follows:

• For the mandatory and lower MOOP limits: The respective copayment limits set for 2022 plus 25 percent of the actuarially equivalent copayment differential.

• For the intermediate MOOP limit: The copayment limits set for 2022 for the mandatory MOOP limit plus 25 percent of the actuarially equivalent copayment differential.

By capping the copayment limits to the ''lesser of'' value for years 2023 through 2025, we aim to smooth the transition from the current (contract year 2022) copayment limits to the copayment limits that will be based on the coinsurance levels permitted for each type of MOOP limit. The transition adopted at § 422.100(f)(8) applies only to copayment limits that were set for contract year 2022. If CMS calculates a copayment limit for a new service category (where a copayment limit was not set for contract year 2022) that would be subject to either § 422.100(f)(6)(iii) or (j)(1) during this transition period, those copayment limits for those new service categories would be calculated at a value that is actuarially equivalent to the coinsurance percentage for the applicable MOOP limit under the rules in paragraphs (f)(6)(iii) and (j)(i).

As referenced in section II.B.5.a. of this FC, CMS may calculate copayment limits for any category of professional services that are basic benefits for 2023 and future years. Our intention is to calculate copayment limits for as many service categories as possible that are subject to § 422.100(f)(6)(i), (iii), and (j)(1). In this FC, we apply § 422.100(f)(6)(iii) to calculate final contract year 2023 copayment limits for the same professional service categories for which CMS set copayment limits in contract year 2022. Tables 14A and 14B show the calculations of contract year 2023 copayment limits for several professional services categories for MA plans that establish a mandatory MOOP type; CMS used contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data) to develop these tables. Calculations similar to those shown in Tables 14A and 14B was used to reach the final contract year 2023 copayment limits included in Table 28 for MA plans that establish a lower or intermediate MOOP type. As an example, calculations of the contract year 2023 copayment limits for the ''cardiac rehabilitation'' service category for all MOOP types is provided in Table 15. The calculation of a contract year 2023 copayment limit for the ''Part B drugs—Other'' service category is not included in Table 14A or 14B, as CMS is not finalizing a range of coinsurance limits based on the type of MOOP limit for this service category, as discussed in section II.B.5.e. of this FC.

Tables 14A and 14B illustrate how CMS applies the methodology in § 422.100(f)(8) to calculate transitional copayment limits for service categories subject to paragraph (f)(6)(iii) for contract year 2023. The total projected Medicare FFS cost for each service category in Tables 14A, 14B, and 15 is based solely on Medicare FFS data (MA encounter data for the same time period was unavailable at the time of writing this FC). In addition, the total projected Medicare FFS cost reflects the lesser value (that is, when a median and weighted average amount were compared, we selected the lesser value) for the service categories in Tables 14A, 14B, and 15 except for ''urgently needed services''. The total projected Medicare FFS weighted average and median amounts for ''urgently needed services'' for contract year 2023 are $134.00 and $113.00, respectively. The standard finalized in paragraph (f)(7)(ii)(C) authorizes CMS to select among different approaches to avoid unnecessary fluctuations in the copayment limit, so we choose to use the higher amount ($134.00) as the contract year 2023 total Medicare FFS projected cost for this service category. Specifically, using the higher $134.00 weighted average to calculate contract year 2023 copayment limits for the ''urgently needed services'' service category decreases the amount of change from the contract year 2022 copayment limit ($65 for both MOOP types) in comparison to the transitional copayment limits that would result from using the $113.00 median value.

As shown in Tables 14A, 14B, and 15, CMS calculated an actuarially equivalent copayment to the coinsurance limit applicable for contract

year 2023 (45 percent for the mandatory MOOP limit, per paragraph (f)(6)(iii)(C)) for each service category by using the total projected Medicare FFS cost (in row B from Tables 14A, 14B, and 15). CMS calculated the transitional copayment value using the methodology finalized in paragraph (f)(8)(ii). As shown in Tables 14A and 14B, we calculated the actuarially equivalent copayment value based on 30 percent coinsurance of the total projected Medicare FFS cost (that is, the coinsurance limit for contract year 2026 for the mandatory MOOP limit, per paragraph (c)(6)(iii)(F)) and compared that value to the contract year 2022 copayment limit for the same service category and MOOP limit to reach the ''actuarially equivalent copayment differential''. Then, we took 25 percent of the ''actuarially equivalent copayment differential'' and added it to the contract year 2022 copayment amount and applied the rounding rules in paragraph (f)(6)(ii) to reach the transitional contract year 2023 copayment value for that service category and MOOP type (the values in row K in Tables 14A and 14B). Then, we compared the transitional copayment values (calculated following paragraph (f)(8)(ii)) to the actuarially equivalent value of the applicable cost sharing standard for contract year 2023 (calculated following paragraph (f)(6)(iii)(C)). The lesser value between these two amounts is included in row L of Tables 14A and 14B as the contract year 2023 copayment limit for that service category and MOOP type.

For example, as shown in Table 14B, the contract year 2022 ''primary care physician'' service category copayment limit for MA plans that established a mandatory or voluntary (lower) MOOP amount was $35. Using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data), a $35 copayment is actuarially equivalent to 30 percent coinsurance. In essence, this means that the final contract year 2023 copayment limit for the ''primary care physician'' service category and mandatory MOOP type reflects an actuarially equivalent copayment to the 2026 standard for that MOOP type in paragraph (f)(6)(iii)(F). In comparison, the copayment limit for this service category and the lower MOOP type is a transitional value, and not fully actuarially equivalent to the 2026 standard for that MOOP type (increasing from $35 for contract year 2022 to $40 for contract year 2023 as shown in Table 28). As a result, the multiyear transition in paragraph (f)(8) for CMS to calculate actuarially equivalent copayment limits avoids unnecessary changes to the copayment limits from year to year.

The ''lesser of'' values in row L of Tables 14A, 14B, and 15 are in Table 28 as the final contract year 2023 copayment limits for the respective MOOP types. Table 28 updates the illustrative cost sharing limits for all three MOOP types from the February 2020 proposed rule's Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits), using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data) and applying the requirements finalized in paragraphs (f)(6), (7), (8), and § 422.100(j)(1). As a result, the final contract year 2023 copayment limits in Table 28 are consistent with how paragraph (f)(8) provides that the lesser of values calculated under paragraphs (f)(6)(iii) and (j)(1) and values calculated under paragraph (f)(8) will be used as the copayment limit for a particular service category and cost sharing level. In addition, Table 28 includes final contract year 2023 copayment limits for several service categories that did not have illustrative copayment limits in the February 2020 proposed rule. Final contract year 2023 copayment limits for the following professional service categories are in Table 28 but were not illustrated in the similar table in the February 2020 proposed rule: Cardiac rehabilitation; intensive cardiac rehabilitation; pulmonary rehabilitation; Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD); and partial hospitalization. These are all professional services subject to the methodology finalized in § 422.100(f)(6)(iii), (f)(7), and (f)(8). This is consistent with the general approach we proposed that the same rules would apply for all professional services if CMS issues copayment limits, regardless of whether we had calculated a copayment limit for the category in the past. By following the ''lesser of'' requirement in paragraph (f)(8), choosing the measure of central tendency which produces the least amount of change from the prior contract year (as allowed in paragraph (f)(7)) when calculating actuarially equivalent values, and setting copayment limits for the service categories we have historically used for contract year 2023, we aim to avoid potentially disruptive copayment changes, such as copayment limits that fluctuate up and down over short periods of time, for enrollees and plan designs.

Tables 14A, 14B, and 15 also illustrate how CMS will generally approach applying the methodology in § 422.100(f)(8) for service categories subject to paragraph (f)(6)(iii) for contract years 2024 and 2025. Specifically, CMS will complete similar calculations of the copayment limits for contract years 2024 and 2025 as shown in Tables 14A, 14B, and 15 with modifications to reflect the specific coinsurance limits for each year, increases in the actuarial equivalent copayment differential used (per paragraph (f)(8)), and updates to the total Medicare FFS costs for each service category using the most recent Medicare FFS data projections.

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TABLE 14A: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR SERVICE CATEGORIES IN PBP SECTIONS 3, 4b, AND 5 SUBJECT TO § 422.100(f)(6)(iii) FOR THE MANDATORY MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Intensive Cardiac Rehabilitation	Pulmonary Rehabilitation	SET for PAD	Urgently Needed Services	Partial Hospitalization
A	Contract year 2022 copayment limit	$100.00	$30.00	$30.00	$65.00	$55.00
B	Contract year 2023 total Medicare FFS projected cost[1]	$132.00[2]	$39.00[2]	$65.00[2]	$134.00[3]	$275.00[4]
C	Contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C)(*1*)	45%	45%	45%	45%	45%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row B multiplied by row C)	$59.40	$17.55	$29.25	$60.30	$123.75
E	Rounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row D rounded per § 422.100(f)(6)(ii))	$60.00	$20.00	$30.00	$60.00	$125.00
F	Contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F)(*1*)	30%	30%	30%	30%	30%
G	Unrounded actuarially equivalent copayment value to contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F) (row B multiplied by row F)	$39.60	$11.70	$19.50	$40.20	$82.50
H	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row G and row A)	($60.40)	($18.30)	($10.50)	($24.80)	$27.50
I	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row H multiplied by 0.25)	($15.10)	($4.58)	($2.63)	($6.20)	$6.88
J	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row I)	$84.90	$25.43	$27.38	$58.80	$61.88
K	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	$85.00	$25.00	$25.00	$60.00	$60.00
L	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value of row E and row K)	$60.00	$20.00	$25.00	$60.00	$60.00

[1]The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7).
[2]These amounts represent the total projected Medicare FFS average per session allowed amount for the service category in contract year 2023, weighted by the type of setting (such as, hospital outpatient departments and provider offices).
[3]This amount for the "urgently needed services" service category represents the total projected Medicare FFS weighted average per visit allowed amount for contract year 2023.
[4]This amount for the "partial hospitalization" service category represents the total projected Medicare FFS average per day allowed amount, weighted by the type of setting (such as, hospital outpatient departments and community mental health centers).

TABLE 14B: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR SERVICE CATEGORIES IN PBP SECTIONS 7a – 7e and 7h-7i SUBJECT TO § 422.100(f)(6)(iii) FOR THE MANDATORY MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Primary Care Physician	Chiropractic Care	Occupational Therapy	Physician Specialist	Mental Health Specialty Services	Psychiatric Services	Physical Therapy and Speech-language Pathology
A	Contract year 2022 copayment limit	$35.00	$20.00	$40.00	$50.00	$40.00[1]	$40.00[1]	$40.00
B	Contract year 2023 total Medicare FFS projected cost[2]	$115.91	$52.00	$125.00	$179.64	$153.30	$145.00	$178.96
C	Contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C)(*1*)	45%	45%	45%	45%	45%	45%	45%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row B multiplied by row C)	$52.16	$23.40	$56.25	$80.84	$68.99	$65.25	$80.53
E	Rounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row D rounded per § 422.100(f)(6)(ii))	$50.00	$25.00	$55.00	$80.00	$70.00	$65.00	$80.00
F	Contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F)(*1*)	30%	30%	30%	30%	30%	30%	30%
G	Unrounded actuarially equivalent copayment value to contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F) (row B multiplied by row F)	$34.77	$15.60	$37.50	$53.89	$45.99	$43.50	$53.69
H	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row G and row A)	($0.23)	($4.40)	($2.50)	$3.89	$5.99	$3.50	$13.69
I	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row H multiplied by 0.25)	($0.06)	($1.10)	($0.63)	$0.97	$1.50	$0.88	$3.42

Row Reference	Description	Primary Care Physician	Chiropractic Care	Occupational Therapy	Physician Specialist	Mental Health Specialty Services	Psychiatric Services	Physical Therapy and Speech-language Pathology
J	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row I)	$34.94	$18.90	$39.38	$50.97	$41.50	$40.88	$43.42
K	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	$35.00	$20.00	$40.00	$50.00	$40.00	$40.00	$45.00
L	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value of row E and row K)[3]	$35.00	$20.00	$40.00	$50.00	$40.00	$40.00	$45.00

[1]This amount reflects the copayment limit for the "psychiatric and mental health specialty services" service category as it was named for contract year 2022.

[2]Each amount represents the total average per visit Medicare FFS allowed amount for the service category, weighted by specialty type utilization (such as, family practice, general practice, internal medicine, and geriatric medicine for the primary care physician service category). The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7)).

TABLE 15: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR THE CARDIAC REHABILITATION SERVICE CATEGORY (SUBJECT TO § 422.100(f)(6)(iii)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Mandatory MOOP Limit	Intermediate MOOP Limit	Lower MOOP Limit
A	Contract year 2022 copayment limit	$50.00	N/A	$50.00
B	Contract year 2023 total Medicare FFS projected cost	$84.00[1]		
C	Contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C)	45%	47%	50%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row B multiplied by row C)	$37.80	$39.48	$42.00
E	Rounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row D rounded per § 422.100(f)(6)(ii))	$40.00	$40.00	$40.00
F	Contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F)	30%	40%	50%
G	Unrounded actuarially equivalent copayment value to contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F) (row B multiplied by row F)	$25.20	$33.60	$42.00
H	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row G and row A)	($24.80)	($16.40)[2]	($8.00)
I	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row H multiplied by 0.25)	($6.20)	($4.10)	($2.00)
J	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row I)	$43.80	$45.90[2]	$48.00
K	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	$45.00	$45.00	$50.00
L	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value of row E and row K)	$40.00	$40.00	$40.00

[1]This amount represents the total average Medicare FFS per session allowed amount for the service category, weighted by the type of setting (such as, hospital outpatient departments and provider offices) for contract year 2023. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (as finalized in § 422.100(f)(7).

[2]For purposes of calculating these values for the intermediate MOOP limit, the comparison amount in row A for the mandatory MOOP limit is used per § 422.100(f)(8)(i)(B).

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As shown in Tables 15 and 28, some contract year 2023 service category copayment limits are the same amount for multiple MOOP types (for example, a $40 ''cardiac rehabilitation services'' service category copayment limit for all MOOP types in contract year 2023). Some copayment limits are the same in the beginning of the transition because most professional categories have the same contract year 2022 copayment limit, along with the rounding rules. We do not expect the number of professional service categories with the same copayment limit will result in the number of MA plans with lower MOOP limits decreasing significantly because the cost sharing flexibilities generally provide differentiation for most service categories by MOOP type throughout the transition period. In addition, we currently project (based on contract year 2023 Medicare FFS data projections) that all service categories subject to paragraph (f)(6)(iii) will have differentiated copayment limits based on the MOOP type once the transition in paragraph (f)(8) is completed in contract year 2026. Under this FC, the OACT will annually update the Medicare FFS data projections used to calculate copayment limits, so the actual copayment limits for professional services for contract year 2024 and subsequent years, calculated by applying the rules in § 422.100(f)(6)(iii), (7), and (8), could increase or decrease accordingly.

As shown in Tables 14A, 15, and 28, the contract year 2023 copayment limits for the cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation service categories reflect decreases from the corresponding contract year 2022 copayment limits for both MOOP types. CMS calculated actuarially equivalent copayments for these service categories by using the contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data) of the total average per session cost (weighted by utilization of office and outpatient facilities). As a result, Medicare FFS data reflects changes in CMS payment policies, provider billing practices, and where services are provided (for example, hospital outpatient department or physician's office). In addition, the contract year 2023 copayment limits set for these service categories reflect application of the ''lesser of'' requirement in § 422.100(f)(8); the actuarially equivalent value to the coinsurance limit for contract year 2023 is less than the value resulting from the actuarially equivalent copayment transition (after application of the rounding rules) for all MOOP types. The projected Medicare FFS amounts for cardiac rehabilitation and intensive cardiac rehabilitation also comply with Medicare FFS payment requirements from sections 1848(A)(5) and 1861(E) of the Act. These factors in combination result in the decreases in copayments limits for these three service categories from the contract year 2022 copayment limits.

As finalized in new § 422.100(f)(8)(ii)(D), the transition to actuarially equivalent copayment limits will be complete by contract year 2026 and no cap on increases in copayment limits apply for contract year 2026 or later years. For contract year 2026 and subsequent years, CMS may calculate copayment limits for—

- In-network professional services that are basic benefits: At an actuarially equivalent copayment value to the coinsurance percentage required for the type of MOOP limit, under paragraph (f)(6)(iii)(F); and
- In-network benefits subject to § 422.100(j)(1)(i): At actuarially equivalent values to the cost sharing under original Medicare (see additional discussion in section II.B.5.e. of this FC).

In essence, we are finalizing a process of continuous recalibration of copayment limits for service categories subject to paragraph (f)(6)(iii) or (j)(1) to ensure those limits are appropriately updated to align with the coinsurance limits based on annually updated Medicare FFS data projections. This is consistent with our proposal to set the actuarially equivalent copayment values each year, by working with the OACT to establish copayment limits that are approximately equal to the identified coinsurance percentage limit based on the most recent Medicare FFS data projections.

Using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data), applying § 422.100(f)(8), combined with the effect of applying the rounding rules, results in some service categories for particular MOOP types reaching an actuarially equivalent copayment value before contract year 2026 while others are currently expected to take the full 4 years to reach a copayment limit that is an actuarially equivalent value to the applicable coinsurance requirement. Some of these potential outcomes for professional service categories are illustrated in Tables 16 and 17.

Table 16 illustrates how CMS would calculate the actuarially equivalent copayment transition (including the ''lesser of'' requirement) over the 4 years for the ''SET for PAD'' service category using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). (We reiterate that the transition provided in § 422.100(f)(8) only applies when: (1) CMS is calculating a copayment limit under paragraph (f)(6)(iii) for basic benefits that are professional services and § 422.100(j)(1) for basic benefits for which the cost sharing may not exceed cost sharing in original Medicare; and (2) there was a copayment limit published for contract year 2022 for that service category. When CMS does not calculate the copayment limit as a specific dollar amount, the MA plan would be in the position of calculating an actuarially equivalent value that the MA plan's copayments may not exceed.) For contract year 2022, the cost sharing limits for the ''SET for PAD'' service category are 50 percent coinsurance or a $30 copayment for MA plans with the voluntary or mandatory MOOP type. As shown in Table 16, the mandatory MOOP limit is currently projected to reach an actuarially equivalent value based on 30 percent coinsurance in contract year 2025 for the ''SET for PAD'' service category, while the lower MOOP limit retains its copayment limit from contract year 2022 as that is the projected actuarially equivalent value to 50 percent coinsurance. Although the February 2020 proposed rule stated that 30 percent coinsurance is most closely related to the professional service category copayment limits from the CY 2020 Call Letter, that is not the case for every service category. For example, using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data), the contract year 2022 copayment limits for the ''urgently needed services'' and ''SET for PAD'' service categories reflect an actuarially equivalent copayment value to 50 percent coinsurance. As a result, the lower MOOP type retains the contract year 2022 copayment limit for the ''urgently needed services'' and ''SET for PAD'' service categories for contract year 2023 and the copayment limit for the mandatory MOOP type reflects a decrease from the contract year 2022 copayment limit in the first year of the transition to the lower coinsurance standard for that MOOP type. However, we emphasize that the copayment limits contained in Table 16 for contract years 2024–2026 are illustrative in nature and may change based on updated Medicare FFS data projections.

TABLE 16: FINAL CONTRACT YEAR 2023 AND ILLUSTRATIVE CONTRACT YEAR 2024 – 2026 COST SHARING LIMITS FOR THE "SET FOR PAD" SERVICE CATEGORY DURING THE MULTIYEAR TRANSITION (§ 422.100(f)(6)(iii) AND (f)(8)(i)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

MOOP Type	Contract Year 2022[1]	Contract Year 2023[2]	Contract Year 2024[3]	Contract Year 2025[3]	Contract Year 2026[3]
Mandatory	50% / $30	45% / $25	40% / $25	35% / $20[4]	30% / $20
Intermediate	N/A	47% / $30	45% / $30	42% / $25[5]	40% / $25
Lower (Previously "voluntary")	50% / $30	50% / $30[6]	50% / $30	50% / $30	50% / $30

[1]Cost sharing limits for contract year 2022 provided for comparison purposes.
[2]The contract year 2023 cost sharing limits are final and calculated using § 422.100(f)(6), (f)(7), and (f)(8).
[3]The copayment limits for these years are illustrative and final amounts will be announced using the subregulatory process at § 422.100(f)(7)(iii). The coinsurance limits for these years are final per § 422.100(f)(6)(iii).
[4]This is the projected year in which the copayment limit will reach an actuarially equivalent value to 30 percent coinsurance for the mandatory MOOP limit.
[5] This is the projected year in which the copayment limit will reach an actuarially equivalent value to 40 percent coinsurance for the intermediate MOOP limit.
[6] The contract year 2023 copayment limit for the lower MOOP limit reflects an actuarially equivalent value to 50 percent coinsurance.

Table 17 illustrates how CMS will apply both the copayment and coinsurance transitions to the ''physician specialist'' service category through contract year 2026, using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). Cost projections for contract years after 2023 were not available at the time of writing this FC, however Table 17 illustrates the potential impact of the transition rule in calculating cost sharing limits for contract years 2024 through 2026. For example, Table 17 shows that in implementing a 4-year transition, an actuarially equivalent copayment limit to 30 percent coinsurance for the mandatory MOOP type may take the full 4 years to reach for the ''physician specialist'' service category. We reiterate that while the transition of the applicable coinsurance percentage and the rules for CMS to calculate the copayment limits are set in this FC, the copayment limits provided in Tables 16 and 17 for contract years 2024 through 2026 are illustrative in nature and may change based on updated Medicare FFS data projections in future years. Tables 16 and 17 highlight how the transition schedules result in annual incremental changes in order to reach the cost sharing limits that we proposed by contract year 2026.

TABLE 17: FINAL CONTRACT YEAR 2023 AND ILLUSTRATIVE CONTRACT YEAR 2024 – 2026 COST SHARING LIMITS FOR THE "PHYSICIAN SPECIALIST" SERVICE CATEGORY DURING THE MULTIYEAR TRANSTION (§ 422.100(f)(6)(iii) AND (f)(8)(i)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

MOOP Type	Contract Year 2022[1]	Contract Year 2023[2]	Contract Year 2024[3]	Contract Year 2025[3]	Contract Year 2026[3,4]
Mandatory	50% / $50	45% / $50	40% / $50	35% / $55	30% / $55
Intermediate	N/A	47% / $55	45% / $60	42% / $65	40% / $70
Lower (Previously "voluntary")	50% / $50	50% / $60	50% / $70	50% / $80	50% / $90

[1]Cost sharing limits for contract year 2022 provided for comparison purposes.
[2]The contract year 2023 cost sharing limits are final and calculated using § 422.100(f)(6), (f)(7), and (f)(8).
[3]The copayment limits for these years are illustrative and final amounts will be announced using the subregulatory process at § 422.100(f)(7)(iii). The coinsurance limits for these years are final per § 422.100(f)(6)(iii).
[4] This is the projected year in which the copayment limits will reach actuarially equivalent values to the coinsurance standard that applies for 2026 for each MOOP type.

The multiyear transition schedule for copayment limits calculated by CMS will generally be applied consistently across professional services (including urgently needed services) and benefits for which cost sharing must not exceed cost sharing in original Medicare (as discussed previously in this response and in sections II.B.5.d. and e. of this FC) in order to streamline the methodology and preserve transparency as much as possible while meeting our goals of avoiding significant year-to-year changes in copayment limits. We expect the completion of the multiyear transition to the range of cost sharing limits proposed will: (1) Improve the accuracy of copayment limits by using

annually updated Medicare FFS data projections; (2) increase the flexibility MA organizations have in establishing copayments; (3) encourage the use of copayments and lower MOOP limits among MA plans; and (4) mitigate potential premium increases or benefit reductions if copayment limits did not accurately reflect projected costs.

In summary, we believe that using the multiyear transitions (for contract years 2023 through 2026) finalized in § 422.100(f)(6)(iii)(C)–(F) and (f)(8) provide sufficient time for MA organizations to address the upcoming changes to these cost sharing requirements; we do not expect this policy to directly cause plans to non-renew or to cause considerable disruption in the MA market or for beneficiaries. CMS requested comments and suggestions on its application and interpretation of the existing MOOP and cost sharing standards, as well as on adding a third, MOOP limit to allow additional cost sharing flexibility for future years, as part of the CY 2020 Call Letter [39] process. CMS took the suggestions received then into account when developing the February 2020 proposed rule. We therefore expect that these opportunities to comment on these concepts provided MA organizations and other stakeholders with additional time to anticipate and prepare for changes like those we are adopting here.

To provide additional transparency regarding how § 422.100(f)(6)(iii), (f)(7), and (f)(8) will be applied in future contract years, we provide an example of the steps CMS will take to calculate copayment limits for the ''physician specialist'' service category for contract year 2027 or a subsequent year. First, CMS will consider and decide whether issuing a copayment limit for the ''physician specialist'' service category is appropriate; we intend to review and consider the following using the most recent Medicare FFS data projections as part of this decision:

- The projected Medicare FFS costs and utilization for the relevant provider specialties for furnishing specialty physician services, such as average costs and utilization for the following provider specialties: Cardiology, gastroenterology, nephrology, and otolaryngology (ENT); and
- Updated analyses of actuarially acceptable approaches to calculate an actuarially equivalent value to the applicable cost sharing standard in § 422.100(f)(6)(iii) from the OACT (for example, with or without waiting for utilization, or projected median total Medicare FFS allowed amounts or a Medicare FFS projected claims cost distribution).

As a result, some potential outcomes of applying paragraphs (f)(6)(iii)(F), (f)(7), and (f)(8)(ii)(D) to calculate copayment limits for the ''physician specialist'' service category for contract year 2027 may include the following:

- Maintaining the contract year 2026 copayment limits for contract year 2027 if the most recent Medicare FFS projections of the weighted average do not result in different actuarially equivalent values to the range of cost sharing standard (after application of the rounding rules in § 422.100(f)(6)(ii)).
- Calculating updated copayment limits for contract year 2027 if the Medicare FFS data projections for the relevant provider specialties for furnishing specialty physician services result in different actuarially equivalent values to the range of cost sharing standard (after application of the rounding rules in § 422.100(f)(6)(ii)).
- Calculating updated copayment limits for contract year 2027 that are based on different actuarial approaches to calculating an actuarially equivalent value (for example, adjusting for outliers by using the median allowed amounts of the various provider specialties) if the different approach reflects an actuarially acceptable approach and avoids disruptive changes (in essence, higher increases to the copayment limit) for beneficiaries and plan designs, consistent with § 422.100(f)(7)(ii)(C). For example, if using the median allowed amount compared to the average allowed amount would result in a lesser increase to the copayment limit from the prior year while still reflecting an actuarially equivalent copayment for the benefit and beneficiary population.
- Not calculating an actuarially equivalent value to be the copayment limit, thus permitting MA plans to analyze their own data on the estimated total MA plan financial liability for that contract year to calculate the dollar amount that is actuarially equivalent to the applicable coinsurance percentage and establish the MA plan's copayment at or below that dollar amount. Each of these potential outcomes would include compliance with § 422.100(f)(7)(iii), which provides for an opportunity for public notice and comment.

By applying the requirements in § 422.100(f)(6)(iii), (f)(7), and (f)(8) to recalibrate copayment limits based on Medicare FFS data projections on an annual basis, we will ensure copayment limits continually align with the coinsurance limits for service categories subject to paragraphs (f)(6)(i), (iii), and (j)(1) in future years. As discussed in section II.A. of this FC, we are also annually recalibrating MOOP limits based on Medicare FFS data projections to accurately reflect changes in expected costs, subject to the limit on changes in the MOOP limit of more than 10 percent from one year to the next. We believe that updates of this type are appropriate to carry out the goal of the February 2020 proposed rule to continue balancing limits on enrollee cost sharing and changes in benefits with maintaining beneficiary access the affordable and sustainable benefit packages and protecting against discriminatory cost sharing. The methodology in this FC coordinates the updates to the MOOP limits and cost sharing standards for contract year 2023 and future years.

In summary, as discussed in the February 2020 proposed rule, we believe providing MA organizations with the cost sharing flexibilities in § 422.100(f)(6)(iii) will ultimately act as an incentive to encourage more favorable benefit designs for beneficiaries. While we are finalizing transitions to the proposed coinsurance and copayment limits in paragraphs (f)(6)(iii)(C)–(F) and (f)(8), we do not expect the breadth of cost sharing flexibilities will be substantially limited between the three MOOP types during the transition. Specifically, we believe the policies in this FC may incentivize MA organizations to design favorable benefit packages such as through establishing lower or intermediate MOOP amounts and adopt cost sharing that is lower or comparable when compared to existing benefit packages while protecting enrollees from significant annual changes during the transition period.

With respect to the commenter's concern about MA plans being challenged to satisfy the total beneficiary cost (TBC) standard if cost sharing requirements are changed to the range of cost sharing limits proposed in a single year, the TBC standard evaluates year-over-year plan changes in premiums and benefits for purposes of CMS's review and acceptance of bids. The TBC change threshold is determined each year based on a number of factors. CMS has authority to reject bids that propose significant increases in beneficiary costs or decreases in benefits under § 422.254 and uses the TBC evaluation to identify bids that make such significant changes compared to the prior year. See also section 1854(a)(5)(C)(ii) of the Act and § 422.256(a). The TBC threshold for

[39] See pages 159–161 of the CY 2020 draft Call Letter at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.*

contract year 2021 was increased to account for changes in ESRD enrollment policy and to provide greater flexibility to MA plans in navigating related MOOP limit changes.[40] The TBC threshold for contract year 2022 was maintained from contract year 2021.[41] CMS released an HPMS memorandum titled ''Preliminary Contract Year 2023 Part C Benefits Review and Evaluation'' on March 3, 2022 (with a comment period) that includes potential changes to the TBC threshold for contract year 2023. CMS will also consider soliciting comment on how CMS sets the TBC threshold for contract year 2024 and future years, if necessary. By finalizing the multiyear transition to the proposed range of cost sharing limits based on the MOOP type in § 422.100(f)(6)(iii) and (f)(8), we do not expect unreasonable challenges for an MA organization to satisfy the TBC evaluation. We intend to continue use of the TBC evaluation to make sure enrollees who continue enrollment in the same plan are not exposed to significant cost increases.

Comment: A commenter requested CMS add cost sharing limits for observation services and ambulance services, and clearly differentiate the maximum copayment limits for these services by the type of MOOP limit.

Response: Ambulance services and observation services (as bundled services under outpatient hospital services) are not inpatient services (§ 422.100(f)(6)(iv)), and are not necessarily professional services (paragraph (f)(6)(iii)), or among the specified categories of services for which cost sharing must not exceed the cost sharing in original Medicare (§ 422.100(j)(1)). Therefore, cost sharing for these services must comply with § 422.100(f)(6)(i) and may not exceed 50 percent coinsurance or actuarially equivalent copayment values (including copayment limits calculated by CMS as discussed in section II.B.5.a. of this FC). The MA plan must not pay less than 50 percent of the estimated total MA plan financial liability for that contract year for these benefits. MA plans may design their benefit package to: (1) Apply one cost sharing amount for all observation services; or (2) apply cost sharing based on the individual services provided during the observation stay (for example, cost sharing amount for each specialist visit and cost sharing for diagnostic services). If a plan applies cost sharing based on individual services provided during the observation stay, it is possible that some of those services may be subject to CMS service category cost sharing standards in paragraph (f)(6)(iii) or paragraph (j)(1). In addition, ambulance services are not subject to the cost sharing limit proposed and finalized for § 422.113(b)(2)(v) because they are not within the definition of emergency services at paragraph (b)(1)(ii). We direct the commenter to the comments and responses about § 422.113 and cost sharing requirements for emergency services in section II.B.5.d. of this FC and to § 422.113(a), which requires MA organizations to be responsible for ambulance services where other means of transportation would endanger the beneficiary's health. CMS will monitor cost sharing structures and implementation of this regulation; as necessary, we will consider future rulemaking to change the limits applicable to these services, if appropriate.

Comment: A few commenters who were opposed to establishing a range of cost sharing limits based on the type of MOOP stated that this proposal would make comparing and choosing between health plan options more difficult for beneficiaries. Commenters stated MA plan benefits should be more standardized from a consumer advocacy perspective. These commenters also noted CMS should not establish varying cost sharing limits for various service categories in order to avoid placing more burden on the beneficiary to understand complicated coverage terms.

Response: We do not expect that calculating a range of cost sharing limits that are based on the MOOP type established by the MA plan would make comparing and choosing a plan more difficult for beneficiaries. CMS expects that beneficiaries may consider the MOOP amount, cost sharing amounts, along with many other factors such as perception of brand, premium, plan type, benefits, quality ratings, and provider network when choosing a health care plan,[42] and this information will continue to be available as they review their MA plan options for the upcoming contract year. From a beneficiary perspective, the individual will have the ability to review information about the MOOP amounts and cost sharing structures used by MA plans as they review their coverage options. We do not expect beneficiaries to learn or be aware of the options and flexibilities that MA organizations have to establish certain MOOP types and cost sharing amounts. Rather, we expect they will mostly compare the specific benefit and cost sharing designs from the MA plans that are available to them. In addition, we expect that the incentives in this FC for MA plans to establish copayment amounts over coinsurances will ultimately improve transparency for MA beneficiaries to understand expected cost sharing between plans if MA organizations increasingly use copayments in their bid designs.

CMS does not expect MA organizations to necessarily offer more plan options than they currently do as a result of this provision. MA organizations are not required to offer plans that use each MOOP type and cost sharing possibility. In our experience, MA organizations typically limit the number of plan options in their product portfolio to avoid beneficiary confusion in considering the options. For example, in past years (including contract year 2021) most MA organizations offer an average of 2 to 3 plans per plan type in each service area (excluding employer, D–SNP, and MSA plans). We expect this rule on cost sharing standards will: (1) Promote transparency for those who care to learn how CMS calculates copayment limits; and (2) incentivize MA organizations to offer MA plans with lower MOOP limits by aligning the cost sharing limits based on the MOOP type established by the MA plan with lower MOOP limits having the most cost sharing flexibility, which may benefit enrollees. In addition, CMS will continue conducting reviews and enforcing its current authority prohibiting plans from misleading beneficiaries in their marketing and communication materials and activities and continue to improve plan comparison tools and resources (for example, Medicare plan finder, Medicare & You and 1–800–MEDICARE).

Comment: Several commenters raised concerns regarding discrimination against beneficiaries with high or specific health care needs. A few commenters opposed the proposal to allow MA plans with lower MOOP limits to establish up to a 50 percent coinsurance and indicated that requiring such significant cost sharing would make obtaining medically necessary care out of reach, financially, for a large number of beneficiaries. A commenter explained that the majority of Medicare beneficiaries live on limited fixed incomes and have little or no savings. As such, the commenter believed these beneficiaries would not

[40] See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020.

[41] See the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021.

[42] Milliman. October 2020. ''Star Rating Changes: How Medicare Advantage Plans React'' may be accessed at: *https://us.milliman.com/en/insight/Star-rating-changes-How-Medicare-Advantage-plans-react.*

be able to access medically necessary care because cost sharing amounts are unaffordable. The commenters, however, did not suggest an alternative safeguard for CMS to use to protect against this type of harm; rather the commenters seem to suggest that CMS should not finalize the proposal to permit cost sharing up to 50 percent of the total MA plan liability for a service in any situation. Another commenter suggested CMS be cautious about increased cost sharing for an already vulnerable patient population but did not specifically tie that concern to a particular proposal; the commenter expressed concern that high cost sharing levels discriminate against enrollees who need those services.

A commenter opposed CMS's proposal to allow MA plans that establish a lower MOOP limit to set cost sharing as high as 50 percent or the actuarially equivalent copayment limit (projected as $85 in the February 2020 proposed rule) for physical therapy and speech-language pathology. The commenter was concerned that permitting cost sharing at these levels would result in MA plans establishing cost sharing that would pose a significant financial burden and barrier to access for beneficiaries who need those services, particularly for services such as physical therapy that are typically associated with a higher frequency in visits. In reference to those concerns, the commenter requested that CMS: (1) Acknowledge the reality of the financial implications of copays that are required for each physical therapist visit on beneficiaries; (2) add physical therapy to the list of services for which an MA plan may not exceed cost sharing required under original Medicare (to make the cost sharing limits more reasonable for physical therapy services); and (3) set lower cost sharing limits for all categories of services that have a higher frequency in visits. The commenter noted appreciation for CMS's rationale for allowing greater flexibility and that CMS will, in its annual review of plan cost sharing, monitor both copayment amounts and coinsurance percentages; however, the commenter had serious concerns with the cost sharing MA plans have imposed for physical therapy. This commenter acknowledged that MA plans may establish one cost sharing amount for multiple visits provided during an episode of care (for example, several sessions of cardiac rehabilitation) as long as the overall cost sharing amount satisfies CMS standards. However, the commenter noted they were not aware of any plans that have adopted one cost sharing amount for multiple visits provided during a physical therapy episode of care. In addition, this commenter stated that some enrollees have reported paying copayments that were higher than the amount the enrollee's Explanation of Benefits showed as the MA plan's payment to the physical therapist; the commenter gave the example of an MA plan reimbursing the physical therapist $25 while the enrollee's copay was $65 for each visit. In addition, the commenter reported the cost sharing established by MA plans for physical therapy imposes a significant barrier to care for beneficiaries and copayments for physical therapy are frequently cited as a reason that some consumers opt to reduce their frequency of care or forgo medically necessary care. The commenter compared the impact of higher cost sharing for physical therapy in relation to primary care and other specialist providers to illustrate the concern that high cost sharing for repetitively utilized services discriminates against patients who need such services. Enrollees typically require multiple physical therapy visits over an extended period to properly recover from an injury or alleviate symptoms related to an acute or chronic condition, while visits to primary care providers and other specialists are typically less frequent. Based on that utilization difference, the commenter noted that higher cost sharing requirements for physical therapy create a significant financial burden for enrollees in need of multiple visits for a full recovery and may be a deterrent to accessing care. The commenter stated that as a consequence of high physical therapy cost sharing, enrollees who fail to receive the rehabilitative care they need from a physical therapist are more likely to require higher-cost interventions to remain functional—potentially resulting in the development or recurrence of severe functional impairments and downstream costs, including surgery, imaging, and pharmacy.

Response: We appreciate the commenters' feedback and acknowledge the concerns about higher cost sharing being a significant financial burden for beneficiaries. As discussed in the February 2020 proposed rule, the policy requiring MA organizations to pay at least 50 percent of the total plan financial liability for benefits has been in place for some time and has its origins in prohibiting discrimination against individuals based on health status, particularly discriminating against beneficiaries that need the particular benefit for which the plan payment is a smaller percentage of the total cost. In our proposal and this FC, we limit this flexibility to use 50 percent cost sharing for in-network professional services to MA plans with lower MOOP limits. In addition, we are codifying the prohibition on cost sharing that exceeds 50 percent of the estimated total MA plan financial liability for that contract year for Part A and Part B benefits that are furnished by an out-of-network provider.

As discussed previously in a response to comment in this section, based on comments and further consideration of strategies CMS can employ to avoid potential disruption for enrollees and plan designs, we are finalizing a 4-year transition from contract year 2022 cost sharing limits to the 30, 40, and 50 percent coinsurance and related actuarially equivalent copayments for professional services that are Part A and B benefits (that is, basic benefits) proposed in § 422.100(f)(6)(iii). The cost sharing limits resulting from the first year of applying this transition (contract year 2023) are reflected in Table 28, including for the ''physical therapy and speech-language pathology'' service category. Compared to the February 2020 proposed rule's illustrative cost sharing limits for the ''physical therapy and speech-language pathology'' service category (30 percent/$50, 40 percent/$65, and 50 percent/$85 for the mandatory, intermediate, and lower MOOP limit respectively), the final contract year 2023 copayment limits (as shown in Table 28: 45 percent/$45, 47 percent/$50, and 50 percent/$50 for the mandatory, intermediate, and lower MOOP limit respectively) are substantively lower due to the transition and ''lesser of'' requirement finalized in § 422.100(f)(8). We used contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data) to calculate the final cost sharing limits for contract year 2023. The calculations CMS made to reach these final contract year 2023 copayment limits for the ''physical therapy and speech-language pathology'' service category (for plans that establish a mandatory MOOP limit) are available in Table 14B. Similar calculations were made to reach the final contract year 2023 copayment limits in Table 28 for the other professional service categories and types of MOOP limits.

Although this rule continues to permit certain MA plans to have cost sharing obligations of up to 50 percent for certain basic benefits, the cost sharing standards and the MOOP limit requirements (section II.A. of this FC) will apply together to protect enrollees.

We expect this, in conjunction with the other cost sharing standards being finalized in this FC, to produce a corresponding level of beneficiary and plan incentive that is unique to each type of MOOP limit, because plans with lower MOOP limits receive the most cost sharing flexibility. Under section 1854(a)(5)(C)(ii) of the Act, CMS is authorized to deny a plan bid if the bid proposes significant increases in enrollee costs or decrease in benefits from one plan year to the next. A plan's TBC is the sum of the plan-specific Part B premium, plan premium, and estimated enrollee out-of-pocket costs. The TBC evaluation is applied at the plan level to ensure enrollees in each applicable plan are not subject to too significant an increase in costs or decrease in benefits from one plan year to the next. As stated previously, MA organizations typically offer benefits with lower cost sharing amounts than the annual limits published by CMS; we believe this is due to multiple factors (other than the TBC standard), including the principles and incentives inherent in managed care, effective negotiations between organizations and providers, and market competition. For MA plans that choose to establish the highest level of cost sharing permitted by § 422.100(f)(6), they must also ensure that: (1) Total MA cost sharing for all basic benefits, excluding out of network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis; (2) for specific basic benefits in § 422.100(j), in-network cost sharing established by an MA plan must not exceed the cost sharing required under original Medicare; and (3) additional cost sharing standards for the plan benefit package service category or for a reasonable group of benefits or services covered under the plan must be met. In addition, in evaluating which benefits would have the highest cost sharing, MA organizations must be mindful not to discriminate against enrollees based on health status. For example, for contract year 2019,[43] the cardiac and pulmonary rehabilitation service categories (utilized by enrollees with certain health conditions such as heart failure and Chronic Obstructive Pulmonary Disease (COPD)) were areas of concern and CMS conducted additional scrutiny of MA plans with higher cost sharing amounts for those services to ensure that the plan designs were not discriminatory. CMS has the authority to continue to evaluate plans for potential discrimination through these mechanisms as discussed is section II.B.5.a. of this FC.

We note the example provided by a commenter of a $65 copayment for a physical therapy visit is above the $40 copayment limit for the in-network ''physical therapy and speech-language pathology'' service category for approved bids for contract year 2020 (which was in effect at the time of the public comment period and for contract year 2021 and 2022). MA organizations contract with providers, including physical therapists, to provide services to enrollees. The terms of contractual arrangements include provider reimbursement, which may also include enrollee cost sharing that the provider is permitted to collect. If enrollees believe that an MA organization is not providing adequate access to services or its contracted providers are not billing enrollees correctly, complaints may be submitted online[44] or by calling 1–800–MEDICARE. CMS monitors and investigates complaints related to plan coverage and CMS caseworkers assist in the resolution of issues with MA organizations. To protect enrollees, CMS may take compliance or enforcement actions against an MA organization for failing to meet any contract requirements, such as providing adequate access to medically necessary services, as warranted. In addition, enrollees who have complaints about their MA plan may file a grievance under § 422.564 and, if they believe that benefits have been improperly denied, file an appeal under the rules in §§ 422.562 through 422.619.

We appreciate the feedback and are finalizing our proposals for cost sharing for professional services with moderate modifications; we are finalizing the methodology used to calculate MA cost sharing standards for professional services and calculating a range of cost sharing limits for benefits furnished on an in-network basis based on the MOOP type established by the MA plan. The modifications include using a 4-year transition to the proposed 30, 40, and 50 percent coinsurance and actuarially equivalent copayment limits (finalized at § 422.100(f)(6)(iii) and (f)(8)). In addition, we are finalizing various edits and restructuring of the regulation text to improve clarity in the regulations. By implementing more than two levels of MOOP limits and limiting the scope of services on which the highest allowable cost sharing could be imposed (50 percent), we expect to encourage plan offerings with favorable benefit designs so that beneficiaries can choose MA plans that meet their needs. CMS will monitor whether changes from this FC result in beneficiaries having access to plan offerings with MOOP limits below the mandatory MOOP limit and lower or comparable cost sharing when compared to existing benefit packages over time.

This rule is focused on addressing particular ways that cost sharing structures could be used to discourage enrollment by beneficiaries with significant or costly health needs. Prohibitions on discrimination continue to apply in the MA program and CMS takes its role in guarding against discrimination on the basis of health status seriously. CMS reviews cost sharing based on the current limits that are intended to address discrimination based on health needs and based on other standards regulating cost sharing, such as requirements in current § 422.100(j) and (k) for certain services to have cost sharing that does not exceed cost sharing in original Medicare. CMS will incorporate the standards adopted in this FC into those reviews, beginning with reviews of bids for contract year 2023. We will not approve a plan bid if its proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals, and cost sharing structures are an important consideration in our reviews. For example, CMS analyzes plan bid submissions to evaluate whether cost sharing levels satisfy MA requirements and are defined or administered in a manner that may discriminate against sicker or higher-cost beneficiaries. These analyses also may evaluate the impact of benefit design on beneficiary health status and/or certain disease states. CMS contacts MA organizations to discuss any issues that are identified in MA plan bids as a result of these analyses and seeks correction or adjustment of the bid as necessary. CMS is not required to accept every bid and has authority to negotiate the benefits offered by MA plans under section 1854(a)(5) and (6) of the Act. CMS will also continue evaluations and enforcement of the current authority prohibiting plans from misleading beneficiaries in their communication materials and continue efforts to improve plan comparison tools and resources (for example, Medicare Plan Finder, Medicare & You, and 1–800–MEDICARE).

[43] See page 202 of the CY 2019 Final Call Letter at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

[44] The online Medicare Compliant Form may be accessed and submitted at: *https://www.medicare.gov/medicarecomplaintform/home.aspx.*

In CMS's experience, for the most part MA organizations typically offer benefits with lower cost sharing amounts than the standards CMS calculates. However, we are concerned about benefit designs that have in-network cost sharing at the highest allowable level for a subset of benefits, including mental health services as discussed in section III. of this FC. In light of these concerns, we are considering whether cost sharing limits for mental health care, such as mental health specialty services, psychiatric services, partial hospitalization, opioid treatment program services, and treatment for substance use disorders should be subject to additional cost sharing limits, such as a requirement that cost sharing for those service not exceed cost sharing in original Medicare. As discussed in section III. of this FC, we seek comments for consideration should we choose to pursue future rulemaking on this topic. While we do not expect to release new rulemaking on this topic in time to apply to contract year 2023, we will rely on our existing authority to closely review plan designs for potential disparity in cost sharing for mental health and psychiatric services compared to other professional services and to review significant increases in enrollee costs. CMS may not approve a plan if the MA organization cannot sufficiently explain how their plan design is not discriminating against beneficiaries that need mental health and psychiatric services.

c. Cost Sharing Limits for Inpatient Hospital Acute and Psychiatric Services (§ 422.100(f)(6)(iv))

Comment: A few commenters were generally supportive of CMS's proposals in section VI.B.2. of the February 2020 proposed rule related to inpatient hospital acute and psychiatric services. A commenter supported CMS adding a 3-day length of stay scenario for inpatient hospital acute services and an 8-day length of stay scenario for inpatient hospital psychiatric services. This commenter noted that inpatient hospital services have a high Medicare utilization and therefore provide a large actuarial value and greater incentive for a plan to choose to establish a lower (previously ''voluntary'') MOOP limit.

Response: We thank commenters for supporting our proposal related to additional length of stay scenarios for inpatient hospital acute and psychiatric services and differentiating the cost sharing limits by the MOOP type established by the MA plan. We agree that permitting greater variation in cost sharing for inpatient hospital services may provide an incentive for MA organizations to offer plans with lower MOOP types. This flexibility allows MA organizations to vary cost sharing for highly utilized services in exchange for a lower MOOP amount that may better meet enrollee needs.

We are finalizing § 422.100(f)(6)(iv) and (f)(6)(iv)(A)–(D) with additional edits to consistently use the same language to reference the inpatient hospital acute and psychiatric service categories for which CMS calculates cost sharing limits and the length of stay scenarios used by CMS to evaluate plan cost sharing for those inpatient scenarios. Cost sharing for in-network basic benefits that are inpatient hospital acute and psychiatric service categories must not exceed a specified percentage of original Medicare cost sharing for the length of stay scenarios based on original Medicare cost sharing for a new benefit period. As finalized in paragraph (f)(6)(iv)(A), this requirement is subject to new paragraph (f)(7) (discussed in detail in section II.B.5.a. of this FC). In brief, this means that the inpatient hospital cost sharing limits are calculated (and plan cost sharing amounts are evaluated) using generally accepted actuarial principles and practices (as finalized in paragraph (f)(7)(i)). In addition, the inpatient hospital cost sharing limits for contract year 2024 and future years will be issued annually through the subregulatory process in paragraph (f)(7)(iii). In paragraph (f)(6)(iv)(B), we are not finalizing the reference to an inpatient facility as we believe individuals could interpret the word facility in a stricter fashion than how the cost sharing limits will be applied; finalizing paragraph (f)(6)(iv)(B) without this reference will more accurately reflect how the cost sharing limits in paragraph (f)(6)(iv) work and how MA organizations may deliver inpatient services. In addition, we are revising the descriptions of the length of stay scenarios to focus on the purpose of the stay (acute versus psychiatric). We are finalizing the proposed rounding rules for inpatient hospital acute and psychiatric cost sharing limits in paragraph (f)(6)(ii) and we are not including a reference to those rounding rules in paragraph (f)(6)(iv) because we believe paragraph (f)(6)(ii) is sufficiently clear about when the rounding rules apply.

We clarify in § 422.100(f)(6)(iv)(C) that CMS calculates the inpatient hospital acute and psychiatric service category cost sharing limits annually using projections of out-of-pocket costs and utilization for the applicable year and length of stay scenario and factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD on the transition schedule described in paragraphs (f)(4)(vi)(A) through (B); the cross reference is updated from the proposed reference to paragraphs (f)(4)(vii)(A) through (D) based on reorganization of the regulation text addressing the ESRD cost transition, as discussed in section II.A. of this FC. In addition, we removed the reference to exceptions for MOOP limit calculations in paragraphs (f)(4)(v)(A) and (C) in paragraph (f)(4)(iv)(C) as this FC does not include the provision that delays the schedule of incorporating ESRD costs into the methodology CMS uses to calculate MOOP limits (as discussed in section II.A. of this FC). This means that CMS is calculating the inpatient hospital acute and psychiatric service category cost sharing limits for contract year 2023 using projected Medicare FFS beneficiary out-of-pocket spending, which necessarily includes both costs and utilization data, for beneficiaries without diagnoses of ESRD plus 70 percent of the ESRD cost differential. Then, for contract year 2024 and subsequent years CMS will calculate the inpatient hospital acute and psychiatric service category cost sharing limits using Medicare FFS data projections (as defined in paragraph (f)(4)(i), which includes data for beneficiaries with and without diagnoses of ESRD). In addition, as proposed, we are finalizing that CMS may also use patient utilization information from MA encounter data in developing the length of stay scenarios. In summary, CMS implements the inpatient hospital cost sharing limits set in paragraph (f)(6)(iv) by evaluating the plan's cost sharing for each length of stay scenario in comparison to the specific limits that are calculated and published annually (as finalized in paragraphs (f)(6)(iv)(C) and (f)(7)(iii)). Inpatient hospital cost sharing above the annual limits for any one of the length-of-stay scenarios is not permissible.

In finalizing § 422.100(f)(6)(iv)(D), we are including several clarifying modifications. Final paragraph (f)(6)(iv) includes the requirement that the total cost sharing for the inpatient benefit must not exceed the plan's MOOP limit or overall cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. We are not finalizing this provision only in paragraph (f)(6)(iv)(D)*(3),* which was proposed, because we intend this requirement to apply regardless of the type of MOOP limit used by the MA plan. This modification clarifies our policy and makes paragraph (f)(6)(iv)

consistent with our proposal in section VI.B.4. in the February 2020 proposed rule (and finalized in section II.B.5.f. of this FC) to include in § 422.100(j)(2)(i)(A) that MA cost sharing for inpatient hospital acute and psychiatric services must not exceed the cost sharing in original Medicare (for the period during which original Medicare has cost sharing) on a per member per month actuarially equivalent basis. Our proposal in paragraph (j)(2)(i)(A) was to codify that this requirement applies for any type of MOOP limit. Considering how our proposals in paragraphs (f)(6)(iv) and (j)(2)(i)(A) combine for cost sharing standards for the inpatient hospital service categories, we believe stating this requirement in paragraph (f)(6)(iv)(D) to apply to all MOOP types is clearer and ensures that the overall cost sharing limit policies are consistent.

We are finalizing § 422.100(f)(6)(iv)(D)*(1)* and *(3)* with minor modifications to clarify that the cost sharing limits for inpatient hospital acute and psychiatric length of stay scenarios are based on the projected Part A deductible and related Part B costs, which is consistent with the illustrative calculations in the February 2020 proposed rule, the final contract year 2023 inpatient hospital cost sharing limits included in Table 28, and longstanding CMS methodology. Our proposal did not include the word ''projected,'' and we wish to ensure clarity and consistency on this point that the projected Part A deductible and related Part B costs for the applicable year will be used. The February 2020 proposed rule would have permitted MA plans with a lower MOOP amount to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing for the inpatient acute 60-day length of stay, as long as the total inpatient benefit cost sharing does not exceed the MOOP limit or cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. This was proposed as part of paragraph (f)(6)(iv)(D)(*3*) and is largely being finalized as proposed. Even though the MA plan may use cost sharing that, for this specific 60-day scenario, is higher than 125 percent of original Medicare cost sharing for that scenario, the cost sharing for that length of stay is capped at the lower MOOP amount, and overall cost sharing for inpatient services must not exceed original Medicare cost sharing for that benefit category on a PMPM basis. While CMS provides this flexibility for plans that establish a lower MOOP amount, we expect that the competition to offer plans that attract beneficiaries is an important incentive for MA organizations and will factor into how MA organizations establish cost sharing for the inpatient hospital benefit portion of the basic benefit package. In summary, the modifications to paragraphs (f)(6)(iv)(D)*(1)* and *(3)* include clarifying: (1) The cost sharing for the entire inpatient benefit must not exceed the MOOP amount for the MA plan; (2) projected cost sharing for the Medicare FFS program will be used; and (3) that the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing is limited to MA plans with a lower MOOP amount and only to the inpatient hospital acute 60-day length of stay scenario.

We are finalizing § 422.100(f)(6)(iv)(D)*(2)* with revisions as well. The revised text adjusts inpatient hospital acute and psychiatric cost sharing limits for MA plans that establish an intermediate MOOP limit in order to address flexibilities and unique situations. We proposed that inpatient hospital acute and psychiatric cost sharing limits for MA plans that establish an intermediate MOOP limit be based on the numeric midpoint between the cost sharing limits established for the mandatory and lower MOOP limits. As proposed and finalized in paragraph (f)(6)(iv)(D) and (f)(6)(iv)(D)*(3),* MA plans with a lower MOOP limit have the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing in limited situations (discussed in the previous paragraph). Given this flexibility, we believe the cost sharing limit for MA plans that use an intermediate MOOP limit is more clearly stated as the numeric midpoint between the cost sharing limits established for the mandatory and lower MOOP limits for the same inpatient hospital length of stay scenario, before application of the rounding rules in paragraph (f)(6)(ii). While MA plans that establish a lower MOOP amount have the flexibility to establish cost sharing above 125 percent in limited situations, operationally the cost sharing limit is capped at the lower MOOP amount for that contract year. This will result in all of the inpatient hospital length of stay scenarios having a more precise cost sharing limit for the intermediate MOOP limit as that cost sharing limit will be based on a numeric midpoint between the cost sharing limits set for the mandatory and lower MOOP types (with ESRD costs factored in using the transition schedule in paragraph (f)(4)(vi) as finalized in paragraph (f)(6)(iv)(C)) after application of the MOOP limit cap. In addition, this revision will avoid the rounding rules in paragraph (f)(6)(ii) being unnecessarily applied twice in the calculation of the inpatient cost sharing limit for MA plans that use an intermediate MOOP type. For example, the cost sharing limits calculated for the inpatient acute 3-day length of stay for the mandatory and lower MOOP limits have already been rounded when calculated to apply to MA plans with those types of MOOP limits and calculating a numeric midpoint between them could produce an amount that requires additional rounding in order to reach a whole dollar amount. In order to address these complexities, we are modifying paragraph (f)(6)(iv)(D)*(2),* so that cost sharing for the intermediate MOOP limit is based on the numeric midpoint between the cost sharing limits established in paragraphs (f)(6)(iv)(D)(1) and (3) for the same inpatient hospital length of stay scenario. The rounding rules finalized at § 422.100(f)(6)(ii) will then be applied to that dollar amount. This change would not have substantially affected most of the illustrative inpatient hospital acute and psychiatric cost sharing limits that were included in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule. For example, by using the numeric midpoint between the illustrative copayment limits for the mandatory and lower MOOP types before the application of the rounding rules based on the same data used in the February 2020 proposed rule and the proposed ESRD cost transition schedule, the illustrative contract year 2022 inpatient hospital acute 3-day length of stay scenario cost sharing limit for the intermediate MOOP limit would have been $2,106 (a $1 increase from the illustrative amount included in Table 5 from the February 2020 proposed rule). However, using this more precise numeric midpoint would have substantially affected the illustrative inpatient hospital acute cost sharing limit for the 60-day length of stay scenario that was included in Table 5 in the February 2020 proposed rule for the intermediate MOOP limit. The illustrative value for the inpatient hospital acute 60-day length of stay for the intermediate MOOP limit in Table 5 of the February 2020 proposed rule was $5,514. This value was calculated using the proposed ESRD cost transition schedule and was based on the numeric midpoint between 125 and 100 percent of estimated Medicare FFS cost sharing

for an inpatient hospital acute 60-day length of stay. As a result, the $5,514 illustrative copayment limit did not reflect the numeric midpoint between the $4,902 illustrative copayment for the mandatory MOOP limit and the cap of the lower MOOP limit ($3,450 for contract year 2022 as illustrated in Table 4 of the February 2020 proposed rule) that would be applied in this scenario (reflected as ''N/A'' in Table 5 of the February 2020 proposed rule). Instead, the illustrative copayment limit for the intermediate MOOP type (based on the same data used in the February 2020 proposed rule and the proposed ESRD cost transition schedule) using the precise numeric midpoint should have been $4,176 (a $1,338 decrease from the $5,514 illustrative amount for the inpatient hospital acute 60-day length of stay scenario included in Table 5 from the February 2020 proposed rule). Using the numeric midpoint between the actual, calculated cost sharing limits (that is the dollar amounts) for the mandatory and lower MOOP types would be consistent with all of the other illustrative inpatient hospital cost sharing limits for all of the other length of stay scenarios applied to the intermediate MOOP. The other cost sharing limits for the intermediate MOOP were not impacted by the cap of the lower or mandatory MOOP limits for the other length of stay scenarios as those amounts did not exceed the illustrative MOOP limits for that contract year. This approach of using the precise numeric midpoint of the cost sharing limits applied to the mandatory and lower MOOP types to calculate the cost sharing limit for the same length of stay scenario for the intermediate MOOP limit, as finalized in paragraph (f)(6)(iv)(D)*(2),* is reflected in the final contract year 2023 inpatient hospital acute and psychiatric cost sharing limits in Table 28. The figures in Table 28 are calculated using projections of 2017–2021 Medicare FFS data and the finalized ESRD cost transition schedule as discussed in a following response to comment in this section.

We believe it is important to reiterate that cost sharing limits applicable for any service category cannot exceed the associated MOOP limit, including the inpatient hospital acute and psychiatric length of stay scenarios as finalized in § 422.100(f)(6)(iv). CMS did not propose to allow, and would not approve a plan bid that allowed, inpatient hospital cost sharing above the related MOOP amount for that plan. The flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing for the inpatient hospital acute 60-day length of stay scenario for MA plans with a lower MOOP amount (in paragraph (f)(6)(iv)(D)*(3)*) is effectively capped at the lower MOOP limit. In addition, if the MA plan establishes a MOOP amount less than the highest allowable lower MOOP limit, then the cost sharing for the inpatient hospital acute 60-day length of stay scenario would also be capped at the MA plan's actual MOOP amount. Consistent with current practice, for MA plans that establish a coinsurance for inpatient hospital standards, supporting documentation must be submitted with the initial bid showing how the plan's coinsurance amount satisfies the standards under § 422.100(f)(6)(iv). This will follow the same process discussed in section II.B.5.a. of this FC for when an MA plan must provide documentation to support its cost sharing and CMS would generally review this documentation as part of its bid evaluation. This is consistent with the overall standard of MA plans not being able to charge the enrollee an amount higher than the MOOP amount they establish.

In Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule, we listed the cost sharing limit for the inpatient hospital acute 60-day length of stay scenario for MA plans that establish a lower MOOP amount as ''N/A'' to reflect the flexibility MA organizations have in establishing cost sharing above 125 percent of estimated Medicare FFS cost sharing. However, using projections of Medicare FFS data from 2015–2019 that was available at the time of writing the February 2020 proposed rule, a cost sharing limit at 125 percent of estimated Medicare FFS cost sharing (plus 80 percent of the ESRD cost differential for contract year 2022 as proposed) would have been $6,127. This amount is $2,677 higher than the illustrative contract year 2022 in-network lower MOOP limit of $3,450 shown in Table 4 (Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections) of the February 2020 proposed rule. The value of 125 percent of estimated Medicare FFS cost sharing using updated projections of Medicare FFS data (from 2017–2021) and the finalized ESRD cost transition schedule for the inpatient hospital acute 60-day length of stay scenario also exceeds the final contract year 2023 lower MOOP limit ($7,162 compared to $3,650). In order to be clear about the highest allowable inpatient hospital cost sharing that an enrollee could experience, we updated the ''N/A'' for the 60-day length of stay scenario to the final contract year 2023 in-network lower MOOP limit amount in Table 28 (that is, $3,650 as listed in Table 5 and discussed in section II.A. of this FC). The complete list of final contract year 2023 inpatient hospital cost sharing limits is available in Table 28, which were calculated using the rules finalized in § 422.100(f)(6)(iv) and the data described in § 422.100(f)(4)(vi)(A) (that is, projected Medicare beneficiary out of pocket spending for 2023 for beneficiaries without diagnoses of ESRD plus 70 percent of the ESRD cost differential).

MA plans that establish a lower MOOP amount will effectively have a cost sharing limit for the inpatient acute 60-day length of stay scenario that is calculated at the in-network lower MOOP limit amount whenever the calculations of 125 percent of Medicare FFS cost sharing exceed the lower MOOP limit. The dollar amount which is applied as the cost sharing limit, before rounding, is used in the calculation of the inpatient acute 60-day length of stay scenario cost sharing limit for MA plans that establish an intermediate MOOP limit (as discussed previously in this response and finalized in § 422.100(f)(6)(iv)(D)*(2)*).The cost sharing limits for the intermediate MOOP limit will be calculated using the numeric midpoint of the cost sharing limits established for the mandatory and lower MOOP limits, consistent with proposed § 422.100(f)(6)(iv)(D)*(2).* Based on the methodology finalized to calculate the cost sharing limit for an inpatient acute hospital 60-day length of stay for the intermediate MOOP limit and the projections of Medicare FFS out-of-pocket costs and utilization based on 2017–2021 Medicare FFS data and using 70 percent of the ESRD cost differential, the associated cost sharing calculation for contract year 2023 equals $4,690 after applying the rounding rules in § 422.100(f)(6)(ii). In comparison, the final contract year 2023 in-network intermediate MOOP limit is $6,000 (as listed in Table 5 and discussed in section II.A. of this FC). As a result, for MA plans with an intermediate MOOP, the final contract year 2023 cost sharing limit for this 60-day length of stay inpatient hospital acute scenario is $4,690 (as listed in Table 28) as it does not exceed the associated MOOP limit for contract year 2023. CMS will continue this process of comparing cost sharing limits calculated using the methodology in paragraph (f)(6)(iv) to the related MOOP limit before issuing the specific cost sharing limits for

inpatient services for contract year 2024 and future years.

In summary, we believe listing specific dollar amounts (instead of ''N/A'') in Table 28 clarifies and avoids potential confusion about the level of flexibility MA plans have, including those that establish a lower MOOP amount, under § 422.100(f)(6)(iv). Listing the in-network MOOP amounts when applicable for particular inpatient length of stay scenarios in Table 28 and in subregulatory guidance for future contract years does not nullify the requirement that the total cost sharing for the inpatient benefit must not exceed the cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis. In addition, CMS provides instructions describing how excess cost sharing is evaluated using BPT information to satisfy the per member per month actuarially equivalent requirement for the benefit categories subject to § 422.100(j)(2) (including inpatient) in section II.B.5.f. of this FC. Our evaluations of the per member per month limits are specific to each MA plan bid and will happen during CMS review of bids, consistent with longstanding practice. For contract year 2024 and future years, instructions on these topics will be provided as part of the annual issuance of subregulatory guidance required by paragraph (f)(7)(iii).

Comment: A commenter generally supported CMS's proposal to consistently implement a multiyear transition of ESRD costs into the methodology CMS uses to set inpatient hospital acute and psychiatric cost sharing limits and MOOP limits. This commenter requested that CMS accelerate the transition of ESRD costs to align with the OACT's projections of how quickly beneficiaries with diagnoses of ESRD may enroll in the MA program and apply the accelerated transition schedule to the methodology CMS uses to set inpatient hospital acute and psychiatric services cost sharing limits and MOOP limits. The commenter included an example of a shortened schedule CMS could consider that would incorporate the ESRD cost differential as follows: 50 percent in 2021, 75 percent in 2022, and 100 percent in 2023. In addition, a commenter requested CMS release the methodology used for setting inpatient hospital acute and psychiatric services cost sharing limits in subregulatory guidance each year consistent with guidance on the MOOP limit methodology.

Another commenter opposed CMS transitioning any ESRD costs into the methodology CMS uses to set inpatient hospital acute and psychiatric cost sharing limits. The commenter noted that by transitioning ESRD costs into the methodology that CMS uses to establish cost sharing limits for the 60-day length of stay scenario for inpatient hospital acute services, the resulting maximum cost sharing limits exceed 100 percent of the Medicare FFS cost sharing for individuals without diagnoses of ESRD. They explained that this results in cost sharing limits for the inpatient hospital acute service category that are not actuarially equivalent for the population of beneficiaries without diagnoses of ESRD and including ESRD costs in the methodology CMS uses to set inpatient hospital acute and psychiatric cost sharing limits could cause unintended disruption or unmanageable costs for beneficiaries without diagnoses of ESRD. In addition, the commenter noted establishing inpatient hospital cost sharing limits that are not actuarially equivalent for the non-ESRD population is illustrative of the concerns they have in general with the changes CMS proposed to address the increased MA plan cost due to changes in eligibility for beneficiaries with ESRD. The commenter explained that the changes CMS proposed involve various forms of cost subsidization by enrollees without diagnoses of ESRD, such as use of the ESRD subsidy in the Bid Pricing Tool (BPT), MOOP limit increases, and increases in Part C cost sharing limits. The commenter believed this non-ESRD enrollee cost subsidization will financially strain MA organizations and beneficiaries, and as a consequence, may reduce competition and beneficiary choice.

Response: We appreciate the feedback on our proposed schedule of transitioning ESRD costs into the methodology CMS uses to calculate cost sharing limits for inpatient hospital acute and psychiatric services and have taken these concerns and suggestions under consideration. We agree that the ESRD cost transition should be consistently applied to both methodologies: For calculating cost sharing for inpatient hospital services and for calculating MOOP limits. This use of a consistent transition and approach to incorporating the ESRD costs will provide stability to MA organizations as they can anticipate changes for the upcoming years. In addition, a consistent application will ease administrative burden (by avoiding an overly complicated methodology) and be more transparent and understandable to stakeholders. As discussed in section II.B.5.b. and e. of this FC, the actuarially equivalent copayment transition in § 422.100(f)(8) is only applicable to service categories subject to § 422.100(f)(6)(iii) and (j)(1). Specifically, we are not incorporating an actuarially equivalent copayment differential (finalized in paragraph (f)(8)(i)) to the inpatient services cost sharing standards in paragraph (f)(6)(iv). Combining the ESRD cost and actuarially equivalent copayment transitions would result in an overly complicated methodology for the cost sharing limits for inpatient hospital acute and psychiatric services. Further, we proposed a specific and separate methodology (the ESRD cost transition) in order to mitigate potentially disruptive changes to the cost sharing limits for inpatient hospital acute and psychiatric services. We believe our final policy for paragraph (f)(6)(iv) (discussed subsequently in this response) is sufficient to mitigate disruptive changes.

We agree that inpatient acute cost sharing limits are projected to continue increasing at a greater rate than if ESRD costs were excluded and understand the commenter's concern about non-ESRD enrollees subsidizing the costs related to the expansion of enrollment into the MA program by beneficiaries with diagnoses of ESRD. However, the 21st Century Cures Act required CMS to lift the enrollment restrictions for beneficiaries with diagnoses of ESRD beginning in 2021 and those beneficiaries are now eligible for MA enrollment on the same basis as other beneficiaries. Setting up separate benefit structures by using different cost sharing for MA enrollees based on whether they have been diagnosed with ESRD is not consistent with the Medicare statute, particularly sections 1852 and 1854(c) of the Act. Beneficiaries with diagnoses of ESRD are entitled to Medicare and therefore entitled to the same benefits and benefit options as other beneficiaries. The plan benefit package (PBP) portion of the bid requires uniformity in benefits and cost sharing pursuant to the uniformity requirements in §§ 422.4 (the definition of an MA plan), 422.100(d) and 422.254(b)(2). Characterizing benefit analysis by pitting healthier enrollees against sicker enrollees ignores the uniformity requirements and would discourage enrollment by less healthy beneficiaries into MA plans. Our approach to incorporate costs of beneficiaries with diagnoses of ESRD in setting inpatient hospital cost sharing limits is consistent with the approach CMS has historically used of spreading the burden of medical costs across all

potential MA enrollees uniformly through the continued use of the projected Part A deductible and related Part B costs for the population that is eligible to enroll in an MA plan. In addition, we proposed to transition ESRD costs over multiple years in a transparent and standardized approach to avoid sudden, significant disruption and unexpectedly higher costs for beneficiaries. Specifically, we expect conducting a multiyear transition of ESRD costs into our methodology to calculate MOOP and cost sharing limits is an important and necessary step to ensure plan designs are not discriminatory and protect beneficiaries from significant changes in financial costs regardless of the MA plan they choose. Bids are based on the projected revenue requirements of the MA plan to furnish benefits to the expected enrollee population of the plan. MA plan payments for enrollees with ESRD include separate (higher) ESRD capitation rates and an ESRD risk adjustment model for furnishing covered benefits on a uniform basis.

CMS acknowledges and understands that some plans may adopt the mandatory MOOP limit, raise cost sharing for specific benefits where possible under the new cost sharing limits in this FC, or increase enrollee premiums, in part due to the costs they expect to incur to cover services for their enrollees. While some MA organizations have experience managing the health care services for beneficiaries with diagnoses of ESRD under the prior enrollment policy and during the first year of expanded enrollment eligibility, our proposal and the final policies provide incentives to MA organizations to adopt MOOP limits below the mandatory level and establish lower or comparable cost sharing when compared to existing benefit packages and utilize effective risk mitigation strategies. Our MOOP limit provision in section II.A. of this FC and the cost sharing limit policies addressed in section II.B. of this FC do not limit market competition and we expect beneficiary choice will continue to act as an incentive for MA organizations to offer favorable benefit designs. For example, we expect beneficiary choice will continue to drive MA organizations to offer supplemental benefits, such as vision and dental services. In addition, MA organizations can use multiple strategies to manage care and costs through provider contracting, reinsurance, care coordination, case management, plan benefit designs, and benefit flexibilities including additional telehealth benefits, Special Supplemental Benefits for the Chronically Ill (SSBCI), and our reinterpretation of the MA uniformity requirement (§ 422.100(d)(2)(ii)). We direct commenters to the June 2020 final rule (85 FR 33796) for how CMS finalized policies related to reinsurance (section IV.A.), SSBCI (section II.A.), and kidney acquisition costs (sections III.B. and III.B.) In addition, under section 1854(a)(5)(C) of the Act, CMS is authorized to deny a plan bid, including if it determines the bid proposes significant increases in enrollee costs or decrease in benefits from one plan year to the next. CMS is also authorized to negotiate with MA organizations regarding their bids by section 1854(6)(B) of the Act. The cost sharing requirements adopted under this FC reflect what is minimally acceptable, for the various reasons discussed in detail throughout the February 2020 proposed rule and this FC, and by codifying them in regulations, these standards are transparent for MA organizations. If an MA organization's bid represents too significant an increase in costs or decrease in benefits from the prior year, we have an established evaluation to identify that and engage with the MA organization to revise its bid. A plan's TBC is the sum of the plan-specific Part B premium, plan premium, and estimated enrollee out-of-pocket costs. CMS uses the TBC standard to evaluate year over year changes when bids are submitted for the upcoming contract year. The TBC standard is applied at the plan level to ensure enrollees in each applicable plan are not subject to too significant an increase in costs or decrease in benefits from one plan year to the next. Because of the availability of these strategies and plan requirements, we do not expect that MA organizations will automatically pass on the anticipated increased costs associated with enrollees with diagnoses of ESRD onto the MA population as a whole. In fact, CMS has observed that historically MA organizations tend to reduce their profit margins, rather than substantially change their benefit package from one year to the next. While we appreciate the commenter's suggestion to align the ESRD cost transition schedule with OACT's projected rate of ESRD enrollment, we believe this would add another layer of complexity and potentially delay the transition process. As discussed in section II.A. of this FC, we did not propose to set the schedule for transitioning ESRD costs into MOOP and inpatient hospital cost sharing limits based upon OACT's projection of ESRD enrollment because actual enrollment per plan may vary and OACT's analysis reflects expectations for the MA program as a whole. As discussed in the February 2020 proposed rule, the OACT expected ESRD enrollment in MA plans to increase by 83,000 beneficiaries as a result of the 21st Century Cures Act provision. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021; the remaining 41,500 additional beneficiaries were expected to enroll in MA plans during the years 2022 to 2026 under the assumption that the number of additional enrollees who have diagnoses of ESRD will continue to increase during that time frame though at a decreasing rate in later years. Based on actual 2021 enrollment data, the OACT continues to project that 83,000 beneficiaries with diagnoses of ESRD will enroll in the MA program over 6 years. If CMS were to match the transition of incorporating ESRD costs to that of OACT's enrollment projections, we would be forced to delay the full transition of ESRD costs until 2026. After publication of the February 2020 proposed rule, CMS announced that it would take the Medicare FFS costs of beneficiaries with diagnoses ESRD into account in developing MOOP and cost sharing limits for 2021.[45] The contract year 2021 inpatient hospital cost sharing limits (which encompassed 40 percent of the ESRD cost differential) were maintained for contract year 2022 while enrollment of beneficiaries with diagnoses of ESRD is projected to increase.[46] As a result, CMS believes any further delays to the ESRD cost transition would not be beneficial as only 40 percent of the ESRD cost differential has been incorporated up to contract year 2022, the year the OACT projected total enrollment of beneficiaries with diagnoses of ESRD into the MA program to exceed 50 percent. In addition, when developing our proposed ESRD cost transition schedule, we considered how OACT's aggregate projections may not reflect the experiences in all geographic locations, which could have different rates of transition and changes in expenditures for providing care to beneficiaries with diagnoses of ESRD. Given these factors, we are not incorporating the request to set the schedule of transitioning ESRD

[45] See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020 for information on MOOP limits for contract year 2021.

[46] See the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021 for information on MOOP limits for contract year 2022.

costs into MOOP and cost sharing limits based exactly on OACT's projection of ESRD enrollment.

For 2021, CMS set the voluntary and mandatory MOOP limits by applying the standard in current §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). Because of the expected changes in enrollment in MA plans by beneficiaries with diagnoses of ESRD, we incorporated 40 percent of the ESRD cost differential for 2021 which increased both types of MOOP limits from 2020. The proposed 3-year transition schedule would have incorporated the ESRD cost differential as follows: 60 percent in 2022; 80 percent in 2023 or next year; and 100 percent in 2024 or the final year of transition. Our proposal attempted to strike a balance between providing plan stability while also protecting enrollees from rapid and significant cost and benefit changes. Based on the timing of this FC, the contract year 2021 MOOP limits were maintained for contract year 2022 (applying the existing standard in current §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3)). As a result, for purposes of the regulation text, our finalized methodology utilizes 2023 as the first year of the ESRD cost transition schedule. As discussed in section II.A. of this FC, we finalized the completion of the ESRD cost transition in the proposed time frame with a slightly lower incorporation of ESRD costs for contract year 2023; this change in schedule will also apply to the methodology CMS uses to calculate the inpatient hospital acute and psychiatric cost sharing limits as proposed and finalized in paragraph (f)(6)(iv)(C). In lowering the ESRD cost differential percentage for contract year 2023 compared to our proposal for 2023, we aim to strike a balance between curbing potential disruptive changes in MOOP and inpatient services cost sharing limits from contract year 2022 and providing MA organizations the ability to continue offering all plan enrollees, regardless of their ESRD status, quality care and service while keeping premiums and cost sharing at non-discriminatory levels. In summary, the final 2-year transition schedule we are codifying in paragraph (f)(4)(vi) incorporates the ESRD cost differential into the Medicare FFS data used for setting inpatient cost sharing limits as follows: 70 percent in 2023; and 100 percent in 2024 or the final year of transition. This builds on how CMS has incorporated 40 percent of the ESRD cost differential in setting the inpatient hospital cost sharing limits for 2021 and 2022. This transition schedule of ESRD costs remains a part of the final methodology CMS uses to calculate inpatient hospital cost sharing limits.

As proposed and finalized in § 422.100(f)(6)(iv)(C), the data used to calculate the inpatient hospital acute and psychiatric cost sharing limits will be aligned with the data used to calculate MOOP limits with regard to using the updated transition schedule to incorporate ESRD costs finalized in section II.A. of this FC. In applying this ESRD cost transition schedule, as finalized in section II.A. of this FC, the cross-reference is being updated to paragraph (f)(4)(vi)(A) through (B) and the reference to paragraph (f)(4)(v)(C) is being removed in the final regulation in paragraph (f)(6)(iv)(C). In addition, paragraph (f)(6)(iv)(C) has a slight modification to make the regulation text more consistent with the other modifications to the rules finalized for MOOP and cost sharing limits as discussed in sections II.A and II.B. of this FC. Specifically, the regulation text consistently refers to the out-of-pocket costs ''incurred by'' (rather than ''representing'') beneficiaries with diagnoses of ESRD in describing the Medicare FFS data CMS would be using are projections for the applicable year and length of stay scenario in paragraph (f)(6)(iv)(C). This use of the phrase ''incurred by'' here is not relevant to the cost sharing that MA plans must count toward the MOOP limit when determining if the MOOP has been reached by a particular enrollee. These changes are consistent with the language finalized in § 422.100(f)(4)(vii), (f)(6)(i)(B), (f)(6)(iii)(B), and (j)(1)(i)(F)*(2)* to clearly describe how Medicare FFS data projections are being used across MOOP limits and cost sharing standards. These changes are aligned with our proposals, the calculations of the illustrative inpatient hospital acute and psychiatric cost sharing limits from the February 2020 proposed rule, and the final contract year 2023 limits included in Table 28.

As finalized, CMS is applying the ESRD cost transition consistently to the methodology for calculating cost sharing limits for inpatient hospital services and the methodology for calculating MOOP limits to provide stability to MA organizations. We are finalizing the proposal to use the same data and the transition schedule finalized for incorporating the ESRD cost differential that we adopted in connection with the MOOP limits, through the updated reference to paragraphs (f)(4)(vi)(A) through (B) in paragraph (f)(6)(iv)(C). We are not finalizing the tolling provision for incorporating the ESRD cost differential, so there is no need to address that part of the proposal in final § 422.100(f)(6)(iv). Inpatient hospital cost sharing limits for contract year 2021 were finalized through the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation'' issued April 8, 2020, and are not addressed in this rule; we used 40 percent of the ESRD cost differential to set those cost sharing limits. In addition, the inpatient hospital cost sharing limits were maintained from contract year 2021 for contract year 2022.[47]

Tables 18 and 19 illustrate how CMS calculated the final contract year 2023 inpatient hospital acute cost sharing limits based on the MOOP type for the 10-day length of stay scenario using the finalized policy in § 422.100(f)(6)(iv) and projections of contract year 2023 costs based on 2017–2021 Medicare FFS data. In addition, Tables 20 and 21 provide similar projections for the same inpatient hospital acute 10-day length of stay scenario to illustrate cost sharing limits for contract year 2024 using contract year 2023 Medicare FFS data projections (as projections for contract year 2024 were not available at the time of writing this FC). Tables 20 and 21 illustrate how the completion of the finalized ESRD cost differential transition may affect the inpatient hospital cost sharing limits for contract year 2024. Tables 18 through 21 are similar to Table 4 (Illustrative Example of Cost Sharing Limits Based on Current Medicare FFS Data For Inpatient Hospital Acute 10-day Length of Stay Scenario) in the February 2020 proposed rule, with updates to apply the methodology as finalized for comparison purposes. Specifically, the inpatient hospital cost sharing limits in Tables 18 through 21 were developed by: (1) Incorporating 70 percent of the projected ESRD cost differential for 2023 and 100 percent of the ESRD cost differential for 2024 (the final year of the ESRD cost transition); (2) applying the modified methodology to calculate inpatient hospital cost sharing limits for MA plans with an intermediate MOOP limit (as discussed previously in a response to comment in this section); and (3) applying the rounding rules finalized in § 422.100(f)(6)(ii). Similar calculations as shown in Tables 18 and 19 were completed to reach the final contract year 2023 inpatient hospital cost sharing limits for the other length of stay scenarios include in Table 28.

As shown in Tables 18, 19, and 28, modifying the ESRD cost transition from

[47] See the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021.

the proposed 80 percent to 70 percent in contract year 2023 and basing the amounts on projections using Medicare FFS data from 2017–2021 (compared to the 2015–2019 data available at the time of the February 2020 proposed rule) produced an increase from the amounts projected in the February 2020 proposed rule, using the proposed methodology; the highest allowable amount for an inpatient hospital acute 10-day length of stay scenario in contract year 2023 for an MA plan that establishes a mandatory MOOP amount increased by $242. However, we reiterate that the contract year 2024 inpatient hospital cost sharing limits in Tables 20 and 21 are illustrative in nature and are subject to update using more recent Medicare FFS data projections when CMS issues the final cost sharing limits for contract year 2024 through the annual subregulatory process in § 422.100(f)(7)(iii). We currently intend to calculate and set contract year 2024 cost sharing limits using contract year 2024 Medicare FFS data projections (based on 2018–2022 Medicare FFS data) after publication of this FC, which may vary from the illustrations in Tables 20 and 21.

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TABLE 18: CMS CALCULATIONS OF THE FINAL CONTRACT YEAR 2023 INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO COST SHARING LIMITS FOR THE MANDATORY AND LOWER MOOP TYPES USING PROJECTIONS FROM 2017 – 2021 MEDICARE FFS DATA AND THE ESRD COST DIFFERENTIAL TRANSITION

Row Reference	Description	Mandatory MOOP Type	Lower MOOP Type
A	Projected Part A Deductible*		$1,572.00
B	Projected Part B Professional Costs for a 10-day length of stay (with ESRD costs)*		$955.00
C	Total estimated Medicare FFS cost sharing for a 10-day length of stay with ESRD costs (row A plus row B)		$2,527.00
D	Projected Part B Professional Costs for a 10-day length of stay (without ESRD costs)		$863.00
E	Total estimated Medicare FFS cost sharing for a 10-day length of stay without ESRD costs (row A plus row D)		$2,435.00
F	Allowable percentage of Medicare FFS estimated cost sharing by MOOP type per § 422.100(f)(4)(iv)	100%	125%
G	Total cost sharing with ESRD costs (row C multiplied by row F)	$2,527.00	$3,158.75
H	Total cost sharing without ESRD costs (row E multiplied by row F)	$2,435.00	$3,043.75
I	ESRD cost differential per § 422.100(f)(4)(vi) (row G - row H)	$92.00	$115.00
J	70% of ESRD cost differential per § 422.100(f)(4)(vi) (row I multiplied by 0.7)	$64.40	$80.50
K	Unrounded contract year 2023 cost sharing limit (row H plus row J)	$2,499.40	$3,124.25
L	Rounded final contract year 2023 cost sharing limit per § 422.100(f)(6)(iv) (row K rounded per § 422.100(f)(6)(ii))	$2,499.00	$3,124.00

*The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (as finalized in § 422.100(f)(7).

TABLE 19: CMS CALCULATIONS OF THE FINAL CONTRACT YEAR 2023 INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO COST SHARING LIMIT FOR THE INTERMEDIATE MOOP TYPE USING PROJECTIONS FROM 2017 – 2021 MEDICARE FFS DATA AND THE ESRD COST DIFFERENTIAL TRANSITION

Row Reference	Description	Intermediate MOOP Type
A	Unrounded contract year 2023 inpatient hospital acute 10-day length of stay scenario cost sharing limit for the mandatary MOOP type per § 422.100(f)(4)(vi) (row K, mandatory MOOP limit column in Table 18)	$2,499.40
B	Unrounded contract year 2023 inpatient hospital acute 10-day length of stay scenario cost sharing limit for the lower MOOP type per § 422.100(f)(4)(vi) (row K, lower MOOP limit column in Table 18)	$3,124.25
C	Unrounded contract year 2023 cost sharing limit per § 422.100(f)(6)(iv) (numeric midpoint between row A and row B)	$2,811.83
D	Rounded contract year 2023 inpatient hospital acute 10-day length of stay cost sharing limit for an intermediate MOOP limit per § 422.100(f)(4)(vi) and (f)(6)(iv) (row C rounded per § 422.100(f)(6)(ii))	$2,812.00

TABLE 20: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO COST SHARING LIMITS FOR THE MANDATORY AND LOWER MOOP TYPES USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Mandatory MOOP Type	Lower MOOP Type
A	Projected Part A Deductible*	$1,572.00	
B	Projected Part B Professional Costs for a 10-day length of stay (with ESRD costs)*	$955.00	
C	Total estimated Medicare FFS cost sharing for a 10-day length of stay with ESRD costs (row A plus row B)	$2,527.00	
D	Allowable percentage of Medicare FFS estimated cost sharing by MOOP type per § 422.100(f)(4)(iv)	100%	125%
E	Unrounded illustrative contract year 2024 cost sharing limit (row C multiplied by row D)	$2,527.00	$3,158.75
F	Rounded illustrative contract year 2024 cost sharing limit (row E rounded per § 422.100(f)(6)(ii)	$2,527.00	$3,159.00

*These amounts are for illustrative purposes only and are the values for contract year 2023 from rows A and B in Table 18. CMS will use updated projected Part A deductible and Part B professional costs to calculate the final contract year 2024 inpatient hospital cost sharing limits.

TABLE 21: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO COST SHARING LIMIT FOR THE INTERMEDIATE MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Intermediate MOOP Type
A	Unrounded illustrative contract year 2024 inpatient hospital acute 10-day length of stay scenario cost sharing limit for the mandatary MOOP type per § 422.100(f)(4)(vi) (row E, mandatory MOOP limit column in Table 20)	$2,527.00
B	Unrounded illustrative contract year 2024 inpatient hospital acute 10-day length of stay scenario cost sharing limit for the lower MOOP type per § 422.100(f)(4)(vi) (row E, lower MOOP limit column in Table 20)	$3,158.75
C	Unrounded illustrative contract year 2024 cost sharing limit per § 422.100(f)(4)(iv) (numeric midpoint between row A and row B)	$2,842.88
D	Rounded illustrative contract year 2024 inpatient hospital acute 10-day length of stay cost sharing limit for an intermediate MOOP limit per § 422.100(f)(4)(iv) (row C rounded per § 422.100(f)(6)(ii))	$2,843.00

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As discussed in section II.A. of this FC, CMS will monitor the percentage of beneficiaries with diagnoses of ESRD enrolled in MA plans compared to Medicare FFS. If appropriate, we will consider future rulemaking to alter the methodology CMS uses to calculate MOOP and cost sharing limits if there are significant unforeseen impacts or negative consequences that need to be addressed. We would also consider whether additional changes would outweigh the interests of maintaining a settled methodology for calculating the MOOP and cost sharing limits and sufficiently protect enrollees from changes in cost sharing and benefits from 1 year to the next. In addition, as proposed and finalized, § 422.113(f)(6)(iv)(C) provides that CMS may also use patient utilization information from MA encounter data. In the February 2020 proposed rule we explained that CMS compared inpatient hospital utilization information from both Medicare FFS and MA encounter data to determine the specific length of stay scenarios for which we proposed to calculate cost sharing limits. As finalized, CMS may pursue future rulemaking to add, remove, or modify the length of stay scenarios applied to inpatient hospital acute and psychiatric cost sharing limits based on comparisons of inpatient hospital utilization information from both Medicare FFS and MA encounter data.

d. Emergency/Post-Stabilization Services and Urgently Needed Services (§ 422.113(b)(2)(v) and (vi))

Comment: Comments were mixed for CMS's proposals (in section VI.B.3.b. of the February 2020 proposed rule) related to emergency/post-stabilization services. A commenter generally supported increasing the copayment limits and the differential in cost sharing tied to the types of MOOP limit for the ''emergency/post-stabilization services'' service category. This commenter noted this was an important service category to change as it would incentivize MA plans to offer lower MOOP limits and enrollees to use the appropriate level of care, such as physicians' offices or urgent care centers, and not overutilize the higher cost emergency room services.

A few other commenters opposed increasing the cost sharing limit for emergency/post-stabilization services. The commenters were concerned that increasing the cost sharing limit (and by extension, permitting increased cost sharing) would have the undesirable outcome of deterring beneficiaries from going to the emergency room when medically necessary, even when immediate medical care is truly needed, as many Medicare beneficiaries will simply be unable to afford the cost sharing. In reference to those concerns, the commenters requested CMS lower or maintain the contract year 2021 emergency/post-stabilization services cost sharing limits ($120 for the lower, voluntary MOOP limit and $90 for the mandatory MOOP limit). The commenters did not specifically address a cost sharing limit (or approach) for emergency/post-stabilization services for MA plans that establish an intermediate MOOP limit.

A commenter stated that CMS is unfairly penalizing Medicare beneficiaries who receive emergency services as CMS has increased the cost sharing limits for emergency services for the voluntary and mandatory MOOP limits by 60 percent and 20 percent respectively over the last several years. In addition, a commenter stated survey results from the Centers for Disease Control and Prevention (CDC) show that only a small percentage of emergency department visits are avoidable.[48] This commenter noted that in many cases, Medicare beneficiaries cannot tell whether their condition is life-threatening or not and regardless of the final diagnosis, if the beneficiary

[48] Centers for Disease Control and Prevention National Hospital Ambulatory Medical Care Survey: 2017 Emergency Department Summary Tables, available at: *https://www.cdc.gov/nchs/data/nhamcs/web_tables/2017_ed_web_tables-508.pdf.*

reasonably believes that they have a medical emergency, they are entitled to go to the emergency department and be treated. Similarly, another commenter stated that while CMS has increased the cost sharing limits in various service categories year by year, such increases can be particularly harmful to beneficiaries in the emergency services context. This commenter explained that due to the age and vulnerability of the Medicare population, visits to the emergency department are necessary and not substitutes for primary care.

Response: We agree with the commenters that excessive cost sharing rates discriminate against enrollees who need those services. CMS has a long-standing interpretation that payment of less than 50 percent of the estimated total MA plan financial liability discriminates against enrollees who need those services. We understand emergency services, by nature, are typically associated with critical health care needs and we agree that it is important that enrollees do not face unexpected and unreasonable financial hardships in accessing needed health care services. In addition, section 1852(d)(3) of the Act and our existing regulation at § 422.113 are clear that the determination whether an emergency medical condition exists is based on the prudent layperson standard. Our proposal was not designed to discourage enrollees from seeking or receiving emergency services to address an emergency medical condition. Our proposed cost sharing standards for emergency and post-stabilization care services were to set the maximum out-of-pocket cost sharing amount that an MA plan may require an enrollee to pay for a visit to an emergency room, inclusive of any variability in the costs of services provided during the emergency visit. Enrollees who are not in need of emergency care typically have access to care with lower or no cost sharing. For example, urgent care, additional telehealth, or supplemental benefits for nursing hotlines or transportation related to medical services are often available to enrollees. For example, based on March 2021 plan data (excluding employer and D–SNPs) approximately 40.6 percent of contract year 2021 plans (reflecting 38.5 percent of total enrollment) offer a transportation supplemental benefit for medical purposes and approximately 65.0 percent offered a nursing hotline (reflecting 66.6 percent of total enrollment). We expect that these types of services assist with care coordination and support enrollees in accessing the most appropriate place of care for their condition. In addition, beneficiaries eligible for full Medicaid benefits and the Qualified Medicare Beneficiary (QMB) program generally would not pay Medicare cost sharing for emergency services in MA plans, including D–SNPs.

Our proposal based the dollar limits on the projected Medicare FFS median total allowed amount for emergency services (including visit and related procedure costs, $755) using contract year 2021 Medicare FFS data projections that were based on the 2015–2019 Medicare FFS data available at the time of the February 2020 proposed rule. We reviewed both the projected median and average total allowed amount from the OACT when determining the methodology for setting cost sharing limits for this category. If we had proposed to base our methodology on the projected average total allowed Medicare FFS amount ($998 including visit and related procedure costs), the highest allowable cost sharing for a plan that established a lower MOOP limit would have been $200, $50 higher than our proposal to use the projected median. However, we chose to use the projected median, which means that roughly half of Medicare beneficiaries in the Medicare FFS program were expected to incur cost sharing that was likely higher than these costs. Since the February 2020 proposed rule, updated contract year 2023 Medicare FFS data projections using Medicare FFS data from 2017–2021 increases the projected median and average total allowed amounts for emergency services (including visit and related procedure costs) to $861 and $1,106, respectively. The maximum cost sharing limits for emergency services are not being changed to reflect these updated projections because our proposal was to calculate specific dollar amounts for cost sharing limits for emergency and post-stabilization services. But understanding the out-of-pocket costs experienced in the Medicare FFS program provides important context for the cost sharing limits that we are adopting in this FC.

As discussed in the February 2020 proposed rule, to calculate the proposed emergency and post-stabilization care services cost sharing limits for the mandatory and lower MOOP limits (Mandatory—$115 and Lower—$150), CMS took 15 percent and 20 percent of the projected median total allowed amount ($755) respectively, rounded to the nearest whole $5 increment. In addition, the proposed cost sharing limit for an intermediate MOOP limit ($130) was calculated based on the numeric midpoint of the related cost sharing limits for MA plans with mandatary and lower MOOP limits, rounded to the nearest whole $5 increment. We realized that using up to 20 percent of this projected Medicare FFS median total allowed amount to set an emergency cost sharing amount for an MA plan that establishes a lower MOOP limit would result in an increase of the MA cost sharing limit, compared to the prior contract year. However, the cost sharing standard we proposed at § 422.113(b)(2)(v) for MA plans that establish a lower MOOP limit is comparable to what a beneficiary in Medicare FFS would be required to pay for a similar trip to the emergency room after reaching the Part B deductible, based on 20 percent of Medicare FFS costs. Therefore, we do not believe that setting a cost sharing standard that is based on costs that are 15 percent (for the mandatory MOOP limit) and 20 percent (for the lower MOOP limit) of the median projected total cost for emergency services (including visit and related procedure costs) experienced in the Medicare FFS program is discriminatory. Nor do we believe utilizing the numeric midpoint of those limits to set a cost sharing limit for intermediate MOOP limit is discriminatory. We believe that basing the MA cost sharing limits for these services to the projected costs for beneficiaries in the Medicare FFS program reasonably addresses and balances our goals for adopting cost sharing limits overall.

We proposed to align the highest permissible cost sharing amount (which is available for MA plans that use the lower MOOP limit) with original Medicare, by allowing a maximum emergency services cost sharing limit permitted per visit of $150, as an incentive for plans to offer a lower MOOP limit, which is another important financial protection for beneficiaries. If the cost sharing limits for emergency services do not change from the current amounts to reflect more recent Medicare FFS data projections and trends, we expect that the limits will act as a disincentive for MA plans to offer lower MOOP amounts. For example, for contract year 2021 (based on March 2021 plan data) approximately 85 percent of MA and MA–PD plans (excluding D–SNPs) established the highest allowable cost sharing for this service category based on the type of MOOP limit, suggesting that these upper limits may not fully reflect the costs MA organizations are experiencing to cover emergency services for enrollees. Conversely, while increasing flexibility in cost sharing

standards may provide an incentive for plans to offer lower MOOP limits, we deliberately did not use percentages higher than 20 percent because we believe it is important to align with the coinsurance percentage that applies to most original Medicare Part B services. Therefore, we continue to believe that the dollar figures we proposed ($115, $130, and $150) as the cost sharing limits for MA plans that use the mandatory, intermediate or lower MOOP limit are the appropriate final cost sharing limits to adopt for emergency services.

The cost sharing limits proposed at § 422.113 are reasonably close to emergency room copayment levels for employer and Qualified Health Plans. For example, the Kaiser Family Foundation (KFF) found that the majority of covered workers either have a coinsurance or copayment for an emergency room visit with the average coinsurance rate of 20 percent and the average copayment of $180 based on a 2017 employer health benefits survey.[49] The annual employer health benefits survey reports since the 2017 survey from KFF have not updated the average emergency room cost sharing rates at the time of writing this FC but are available online.[50] In addition, utilizing 2015 data from the Exchanges, KFF found that the average Qualified Health Plan copayment ranged from $155 to $318 and the average coinsurance ranged from 20 percent to 32 percent based on the type of plan (bronze, silver, gold, or platinum).[51] This report was last updated using 2016 data from the Exchanges, and KFF found that the average Qualified Health Plan copayment increased to $171–$430 and the average coinsurance changed to 19 percent to 34 percent based on the type of plan (bronze, silver, gold, or platinum).[52] While setting cost sharing limits based on 15 and 20 percent of Medicare FFS costs in itself is not discriminatory or out of line with the market, we acknowledge that a substantial change in cost sharing limits from one year to the next may produce disruption for enrollees. As discussed in sections II.B.5.b. and e. of this FC, CMS is making several changes in implementing the proposed cost sharing policies addressed in this FC to minimize potential disruption in implementing the changes in cost sharing proposed in this rulemaking. For example, we are using a 4-year transition to reach the proposed range of cost sharing limits for professional services. As discussed in section V.H.2. of this FC, CMS also considered several alternatives to implementing the proposed cost sharing limits for emergency services (renamed for clarity as discussed in a following response to comment in this section) to minimize potential enrollee disruption. After consideration of those alternatives, we believe a multiyear transition to the proposed cost sharing limits for emergency services would be beneficial and responsive to comments. Applying a transition to the new copayment limits (for emergency services) and use of maximum coinsurance percentages and actuarially equivalent copayment amounts (for urgently needed services) should be helpful as it will: (1) Smooth the possible changes in cost sharing for these service categories over several years to avoid potentially disruptive increases in costs for enrollees; and (2) provide MA organizations several years of advance notice of what the specific cost sharing limits will be (for emergency services) and what the coinsurance limits will be (for urgently needy services) to consider whether it makes sense for their plans to use the maximum permitted cost sharing when planning their bid designs. As a result, we are modifying § 422.113(b)(2)(v) to apply a 4-year transition to reach the proposed cost sharing limits based on the type of MOOP limit for emergency services. With regard to urgently needed services, where we proposed and are finalizing that the cost sharing limits for in-network basic benefits that are professional services apply to MA plans, the transition adopted in § 422.100(f)(6)(iii) and (f)(8) will also apply. This applies regardless whether the urgently needed services are furnished in-network or out-of-network because § 422.113 requires MA plans to cover urgently needed services without regard to whether the services are furnished by an in-network provider or prior authorization. As a result, we are adopting a transition for the cost sharing limits proposed for both emergency services and urgently needed services. We believe this approach to implement these cost sharing proposals in §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2) through a 4-year transition will support a consistent and streamlined approach in updating MOOP and cost sharing limits.

We developed the transition schedule finalized in § 422.113(b)(2)(v) by taking the difference between the proposed cost sharing amounts for emergency services and the current (contract year 2022) cost sharing limits and incorporating 25 percent of the difference each year over a 4-year period and applying the rounding rules. In addition, contract year 2023 will be the first year CMS sets an intermediate MOOP limit. For purposes of calculating the transitional cost sharing limits for the intermediate MOOP limit, CMS used the numeric midpoint between the transitional cost sharing limits for the mandatory and lower MOOP limits before application of the rounding rules, then applied the rounding rules to that midpoint amount. This is consistent with our proposal to set maximum cost sharing limits for MA plans with an intermediate MOOP limit based on the numeric midpoint of the related cost sharing limits for MA plans with mandatory and lower MOOP limits, rounded to the nearest whole $5 increment. The calculations CMS completed to reach the final contract year 2023 emergency services cost sharing limits are available in Table 22 and 23. Similar calculations as shown in Tables 22 and 23 were completed to reach the final cost sharing limits for the following years of the transition, contract years 2024 through 2026. In summary, applying this transition and the rounding rules in § 422.100(f)(6)(ii) results in the emergency services cost sharing limits summarized in Table 24 for contract year 2023 and future years, which is what we are finalizing in § 422.113(b)(2)(v). Specifically, emergency services cost sharing limits will be transitioned to the amounts proposed for contract year 2026 and maintained for subsequent years. CMS modified the cost sharing limits proposed in paragraphs § 422.113(b)(2)(v)*(1), (2),* and *(3)* and is finalizing a new paragraph (b)(2)(v)*(4)* to set the cost sharing limits as shown in Table 24. The final contract year 2023 emergency services cost sharing limits are also summarized in Table 28 which updates the illustrative cost sharing limits from the February 2020 proposed rule's Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost

[49] Kaiser Family Foundation. 2017 Employer Health Benefits Survey—Section 7: Employee Cost Sharing. Published September 19, 2017. Retrieved from *https://www.kff.org/report-section/ehbs-2017-section-7-employee-cost-sharing/*.

[50] Kaiser Family Foundation. Employer Health Benefits Annual Survey Archives. Published November 10, 2021. Retrieved from: *https://www.kff.org/health-costs/report/employer-health-benefits-annual-survey-archives/*.

[51] Kaiser Family Foundation. The Cost of Care with Marketplace Coverage. Published February 11, 2015. Retrieved from *https://www.kff.org/health-costs/issue-brief/the-cost-of-care-with-marketplace-coverage/*.

[52] Kaiser Family Foundation. Patient Cost-Sharing in Marketplace Plans, 2016. Published November 13, 2015. Retrieved from: *https://www.kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016/*.

Sharing Limits) for comparison purposes.

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TABLE 22: CMS CALCULATIONS OF FINAL CONTRACT YEAR 2023 EMERGENCY SERVICES COST SHARING LIMITS FOR THE MANDATORY AND LOWER MOOP TYPES (§ 422.113(b)(2)(v))

Row Reference	Description	Lower MOOP	Mandatory MOOP
A	Contract year 2022 emergency care/post stabilization care cost sharing limits	$120.00	$90.00
B	Proposed emergency care/post stabilization care cost sharing limits	$150.00	$115.00
C	Total Difference (row A minus row B)	$30.00	$25.00
D	25% of the Difference (row C multiplied by 0.25)	$7.50	$6.25
E	Unrounded contract year 2023 emergency services cost sharing limits (row A plus row D)	$127.50	$96.25
F	Rounded contract year 2023 emergency services cost sharing limits (row E rounded per § 422.100(f)(6)(ii))	$125.00	$95.00

TABLE 23: CMS CALCULATIONS OF THE FINAL CONTRACT YEAR 2023 EMERGENCY SERVICES COST SHARING LIMIT FOR THE INTERMEDIATE MOOP TYPE (§ 422.113(b)(2)(v))

Row Reference	Description	Intermediate MOOP
A	Unrounded contract year 2023 emergency services cost sharing limit for the lower MOOP limit (value in row E for the lower MOOP column from Table 22)	$127.50
B	Unrounded contract year 2023 emergency services cost sharing limit for the mandatory MOOP limit (value in row E for the mandatory MOOP column from Table 22)	$96.25
C	Unrounded contract year 2023 emergency services cost sharing limit for the intermediate MOOP limit (numeric midpoint between row A and row B)	$111.88
D	Rounded contract year 2023 emergency services cost sharing limit for the intermediate MOOP limit (row C rounded per § 422.100(f)(6)(ii))	$110.00

TABLE 24: FINAL MULTIYEAR TRANSITION FOR EMERGENCY SERVICES COST SHARING LIMITS BASED ON THE MOOP TYPE (§ 422.113(b)(2)(v))

MOOP Level	2022*	2023	2024	2025	2026 and Future Years
Lower (Previously "voluntary")	$120	$125	$135	$140	$150
Intermediate	N/A	$110	$120	$125	$130
Mandatory	$90	$95	$100	$110	$115

*Cost sharing limits for contract year 2022 provided for comparison purposes.

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In setting a 4-year transition to the proposed cost sharing limits, CMS is attempting to strike a balance between the needs of beneficiaries to seek emergency care and plan costs associated with the variety and expense of services included in the cost sharing limit. The dollar amounts for emergency services represent the maximum cost sharing permitted per visit (including related procedure costs) and are not subject to plan level deductibles or network restrictions. CMS will continue to track Medicare FFS cost trends for emergency services and may consider future rulemaking to update these cost sharing limits, if appropriate. For example, we will continue to review the projected average and median Medicare FFS allowed amounts from the OACT annually, consult with the OACT on whether any applicable cost trends are expected to be consistent for future contract years, and consider how market competition or payment policies may affect or necessitate changes to the methodology CMS used to calculate cost sharing limits proposed and finalized here.

We are also finalizing the proposal, at § 422.113(b)(2)(vi), that cost sharing for urgently needed services must not exceed the limits on cost sharing that are specified for professional services in § 422.100(f)(6)(iii). This means that cost sharing limits for urgently needed services may vary with the type of MOOP limit. Further, as with professional services, the cost sharing for urgently needed services may not exceed a set coinsurance percentage or an actuarially equivalent copayment value, and the values for copayment limits may be calculated by CMS applying the methodology in this FC or by the MA organization based on the estimated total MA plan financial liability for that contract year if CMS does not calculate the copayment limit for the specific service or service category. In addition, our proposed in-network cost sharing standards for urgently needed services represent the maximum out-of-pocket cost sharing amount that an MA plan may require an enrollee to pay for these services, inclusive of any variability in the costs provided during the visit. Specifically, CMS may calculate copayment limits for urgently needed services based on § 422.100(f)(6)(iii) (and new paragraph (f)(8)(i) during the transition to actuarially equivalent copayment limits). A more complete discussion related to the requirement for cost sharing for professional services, the range of permissible cost sharing, and the transition to actuarially equivalent copayment limits is available in section II.B.5.b. of this FC.

We are finalizing our proposals related to emergency services and urgently needed services generally as proposed, with 4-year transitions to reach the proposed cost sharing limits. We are not finalizing the proposal to consolidate the cost sharing limits for emergency and post-stabilization services (as discussed in a following response to comment in this section).

Comment: A commenter was concerned that increasing the cost sharing limits for emergency/post-stabilization services (and by extension, permitting increased cost sharing amounts) may further burden hospitals with uncollectable bad debts. The commenter believed this proposed increase in cost sharing would burden hospitals because: (1) Many Medicare beneficiaries will be unable to afford the cost sharing; (2) MA organizations are not required to pass along to hospitals (or other providers) payments of uncollected cost sharing (that is, bad debt) that are built into the capitated payments that MA organizations receive from CMS; and (3) MA organizations have considerable bargaining power over their network providers—particularly as the payer market has consolidated nationwide—which makes it unrealistic to expect an MA organization would agree to pass on these payments to providers. As a comparison, this commenter noted that the traditional Medicare program accounts for beneficiaries not being able to afford emergency room cost sharing and reimburses providers for uncollected cost sharing, such as copayments and co-insurance. In addition, the commenter noted that while it may be suggested that this is a matter for MA organizations and providers to resolve through their private agreements, it is unclear why providers should not be reimbursed for uncollected cost sharing amounts solely because the patient is enrolled in an MA plan instead of Medicare FFS. Due to these factors, the commenter requested CMS require MA organizations reimburse providers for uncollected cost sharing from beneficiaries.

Response: To clarify information in the comment, under Medicare FFS, CMS permits inclusion of uncollectible Medicare deductible and coinsurance amounts in allowable costs for certain providers (42 CFR 413.89) and reimburses these amounts subject to the limitations set forth in § 413.89(h), however this reimbursement does not apply to MA plans. We agree with the commenter that currently MA organizations, hospitals, and provider groups negotiate contractual terms, including payment arrangements, to meet the needs of each party, including how uncollected cost sharing is handled. Allowing for private organizations to negotiate with one another to provide health care services for beneficiaries is core to the MA program. We believe the MA program affords flexibility and allows market competition to provide plan options that meet the needs of beneficiaries. Further, and perhaps most importantly, section

1854(a)(6)(B)(iii) of the Act and § 422.256(a)(2)(ii) prohibit CMS from requiring a particular price structure to be used between MA organizations and their contracted providers; we view this issue regarding payment by the MA organization of certain amounts to a contracted provider to be within the scope of this prohibition. In addition, the commenter's overarching request that CMS require MA organizations to reimburse providers for uncollected cost sharing from beneficiaries (for all cost sharing, not limited to emergency and post-stabilization care services) is out-of-scope of our proposal. We proposed to adopt specific cost sharing limits for this service category based on a particular methodology.

Comment: A few commenters supported CMS creating a single cost sharing limit for emergency/post-stabilization services. A commenter that supported a single cost sharing limit (using a specific dollar amount) for emergency/post-stabilization services appreciated the greater transparency the February 2020 proposed rule provided in how CMS establishes these cost sharing limits and agreed that it can be difficult for enrollees to differentiate emergency services from post-stabilization services. Another commenter requested CMS confirm and provide clarification that the emergency/post-stabilization services category will remain consistent with the current industry practice regarding which services are included (services provided while in the emergency department) and which are excluded (inpatient acute care services). This commenter noted that if inpatient services were included this would be contrary to and a drastic change from current industry practice.

Response: We thank the commenters for their feedback on our proposal to create a single cost sharing limit for emergency and post-stabilization care services. Currently, § 422.113(b)(1)(ii) and (c)(1) defines the terms ''emergency services'' and ''post-stabilization care services.'' ''Emergency services,'' which is also defined in section 1852(d)(3) of the Act, means, with respect to an individual enrolled with an MA organization, covered inpatient and outpatient services that are furnished by a provider qualified to furnish emergency services and needed to evaluate or stabilize an emergency medical condition. ''Post-stabilization care services'' means covered services related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in § 422.113(c)(2)(iii), to improve or resolve the enrollee's condition. We also direct readers to section 1852 of the Act and § 422.113(c) which require MA organizations to cover post-stabilization care services in specified circumstances. Although post-stabilization may encompass a wide variety of services, we proposed to include post-stabilization care services with the emergency services category in order to reflect the services the enrollee receives immediately following stabilization in the emergency department. We agree with the commenter that including post-stabilization care services received as an admitted inpatient in the hospital as subject to the dollar limits proposed in § 422.113(b)(2)(v) would be a significant change from current industry practice. CMS has not and does not intend to include inpatient acute care services in these dollar limits because we proposed (and finalized as discussed in section II.B.5.c. of this FC) separate cost sharing limits for inpatient hospital acute and psychiatric length of stays in § 422.100(f)(6)(iv). MA plans must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization and for purposes of cost sharing, post-stabilization care services begin upon inpatient admission under § 422.113(c)(2)(iv). Limiting post-stabilization care services—and thus limiting the cost sharing limit for those services—to services that begin upon inpatient admission continues a policy in place since at least 2005 (70 FR 4632–33) and we did not propose to revise § 422.113(c)(2)(iv). As a result, we are finalizing the cost sharing limits proposed for emergency services under § 422.113(b)(2)(v) without reference to post-stabilization care services.

CMS described how post-stabilization may encompass a wide variety of services but is used in § 422.113 to reflect the services the enrollee receives immediately following stabilization in the emergency department in the CY 2019 Final Call Letter (issued April 2, 2018). This approach separates post-stabilization care services received as an admitted inpatient from emergency services and is also consistent with CMS's policy in the ''Medicare Program; Establishment of the Medicare Advantage Program; Final Rule'' published January 28, 2005 (referred to as the January 2005 final rule). For example, comments summarized in the January 2005 final rule supported CMS's clarification that the cost sharing limit for emergency services applied only to emergency department services and the notion that once an MA enrollee is admitted to a hospital, normal hospital cost sharing levels apply, even if the inpatient admission originates in the emergency department. As such, we clarify and reiterate that while the definition of emergency services references covered inpatient and outpatient services, CMS is not including post-stabilization inpatient acute care services for purposes of setting the cost sharing limits for emergency services in paragraph (b)(2)(v).

This distinction between services furnished in an emergency department from inpatient services after admission was used in our development of the cost sharing limits we are finalizing in § 422.113(b)(2)(v) for emergency services. As discussed previously in this section and in the February 2020 proposed rule, we used the projected median total allowed amount for emergency services (including visit and related procedure costs), based on the Medicare FFS data projections available at the time of the February 2020 proposed rule. These data were based on a sample of approximately 10,000 beneficiaries, excluding those that were admitted from the emergency room to the hospital as an inpatient within 3 days. In those cases where the beneficiary was admitted to the hospital, the emergency room or outpatient department services are paid for as part of the inpatient stay based on Medicare's ''3-day payment window'' for inpatient admissions. As a result, the projected median total allowed amount for emergency services used to calculate the proposed dollar limits did not need to be recalculated to remove any post-stabilization care costs related to services beneficiaries received once admitted to the hospital as an inpatient. Likewise, our proposed (and finalized) methodology to calculate inpatient hospital acute and psychiatric cost sharing limits did not require modification because post-stabilization care costs received as an inpatient are included in the projected Part B costs.

We are finalizing the proposed provisions regarding cost sharing for emergency services with modifications to apply a 4-year transition to reach the proposed cost sharing limits, remove post-stabilization care services language in § 422.113(b)(2)(v), and complete non-substantive formatting changes to ensure consistency in the regulation text in paragraphs (b)(2)(v)*(1), (2), (3),* and *(4).* We are not revising § 422.113(c)(2)(iv) and therefore continue current policy that for purposes of cost sharing, post-

stabilization care services begin upon inpatient admission; the cost sharing limits finalized at § 422.112(c)(2)(v) do not apply to post-stabilization inpatient acute care services. We note here that as ambulance services are not emergency or post-stabilization care services, there may be a separate cost sharing amount required for ambulance services. As discussed in section II.B.5.b. of this FC, ambulance services are not professional services for which cost sharing is set under § 422.100(f)(6)(iii) but are subject to the cost sharing limits set under § 422.100(f)(6)(i).

e. Services No Greater Than Original Medicare (§ 422.100(j)(1))

Comment: As discussed in other comment summaries in section II.B.5. of this FC and in this section, some commenters suggested that the proposed cost sharing limits in general and for specific service categories (including those subject to the statutory requirements in section 1852 (1)(B)(iv) of the Act, such as dialysis services) are discriminatory, pose too significant increases from the prior contract year, and would substantially discourage enrollment by beneficiaries who require those services. In addition, as referenced in other comment summaries in section II.A.4. and II.B.5. of this FC, a few commenters had concerns that the proposed changes to the MOOP and cost sharing standards within one year would negatively affect a plan's ability to meet the TBC standard. While these comments explicitly referred to specific parts of the MOOP and cost sharing proposals, the commenters' concerns regarding TBC are also relevant to the cost sharing proposals at § 422.100(j)(1) as they will also impact the TBC standard.

Response: We appreciate the feedback from commenters and address specific service category concerns in other responses to comment in section II.B.5. of this FC. Here, we address the general changes CMS is incorporating to address commenter concerns about potentially disruptive or discriminatory increases to cost sharing limits within one year as they relate to service categories subject to § 422.100(j)(1). As proposed and finalized paragraph (j)(1) requires MA plans to have cost sharing that does not exceed cost sharing in original Medicare for specified service categories. In section III. of this FC, CMS is soliciting comment for future additions to the cost sharing regulations as well.

As referenced in section II.B.5.a. of this FC, CMS may calculate copayment limits for any category of in-network professional services for 2023 and future years and our intention is to calculate copayment limits using the methodology in this FC for as many service categories as possible, including those service categories that are subject to § 422.100(j)(1). We believe calculating and issuing limits on cost sharing for covered services and ensuring MA organizations comply with these limits are important ways to ensure that the cost sharing aspect of a plan design does not discriminate against or discourage enrollment in an MA plan by beneficiaries who have high health care needs. CMS issued annual limits on cost sharing for covered services and guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letter (issue dates prior to 2020 [53]) and in bidding instructions. In addition, Chapter 4 of the Medicare Managed Care Manual (MMCM) [54] has contained long-standing polices regarding discriminatory cost sharing based on the requirements under paragraph § 422.100(f). The review of bids can be streamlined and simplified if CMS has specific copayment limits to apply as well as coinsurance limits for the service categories in the bid. While the coinsurance limits are also applicable, we believe that copayments are more readily understood by beneficiaries and provide beneficiaries with more definite means to predict their out-of-pocket costs when selecting among Medicare coverage options. Section 1852(a)(1)(B) of the Act specifies that MA plans may not charge higher cost sharing than is charged under original Medicare for certain benefits and provides authority for CMS to add other benefits for which enrollees will have this protection. CMS believes that calculating copayment limits at actuarially equivalent values to cost sharing required under original Medicare (based on the most recent Medicare FFS data projections) for these services will protect enrollees. This approach provides a clearer standard for both types of cost sharing (coinsurance and copayments). We are finalizing paragraph (j)(1) with some reorganization and edits for clarification and additional policies related to the policy. In order to better address this in the regulation and accommodate other changes as discussed in this response, proposed paragraphs (j)(1)(i)–(v) are re-designated as paragraphs (j)(1)(i)(A)–(E) in this FC.

We are finalizing § 422.100(j)(1) and (j)(1)(i) with the substance of proposed paragraph (j)(1) that in-network cost sharing established by an MA plan may not exceed the cost sharing required under original Medicare for the specific basic benefits and categories of basic benefits identified in paragraphs (j)(1)(i)(A) through (F). The revisions in this FC clarify that this requirement applies to coinsurance and copayments used by MA plans, that copayment limits are subject to the rounding rules finalizing in § 422.100(f)(6)(ii), and that when CMS calculates a copayment limit under paragraph (j)(1)(ii), copayments used by MA plans must not exceed those copayment limits. Copayments used by MA plans for the benefits listed in paragraph (j)(1) would generally be calculated at values that are actuarially equivalent to the cost sharing used in original Medicare, subject to limits on the increase in copayment levels when CMS calculates the copayment limit during a 4-year transition period. The transition period for the copayments for the service categories specified in paragraph (j)(1)(i) is the same as the transition period finalized for in-network basic benefits that are professional services specified in § 422.100(f)(6)(iii) and is codified at § 422.100(f)(8) (as discussed in more detail in section II.B.5.b. of this FC and subsequently in this response). We reiterate that MA plans always have the option to use either coinsurance or copayments in establishing the cost sharing obligations for their enrollees. The maximum coinsurance percentage permitted as cost sharing for the service categories listed in paragraph (j)(1)(i) regardless of MOOP type (excluding skilled nursing care, home health, and DME service categories) is 20 percent, which is the coinsurance used in original Medicare for those benefits.

We are finalizing the rules for calculating the copayment limits applicable to these services in § 422.100(j)(1)(ii). Section 422.100(j)(1)(i) requires that any copayment for these benefits used by an MA plan must not exceed the actuarially equivalent value calculated using the rules in paragraph (j)(1)(ii). When CMS calculates the copayment limit, we will follow the methodology in paragraphs (f)(7) and (8), as discussed in section II.B.5.a. of this FC. In brief, this means that CMS will use Medicare FFS data projections (as defined in § 422.100(f)(4)(i)) for the applicable year and service category and, where

[53] See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021 and the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

[54] Chapter 4 of the MMMCM can be accessed at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

consistent with paragraph (f)(7)(ii), MA encounter data. In addition, CMS will calculate copayment limits to be actuarially equivalent to the coinsurance required under original Medicare for the specified benefits and service categories in paragraph (j)(1), subject to the annual cap on increases to copayment limits calculated by CMS from year to year during the transition period in paragraph (f)(8). As with all of the projections and calculations performed under this FC, the final regulation requires that generally accepted actuarial principles and practices will be followed. If CMS does not calculate a copayment limit for a service category listed in paragraph (j)(1) and an MA plan wishes to use a copayment, it must establish a copayment that is equal to or less than an actuarially equivalent value to cost sharing required under original Medicare. Paragraph (j)(1)(ii) provides that an MA plan may use either the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year in calculating the actuarially equivalent value. Allowing MA organizations to use the estimated total MA plan financial liability for that contract year is consistent with longstanding practice for the supporting documentation process CMS has used when we have not calculated a copayment limit but a coinsurance limit does apply, as discussed in section II.B.5.a. of this FC. We are finalizing the flexibility for MA plans to also use the average Medicare FFS allowed amount as that data would clearly reflect cost sharing under original Medicare for the benefit and service area and may reduce burden for MA plans. It is not necessary for an MA organization to use one data source over the other. Regardless of whether the MA organization uses the average Medicare FFS allowed amount for the benefit and service area or the estimated total MA plan financial liability for that contract year to calculate actuarially equivalent copayments, the calculations would be calculated at the plan level (or segment, if applicable).

Following the finalized methodology set through this FC, CMS calculated copayment limits for most of the service categories listed in § 422.100(j)(1) for contract year 2023. CMS does not expect that calculating copayment limits for the same service categories subject to paragraph (j)(1) as we have traditionally done in past years, will increase the burden of complying with these standards for MA organizations. The PBP software includes validations to prevent an MA organization from entering cost sharing for a particular service category that is above the cost sharing limit calculated and issued by CMS. This process will be maintained for contract year 2023 using the final cost sharing limits in Table 28. In addition, CMS expects to maintain this PBP validation in future years. This approach will help manage the administrative burden in developing and reviewing plan bids because without a copayment limit calculated by CMS, each plan bid would need to be prepared and evaluated in relation to either the average Medicare FFS allowed amount for the plan service area or the estimated total MA plan financial liability for the benefit for that contract year. In the absence of specific copayment limits, MA organizations may need to prepare supporting documentation for the cost sharing established. A more detailed discussion about how MA organizations may approach preparing supporting documentation for service categories subject to paragraph (j)(1) is available in section II.B.5.a. of this FC.

Our intention in this rulemaking is to set and codify a body of cost sharing standards that by themselves, and in combination with one another, guard against discriminatory plan designs by limiting the amount of cost sharing and out-of-pocket costs that MA plans may impose on enrollees for basic benefits. Since contract year 2011, we have calculated cost sharing limits for this purpose, but codifying the methodology will provide additional transparency for stakeholders and stability for the MA program. This FC will result in changes from the cost sharing limits that apply for contract year 2022, primarily for copayment limits, for many service categories. As discussed in section II.B.5.b. and d. of this FC in relation to copayment limit changes for professional services and emergency services, we agree with commenters that substantive changes to copayment limits should be implemented over several years to reduce disruption in the market and for enrollees. Use of a transition period to smooth these changes also aligns with our approach in several places in the February 2020 proposed rule, such as the multiyear incorporation of ESRD costs into the methodology that CMS uses to calculate MOOP and inpatient hospital cost sharing limits. Further, we acknowledge the concerns from commenters regarding changes resulting from this FC impacting the TBC standard. We expect the changes we are finalizing here (including a transitional period to update copayment limits for service categories subject to § 422.100(j)(1)) combined with the TBC evaluation will ensure that enrollees who continue enrollment in the same plan from one year to the next are not exposed to significant cost increases (or benefit decreases) in one year while, at the same time, ensure that MA organizations do not face unreasonable challenges to satisfy the TBC evaluation.

Table 28 includes final contract year 2023 cost sharing limits for most of the service categories that we proposed to add to § 422.100(j). The copayment values in Table 28 also reflect the requirements in new § 422.100(f)(7) and (8). As discussed in section II.B.5.b. of this FC, the copayment limits set for some service categories in past years do not reflect values that are actuarially equivalent to the applicable coinsurance levels, including those service categories subject to paragraph (j)(1) where the comparison is to 20 percent coinsurance used in original Medicare. Rather, some of the contract year 2022 copayment limit amounts have been in place without change for a number of years and were originally set to strike a balance between limiting beneficiary out-of-pocket costs and the potential impact to plan design and costs. The overarching goal of these copayment limits was to ensure beneficiary access to affordable and sustainable benefit packages rather than to be precisely tied to cost sharing in original Medicare each year. Our proposed methodology to calculate copayment limits based on actuarially equivalent values to the coinsurance limit, in effect, would recalibrate copayment limits within 1 year by using the methodology finalized here (while coinsurance limits for the service categories subject to paragraph (j)(1) remain consistent with longstanding practice by being set at the cost sharing required under original Medicare). Following this methodology, some of the illustrative copayment limits for professional services provided in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule reflected potentially substantial increases from the prior contract year. Table 5 from the February 2020 proposed rule illustrated that the copayment limits were projected to increase, despite decreasing the coinsurance limits based on the MOOP type for the professional service categories from past years, as a result of using the most recent Medicare FFS data available to calculate actuarially equivalent copayment values at the time

of the February 2020 proposed rule. Several commenters submitted general concerns about cost sharing increases, including for particular service categories. While illustrative copayment limits that were actuarially equivalent to the cost sharing under original Medicare for all of the services categories subject to paragraph (j)(1) were not provided in the February 2020 proposed rule (rather, only coinsurance limits were provided in Table 5), based on the comments received, and in relation to the ''Part B drugs—Other'' service category (as discussed in section II.B.5.f. of this FC and a subsequent response to comment in this section), we believe feedback from the commenters was clear that enrollees should be protected from potentially significant increases in copayment amounts, especially within a one year timeframe.

Using on contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017–2021), the actuarially equivalent values to 20 percent coinsurance for certain service categories subject to § 422.100(j)(1) would produce significant increases to the copayment limits compared to those set for contract year 2022. For example, the contract year 2023 projected total median cost per session for the ''Part B—chemotherapy/radiation drugs'' service category equals $1,397.00 and the total weighted average cost per session equals $4,038.00 based on contract year 2023 Medicare FFS data projections. Using these projections, an actuarially equivalent copayment limit to the 20 percent coinsurance limit would be $280 (based on the total median cost per session) or $810 (based on the total weighted average cost per session), after applying the rounding rules in § 422.100(f)(6)(ii). In comparison, the contract year 2022 copayment limit was $75 for the ''Part B—chemotherapy/radiation drugs'' service category. As a result, calculating a copayment limit at an actuarially equivalent dollar amount to 20 percent of $1,397.00 or $4,038.00 in contract year 2023 would be a substantial increase (from $75 in contract year 2022 to $280 or $810 in contract year 2023 based on the projected median and average per session costs, respectively) and would not adequately protect enrollees from potentially disruptive changes compared to the prior contract year. However, not updating the copayment limits to reflect the most recent actuarially equivalent values would not be consistent with our proposal, would result in copayment limits that require MA plans to have copayments that are significantly less than the cost sharing in original Medicare when section 1852(a)(1)(B) of the Act imposes the cost sharing in original Medicare as the maximum permitted for an MA plan, and would not address the rapid scientific advancements in cancer treatments and the costs MA organizations are expected to incur in providing these services for MA enrollees. For example, the OACT is projecting the utilization of chimeric antigen receptor T cells (CAR–T) therapy and other expensive immunological treatments will increase and substantively impact aggregate costs for the ''Part B drug—chemotherapy/radiation drugs'' service category starting in 2022. A similar increase in expensive drugs is projected for the Medicare FFS data that CMS may use for the copayment limits for the ''Part B drugs—Other'' service category (as discussed in a subsequent response to comment in this section and shown in Table 25B). As discussed in the February 2020 proposed rule, enrollees generally find copayments more predictable and less confusing than coinsurance.[55] As discussed in a subsequent response to comment in this section, currently, the vast majority of MA plans have designed their ''Part B drugs—other'' benefit with cost sharing greater than zero and use coinsurance rather than a copayment. For contract year 2021 (based on March 2021 plan data) approximately 2 percent of MA and MA–PD plans (excluding employer, D–SNPs, and MSA plans) established a copayment for the ''Part B drugs—other'' service category ($50 or greater than zero), suggesting that the upper copayment limits for contract year 2021 (which were maintained for contract year 2022) may not fully reflect the costs MA organizations are experiencing to cover this benefit for enrollees or the out-of-pocket payments required from most MA enrollees. We believe recalibrating copayment limits to be actuarially equivalent to the coinsurance percentage used for the benefits listed in paragraph (j)(1) may incentivize MA organizations to design benefit packages using copayment structures for more service categories than in prior years.

Based on the potentially disruptive changes from updating contract year 2022 copayment limits to actuarially equivalent values for service categories subject to § 422.100(j)(1) for contract year 2023, concerns from commenters regarding discriminatory benefit designs for service categories subject to paragraph (j)(1) (such as dialysis services as discussed in a subsequent response to comment in this section), and the variability of provider contracting arrangements among MA organizations, we considered alternatives to ensure that copayment limits would be appropriately updated to reflect the most recent Medicare FFS data projections while also limiting the amount of change that could be incorporated within one year to protect enrollees. The alternatives we considered are discussed in section V.H. of this FC. After consideration of those alternatives, we believe a multiyear transition to actuarially equivalent copayment limits based on the most recent Medicare FFS data projections for service categories subject to paragraph (j)(1) would be beneficial and responsive to comments. Specifically, applying a multiyear transition to actuarially equivalent copayments during a period of potential disruption should be helpful as it will facilitate incremental changes and provide advance notice for MA organizations to consider in planning their bid designs.

As discussed in section II.B.5.b. of this FC, we are finalizing at § 422.100(f)(8) a provision that will cap the amount of change in copayment limits from year to year. That constraint permits a gradual transition from the copayment limits that are in place for contract year 2022 to copayment limits that are calculated using the actuarially equivalent value to cost sharing under original Medicare. If CMS calculates copayment limits for the services listed in § 422.100(j)(1), we will apply new paragraph (f)(8) to those copayment limits for the transition period of 2023 through 2026. This is explicit in § 422.100(j)(1)(ii) as finalized here. This copayment transition is discussed in detail in section II.B.5.b. of this FC as it is being operationalized in the same manner for service categories subject to paragraph (f)(6)(iii). The only substantive difference between service categories subject to paragraph (f)(6)(iii) and (j)(1) is the applicable coinsurance limit(s) used to calculate actuarially equivalent values. Under paragraph (j)(1), most of the service categories (excluding skilled nursing care, home health, and DME) are subject to a 20 percent coinsurance limit regardless of the MOOP type which is the cost sharing beneficiaries must pay under original Medicare; our current guidance on cost sharing limits for those services

[55] Loewenstein G, Friedman JY, McGill B, Ahmad S, Linck S, Sinkula S, Beshears J, J.Choi J, Kolstad J, Laibson D, Madrian BC, List JA, Volpp KG. ''Consumers' misunderstanding of health insurance''. Journal of Health Economics 2013;32(5):850–862. Retrieved from: *https://scholar.harvard.edu/laibson/publications/consumers-misunderstanding-health-insurance.*

where MA plans cannot exceed the cost sharing in original Medicare also reflects this 20 percent coinsurance and it was included in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule. Also consistent with Table 5 from the February 2020 proposed rule: The cost sharing limit for home health is 20 percent coinsurance for MA plans that choose a lower MOOP type and the cost sharing limit for each of the DME service categories is 20 percent coinsurance for MA plans that choose a mandatory MOOP type. As such, making a transition to that coinsurance limit is unnecessary (even for standards applied to the intermediate MOOP limit finalized in section II.A. of this FC, which are technically newly codified but are consistent with standards for the voluntary and mandatory MOOP limits from prior contract years). For example, in contract year 2022 the coinsurance limit for the ''therapeutic radiological services'' service category for MA plans is 20 percent, regardless of the MOOP type chosen. Following the methodology set through this FC, the ''therapeutic radiological services'' service category coinsurance limit that will be applicable for contract year 2023 and future years for MA plans that establish an intermediate MOOP limit will be 20 percent. MA organizations were able to, and may continue to, establish cost sharing equal to original Medicare for all benefits subject to paragraph (j)(1) in contract year 2021 and prior years by using coinsurance structures, which some MA organizations may have chosen to do because of geographic variation in health care costs.

For purposes of calculating the actuarially equivalent copayment differential defined in § 422.100(f)(8)(i), the actuarially equivalent copayment values for service categories subject to § 422.100(j)(1) are based on 20 percent coinsurance, except for: Skilled nursing care (as finalized in paragraph (j)(1)(i)(C)), home health services (for MA plans with an intermediate or mandatory MOOP, as finalized in paragraph (j)(1)(i)(D)), and each of the DME service categories (for MA plans with a lower or intermediate MOOP, as finalized in paragraph (j)(1)(i)(E)). We clarify this point because paragraph (f)(8)(i) requires use of the coinsurance limits that would apply in 2026, which is necessary for service categories subject to paragraph (f)(6)(iii), where the coinsurance percentages are changing over time. For purposes of paragraph (j)(1), the applicable coinsurance percentage is the same for contract years 2023 through 2026 and thereafter, unless the cost sharing requirements in original Medicare change. We are including a reference to paragraph (f)(8) in paragraph (j)(1) to apply the multi-year transition for copayment limits to the copayment limits calculated for these services.

CMS may calculate copayment limits for service categories subject to § 422.100(f)(6) and (j)(1) in contract year 2023 and subsequent years if we believe calculating such a copayment limit is feasible and appropriate to carry out program purposes, such as to protect beneficiaries against discriminatory cost sharing or to have further oversight of MA plans to ensure compliance with the regulatory standards. While certain factors complicated providing illustrative copayment amounts for all of the service categories listed in paragraph (j)(1) at the time of the February 2020 proposed rule, we are providing final contract year 2023 copayment limits in Table 28 for most of these service categories. The calculations to reach the contract year 2023 copayment limits for service categories subject to paragraph (j)(1) in Table 28 use contract year 2023 Medicare FFS data projections (based on 2017—2021 Medicare FFS data) and comply with the requirements in new paragraphs (f)(7) and (8). This includes projecting cost sharing which may be incurred by beneficiaries in 2023 using generally accepted actuarial principles and practices (as finalized in paragraph (f)(7)(i)).

As described in § 422.100(f)(7)(ii)(C), when there may be multiple or a range of actuarially equivalent copayment values for a service category, CMS will select a particular approach to calculate an actuarially equivalent copayment value to avoid disruptive changes for beneficiaries and plan designs. For example, CMS may choose to use the median rather than the average Medicare FFS allowed amount to calculate an actuarially equivalent copayment value for a service category subject to § 422.100(j)(1) if that measure of central tendency results in the least amount of change to the copayment limit from the prior contract year. This approach is consistent with our prior approach to set copayment limits. We may also consider choosing the median or average Medicare FFS allowed amount based on which value is most consistent with trends and patterns in MA utilization and costs (if available). For example, in the February 2020 proposed rule, we explained that CMS proposed to add new cost sharing limits for an inpatient hospital acute 3-day length of stay scenario because it represented the median length of stay based on separate analyses of Medicare FFS and MA encounter data (for the same time period). A similar comparison may be completed if MA encounter data is also available related to a service category subject to paragraph (j)(1). While helpful for comparison purposes and to inform which measure of central tendency CMS should use, MA encounter cost data will not be used to calculate the copayment limits. This approach further protects beneficiaries and plan designs from potentially disruptive changes to cost sharing. New paragraph (f)(7) is discussed in greater detail in section II.B.5.a. of this FC.

Tables 25A and 25B show the calculations to reach the transitional contract year 2023 copayment limits for service categories subject to paragraphs § 422.100(j)(1) and (f)(8). As shown in row D in Tables 25A and 25B, for most of the service categories subject to paragraph (j)(1), we calculated an actuarially equivalent value to the original Medicare coinsurance requirement using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). The total projected Medicare FFS cost for each service category in Tables 25A and 25B is based solely on Medicare FFS data (MA encounter data for the same time period was unavailable at the time of writing this FC). In addition, the total projected Medicare FFS cost reflects the lesser value of the median and weighted average amount (in selecting among these actuarial approaches, we selected the lesser value) for each of the service categories in Tables 25A and 25B. This approach results in the least amount of change from the copayment limits set for contract year 2022 and is consistent with avoiding unnecessary fluctuations in cost sharing as finalized in paragraph (f)(7)(ii)(C). As a result, we calculate the actuarially equivalent values based on a 20 percent coinsurance limit regardless of the type of MOOP limit for most of the service categories subject to paragraph (j)(1) (as illustrated in Tables 25A and 25B). This excludes all of the DME service categories for the lower and intermediate MOOP types, for which actuarially equivalent copayment values are based on a 50 percent coinsurance limit as discussed in section II.B.5.a. of this FC. In addition, for the following two service categories subject to paragraph (j)(1) the original Medicare cost sharing limit is unique: $0 for the first twenty days and one-eighth of the projected Part A deductible per day for days 21–100 of skilled

nursing care (paragraph (j)(1)(i)(C)) and $0 for home health services (paragraph (j)(1)(i)(D)). Specifically, for those benefits, CMS is finalizing regulation text with specific cost sharing limits to ensure that MA plans use cost sharing that does not exceed cost sharing in original Medicare:

• Skilled nursing care: Codifies specific cost sharing limits for days 1–20 in § 422.100(j)(1)(i)(C) based on the type of MOOP limit established and a specific methodology to calculate cost sharing limits for days 21–100, regardless of the MOOP amount established calculated, in paragraph (j)(1)(i)(C)*(1).*

• Home health: Applies the original Medicare cost sharing of $0 for MA plans that establish a mandatory or intermediate MOOP type and uses an actuarially equivalent value to 20 percent coinsurance to calculate the cost sharing limit for MA plans that establish a lower MOOP limit, in paragraph (j)(1)(i)(D).

Barring these exceptions and as shown in Tables 25A and 25B, a value that is actuarially equivalent to 20 percent coinsurance for a particular service category subject to § 422.100(j)(1) was compared to the contract year 2022 copayment limit for the same service category. The difference between those two values equals the actuarially equivalent copayment differential (which is a unique figure for each service category and contract year). Then, we took 25 percent of the actuarially equivalent copayment differential and added it to the contract year 2022 copayment amount and applied the rounding rules in § 422.100(f)(6)(ii) to reach the transitional copayment for that service category based on the first year of the actuarially equivalent copayment transition. The values in row I in Tables 25A and 25B are the result of this application of the formula in paragraph (f)(8)(ii). As discussed in section II.B.5.b. of this FC, paragraph (f)(8) requires CMS to set the copayment limit for a given year at the value that is the lesser of amounts resulting from: (1) An actuarially equivalent value to the applicable cost sharing standard (in paragraphs (f)(6)(iii) and (j)(1)); and (2) an amount resulting from the actuarially equivalent copayment transition formula in paragraph (f)(8)(ii). To illustrate this comparison, row J in Tables 25A and 25B compares all of the transitional values from row I (resulting from paragraph (f)(8)(ii)) to the actuarially equivalent value to the applicable cost sharing standard in row E (20 percent coinsurance for most service categories subject to paragraph (j)(1)). As shown in row J of Tables 25A and 25B, all of the transitional values are less than (or equal to) the actuarially equivalent amount to cost sharing under original Medicare. As a result, the ''lesser of'' values in row J of Tables 25A and 25B are used in Table 28 as the final contract year 2023 copayment limits for those service categories and applicable MOOP types. By following the ''lesser of'' requirement in paragraph (f)(8) and choosing the measure of central tendency which produces the least amount of change from the prior contract year (as allowed in paragraph (f)(7)) when calculating actuarially equivalent values, we aim to avoid potentially disruptive copayment changes for enrollees and plan designs.

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TABLE 25A: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR SERVICE CATEGORIES IN PBP SECTIONS 6A, 8B, AND 11C SUBJECT TO COST SHARING NO GREATER THAN ORIGINAL MEDICARE (§ 422.100(j)(1)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON MEDICARE FFS DATA FROM 2017 – 2021)

Row Reference	Description	Home Health[1]	Therapeutic Radiological Services	DME-Diabetic Shoes or Inserts[2]	DME-Diabetes Monitoring Supplies[2]
A	Contract year 2022 copayment limit	$35.00	$60.00	$10.00	$10.00
B	Contract year 2023 total Medicare FFS projected cost[3]	$271.00[4]	$414.00[5]	$47.51[6]	$39.48[6]
C	Coinsurance limit per § 422.100(j)(1)				20%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(j)(1) (row B multiplied by row C) (This figure is used to calculate the actuarially equivalent copayment differential as defined in § 422.100(f)(8)(i).)[7]	$54.20	$82.80	$9.50	$7.90
E	Rounded actuarially equivalent copayment value to coinsurance limit per § 422.100(j)(1) (row D rounded per § 422.100(f)(6)(ii))	$55.00	$85.00	$10.00	$10.00
F	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row A and row D)	$19.20	$22.80	($0.50)	($2.10)
G	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row F multiplied by 0.25)	$4.80	$5.70	($0.12)	($0.53)
H	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row G)	$39.80	$65.70	$9.88	$9.47
I	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	$40.00	$65.00	$10.00	$10.00
J	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value comparing row E and row I)	$40.00	$65.00	$10.00	$10.00

[1]The 20 percent coinsurance limit for home health (reflected in this table) only applies to MA plans that use the lower MOOP limit per § 422.100(j)(1)(i)(D). The home health copayment limit for the mandatory and intermediate MOOP limits is $0 in alignment with original Medicare that has no cost sharing for home health.

[2]The 20 percent coinsurance limit for the DME service categories (reflected in this table) only applies to the mandatory MOOP limit. As discussed in section II.B.5.a. of this FC and as shown in Table 28, the 50 percent coinsurance limit and associated actuarially equivalent copayment limit for DME service categories applies only to the lower and intermediate MOOP limits.

[3]The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7).

[4]This amount for the "home health" service category represents the projected total Medicare FFS weighted average per visit cost for contract year 2023, including services in the Medicare FFS home health bundle (such as, nurse, aid, therapist, certain medical supplies and medications) but no other services (such as other medications, supplies, and DME).

[5]This amount for the "therapeutic radiological services" service category represents the projected total Medicare FFS median per session cost for contract year 2023.

[6]These amounts represent the projected total Medicare FFS weighted average cost for contract year 2023, weighted by utilization of the various types for the DME "diabetic shoes or inserts" and "diabetes monitoring supplies" service categories.

[7]Section 422.100(f)(8)(i) requires use of Medicare FFS data projections based on the coinsurance limits that would apply in 2026, which is necessary for service categories subject to paragraph (f)(6)(iii), where the coinsurance percentages are changing over time. For purposes of paragraph (j)(1), the applicable coinsurance percentage is the same for contract years 2023 through 2026 and thereafter, unless the cost sharing requirements in original Medicare change.

TABLE 25B: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR SERVICE CATEGORIES IN PBP SECTIONS 12 AND 15 SUBJECT TO COST SHARING NO GREATER THAN ORIGINAL MEDICARE (§ 422.100(j)(1)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON MEDICARE FFS DATA FROM 2017 – 2021)

Row Reference	Description	Dialysis Services	Part B Drugs Chemotherapy/ Radiation Drugs	Part B Drugs-Other
A	Contract year 2022 copayment limit	$30.00	$75.00	$50.00
B	Contract year 2023 total Medicare FFS projected cost[1]	$321.00[2]	$1,397.00[3]	$1,603.00[4]
C	Coinsurance limit per § 422.100(j)(1)			20%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(j)(1) (row B multiplied by row C) (This figure is used to calculate the actuarially equivalent copayment differential as defined in § 422.100(f)(8)(i).)[5]	$64.20	$279.40	$320.60
E	Rounded actuarially equivalent copayment value to coinsurance limit per § 422.100(j)(1) (row D rounded per § 422.100(f)(6)(ii))	$65.00	$280.00	$320.00
F	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row A and row D)	$34.20	$204.40	$270.60
G	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row F multiplied by 0.25)	$8.55	$51.10	$67.65
H	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row G)	$38.55	$126.10	$117.65
I	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	$40.00	$125.00	$120.00
J	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value comparing row E and row I)	$40.00	$125.00	$120.00

[1]The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7).

[2]This amount for the "dialysis services" service category represents the total weighted average cost per session for contract year 2023 (including facility fees and approximated physician fees). This amount considers all types of dialysis and settings (such as, hospital outpatient departments and provider offices).

[3]This amount for the "Part B drugs-chemotherapy/radiation drugs" service category represents the projected total Medicare FFS median per session cost for contract year 2023. This amount reflects costs from betos/HCPC codes that have a chemotherapy grouper and takes into consideration drug, administration, and place of service costs.

[4]This amount for the "Part B drugs-other" service category represents the projected total Medicare FFS median allowed amount for contract year 2023.

[5]Section 422.100(f)(8)(i) requires use of Medicare FFS data projections based on the coinsurance limits that would apply in 2026, which is necessary for service categories subject to paragraph (f)(6)(iii), where the coinsurance percentages are changing over time. For purposes of paragraph (j)(1), the applicable coinsurance percentage is the same for contract years 2023 through 2026 and thereafter, unless the cost sharing requirements in original Medicare change.

Tables 25A and 28 contain final contract year 2023 copayment limits for only two of the DME service categories (specifically, the DME "diabetic shoes or inserts" and "diabetes monitoring supplies" service categories). CMS is

not calculating a copayment limit for the other DME service categories listed in § 422.100(j)(1)(i) for contract year 2023. Therefore, MA organizations that use copayments for those other DME service categories in contract year 2023 must establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare. CMS may calculate copayment limits for the other DME service categories in a future year if sufficient Medicare FFS data projections become available and it is appropriate for program purposes, as provided in § 422.100(f)(7)(ii). We reiterate that, beginning for contract year 2024, paragraph (f)(7)(iii) applies in that CMS will issue guidance and may solicit public comment on the actuarial approaches used to reach an actuarially equivalent copayment value for each copayment limit CMS calculates. In general, CMS will follow § 422.100(f)(7), (f)(8) and (j)(1) to calculate copayment limits for contract year 2023 and subsequent years for the benefits specified in paragraph (j)(1). This is consistent with the general approach we took in the February 2020 proposed rule in that the same rules would apply for the professional services if CMS issues copayment limits, regardless of whether we had illustrative cost sharing limits to share at the time of the February 2020 proposed rule.

We do not expect that calculating copayment limits at values that are less than a value that is actuarially equivalent to original Medicare (based on the most recent Medicare FFS data projections) during the applicable transition year(s) will directly result in MA organizations incorporating higher MOOP amounts, increasing premiums, or reducing supplemental benefits in their plan designs. This is because MA organizations can continue to use coinsurance that does not exceed cost sharing under original Medicare. Further, applying this methodology we are finalizing—to use actuarially equivalent values subject to a cap that acts to transition changes from the copayment limits set for contract year 2022 copayment limits to actuarially equivalent values—is projected to increase copayment limits from the contract year 2022 levels for service categories subject to § 422.100(j)(1). In addition, if the actuarially equivalent copayment amount did not reflect a substantive change in comparison to the cost sharing limit set in contract year 2022, the contract year 2023 copayment limit may reflect the full amount. As shown in Tables 25A and 28, this is the case for the DME ''diabetic shoes and inserts'' and ''diabetes monitoring supplies'' service categories for the mandatory MOOP limit. The $10 copayment limit from contract year 2022 for both of these service categories remains unchanged for contract year 2023 because $10 reflects an actuarially equivalent value to 20 percent coinsurance after application of the rounding rules in § 422.100(f)(6)(ii), using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data).

MA organizations may have benefit designs that include different copayment levels within the same service category (referred to as minimum and maximum copayment in the plan benefit package software). This capability helps address service categories that may include a wide range of items or services with lower and higher costs, such as Part B drugs. For example, a plan can have a lower copayment amount for lower cost services and a higher copayment amount for other higher cost services within the same service category, as long as the cost sharing satisfies CMS standards.

Table 26 provides an illustrative example of how the copayment limits may change in future years for a particular service category subject to § 422.100(j)(1) as more of the actuarially equivalent copayment differential is incorporated and the ''lesser of'' value is used to set copayment limits during the transitional period. Specifically, Table 26 provides the final contract year 2023 cost sharing limits and illustrative copayment limits across the multiyear transition schedule to actuarially equivalent values for the ''Part B Drugs—chemotherapy/radiation drugs'' service category using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). We reiterate that the copayment limits for contract years 2024 through 2026 in Table 26 remain illustrative in nature and may change based on updated and more recent Medicare FFS data projections in future years. Projections for contract years after 2023 were not available at the time of writing this FC and the copayment limits for those years in Table 26 illustrate the transition over the 4 years.

TABLE 26: FINAL CONTRACT YEAR 2023 AND ILLUSTRATIVE CONTRACT YEAR 2024 – 2026 COST SHARING LIMITS FOR THE "PART B DRUGS – CHEMOTHERAPY/RADIATION" SERVICE CATEGORY SUBJECT TO § 422.100(j)(1) USING ON CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 - 2021 MEDICARE FFS DATA)

Contract Year	Cost Sharing Limit
2022[1]	20% / $75
2023[2]	20% / $125
2024[3]	20% / $175
2025[3]	20% / $230
2026[3]	20% / $280[4]

[1]The cost sharing limits for contract year 2022 are provided for comparison purposes.
[2]The contract year 2023 cost sharing limits are final and calculated using § 422.100(f)(7), (f)(8), and (j)(1).
[3]The copayment limits for these years are illustrative and final amounts will be announced using the subregulatory process at § 422.100(f)(7)(iii) using updated Medicare FFS data projections.
[4]This is the first year that the copayment limit is projected to reach an actuarially equivalent value to the 20 percent coinsurance limit.

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Table 26 illustrates how implementing a multiyear transition to actuarially equivalent copayment values with the ''lesser of'' requirement avoids the sudden significant and potentially disruptive increases that would occur without such a transition. Specifically, for the ''Part B Drugs—Chemotherapy/Radiation'' service category, which had a $75 copayment limit in contract year 2022, it transitions the $205 difference from the 2022 amount and the actuarially equivalent value of $280 by approximately $50 increments annually until the actuarially equivalent value is reached in contract year 2026. We acknowledge in order to reach an actuarially equivalent copayment limit during what we consider a reasonable transition timeframe of 4 years, the year over year change in the copayment limit for some service categories subject to paragraph (j)(1) is more than what CMS likely would have adopted in prior years. Applying this multiyear transition to benefits that must not exceed cost sharing under original Medicare will strike a balance in making the changes necessary to reach actuarially equivalent copayments while protecting beneficiaries. In addition, we believe that it is important to begin transitioning copayment limits to be actuarially equivalent to the cost sharing in original Medicare to encourage MA plans to consider copayments instead of coinsurance. As noted in the February 2020 proposed rule, although MA plans have the flexibility to establish cost sharing amounts as copayments or coinsurance, enrollees generally find copayment amounts more predictable and less confusing than coinsurance.[56] By updating copayment limits to reflect the expected costs of providing the benefit based on the most recent Medicare FFS data projections, we expect more MA organizations may consider copayment structures when designing their cost sharing. In addition, we expect that MA organizations will be able to plan aspects of their benefit designs several years in advance based on the projected copayment limits CMS is sharing through this FC and through the specific transition codified in § 422.100(f)(8). We do not anticipate significant increases in enrollee cost sharing as a result of these changes in cost sharing standards. About 98 percent of contract year 2021 MA plans (including D–SNPs and institutional and chronic condition SNPs) have supplemental benefits that reduce Part A and B cost sharing and 93 percent of these plans use a portion of their rebates to pay for some or all of the reduced cost sharing of Part A and B benefits (the other 7 percent and any amount remaining after applying a portion of rebates have the reduction of cost sharing paid for through the member's premium). Excluding SNPs, 100 percent of contract year 2021 MA plans have supplemental benefits that reduce cost sharing and 94 percent use a portion of their rebates to pay for some or all of that benefit (after applying a portion of the rebates, any amount remaining is paid through the member's premium).

As also discussed in section II.B.5.b. of this FC, CMS is finalizing new § 422.100(f)(8) to transition current (contract year 2022) copayment limits to actuarially equivalent values by contract year 2026. The completion of the transition to actuarially equivalent copayment values as provided in new paragraph (f)(8) means that CMS will annually update the copayment limits (including those subject to § 422.100(j)(1)) to new actuarially equivalent values based on the most recent Medicare FFS data projections available (subject to the rounding rules in paragraph (f)(6)(ii)) beginning for contract year 2026 and subsequent years. We believe annually updating copayment limits ensures that all cost sharing limits are consistent with cost sharing in original Medicare, will provide a measure of predictability and stability for MA organizations, and ensures copayment limits do not become outdated in future years.

Comment: A few commenters opposed implementing the statutory requirement (section 1852 (1)(B)(iv) of the Act, currently implemented § 422.100(j)(2) and proposed to be re-designated in this rulemaking) that requires MA plans to establish cost sharing for renal dialysis services that does not exceed the cost sharing under original Medicare (that is, 20 percent coinsurance or an approximate actuarially equivalent copayment). These commenters suggested that this level of cost sharing is discriminatory and would substantially discourage enrollment by beneficiaries who require dialysis services. A commenter noted that the MOOP limit is insufficient to prevent enrollees with diagnoses of ESRD from experiencing cost-prohibitive dialysis cost sharing based on the MA organization's ability to charge up to 20 percent coinsurance; the commenter also stated these situations are counter-productive to enrollees' health should they be unable to afford such ongoing costs prior to the triggering the MOOP limit. The commenters requested that CMS: (1) Prohibit any cost sharing or, at the least, lower the cost sharing limit for dialysis services for all MA plans regardless of the MOOP limit established; and (2) issue clear statements to MA plans before the contract year 2021 bid deadline (June 1, 2020) that benefit designs that establish a 20 percent coinsurance for dialysis services are discriminatory and will not be allowed.

A commenter noted a mandate of zero cost sharing for dialysis across all types of MOOP limits would ensure that all plans are on an even footing in their plan offerings, and beneficiaries would have access to the optimal benefit structure most likely to duplicate the positive results achieved by chronic condition SNPs (C–SNPs) and ESRD Seamless Care Organization (ESCOs). The commenter stated that while this approach is beneficiary-friendly, it does have a drawback in that MA plans which enroll a disproportionate share of ESRD patients could suffer relative to competitors. However, the commenter noted a zero-cost sharing mandate also would permit plans to encourage patient adherence to dialysis without fear of attracting too many ESRD patients. The commenter explained such a mandate would be consistent with the agency's interest in promoting value-based insurance design (VBID) principles.

Another commenter cited several provisions (the anti-discrimination provisions in section 1852(b)(1) of the Act and section 3202 of the Affordable Care Act (ACA), which added the statutory requirement that MA plans have cost sharing for renal dialysis (and other services) that does not exceed cost sharing in original Medicare, and § 422.100(f)(2)), and CMS's review of bids as the basis for requesting that CMS ensure MA plans' cost sharing designs do not discriminate against individuals with ESRD. A commenter stated that charging maximum cost-sharing that is permissible under the law for a particular service used by a particular population could be viewed as discriminatory on its face. This commenter explained that the intent of cost sharing is to prevent the over-utilization of health care services, but that dialysis is a regular, medically necessary service for a population with a particular diagnosis and not a service that is over-utilized by those diagnosed with ESRD. Therefore, the commenter believed that dialysis was not a service that would benefit from cost sharing limits that were designed to control

[56] Loewenstein G, Friedman JY, McGill B, Ahmad S, Linck S, Sinkula S, Beshears J, J.Choi J, Kolstad J, Laibson D, Madrian BC, List JA, Volpp KG. ''Consumers' misunderstanding of health insurance''. Journal of Health Economics 2013;32(5):850–862. Retrieved from: *https://scholar.harvard.edu/laibson/publications/consumers-misunderstanding-health-insurance*.

utilization. The commenter also stated that an MA plan that changes from zero cost sharing for dialysis services to a 20 percent coinsurance from one contract year to next, may discourage individuals with ESRD from staying enrolled in the plan or may unintentionally discourage people requiring dialysis from enrolling in the plan. The commenter further noted that once the right for any Medicare beneficiary with ESRD to enroll in any MA plan is effective in 2021, an MA plan's use of 20 percent cost sharing would encourage such enrollees to look for plans that do not impose such costs. The commenter noted CMS has already approved benefit designs for the 2020 contract year that have 20 percent coinsurance for dialysis services. In effect, the commenter stated if benefit designs with 20 percent coinsurance for dialysis services becomes the norm, MA plans might attempt to dissuade enrollment by individuals with ESRD across the board.

Response: Section 1852(a)(1)(B)(iv) of the Act and § 422.100(j) already require MA plans to have cost sharing that does not exceed that in original Medicare for renal dialysis services; our proposal was to re-designate that provision and it is being finalized as paragraph (j)(1)(i)(B). We appreciate the feedback on this provision and recommendations to adopt a stricter standard for cost sharing for renal dialysis. This regulation implements the statutory requirement in section 1852(a)(1)(B)(iv) of the Act, which has been in place since 2011, that MA plans use cost sharing that does not exceed the cost sharing in original Medicare for renal dialysis services (as defined in section 1881(b)(14)(B) of the Act). Under this statute, CMS has allowed MA organizations to establish a coinsurance up to 20 percent for dialysis services since 2011.[57] We nonetheless do not believe the anti-discrimination provisions in section 1852(b)(1) of the Act and § 422.100(f)(2) would be violated merely by permitting an MA plan to use the same coinsurance amounts that are used in the original Medicare program. This is consistent with longstanding MA program requirements that plan bids be at least actuarially equivalent to original Medicare on an overall basis. In addition, as the 20 percent coinsurance limit for dialysis services is equally applicable to the original Medicare and MA programs, the additional requirements of a MOOP limit and the ability to receive supplemental benefits through an MA plan may address the commenter's concern about beneficiaries with diagnoses of ESRD being discouraged from enrolling in MA plans compared to the Medicare FFS program. In relation to the commenter's request to mandate a zero cost sharing limit for dialysis across all types of MOOP limits to ensure that all plans are on an even footing in their plan offerings, we note that the MA program was established to provide options in addition to the original Medicare program for beneficiaries to obtain Medicare benefits and we believe this FC adopts policies to ensure the continued offering of MA plans that are viable options for Medicare beneficiaries as a whole.

The percentage of MA and MA–PD plans (excluding employer, D–SNP, and Medicare MSA plans) with zero cost sharing for dialysis services has remained relatively consistent between contract year 2012 (approximately 2.6 percent) and contract year 2021 (approximately 2.9 percent) based on March 2021 data. The vast majority of MA plans have designed their dialysis benefit with cost sharing greater than zero and use coinsurance rather than a copayment. The percentage of these MA plans with non-zero cost sharing that established the same coinsurance as original Medicare for dialysis services was approximately 94.7 percent in contract year 2012 and is approximately 99.9 percent for contract year 2021 (as a percentage of enrollment, 91.4 percent in contract year 2012 and 99.9 percent in contract year 2021). There are MA plans where coinsurance for dialysis services is equal to original Medicare and program enrollment of beneficiaries with diagnoses of ESRD has not decreased and, therefore, does not suggest that this aspect of MA plan designs is discouraging enrollment of enrollees with diagnoses of ESRD.[58] While that enrollment experience was during a time when there were limits on the ability of beneficiaries with ESRD to enroll in MA plans, we believe it is persuasive that the ability for MA plans to have cost sharing for dialysis services that is equal to the cost sharing used in original Medicare does not in and of itself discourage enrollment of beneficiaries with diagnoses of ESRD.

The contract year 2022 copayment limit of $30 for dialysis services has been in place for a number of years and does not reflect a current actuarially equivalent value equal to 20 percent coinsurance based on contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). Under the current regulation at § 422.100(f)(6), the contract year 2022 copayment limit for dialysis services was originally set to strike a balance between limiting beneficiary out-of-pocket costs the and potential impact to plan design and costs, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. Since most MA plans use 20 percent coinsurance for the cost sharing for dialysis services, calculating a copayment limit that is lower than the coinsurance level does not actually result in lower out of pocket cost sharing payments by enrollees. Setting copayment limits using actuarially equivalent values to cost sharing under original Medicare (20 percent coinsurance for most services categories subject to § 422.100(j)(1)) would, in effect, recalibrate copayment limits compared to current levels. We believe that this recalibration and better alignment of the copayment and coinsurance limits for dialysis services, like for the other services listed in § 422.100(j)(1), is important to incentivize MA organizations in how they structure cost sharing for enrollees and to have a more transparent methodology and process for MA cost sharing limits.

While an illustrative actuarially equivalent copayment limit for dialysis services was not available to share at the time of the February 2020 proposed rule, using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data), calculating a copayment limit at an actuarially equivalent value equal to 20 percent coinsurance (after applying the rounding rules in § 422.100(f)(6)(ii)) would equal $65, a substantive increase from the $30 copayment limit used for contract year 2022. Less than 1 percent of 2021 plans that require cost sharing for dialysis (based on March 2021 data, excluding employer, D–SNP, and MSA plans) charge a copayment for these services in their benefit design. As previously discussed, we expect that transitioning copayment limits to be actuarially equivalent to the cost sharing in original Medicare will encourage MA plans to consider the use of copayments instead of coinsurance. However, given the potential disruption that could result from substantive increases in one year for those plans with copayments and to be responsive to commenters, CMS is adopting a multiyear transition to actuarially equivalent copayment

[57] Call Letters communicating CMS policy for contract years prior to 2021 may be accessed here: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[58] See enrollment projections for ESRD enrollment, See page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

limits for service categories subject to § 422.100(j)(1) (including dialysis services). This transition is finalized in new paragraph (f)(8) and explained more completely in section II.B.5.b. of this FC and in a prior response to comment in this section. In brief, applying this transition (and the ''lesser of'' requirement) moderated the increase to the copayment limit for dialysis services from $30 in contract year 2022 to $40 for contract year 2023 (as calculated in Table 25B and finalized in Table 28).

CMS contracts with MA organizations for one year at a time, and MA organizations may change their benefit designs and cost sharing structures annually within statutory and regulatory requirements. We remind commenters that existing statutory (Section 1852(a)(1)(B)(iv) of the Act) and regulatory requirements (§ 422.100(j)) require that renal dialysis services not exceed cost sharing under original Medicare (that is, 20 percent coinsurance). CMS will continue to monitor MA plan benefit designs to observe whether there is information indicating potential discrimination or efforts by MA plans to discourage enrollment by beneficiaries with diagnoses of ESRD. We are finalizing our proposal to keep this existing requirement and updating the re-designation to § 422.100(j)(1)(i)(B) from proposed paragraph (j)(1)(ii).

Comment: A few commenters generally supported the proposal (in section VI.B.3.c. of the February 2020 proposed rule) to codify CMS's existing policy to establish nominal cost sharing limits for the first 20 days in a skilled nursing facility (SNF) based on the type of MOOP limit. A commenter believed that the current level of differentiation between the cost sharing limits by the MOOP limit is reasonable and did not support increasing the differentiation any further. This commenter stated the utilization of this service is very low and increasing the cost sharing limit differentiation by the type of MOOP limit further would not provide a strong actuarial incentive for an MA organization to offer a lower (previously ''voluntary'') MOOP limit.

Response: We thank the commenters for their support. We proposed differentiating cost sharing limits across highly utilized services (for example, inpatient and primary care) and various other cost sharing services categories to produce a cumulative incentive for MA plans to use lower MOOP limits. We believe that MA organizations will have more incentive to establish an MA plan with lower total MOOP costs for enrollees as a result of this FC which provides the greatest flexibility in designing cost sharing to lower MOOP limits and are finalizing that policy approach. In addition, we are finalizing § 422.100(j)(1)(i)(C) (which is an updated designation from paragraph (j)(1)(iii) in the February 2020 proposed rule) with additional requirements to address the per day cost sharing amounts for skilled nursing care that may be charged by MA plans that adopt the lower or intermediate MOOP type. Specifically, permissible cost sharing for the first 20 days must be no greater than $20 per day for a plan with a lower MOOP amount and $10 per day for plan with an intermediate MOOP amount; these are the nominal cost sharing figures from Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule for MA plans that use an intermediate or lower MOOP amount. Authority for these cost sharing amounts is limited to the first 20 days of a SNF stay. We believe detailing specific per day cost sharing is appropriate to ensure clarity in the regulation text regarding our proposal from section VI.B.3. of the February 2020 proposed rule.

We also take this opportunity to provide guidance as to how we intend to implement the SNF cost sharing limits in the current PBP data entry options. Consistent with current practice, MA organizations may indicate in the PBP that the plan establishes a coinsurance for the SNF service category instead of using the specific per day copayment amounts that are permitted. The process of developing supporting documentation that shows how the coinsurance meets the cost sharing standard under § 422.100(j)(1) is consistent with prior years and is referenced in our general discussion related to supporting documentation in section II.B.5.a. of this FC. In addition, MA organizations may submit their plan bids based on the CMS SNF copayment limits (in the regulation for the first 20 days and published prior to MA bid submission for days 21 through 100) or choose to indicate in the PBP SNF service category that the plan will use the actual Medicare FFS cost sharing amount for both SNF benefit periods, that is the first 20 days and days 21 through 100. CMS typically publishes the original Medicare cost sharing parameters (for example, Part A and B deductibles) a few months prior to the upcoming year, but this generally happens well after the MA bid deadline. As explained in the preamble of the February 2020 proposed rule, we calculate the cost sharing limit for days 21–100 in a SNF by taking one-eighth of the projected Part A deductible for the contract year. To ensure clarity in the regulation on these points, we are finalizing a change to § 422.100(j)(1)(i)(C)*(1)* (that is an updated designation from § 422.100(j)(1)(iii)(A) in the February 2020 proposed rule), that the SNF cost sharing limit for days 21 to 100 is based on one-eighth (not the total amount) of the projected (or actual) Part A deductible. We are finalizing the remainder of what was proposed at § 422.100(j)(1)(iii)(B) as paragraph (j)(1)(i)(C)*(2)* and clarifying that the total cost sharing for the overall SNF benefit must not be greater than the PMPM actuarially equivalent cost sharing in original Medicare. CMS will utilize these regulatory standards for calculating cost sharing limits for SNF and evaluating MA plans during bid review.

Comment: A few commenters opposed allowing up to 20 percent coinsurance or the approximate actuarially equivalent copayment for home health services for MA plans with lower MOOP limits and allowing MA plans that establish a lower or intermediate MOOP limit the flexibility to set cost sharing limits for specific items of DME that exceed the cost sharing in original Medicare. These commenters requested CMS prohibit cost sharing for home health services consistently across all types of MOOP limits and not finalize the proposal to allow cost sharing flexibility for DME or, at the very least, require uniformity across MA plans with respect to cost sharing for DME. In lieu of prohibiting these cost sharing flexibilities for DME, the commenters requested that CMS provide guidance about what types of DME items can be subject to higher cost sharing rates under the proposal. They noted that cost sharing applied to certain DME that is typically used by beneficiaries with certain conditions can constitute discriminatory cost sharing on its face, particularly without guidance from CMS about what types of DME items can be subject to higher cost sharing rates under the proposal. In addition, the commenters stated that Medicare FFS does not charge cost sharing for home health and the application of the lower MOOP limit in the MA program should not be used to justify an MA plan charging cost sharing for services that that are insulated from any costs in traditional Medicare.

Response: We appreciate the feedback on our proposals related to adding home health and DME to the list of services for which cost sharing charged by an MA plan may not exceed cost sharing

required under original Medicare. The ability to use cost sharing for specific service categories of DME that exceeds the level of cost sharing used in the original Medicare program provides an acceptable level of incentive for MA organizations to offer plans with lower or intermediate MOOP limits, particularly when combined with the other flexibilities finalized in this FC, by balancing the overall protection for enrollees related to total out-of-pocket spending with the protection for cost sharing for specific benefits. As proposed and finalized, this flexibility is limited to use of the lower or intermediate MOOP limit and subject to both a requirement that the overall DME benefit be actuarially equivalent on a per member per month basis to cost sharing in original Medicare and the requirement that cost sharing for specific DME categories not exceed 50 percent of the estimated total MA plan financial liability for that contract year. Further, the intermediate and lower MOOP types provide additional protection for enrollees. These policies regarding DME cost sharing are consistent with longstanding CMS policy and how benefits have been submitted through the PBP. Taken together, we believe that these proposals related to cost sharing for DME will provide protection to MA enrollees from high out-of-pocket costs related to DME. Based on this, we do not believe additional regulatory standards are necessary at this time. We will continue to evaluate experience with this longstanding CMS policy during bid review and may revisit these requirements, if necessary, to ensure that our overall goals for the cost sharing policies are met, including that beneficiaries are not subject to discriminatory cost sharing structures or benefit designs that discourage enrollment based on significant health needs.

In approaching how to set cost sharing limits for DME, CMS is mindful that the category includes items and services that vary significantly in cost and that MA plans are not uniform in whether and to what extent the MA organization uses specific contracting arrangements permitted by § 422.100(l). We did not intend to require MA plans to establish cost sharing at the individual item or service level for DME and it would not follow current industry practice, nor how benefits are submitted through the PBP, to do so. As indicated in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule, the proposed service categories with higher cost sharing flexibility for MA plans that establish lower or intermediate MOOP limits for DME are: Equipment, prosthetics, medical supplies, diabetes monitoring supplies, and diabetic shoes or inserts. However, this flexibility is limited by how, for all MA plans and regardless of MOOP type, the total cost sharing for all DME service categories combined must not exceed original Medicare on a per member per month actuarially equivalent basis. Under this FC, MA plans that establish a lower or intermediate MOOP limit may have cost sharing equal to or less than 50 percent coinsurance (or an actuarially equivalent copayment) for specific service categories of DME while MA plans that use a mandatory MOOP limit must have cost sharing that does not exceed cost sharing in original Medicare for DME in those categories. We finalize this flexibility in proposed § 422.100(j)(1)(v) as paragraph (j)(1)(i)(E) with a modification to reference the specific service categories of DME (equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts). This flexibility is consistent with previous CMS policy and subject to the requirement in § 422.100(f)(6)(i) that an MA plan must pay at least 50 percent of the estimated total MA plan financial liability for that contract year where another, more specific rule on cost sharing limits does not apply. We provide a more complete discussion of this requirement in section II.B.5.a. of this FC. In brief, this rule that cost sharing cannot exceed 50 percent of the MA plan's estimated total financial liability for that contract year applies to DME at the service category level and in addition to the specific cost sharing rules that apply to items and services under paragraph (j) or rules other than paragraph (f)(6).

To provide additional transparency and better guidance on the level of cost sharing allowed for DME service categories for MA plans that establish a lower or intermediate MOOP amount, as discussed in section II.B.5.a. of this FC, the ''N/A'' descriptions that were used in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule are updated to 50 percent in Table 28 (which generally updates the information from Table 5 in the February 2020 proposed rule). We believe this change better reflects how the requirement at § 422.100(f)(6)(i), that the MA plan pay at least 50 percent of estimated total MA plan financial liability for that contract year, applies to the cost sharing for service categories of DME for MA plans with the lower or intermediate MOOP amounts while the requirement of 20 percent coinsurance applies only to MA plans with a mandatory MOOP amount. As indicated in the footnotes of Table 28, all MA plans must have total cost sharing for the overall DME benefit that is not greater than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare. The clarifications discussed previously are incorporated into the final language in § 422.100(j)(1)(i)(E).

If CMS does not calculate an actuarially equivalent copayment limit for any of the DME service categories, MA organizations may still establish an actuarially equivalent copayment to the applicable coinsurance limit instead of using coinsurance. This is consistent with footnote 5 from Table 5 (Illustrative Contract Year 2021 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule, which noted that MA plans may establish a copayment that is actuarially equivalent to, or less than, the applicable coinsurance limit for service categories for which CMS does not calculate a copayment limit (85 FR 9087). The information in this footnote is updated to reflect our final policy in footnote 7 from Table 28. Specifically, for DME service categories without a copayment limit calculated by CMS, MA organizations may establish a copayment based on the average Medicare FFS allowable amount for the plan service area or their estimated total MA plan financial liability for the benefit (subject to the rounding rules in § 422.100(f)(6)(ii)) as finalized in paragraph (f)(6)(i) (for the lower and intermediate MOOP limits) and § 422.100(j)(1)(i) (for the mandatory MOOP limit). For example, CMS did not set a final contract year 2023 copayment limit for the DME ''equipment'' service category and MA plans may calculate an actuarially equivalent copayment for that service category using the rules in paragraph (j)(1)(ii) for that contract year. Further information on how MA organizations may calculate actuarially equivalent copayments and develop supporting documentation in the absence of a copayment limit calculated by CMS is available in section II.B.5.a. of this FC. CMS will continue to gather and review the data described in finalized § 422.100(f)(7)(ii) for use in calculating copayment limits related to the remaining DME service categories for future years and we may calculate copayment limits for these categories in the future.

CMS also proposed to codify our longstanding policy of limiting cost sharing for home health services for MA plans that establish a mandatory or intermediate MOOP amount to that charged under original Medicare and 20 percent coinsurance for plans with a lower MOOP amount. As discussed in the February 2020 proposed rule, maintaining the maximum cost sharing flexibility for lower MOOP limits acts as an important incentive for plans to offer a lower MOOP amount, which is another important financial protection for beneficiaries. We generally rely on our authority at 1852(a)(1)(B)(iv)(IV) of the Act to apply original Medicare cost sharing limits to other Part A or B benefits that the Secretary determines appropriate; for benefits where cost sharing in original Medicare is zero, we also rely on our authority in section 1856(b)(1) of the Act to calculate MA standards by regulation, and in section 1857(e)(1) of the Act to impose additional terms and conditions found necessary and appropriate to require that cost sharing for these services under MA plans conform to that under original Medicare, meaning that no cost sharing could be imposed for these services. Despite the limitation in section 1852(a)(1)(B)(v) of the Act on our authority to identify additional benefits for which MA cost sharing must not exceed the cost sharing in original Medicare, we believe that it is necessary and appropriate to limit cost sharing for these services to avoid discouraging enrollment by beneficiaries who need those services and to incentivize MA plans to use the lower MOOP limits. This FC generally limits cost sharing to zero for those services where original Medicare does not impose costs only when an MA plan establishes a mandatory or intermediate MOOP amount. Therefore, an MA plan is not prohibited from using cost sharing for these services and may elect to use cost sharing for them by establishing a lower MOOP amount. In addition, codifying specific benefit standards that we believe are appropriate for MA plan designs provides transparency as to how CMS would use its authority under section 1854(a)(5)(C)(i) and (a)(6)(B) of the Act to evaluate and negotiate bids for MA contracts. Overall, this approach to regulating cost sharing is consistent with the statute as it protects beneficiaries while also preserving a measure of flexibility for MA plans. Finally, we believe that maintaining this longstanding standard does not limit market competition and we expect beneficiary choice will continue to act as an incentive for MA organizations to offer favorable benefit designs.

With regard to comments about MA plans being able to include cost sharing for home health when original Medicare does not permit cost sharing, we note that commenters on the Final Rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' published April 15, 2011 (referred to as the April 2011 Final Rule), including MedPAC, opposed CMS's prior proposal to limit cost sharing for home health services, under MA and cost plans at original Medicare levels. For example, in the April 2011 Final Rule, MedPAC commented that home health cost sharing should be one of the tools that MA plans can use at their discretion as a means of ensuring appropriate utilization. In addition, MedPAC's March 2020 ''Report to Congress: Medicare Payment Policy,'' Chapter 9 Home Health Care Services (page 258), states the following: ''Medicare does not provide any incentives for beneficiaries or providers to consider alternatives to home health care, such as outpatient services. Beneficiaries who meet program coverage requirements can receive an unlimited number of home health episodes and face no cost sharing.'' We agree that finalizing the flexibility for MA plans in connection with cost sharing for these benefits where original Medicare does not have cost sharing is appropriate for these reasons as well as others discussed throughout this FC for our cost sharing policies. MA plans that establish a lower MOOP amount may use cost sharing up to certain levels for specific services (as identified in § 422.100(j)(1)(i)) as a means of incentivizing use of alternative services or ensuring an overall balance of enrollee payments and plan financial liability for the entire package of basic benefits is competitive and attractive to beneficiaries.

CMS is finalizing the proposal concerning cost sharing for home health benefits—which was generally consistent with current policy—to require MA plans with a mandatory or intermediate MOOP amount to have cost sharing that does not exceed original Medicare for home health, but to permit MA plans with a lower MOOP amount to charge cost sharing up to 20 percent coinsurance with a modification to avoid duplicative language in the regulation. As discussed in a previous response to comment in this section, § 422.100(j)(1)(ii) requires that MA organizations use the average Medicare FFS allowable cost in the plan service area or the estimated total MA plan financial liability for the benefit for that contract year to calculate an actuarially equivalent copayment value to cost sharing under original Medicare, in the absence of a copayment limit calculated by CMS, for benefits subject to paragraph (j)(1). We are finalizing the rule for cost sharing for home health services largely as provided in proposed paragraph (j)(1)(iv) (re-designated to paragraph (j)(1)(i)(D)), with edits to be consistent with paragraph (j)(1)(ii) and to avoid limiting MA organizations to using only the estimated total MA plan financial liability for that contract year to calculate a copayment that is actuarially equivalent to, or less than, 20 percent coinsurance. We note MA organizations may use the total MA plan financial liability to establish a copayment for home health services, as proposed, under the modifications finalized to paragraph (j)(1) if CMS does not set a copayment limit. CMS will continue to review plans' cost sharing amounts to make sure that plan designs are consistent with MA rules, do not impose significant increases in cost sharing or decreases in benefits from the prior contract year, and are not discriminatory.

Comment: A commenter supported our proposal to add home health services and DME to the list of services for which cost sharing charged by an MA plan may not exceed cost sharing required under original Medicare for plans with mandatory and intermediate MOOP limits. Another commenter noted that although they supported differentiating copayment limits for home health services by the type of MOOP limit, cost sharing limit differentiation for this service category does not equate to much actuarial value for MA plans given its low utilization and stated that many plans do not impose home health copayments, primarily because it is difficult to collect copays, and many home health agencies are not set up to collect cost sharing under Medicare.

Response: We appreciate the commenters' support. We expect differentiating cost sharing limits across highly utilized services (for example, inpatient and primary care) and various other cost sharing services categories (for example, home health) may produce a cumulative incentive for MA plans to use lower MOOP limits. CMS is finalizing the proposals, to codify cost sharing limits for chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen, dialysis, SNF, home health, and DME service categories at

§ 422.100(j)(1)(i)(A)–(E) (proposed in paragraphs (j)(1)(i)–(v)) and (j)(2)(i)(A), (B), and (D) with the modifications discussed in responses to comment in this section.

Comment: A commenter opposed the proposal providing additional flexibility that could increase cost sharing limits for drugs and biologics covered under Part B. The commenter believed maintaining the current upper limits (which have been 20 percent coinsurance or $50 copayment) protects particular beneficiaries who might be impacted by cost sharing in excess of the amounts established for the original Medicare program.

Response: We thank the commenter for their feedback on our proposal to apply a range of cost sharing limits in § 422.100(f)(6)(iii) for the ''Part B drugs—Other'' service category. We agree with the commenter, as a result of an analysis of the most recent Medicare FFS data projections available at the time of this FC, that increasing the cost sharing limits from our longstanding 20 percent coinsurance or $50 copayment limit to a range of cost sharing limits based on the type of MOOP limit (30, 40, and 50 percent, respectively) in one year would likely result in disruption for enrollees. Using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data), the projected total median cost for ''Part B drugs—Other'' service category equals $1,603.00 and the weighted average cost equals $2,437.00 (including drug and related service costs). To calculate a copayment limit for the ''Part B drugs—Other'' service category at an actuarially equivalent dollar amount to 50 percent using either of these projections when the contract year 2022 limit was 20 percent or $50 does not adequately protect enrollees from potentially significant changes in costs. While the annual cap on change to copayment limits during the transition to actuarially equivalent values finalized in paragraph (f)(8) (as discussed in section II.B.5.b. of this FC) would help offset the increase in contract year 2023, it would be insufficient to fully protect beneficiaries from the potentially significant changes in their out of pocket costs. This is because despite applying paragraph (f)(8), the coinsurance limit for the ''Part B drugs—Other'' service category would still increase from 20 percent to 50 percent for MA plans that establish a lower MOOP amount and the associated transitional copayment limit for the lower MOOP type would increase from $50 to $240 within one year (based on contract year 2023 Medicare FFS data projections and applying the rounding rules in paragraph (f)(6)(ii)). These increases represent the maximum permissible cost sharing, but not all MA plans may adopt cost sharing at these maximum levels. However, the potential for these increases in cost sharing, particularly a change from current policy for the ''Part B drugs—Other'' service category, requires us to reconsider this aspect of our proposal.

After consideration of several alternatives as discussed in section V.H.2. of this FC, instead of finalizing this aspect of our proposal, CMS is maintaining and codifying our longstanding 20 percent coinsurance limit for the ''Part B Drugs—Other'' service category, by adding new § 422.100(j)(1)(i)(F), which adds other drugs covered under Part B of original Medicare (that is, Part B drugs not included in paragraph (j)(1)(i)(A)) to the list of benefits for which cost sharing must not exceed cost sharing under original Medicare. The use of Part B drugs to treat serious illnesses and the potential for those drugs to be costly likely presents significant potential for discrimination against (or potential for discouraging enrollment by) beneficiaries who have health conditions treated by Part B drugs other than chemotherapy/radiation. We believe that maintaining our long-standing policy of having 20 percent coinsurance and copayment limits for all Part B drugs, in addition to a per member per month actuarially equivalent requirement for the Part B drug service category, protects beneficiaries with high health care needs from benefit designs that discriminate against or discourage enrollment in an MA plan, steer subsets of Medicare beneficiaries to particular MA plans, or inhibits access to services. The language in paragraph (j)(1)(i)(F) is clear that this requirement is separate from the service category specific to Part B chemotherapy drugs and radiation therapy. In comparison, these service categories were combined in our proposal to include ''drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs integral to the treatment regimen and other drugs covered under Part B)'' in paragraph (j)(2). Having coinsurance and copayment limits in addition to a PMPM actuarially equivalent requirement is consistent with our long standing practice and policy for cost sharing for Part B drugs. As a practical matter, in proposing both: (1) Applying a range of cost sharing limits to the ''Part B drugs—Other'' service category; and (2) requiring cost sharing to be actuarially equivalent to Medicare FFS on a PMPM basis for Part B drugs (which is inclusive of the ''Part B drugs—Other'' service category), the flexibility that seems available by proposing a range of cost sharing limits up to 50 percent coinsurance or actuarially equivalent copayment for this service category is very limited.

Currently, § 422.100(j)(1) requires MA plans to use cost sharing that does not exceed cost sharing in original Medicare for ''chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen;'' we proposed to revise the text to describe these benefits as ''chemotherapy administration services to include chemotherapy/radiation drugs integral to the treatment regimen'' and to redesignate it as paragraph (j)(1)(i). We are finalizing continued application of this cost sharing limit, but redesignating it as paragraph (j)(1)(i)(A) and refining the text to clarify this limit applies to chemotherapy administration services to include chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen. We are fundamentally maintaining the current regulatory description and aligning the language with the current structure of the PBP (which captures cost sharing information for therapeutic radiological services and chemotherapy/radiation drugs in separate sections). We are not making any changes to our longstanding bid review practices or policies related to this service category by making this change to the name of the benefit in paragraph (j)(1)(i)(A).

As discussed in section II.B.5.b. of this FC, copayment limits set for certain service categories in past years do not reflect current actuarially equivalent values based on 20 percent coinsurance. Rather, our proposed methodology to calculate copayment limits based on values that are actuarially equivalent to the coinsurance limit, will result in recalibration of the copayment limits by applying a methodology adjusted from longstanding policy to the most recent Medicare FFS data projections available. Commenters expressed concerns about potentially significant increases to cost sharing limits within one year, such as for the ''physical therapy and speech-language pathology'' and ''dialysis services'' service categories in addition to the ''Part B drugs—Other'' service category. As discussed in other responses to comment in section II.B. of this FC, CMS agrees with the commenters that the proposed policies can be improved by providing for a transition process to recalibrate copayment limits over time. This

transition is also being applied to the ''Part B drugs—Other'' service category. Specifically, we will transition from the $50 contract year 2022 copayment limit to an actuarially equivalent value to 20 percent based on the most recent Medicare FFS data projections by contract year 2026 (as finalized in § 422.100(j)(1)(ii), (f)(7), and (f)(8)). To illustrate the impact of applying an annual cap on changes to the copayment limits during the actuarially equivalent copayment transition for the ''Part B drugs—Other'' service category, the calculations to reach the final contract year 2023 copayment limit for the ''Part B drugs—Other'' service category are provided in Table 25B. As shown in Table 25B, the calculations of the transitional copayment limit for this service category are based on the median Medicare FFS cost projection of $1,603.00 using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). Using the median amount results in a lower copayment limit than if the weighted average Medicare FFS allowed amount was used; we choose between these actuarial approaches under § 422.100(f)(7)(ii)(C) and were guided by the purposes of the MA program. As part of that, we considered how which approach would most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protect against discriminatory cost sharing, and be in the best interests of beneficiaries, including protection against fluctuations in cost sharing or sudden, disruptive increases in cost sharing. In this specific case we believe choosing the lower actuarially equivalent copayment value would better protect beneficiaries from potentially disruptive increases to the cost sharing for that benefit in comparison to prior years. We emphasize that there is significant potential for discrimination against (or potential for discouraging enrollment by) beneficiaries who have health conditions treated by costly Part B drugs. We believe that choosing the lower actuarially equivalent copayment value protects beneficiaries with high health care needs from benefit designs that discriminate against or discourage enrollment in an MA plan, steer subsets of Medicare beneficiaries to particular MA plans, or inhibits access to services.

Row J in Tables 25A and 25B illustrates the comparison CMS will complete after calculating both the actuarially equivalent value to cost sharing under original Medicare and the transitional copayment limit for each service category subject to paragraph (j)(1) during the multiyear transition to actuarially equivalent copayment limits. For example, as shown in row J in Table 25B, the transitional copayment value for contract year 2023 is less than the actuarially equivalent value compared to cost sharing under original Medicare for the ''Part B drugs—Other'' service category. As a result of the ''lesser of'' requirement in paragraph (f)(8), this transitional copayment value from row J in Table 25B is included in Table 28 as the final contract year 2023 copayment limit for this service category. In addition, no transition is being applied to the coinsurance limit for the ''Part B drugs—Other'' service category because the 20 percent limit has been in place under our current policy since 2012.

We acknowledge that under our final policy, the copayment limit for the ''Part B drugs—Other'' service category is still increasing from $50 in contract year 2022 to $120 for contract year 2023 after incorporating 25 percent of the actuarially equivalent copayment differential in § 422.100(f)(8)(ii)(A) and application of the rounding rules in § 422.100(f)(6)(ii). However, updating the copayment limits to reflect the most recent actuarially equivalent values will address the costs MA organizations are expected to incur in providing these services for MA enrollees and make appropriate adjustments for medical inflation since the current copayment limits were last updated. Currently, the vast majority of MA plans have designed their ''Part B drugs—other'' benefit with cost sharing greater than zero and use coinsurance rather than a copayment. For contract year 2021 (based on March 2021 plan data) approximately 2 percent of MA and MA–PD plans (excluding employer, D–SNPs, and MSA plans) established a copayment for the ''Part B drugs—other'' service category ($50 or greater than zero), suggesting that the upper copayment limits for contract year 2022 may not fully reflect the costs MA organizations are experiencing to cover this benefit for enrollees. This trend of a small percentage of plans offering a copayment has remained relatively consistent since 2012. In 2012, approximately 5 percent of MA and MA–PD plans (excluding employer, D–SNPs, and MSA plans) established a copayment of $50 or greater than zero for the ''Part B drugs—other'' service category. Considering the percent of plans and enrollees where coinsurance is equal to original Medicare for the ''Part B drugs—other'' service category (approximately 97 percent and 93 percent in contract year 2021, respectively), we believe it is persuasive that having a copayment set at an amount that is less than an actuarially equivalent value to the coinsurance limit does not necessarily result in lower cost sharing, but might encourage plans to use coinsurance instead. The copayment limits for the ''Part B Drugs—Other'' category set for contract year 2022 have been in place since at least 2012. We expect that this transition to actuarially equivalent values will ultimately result in stable benefit packages by ensuring cost sharing limits are calculated following established actuarial methods, using the most recent Medicare FFS data projections available, and by keeping copayment limits aligned with coinsurance limits. CMS will track cost sharing changes for the ''Part B drugs—Other'' service category and pursue future rulemaking, if appropriate. For example, we will continue to review the projected weighted average and median Medicare FFS allowed amounts from the OACT annually, consult with the OACT on whether any applicable cost trends are expected to be consistent for future contract years, and consider how market competition or payment policies may affect or necessitate changes to the methodology CMS used to calculate cost sharing limits finalized here.

f. Per Member per Month Actuarial Equivalent (AE) Cost Sharing Limits for Basic Benefits (§ 422.100(j)(2))

Comment: A few commenters generally supported CMS's proposals (in section VI.B.4. of the February 2020 proposed rule) to require cost sharing for specific categories of basic benefits that does not exceed cost sharing in original Medicare on per member per month actuarially equivalent basis. These commenters also requested clarifications or modifications on these proposals as summarized in this section, which would be codified at § 422.100(j)(2). A commenter questioned whether CMS adjusted the calculations and methodology used to compare per member per month plan cost sharing to the adjusted original Medicare actuarially equivalent cost sharing to account for the impact of beneficiaries with diagnoses of ESRD enrolling in the MA program beginning in contract year 2021 as a result of the 21st Century Cures Act. In addition, the commenter requested that CMS clarify how the plan level inpatient calculations and limits for per member per month actuarially equivalent cost sharing are impacted by the projected increase to inpatient hospital acute and psychiatric services cost sharing limits based on CMS's proposal to transition ESRD costs into

the methodology used to set limits for that service category.

Response: We thank the commenters for their support and feedback on our proposals related to per member per month actuarially equivalent cost sharing limits for basic benefits. We are finalizing § 422.100(j)(2) generally as proposed, with modifications to ensure clarity in the regulations (as discussed in each response to comment in this section). We generally proposed to codify the longstanding policy that MA cost sharing for all basic benefits and certain categories of basic benefits must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis. This determination of per member per month actuarial equivalence is how the OACT currently evaluates the requirement in § 422.254(b)(4) and section 1852(a)(1)(B) of the Act that MA plans must cover Part A and B benefits (subject to exclusions for hospice benefits and costs for kidney acquisitions for transplants) with cost sharing for those services at least as required under Part A and B or an actuarially equivalent level of cost sharing. We are modifying the heading of paragraph (j)(2) to clarify that (j)(2) is an evaluation of all basic benefits and specific categories of basic benefits in the aggregate. For example, paragraph (j)(1) addresses the cost sharing limit applicable to each service category of DME and paragraph (j)(2) addresses the overall evaluation of the DME benefit category (the aggregate of all DME service categories). As with all MA requirements, § 422.100(j)(2) applies as well to employer plans unless there is a waiver provided by CMS under section 1857(i) of the Act. (Generally, all MA plans must comply with the cost sharing and MOOP limits adopted by this FC except for MA MSA plans because MA MSA plans must not cover basic benefits under the plan's deductible has been reached and after the deductible is reached, the plan must cover 100 percent of the costs of basic benefits. See section 1859(b)(3) of the Act and § 422.4(a)(2).) This includes both the aggregate and service-category specific PMPM actuarially equivalent requirements in paragraph (j)(2). As proposed and finalized in paragraph (j)(2), this requirement that cost sharing for basic benefits not exceed cost sharing in original Medicare does not apply to out-of-network benefits for a regional MA plan; this is consistent with section 1852(a)(1)(B)(ii). We proposed and are finalizing a longstanding bid evaluation of per member per month actuarial equivalence (rather than a specific cost sharing limit).

As finalized, § 422.100(j)(2)(i)(A) includes a clarification in the definition and scope of inpatient hospital acute and psychiatric services to which the PMPM limit will apply. For this regulation, ''inpatient hospital acute and psychiatric services'' means services provided during a covered inpatient stay during the period for which cost sharing would apply under original Medicare. We are not finalizing the reference to an inpatient facility as we believe individuals could interpret the word facility in a stricter fashion than how this category is reviewed for the PMPM evaluation. As finalized, the regulation is consistent with how CMS has completed the PMPM evaluation in longstanding practice and with section 1852(a)(1)(B)(ii) of the Act (85 FR 9087).

As part of the annual release of subregulatory guidance under new § 422.100(f)(7)(iii), CMS intends to issue instructions describing how excess cost sharing is evaluated using bid pricing tool (BPT) information to satisfy the per member per month actuarially equivalent requirement for the benefit categories subject to § 422.100(j)(2) (including inpatient). We include instructions for contract year 2023 in this section of this FC and will issue instructions for future contract years through annual subregulatory guidance. The approach evaluating compliance with the per member per month limits uses information specific to each MA plan bid and will happen during CMS review of bids consistent with longstanding practice. We are codifying this evaluation to protect beneficiaries against discriminatory cost sharing. The per member per month actuarial equivalence factors for the Inpatient and SNF benefit categories had historically included costs from beneficiaries with diagnoses of ESRD. A correction was made beginning for contract year 2021 bids to exclude costs from beneficiaries with diagnoses of ESRD in order to be consistent with the treatment of ESRD in the BPT. ESRD costs are excluded since the bid development is for the non-ESRD population to correspond with payment policy. Although the limits on eligibility for MA plan enrollment by beneficiaries with ESRD diagnoses were removed beginning for contract year 2021, ESRD utilization and payment information is different, when compared to other enrollees, and CMS will continue to exclude these factors from the primary pricing sections of the MA BPT. Additionally, the Medicare FFS Actuarial Equivalent Cost Sharing Factors in the MA BPT are calculated excluding ESRD utilization and payment information because the pricing in the bid is for the non- ESRD population. Therefore, in response to the commenter's question on whether the calculations and methodology used to compare per member per month plan cost sharing to the adjusted original Medicare actuarially equivalent cost sharing was modified to account for the impact of beneficiaries with diagnoses of ESRD enrolling in the MA program beginning in contract year 2021 as a result of section 17006 of the 21st Century Cures Act, we note that the evaluations and analyses to determine compliance with § 422.100(j)(2) will not include beneficiaries with diagnoses of ESRD in the development of the adjustment factors that account for physician allowed costs and cost sharing for the Inpatient and SNF benefit categories subject to § 422.100(j)(2). This approach does not have a material impact on MA plans being able to meet the Inpatient hospital and SNF cost sharing PMPM actuarial equivalence evaluation and is consistent with how information is collected in the BPT. The actuarially equivalent cost sharing factors used in the MA BPT exclude enrollees in ESRD status, as does the projection of bid expenditures. That is, MA organizations are paid the full risk-adjusted benchmark rate for ESRD enrollees and ESRD enrollees are excluded from the BPT and benchmark projections. In order to account for the projected marginal costs (or savings) of enrollees in ESRD status (as referenced in BPT instructions) the BPT allows for an adjustment that is allocated across ESRD and non-ESRD members (including out-of-area members).

In response to the request for clarity about the impact of the ESRD cost transition on the Inpatient hospital PMPM actuarial equivalence evaluation required by § 422.100(j)(2)(i)(A), we note that the PMPM actuarial equivalence evaluation is separate from and is conducted differently than evaluating the MA cost sharing standards. Both evaluations are used to protect against benefit designs that discriminate against and discourage enrollment by beneficiaries with a health status that requires those services. The per member per month actuarial equivalence evaluation uses BPT data in four service categories (Inpatient, SNF, DME, and Part B drugs) in a manner consistent with the BPT data collection that excludes ESRD costs. The BPT is used for establishing payments for non-ESRD enrollees, while payments for ESRD enrollees are based on the ESRD ratebook. The service category cost sharing standards adopted in this rule

(at § 422.100(f)(6)(iv)) for inpatient scenarios and (at § 422.100(f)(6)(i) and (iii) and (j)(1)) for other basic benefits are based on enrollee cost sharing entered in the PBP and includes cost sharing for all beneficiaries, including those with diagnoses of ESRD. Benefits and cost sharing must be uniform for all MA plan enrollees, or similarly situated enrollees [59] pursuant to existing regulations that are not being changed. As discussed in several other responses in this FC, payment by CMS to MA plans for coverage of enrollees with ESRD is, consistent with section 1853(a)(1)(H) of the Act, not the same as payment to MA plans for other enrollees.

Comment: As summarized in section II.B.5.e., a commenter opposed the proposal providing additional flexibility that could increase cost sharing limits for drugs and biologics covered under Part B. This commenter also supported CMS's proposal (in § 422.100(j)(2)(i)(C)) to codify existing policy regarding the specific benefit categories for which MA plans must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis, including drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs and other drugs covered under Part B). Specifically, this commenter supported CMS maintaining the current upper limits for Part B drug cost sharing to help ensure that cost sharing is not discriminatory. This commenter did not want this category to be modified to provide any additional flexibility that could increase cost sharing limits for drugs and biologics covered under Part B. The commenter supported CMS continuing to set specific cost sharing limits for individual service categories (including Part B drug cost sharing) based on the belief that maintaining these upper limits protects beneficiaries who might be impacted by cost sharing in excess of the amounts established for the original Medicare program.

Response: We thank the commenter for their feedback on our proposal to codify the current requirement that cost sharing for Part B drugs and biologics must not exceed cost sharing for that benefit category in original Medicare on a PMPM actuarially equivalent basis. We are finalizing this proposal with modification to clarify that cost sharing in MA plans must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis for all drugs and biologics covered under Part B of original Medicare. CMS is not finalizing the proposed language referencing both chemotherapy/radiation drugs integral to the treatment regimen and other drugs covered under Part B in § 422.100(j)(2)(i)(C) because that text is unnecessary. This change simplifies the regulation and more accurately reflects the breadth of drugs that are applicable to paragraph (j)(2)(i)(C). These changes do not impact how CMS conducts the PMPM actuarial equivalence evaluation for any benefit category. In respect to the comments related to providing additional flexibility that could increase cost sharing limits for drugs and biologics covered under Part B, we address these concerns in section II.B.5.e. of this FC.

Comment: A commenter recommended that CMS broaden the benefit categories listed in proposed § 422.100(j)(2) to include home health and physical therapy services to protect beneficiaries from excessive cost sharing for those services.

Response: We appreciate the commenter's request to add physical therapy and home health to the list of service categories in § 422.100(j)(2) for which an MA plan may not exceed cost sharing required under original Medicare on a per member per month actuarially equivalent basis, but we are not adopting such a change. The BPT categories typically include multiple PBP service categories and may not collect details necessary to evaluate a specific specialty category on the basis of per member per month actuarial equivalence; this is the case for physical therapy, for example. We will consider future revisions to the PBP and/or BPT to gather more information and will pursue future rulemaking, if appropriate.

CMS's longstanding policy has been to allow MA plans to establish up to 50 percent coinsurance or an actuarially equivalent copayment for in-network professional services except for those services for which cost sharing cannot exceed original Medicare, regardless of the MOOP type (including cost sharing for physical therapy). In this FC, we are limiting, subject to a transition period, this flexibility to MA plans that establish a lower MOOP amount. We also note a more complete discussion related to CMS's considerations of changing our longstanding policy to limit certain cost sharing flexibilities to MA plans that establish a lower MOOP amount is provided in section II.B.5.b. of this FC. As discussed in section II.B.5.b. of this FC, in response to comments specifically about physical therapy, the provisions we proposed and are finalizing ensure that, beginning with contract year 2023, MA plans always pay at least 50 percent of the estimated total financial liability (for plans with a lower MOOP amount) and a higher percentage for those services in plans that establish an intermediate or mandatory MOOP amount than in prior contract years.

We believe the cost sharing standards we are finalizing in § 422.100(f)(6)(iii) for physical therapy and in § 422.100(j)(1)(i)(D) for home health will adequately protect beneficiaries from discriminatory cost sharing with regard to those services. Because original Medicare has no cost sharing for home health, it would be difficult to apply the PMPM actuarial equivalence evaluation in paragraph (j)(2) to this service category. The highest allowable MA plan cost sharing limit for home health is 20 percent or an actuarially equivalent copayment (including a copayment limit calculated by CMS as discussed in sections II.B.5.a., b., and e. of this FC) which is limited to MA plans with a lower MOOP amount. MA plans that establish a mandatory or intermediate MOOP amount must establish $0 cost sharing for home health services under the provision we are finalizing in § 422.100(j)(1)(i)(D) (proposed in paragraph (j)(1)(iv)). CMS will continue to evaluate MA plans during bid review in relation to these cost sharing categories and will pursue future rulemaking to address any concerns, if appropriate.

We are finalizing § 422.100(j)(2)(ii) generally as proposed, but with modifications to: (1) Correct the reference to generally accepted actuarial principles and practices (rather than only principles) in the regulation; (2) clarify the requirements in paragraph (j)(2)(i) apply to the MA plan's cost sharing for all for basic benefits and specific categories of basic benefits, rather than specific services; and (3) clarify that CMS may extend flexibility regarding compliance with the requirements in paragraph (j)(2)(i) to an MA plan that has excess cost sharing (meaning the PMPM actuarial value of the plan's cost sharing is higher than the PMPM actuarial value of the cost sharing in original Medicare) to the extent that it is actuarially justifiable and provided that certain conditions are met. Specifically, the MA plan's cost sharing must be based on generally accepted actuarial principles and practices (consistent with paragraph (f)(7)) and supporting documentation included in the bid, and the MA plan's cost sharing must otherwise comply with applicable cost sharing standards.

[59] Except in the case of special supplemental benefit for the chronically ill (SSBCI) offered in accordance with § 422.102(f), in which CMS may waive uniformity requirements in connection with providing SSBCI to eligible chronically ill enrollees.

We anticipate this exception would apply in limited situations, such as when the MA plan uses capitated arrangements with provider groups, operates their own facilities, or other unique arrangements. This flexibility is consistent with long-standing policy and practice.

We are finalizing in § 422.100(j)(2), with the modifications discussed previously in this section, our proposals to impose requirements related to the per member per month (PMPM) actuarial value of the cost sharing for basic benefits. As a result, for contract year 2023 and subsequent years, CMS will separately evaluate the PMPM actuarial value of the cost sharing used by each MA plan for the following service categories: Inpatient, Skilled Nursing Facility (SNF), Durable Medical Equipment (DME), and Part B drugs. Whether in aggregate, or on a service-specific basis, this evaluation is done by comparing two values in the plan's BPT. In essence, CMS compares the actuarial value of a plan's PMPM cost sharing for the benefit category to the estimated actuarial value of original Medicare cost sharing for the same benefit category in order to determine plan compliance. Specifically, for contract year 2023, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) will be compared to Medicare covered actuarially equivalent cost sharing (BPT Worksheet 4, Section IIA, column n). For Inpatient hospital and SNF services, the Medicare actuarially equivalent cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing. Therefore, an adjustment factor is applied to these Medicare actuarially equivalent values to incorporate Part B cost sharing and to make the comparison valid. CMS annually updates and communicates the Part B adjustment factors prior to bid submission. Please note that factors for Inpatient and Skilled Nursing Facility in column #4 of Table 27 (Part B Adjustment Factor to Incorporate Part B Cost Sharing) have been updated for contract year 2023. Once the comparison amounts have been determined, CMS can evaluate excess cost sharing. Excess cost sharing is the difference (if positive) between the plan cost sharing amount (column #1 in Table 27) and the comparison amount in column #5 of Table 27 (which reflects an estimated original Medicare cost sharing which is weighted based on the plan's projected county enrollment). This evaluation process remains consistent with prior years.[60] Table 27 uses illustrative values to demonstrate the mechanics of this determination for contract year 2023. We also note that, beginning in contract year 2017, CMS waived the requirement, under section 1857(i) of the Act, for MA employer plans (EGWPs) to submit a BPT, which affects our ability to evaluate EGWPs on the PMPM Actuarial Equivalent Cost Sharing standards discussed in this section. MA EGWPs continue to be subject to all MA regulatory requirements that have not explicitly been waived by CMS, including the cost sharing requirements we are finalizing in § 422.100(j)(2), regardless of whether they are affirmatively evaluated as part of bid review or in connection with other reviews.

TABLE 27: ILLUSTRATIVE COMPARISON OF SERVICE-LEVEL ACTUARIAL EQUIVALENT COSTS TO IDENTIFY EXCESSIVE COST SHARING FOR CONTRACT YEAR 2023

	#1	#2	#3	#4	#5	#6	#7
BPT Benefit Category	**PMPM Plan Cost Sharing (Parts A&B)** *(BPT Col. l)*	**Medicare FFS Allowed Amount** *(BPT Col. m)*	**Medicare FFS Actuarially Equivalent Cost Sharing** *(BPT Col. n)* [1]	**Part B Adjustment Factor to Incorporate Part B Cost Sharing (Based on Medicare FFS Data Projections)**	**Comparison Amount**[2] *(#3 × #4)*	**Excess Cost Sharing (#1 − #5, min of $0)**	**Pass/Fail**
Inpatient	$33.49	$331.06	$25.30	1.362	$34.46	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.083	$10.71	$0.12	Fail
DME	$3.00	$11.37	$2.65	1	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1	$0.33	$0.00	Pass

[1] PMPM values in column #3 for Inpatient and SNF only reflect Part A FFS actuarial equivalent cost sharing for that service category.

[2] Estimated original Medicare cost sharing weighted based on the plan's projected county enrollment.

[60] For information on per member per month actuarial equivalent cost sharing bid review criteria in contract year 2021 and 2021, see the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020 for contract year 2021 and the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021 for contract year 2022.

CMS will, as described in new § 422.100(f)(7)(iii) (and previously discussed in section II.B.5.a. of this FC), issue subregulatory guidance for contract year 2024 and future years prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. This guidance will include how CMS will evaluate compliance with § 422.100(j)(2) and identify excessive cost sharing. The information will be consistent with prior years [61] and may be shared through publicly-available HPMS memoranda.[62] Consistent with prior practice (for example, the HPMS memorandum addressing MOOP and cost sharing standards for contract year 2022), CMS may avoid repeating guidance that is unchanged from the prior year. For example, if the per member per month evaluation will be conducted in the same manner as the prior contract year and was sufficiently explained in the prior year's guidance or within this FC, we may only cite to the prior year's communications, summarize, or highlight information that has changed to streamline annual guidance.

g. In-Network Service Category Cost Sharing Requirements

Comments received on section VI.B.3.d. from the February 2020 proposed rule were summarized and responded to in sections II.B.5.a.–f. of this FC. Table 28 provides a summary of final contract year 2023 in-network service category cost sharing limits based on the finalized policies discussed in section II.B.5.a.–f. of this FC. This table is an updated version of Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from section VI.B. of the February 2020 proposed rule. Some of the changes, in comparison to Table 5 from the February 2020 proposed rule, are a result of various factors: (1) Using the more recent Medicare FFS beneficiary data projections available at the time of this FC; (2) applying the updated ESRD cost transition schedule finalized at § 422.100(f)(4)(vii) for inpatient hospital cost sharing limits (and for MOOP limits where the MOOP limit amount restricts the available cost sharing); (3) applying the cost sharing limit transition provisions (finalized at §§ 422.100(f)(6), (f)(8), and 422.113(b)(2)(v)) for professional services, benefits for which cost sharing must not exceed cost sharing under original Medicare, and emergency services; (4) calculating the actuarially equivalent copayment limits for the ''primary care physician'' and ''physician specialist'' service categories based on the revised group of provider specialties discussed in section II.B.5.b. in this FC; and (5) applying the requirement finalized at § 422.100(j)(1)(i)(F) that MA plans must not use cost sharing that exceeds cost sharing in original Medicare for Part B drugs other than the specific drugs listed in paragraph (j)(1)(i)(A). In addition, we updated prior ''N/A'' designations for certain service categories as discussed in section II.B.5.a. and c. of this FC and the footnotes for clarity and to reflect the finalized policies.

As discussed in the February 2020 proposed rule, CMS will annually update the cost sharing limits, using the methodology adopted in this FC (at §§ 422.100(f)(4) through (f)(8), 422.100(j), and 422.113(b)(2)) to calculate and issue the cost sharing limits each year. As this FC is being published in advance of the bidding deadline for contract year 2023 and with the availability of contract year 2023 Medicare FFS data projections, the contract year 2023 cost sharing limits in Table 28 are final. In addition, CMS will calculate updated limits for contract year 2024 and future years based on more recent Medicare FFS data projections from the OACT and the methodology finalized through this FC. As a result, in-network service category cost sharing limits for contract year 2024, as well as subsequent years, will be issued annually using a subregulatory guidance process that includes an opportunity for comment, as finalized in paragraph (f)(7)(iii).

Except for the requirement in § 422.100(f)(6)(i) that MA plans pay at least 50 percent of estimated total MA financial liability for basic benefits, even when furnished out of network, the standards in Table 28 only apply to in-network Parts A and B services. All standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles (for example, deductibles that include several service categories). Together, the per member per month actuarial equivalence evaluation and the Part C service category cost sharing standards make sure that benefit designs are not discriminatory to beneficiaries based on health status.

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[61] See Table 4: Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing in the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation'' issued April 8, 2020 for an example.

[62] Individuals and organizations may request placement on a listserv at *https://hpms.cms.gov/app/ng/home/* to receive future HPMS memoranda.

TABLE 28: FINAL CONTRACT YEAR 2023 IN-NETWORK SERVICE CATEGORY COST SHARING LIMITS USING PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

Service Category	PBP Section B Data Entry Field	Lower MOOP	Intermediate MOOP	Mandatory MOOP
Inpatient Hospital – Acute - 60 days[1]	1a	$3,650	$4,690	$5,729
Inpatient Hospital – Acute - 10 days[1]	1a	$3,124	$2,812	$2,499
Inpatient Hospital – Acute - 6 days[1]	1a	$2,801	$2,521	$2,241
Inpatient Hospital – Acute - 3 days[1]	1a	$2,562	$2,306	$2,050
Inpatient Hospital Psychiatric - 60 days[1]	1b	$3,650	$3,325	$3,000
Inpatient Hospital Psychiatric - 15 days[1]	1b	$2,530	$2,277	$2,024
Inpatient Hospital Psychiatric - 8 days[1]	1b	$2,340	$2,106	$1,872
Skilled Nursing Facility – First 20 Days[2,3]	2	$20/day	$10/day	$0/day
Skilled Nursing Facility – Days 21 through 100[2,3]	2	$196/day	$196/day	$196/day
Cardiac Rehabilitation[4,5]	3	50% / $40	47% / $40	45% / $40
Intensive Cardiac Rehabilitation[4,5]	3	50% / $65	47% / $60	45% / $60
Pulmonary Rehabilitation[4,5]	3	50% / $20	47% / $20	45% / $20
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD)[4]	3	50% / $30	47% / $30	45% /$25
Emergency Services[4,6]	4a	$125	$110	$95
Urgently Needed Services[4,6]	4b	50% / $65	47% / $60	45% / $60
Partial Hospitalization[4]	5	50% / $75	47% / $70	45% / $60
Home Health[2]	6a	20% / $40[4]	$0	$0
Primary Care Physician[4]	7a	50% / $40	47% / $40	45% / $35
Chiropractic Care[4]	7b	50% / $20	47% / $20	45% / $20
Occupational Therapy[4]	7c	50% / $45	47% / $40	45% / $40
Physician Specialist[4]	7d	50% / $60	47% / $55	45% / $50
Mental Health Specialty Services[4]	7e	50% / $50	47% / $45	45% / $40
Psychiatric Services[4]	7h	50% / $50	47% / $45	45% / $40
Physical Therapy and Speech-language Pathology[4]	7i	50% / $50	47% / $50	45% / $45
Therapeutic Radiological Services[2,4]	8b	20% / $65	20% / $65	20% / $65
DME-Equipment[7]	11a	50%	50%	20%[2,4]
DME-Prosthetics[7]	11b	50%	50%	20%[2,4]
DME-Medical Supplies[7]	11b	50%	50%	20%[2,4]
DME-Diabetes Monitoring Supplies	11c	50% / $20	50% / $20	20% / $10[2,4]
DME-Diabetic Shoes or Inserts	11c	50% / $25	50% / $25	20% / $10[2,4]
Dialysis Services[2,4]	12	20% / $40	20% / $40	20% / $40
Part B Drugs-Chemotherapy/Radiation[2,4]	15	20% / $125	20% / $125	20% / $125
Part B Drugs-Other[2,4]	15	20% / $120	20% / $120	20% / $120

[1] All MA plans are required to establish cost sharing that does not exceed the plan's MOOP limit or overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis.

[2] MA plans (per § 422.100(j)(1)) and 1876 Cost Plans (per § 417.454(e)) may not charge enrollees higher cost sharing than is charged under original Medicare for Part B chemotherapy administration services, including chemotherapy drugs and radiation therapy integral to the treatment regimen, skilled nursing care, and renal dialysis services. As finalized, MA plans (§ 422.100(j)(1)(i)(F)) may not charge enrollees higher cost sharing than is charged under Original Medicare for "Part B drugs – Other." MA plans that establish a lower MOOP limit may charge cost sharing for home health, while plans with an intermediate or mandatory MOOP must not charge higher cost sharing than in original Medicare (§ 422.100(j)(1)(i)(D)). MA plans that establish a mandatory MOOP limit may also not charge enrollees higher cost sharing than is charged under original Medicare for DME service categories (§422.100(j)(1)(i)(E)).

[3] MA plans that establish a lower or intermediate MOOP limit may have cost sharing for the first 20 days of a SNF stay (§ 422.100(j)(1)(i)(C)). The per-day cost sharing for days 21 through 100 must not be greater than one eighth of the projected (or actual) Part A deductible amount, per § 422.100(j)(1)(i)(C)*(1)*. The SNF copayment limit for days 21 through 100 is based on 1/8th of the projected Part A deductible for 2023. Total cost sharing for the overall SNF benefit must be not be greater than the actuarially equivalent cost sharing in original Medicare, pursuant to section 1852(a)(1)(B) of the Act, and § 422.100(j)(1)(i)(C).

[4] Cost sharing limits for these service categories (and the mandatory MOOP type for the DME service categories) are subject to the multiyear transition schedules finalized in §§ 422.100(f)(6)(iii), (f)(8), (j)(1), and 422.113(b)(2)(v). In addition, the copayment limits for the primary care physician and physician specialist service categories reflect the change in applicable provider specialties used to calculate the actuarially equivalent copayment value, as described in section II.B.5.b. of this FC.

[5] The copayment limit set for these service categories reflect application of the "lesser of" requirement in § 422.100(f)(8); the actuarially equivalent value to the coinsurance limit for contract year 2023 is less than the value resulting from the actuarially equivalent copayment transition (after application of the rounding rules).

[6] The dollar amount for Emergency Services and Urgently Needed Services included in the table represents the maximum cost sharing permitted per visit (copayment or coinsurance) and the cost sharing limit applies whether the services are received inside or outside the MA organization, per § 422.113(b)(2)(i), (v), and (vi). Emergency and Urgently Needed Services benefits are not subject to plan level deductible amount and/or out-of-network providers. In addition, the cost sharing limit for Urgently Needed Services is based on the limits specified for professional services in § 422.100(f)(6)(iii) (which includes being subject to the transition limits in § 422.100(f)(8)), as finalized in § 422.113(b)(2)(vi).

[7] For contract years where CMS has not calculated an actuarially equivalent copayment limit, MA plans may establish cost sharing at or less than either (i) the coinsurance limits or (ii) the dollar value that is actuarially equivalent to the coinsurance limit based on their estimated total MA plan financial liability for the benefit for that contract year or the average Medicare FFS allowable amount for the benefit in the plan's service area, as applicable, under § 422.100(f)(6)(i), (iii), and (j)(1).

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MA plans may not charge enrollees higher costs sharing than is charged under Original Medicare for COVID–19 testing and testing-related services identified in section 1833(cc)(1) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2) during the period from March 18, 2020 through to the end of the emergency period described in section 1135(g)(1)(B), pursuant to amendments to section 1852 of the Act, as amended by the Families First Coronavirus Response Act. We have not incorporated that cost sharing limit into Table 28 because of the time-limited nature of the requirement. However, MA organizations must comply with it and other statutory cost sharing limits, such as the requirement that cost sharing must not exceed cost sharing in Original Medicare for a COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act, regardless whether CMS specifically addresses such limits when issuing the cost sharing limits calculated annually under §§ 422.100(f) and (j) and 422.113(b)(2).

h. Out-of-Scope Comments

Comment: A few commenters also provided feedback that was outside the scope of the cost sharing limit changes proposed for §§ 422.100 and 422.113 in section VI.B of the February 2020 proposed rule. These commenters requested CMS change ESRD payments for MA plans in addition to, or in place of, transitioning ESRD costs into the data used to set cost sharing limits and raising cost sharing limits. Commenters were concerned that payment changes were needed in order to ensure MA plans and ultimately providers have the resources needed to treat this chronically ill patient population, support MA plans that must cover the higher costs of beneficiaries with diagnoses of ESRD, and prevent detrimental changes to plan options, premiums, cost sharing, and supplemental benefits.

Response: We direct commenters to the two most recent Rate Announcements (Calendar Year 2021 and 2022) at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents* for a discussion of MA program payment policies.

6. Final Decision

We received feedback from 17 commenters pertaining to the proposal for setting cost sharing limits, with the majority providing general support, suggested clarifications, or concerns about certain elements of the proposed amendments to §§ 422.100(f)(6), 422.100(j)(1) and (2), and 422.113(b)(2). We thank commenters for their input in helping to inform our final policy concerning cost sharing limits. We are soliciting comments to potentially inform future rulemaking on cost sharing limits as discussed in section III of this FC.

After careful consideration of all the comments we received, and for the reasons set forth in the February 2020 proposed rule and in our responses to the related comments discussed previously, we are finalizing the proposals to amend §§ 422.100(f)(6), 422.100(j)(1) and (2), and 422.113(b)(2) with some modifications and additional provisions to: (1) Delay the beginning of implementation of the cost sharing policies by one year; (2) codify the long-standing policy that MA plans must not charge cost sharing that exceeds 50 percent coinsurance or an actuarially equivalent copayment, regardless of the MOOP limit established, for basic benefits (identified within the PBP service category or a reasonable group of benefits or services) that are provided in-network and out-of-network that are not explicitly addressed in § 422.100(f)(6), (j)(1), or § 422.113(b)(2); (3) codify, with some updates and changes, the current process for calculating non-discriminatory cost sharing limits, taking into account ESRD costs; (4) apply a multiyear transition to calculate cost sharing limits for professional services (furnished on an in-network basis based on the MOOP limit established by the MA plan), emergency services, and benefits for which cost sharing must not exceed cost sharing under original Medicare; (5) codify, with some updates and changes (including applying the revised multiyear transition of ESRD costs finalized in section II.A. of this FC), the methodology used to calculate the cost sharing standards for inpatient hospital acute and psychiatric services; (6) set specific cost sharing requirements for emergency services; (7) apply the range of cost sharing limits calculated for professional services to the urgently needed services category; (8) codify that MA plans must not impose cost sharing that exceeds original Medicare for certain specific benefits in addition to the current list in § 422.100(j); (9) codify the cost sharing under original Medicare (20 percent coinsurance) as a cost sharing limit for the ''Part B drugs—Other'' service category; (10) codify the requirement that total MA cost sharing for all basic benefits and for certain categories of benefits must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis; (11) provide that an MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s); (12) provide for an subregulatory comment period for how these regulations are applied for annual cost sharing limits beginning for contract year 2024; and (13) codify the use of generally accepted actuarially principles and practices in applying the MOOP and cost sharing limit regulations. These provisions are applicable for coverage beginning January 1, 2023 and later. We will therefore use these rules and the final contract year 2023 cost sharing limits in Table 28 to evaluate MA bids submissions due the first Monday in June (June 6, 2022) for the 2023 contract year. We will also use these rules to evaluate MA bid submissions for subsequent contract years going forward. In summary, the proposed changes to §§ 422.100(f)(6), 422.100(j)(1) and (2), and 422.113(b)(2) are being finalized substantially as proposed with

the following modifications from the proposal:

- The methodology for calculating cost sharing limits in the amendments to §§ 422.100(f), (j), and 422.113(b)(2)(vi) and the specific cost sharing limits in § 422.113(b)(2)(v) are applicable beginning on or after January 1, 2023 instead of January 1, 2022.
- Adding descriptive headings to paragraphs in § 422.100(f)(6) and (j)(1)–(2) to orient the reader to the content in each paragraph.
- Revising § 422.100(f) and (j) to use consistent language in regulation text when referring to: (1) A cost sharing requirement that the MA plan ''must'', not ''may'', follow; (2) out-of-pocket costs ''incurred by'' beneficiaries with and without diagnoses of ESRD; (3) ''service categories'' instead of ''services'' or ''items''; (4) cost sharing limits ''calculated'' by CMS by applying these regulations; and (5) cost sharing ''established'' by MA plans as part of their benefit designs.
- Revising introductory language in § 422.100(f)(6) to: (1) Clarify that the cost sharing limits (coinsurance or copayments) are calculated at the plan benefit package service category level or for a reasonable group of benefits covered under the plan; (2) add references to §§ 422.100(j) and 422.113(b)(2), to encompass the cost sharing requirements that apply in those sections; (3) clarify that § 422.254(b)(4) requires that overall MA cost sharing for basic benefits be actuarially equivalent to, or less than, Medicare FFS cost sharing; (4) clarify that cost sharing evaluations will be completed at the plan (or segment) level; and (5) codify the requirement that an MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s).
- Consolidating the requirements in § 422.100(f)(6)(i)(A), (B), and (C) into one regulatory paragraph at (f)(6)(i) with revisions to: (1) Clarify the requirements MA plans must follow to establish a cost sharing amount for service categories subject to paragraph (f)(6)(i); (2) specify the data MA plans must use to determine that its copayment amount for a service category or for a reasonable group of benefits in the PBP does not exceed an actuarially equivalent value to 50 percent coinsurance; (3) clarify that the copayment limits calculated by CMS take precedence; (4) add references to other applicable regulations to clarify the scope of the requirements in paragraph (f)(6)(i); and (5) generally simplify and clarify regulation text.
- Adding language to § 422.100(f)(6)(ii) to: (1) Clarify that CMS will apply the same rounding methodology when calculating copayment limits and evaluating MA plan compliance with paragraphs (f)(6), (f)(7), (f)(8), and (j)(1); and (2) reorganize the regulation text to apply the rounding rules when MA organizations calculate actuarially equivalent values and to increase clarity.
- Revising § 422.100(f)(6)(ii)(A) to add references to paragraphs (f)(6)(i), (f)(6)(iii), and (j)(1) to apply the $5 rounding methodology consistently to cost sharing limits for professional services and benefits for which cost sharing must not exceed cost sharing under original Medicare.
- Moving the rule for rounding inpatient hospital acute and psychiatric and skilled nursing facility cost sharing limits from § 422.100(f)(6)(ii)(A) to § 422.100(f)(6)(ii)(B) and adding references to paragraphs (f)(6)(iv) and (j)(1)(i)(C) to clarify the regulations that govern the methodology to calculate cost sharing limits for those service categories.
- Moving the rule for rounding copayments when a copayment limit is projected to be exactly between two increments from proposed paragraph (f)(6)(ii)(B) to new § 422.100(f)(6)(ii)(C).
- Revising § 422.100(f)(6)(iii)(A) to refer to paragraph (f)(6)(iii) (instead of paragraph (f)(6)(ii)).
- Moving the rule identifying the Medicare data that CMS may utilize to calculate copayment limits subject to paragraph (f)(6)(iii) from proposed paragraph (f)(6)(iii)(B) to new § 422.100(f)(7)(i)(A).
- Finalizing new language at § 422.100(f)(6)(iii)(B) to: (1) Clarify how CMS will apply the regulations to calculate copayments that are actuarially equivalent to the coinsurance limits, subject to other cited regulations; (2) refer to new paragraphs (f)(7) and (f)(8) to apply generally accepted actuarial principles and practices and restrictions on increases to the copayment limits to CMS's calculations of actuarially equivalent copayments; and (3) to provide if CMS does not calculate a copayment limit, the MA plan must not establish a copayment that exceeds the actuarially equivalent value to the coinsurance limits in paragraph (f)(6)(iii) based on the estimated total MA plan financial liability for that benefit for that contract year.
- Revising and adding new paragraphs at § 422.100(f)(6)(iii)(C) through (F) to adopt a transition over 4 years to the cost sharing limits for professional service categories based on use of the lower, intermediate, or mandatory MOOP type.
- Revising § 422.100(f)(6)(iv)(A) to add a reference to new paragraph (f)(7).
- Revising § 422.100(f)(6)(iv)(B) to: (1) Clarify the cost sharing limits calculated for the seven length of stay scenarios apply to inpatient hospital acute and psychiatric service categories; (2) remove the reference to an inpatient facility to match how CMS applies the inpatient hospital cost sharing limits; and (3) generally improve the flow of the regulation text.
- Revising § 422.100(f)(6)(iv)(C) to: (1) Update the description of the Medicare FFS data used to calculate the inpatient hospital service category cost sharing limits for the applicable year and length of stay scenario to reflect the ESRD cost transition; and (2) update the reference to the ESRD cost transition schedule to paragraphs (f)(4)(vii)(A) through (B) to reflect the modified transition finalized in section II.A. of this FC.
- Revising § 422.100(f)(6)(iv)(D) to: (1) Clarify that this paragraph is applicable to inpatient hospital acute and psychiatric service categories; and (2) apply the rule proposed in paragraph (f)(6)(iv)(D)*(3)* that the total cost sharing for the inpatient benefit must not exceed the MA plan's MOOP limit or overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis (based on original Medicare cost sharing for a new benefit period) to all inpatient hospital cost sharing rather than only limited to MA plans that establish a lower MOOP amount.
- Revising § 422.100(f)(6)(iv)(D)*(1)* to clarify that the cost sharing for MA plans with a mandatory MOOP amount must not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario.
- Revising § 422.100(f)(6)(iv)(D)*(2)* to clarify that the cost sharing for MA plans with an intermediate MOOP amount must not exceed the cost sharing limits established in paragraphs (f)(6)(iv)(D)*(1)* and *(3)* for the same inpatient hospital length of stay scenario, before application of the rounding rules in paragraph (f)(6)(ii).
- Revising § 422.100(f)(6)(iv)(D)*(3)* to (1) clarify that CMS uses the projected Part A deductible to determine cost sharing limits for inpatient hospital acute and psychiatric services; (2) clarify that the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing is limited to the inpatient hospital acute 60 day length of stay for MA plans that establish a lower MOOP limit; (3) use consistent language when referring to inpatient hospital cost sharing; and (4)

avoid repeating the rule moved to paragraph (f)(6)(iv)(D).

• Also, as discussed in section II.A. of this FC, adding § 422.100(f)(7)(i) to clarify that generally accepted actuarial principles and practices must be applied in the process of developing the projections and calculations described in §§ 422.100(f)(4), (f)(5), (f)(6), (f)(7)(ii), (f)(8) and (j) and in 422.101(d)(2) and (3).

• Adding § 422.100(f)(7)(i)(A) to clarify in applying generally accepted actuarial principles and practices, actuarial judgment and discretion may be used, including to take into account relevant information, select among different approaches, and select data or data samples used in the calculations.

• Adding § 422.100(f)(7)(i)(B) to require MA organizations to also use generally accepted actuarial principles and practices in complying with the regulations in paragraphs (f)(6) and (j).

• Adding § 422.100(f)(7)(i)(C) to clarify that CMS will apply generally accepted actuarial principles and practices in evaluating MA organization compliance with § 422.100(f)(6) and (j).

• Adding § 422.100(f)(7)(ii) to adopt standards for whether and how CMS will calculate actuarially equivalent copayment limits for basic benefits subject to § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1).

• Adding § 422.100(f)(7)(ii)(A) to provide that CMS will use Medicare FFS data projections (defined in paragraph (f)(4)(i)) to calculate an actuarially equivalent copayment value for the applicable year and service category.

• Adding § 422.100(f)(7)(ii)(B) to describe how CMS may use MA encounter data in addition to the Medicare FFS cost data projections.

• Adding § 422.100(f)(7)(ii)(C) to clarify how CMS may select among particular approaches to calculate actuarially equivalent copayment values in order to carry out program purposes.

• Adding § 422.100(f)(7)(ii)(D) to provide for applying the actuarially equivalent copayment transition in paragraph (f)(8) for calculating copayment limits.

• Adding § 422.100(f)(7)(ii)(E) to clarify use of the rounding rules in paragraph (f)(6)(ii) when calculating copayment limits at an actuarially equivalent value to the applicable cost sharing standard.

• Finalizing § 422.100(f)(7)(iii) to: (1) Clarify that CMS will issue subregulatory guidance (beginning with contract year 2024) that specifies the MOOP limits and cost sharing standards for the upcoming contract year that are set and calculated using the methodology and standards in §§ 422.100(f) and (j), 422.101(d), and 422.113; (2) codify that this subregulatory guidance will be released prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids; and (3) provide for a public notice and comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year unless a public comment period is impracticable, unnecessary, or contrary to the public interest.

• Adding § 422.100(f)(8) to adopt a definition of and methodology for using an actuarially equivalent copayment differential (defined in paragraph (f)(8)(i)) to cap increases to copayment limits (for service categories subject to paragraph (f)(6)(iii) or (j)(1)) during the transition to actuarially equivalent copayment limits that ends in 2026, as described in detail in section II.B.5.b. and e. of this FC.

• Adding § 422.100(f)(9) to require MA organizations to bundle cost sharing amounts where separate cost sharing applies for that particular service(s) and setting(s) and be clearly reflected as a single, total cost sharing in appropriate materials distributed to beneficiaries for basic benefits.

• Redesignating the text at § 422.100(j)(1) to paragraph (j)(1)(i) and redesignating with modifications current paragraphs (j)(1), (j)(2) and (j)(3) as (j)(1)(i)(A), (j)(1)(i)(B), and (j)(1)(i)(C).

• Reorganizing the regulation text in paragraph (j)(1) and clarifying the description of the benefit in paragraph (j)(1)(i)(A) (proposed in § 422.100(j)(1)(i)).

• Revising § 422.100(j)(1)(i) to: (1) Clarify the scope of the requirement that cost sharing for certain services must not exceed cost sharing under original Medicare; and (2) require MA plans establishing a copayment for a service category subject to paragraph (j)(1)(i) to establish an amount that is equal to or less than an actuarially equivalent value to cost sharing required under original Medicare using the rules in paragraph (j)(1)(ii).

• Moving the regulatory text in proposed § 422.100(j)(1)(iii) to paragraph (j)(1)(i)(C) with the addition of specific per day cost sharing limits for the first 20 days of a SNF stay for each MOOP type.

• Moving the regulatory text in proposed § 422.100(j)(1)(iii)(A) and (B) to paragraphs (j)(1)(i)(C)*(1)* and *(2)* with a clarification that the per-day cost sharing for days 21 through 100 in a SNF must not be greater than one eighth of the projected (or actual) Part A deductible amount and a clarification that total cost sharing for the overall SNF benefit is also evaluated based on the per member per month actuarial equivalent value.

• Moving the regulatory text in proposed § 422.100(j)(1)(iv) to paragraph (j)(1)(i)(D) with modifications to change the requirement from cost sharing up to 20 percent of the total MA plan financial liability to cost sharing not greater than 20 percent or an actuarially equivalent copayment (the data which would make this determination is now contained in paragraph (j)(1)(ii)).

• Moving the regulatory text in proposed § 422.100(j)(1)(v) to paragraph (j)(1)(i)(E) with the following clarifications and additions: (1) The specific service categories applicable to paragraph (j)(1)(i)(E) for MA plans that establish a mandatory MOOP limit are: Equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts; and (2) the requirement that the total cost sharing for the overall DME benefit must be no greater than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare is applicable for all MOOP limits.

• Adding § 422.100(j)(1)(i)(F) to apply the requirement that cost sharing must not exceed cost sharing under original Medicare to the other drugs covered under Part B of original Medicare (that is, Part B drugs not included in paragraph (j)(1)(i)(A)).

• Adding § 422.100(j)(1)(ii) to codify the rules for calculating copayment limits for the basic benefits listed in paragraph (j)(1)(i) which include: (1) How CMS calculates copayment limits following the requirements in paragraph (f)(7) and the restrictions on changes in copayment amounts in paragraph (f)(8); and (2) how an MA plan must establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare when CMS does not calculate a copayment limit for a benefit listed in paragraph (j)(1)(i) using actuarially accepted principles and practices included in paragraph (f)(7)(i) and basing calculations of an actuarially equivalent value on the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year.

• Revising § 422.100(j)(2) to clarify that this paragraph addresses the evaluation of all basic benefits and specific categories of basic benefits in the aggregate for which an MA plan's total cost sharing for all basic benefits (excluding out of network benefits covered by a regional MA plan) must not exceed cost sharing in original

Medicare on a per member per month actuarially equivalent basis.

- Revising § 422.100(j)(2)(i) to generally simplify and clarify regulation text.
- Revising § 422.100(j)(2)(i)(A) to: (1) Clarify that services provided are during a covered inpatient stay; and (2) remove the language referencing an inpatient facility.
- Revising § 422.100(j)(2)(i)(C) to apply the requirement under paragraph (j)(2) to all drugs and biologics covered under Part B of original Medicare.
- Revising § 422.100(j)(2)(ii) to: (1) Clarify that CMS extends the proposed flexibility to the evaluation of compliance with the requirements in paragraph (j)(2)(i) regarding actuarial equivalent cost sharing for all basic benefits and specific categories of basic benefits; and (2) clarify that the flexibility is based on whether the MA plan's cost sharing for specific service categories otherwise satisfies applicable cost sharing standards and is based on ''generally accepted actuarial principles and practices'' (consistent with paragraph (f)(7)).
- Removing references to post-stabilization services costs in § 422.113(b)(2)(v).
- Revising § 422.113(b)(2)(v)(B)*(1)* to adopt the following emergency services cost sharing limits for 2023: $95 for a mandatory MOOP limit, $110 for an intermediate MOOP limit, and $125 for a lower MOOP limit.
- Revising § 422.113(b)(2)(v)(B)*(2)* to adopt the following emergency services cost sharing limits for 2024: $100 for a mandatory MOOP limit, $120 for an intermediate MOOP limit, and $135 for a lower MOOP limit.
- Revising § 422.113(b)(2)(v)(B)*(3)* to adopt the following emergency services cost sharing limits for 2025: $110 for a mandatory MOOP limit, $125 for an intermediate MOOP limit, and $140 for a lower MOOP limit.
- Adding § 422.113(b)(2)(v)(B)*(4)* to adopt the following emergency services cost sharing limits for 2026 and subsequent years: $115 for a mandatory MOOP limit, $130 for an intermediate MOOP limit, and $150 for a lower MOOP limit.
- Adding various minor technical and grammatical changes from the proposed regulation text at §§ 422.100(f)(6) and 422.113(b)(2) to ensure clarity and avoid repetitive text in the regulations.

Finally, in addition to the authority outlined in the February 2020 proposed rule for these cost sharing limits, section 1854(a)(5) and (6) of the Act provides that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. Under section 1854(a)(5)(C)(ii) of the Act, CMS is authorized to deny a plan bid if the bid proposes too significant increases in enrollee costs or decrease in benefits from one plan year to the next. While the rules adopted here do not limit our negotiation authority (§ 422.256), they provide minimum standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids in addition to establishing important protections to ensure that enrollees with high health care costs are not discouraged from enrolling in MA plans.

III. Request for Comment Regarding the Methodology for CMS To Update and Change Service Category Cost Sharing Limits (§ 422.100(f)(6)(i), (iii), and 422.100(j)(1))

We are requesting comments and information on new or different ways to update and change cost sharing limits for all service categories subject to §§ 422.100(f)(6)(i), (iii), and 422.100(j)(1), including mental health services, to inform future rulemaking. In brief, we are soliciting comments on: (1) Modifying the cost sharing limits for specific service categories to better protect against potentially discriminatory cost sharing; and (2) the necessity, appropriateness and feasibility of adding parameters to update copayment limits after the cost sharing limit transitions are completed (based on § 422.100(f)(8)).

For the most part MA organizations typically offer benefits with lower cost sharing amounts than the cost sharing limits CMS has used in the past. However, we are concerned about benefit designs that have in-network cost sharing at the highest allowable level for a subset of benefits, including mental health services, even if the MA plans uses lower cost sharing for other benefits or categories of services. As a result, we are soliciting recommendations regarding the service categories for which CMS should consider modifying cost sharing limits (including specific cost sharing limits changes) to ensure beneficiaries are protected from potentially discriminatory cost sharing. For example, these recommendations could include adding new service categories, such as ''mental health services'' or categories that address substance use disorders, such as opioid treatment program services, to existing service categories at § 422.100(j)(1). The goal of these modifications would be to prohibit cost sharing amounts for those service categories that exceed cost sharing in original Medicare. By comparison, coinsurance limits for the ''mental health services'' service category in contract year 2022 were 50 percent regardless of the MOOP type established, and under this FC, by contract year 2026, the limit for the mental health services category will be, at the lowest, at the 30 percent coinsurance limit (or actuarially equivalent copayment limit) for MA plans that establish a mandatory MOOP amount.

As established in this FC, CMS will annually update cost sharing limits based on more recent data and will use a 4-year transition period to move from the cost sharing limits set for contract year 2022 to a new set of coinsurance limits and actuarially equivalent copayment limits. For 2026 and subsequent years, this FC does not contain specific restrictions on increases in copayment limits and requires them to increase as the dollar value of the coinsurance percentage increases. We are soliciting comments on the necessity, appropriateness, and feasibility of preventing copayment limits from changing dramatically or fluctuating from year to year.

Our goal is to allow MA organizations to design stable benefit structures from year to year and meet beneficiary needs while ensuring that cost sharing is not discriminatory or excessive. We expect that having cost sharing standards that are predictable and stable from year to year supports this goal. A process that allows standards to change dramatically or fluctuate by minimal amounts from year to year would not promote stable benefit packages over time. In addition, we believe copayment limits should closely reflect the coinsurance amounts that MA enrollees are expected to pay and that copayment limits should be calculated using the applicable coinsurance percentages and considering and applying sound actuarial methods to reach an approximate actuarially equivalent value. We are soliciting ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include recommendations of specific actuarial approaches or parameters to do the following:

- Establish rules for when CMS should maintain or moderate the change from the prior year's copayment limits when calculating copayment limits for the upcoming contract year, while keeping copayment limits approximately in line with the coinsurance limits established in § 422.100(f)(6) and (j).
- Apply specific minimum and maximum thresholds to the

methodology CMS uses to update copayment limits (with or without exceptions, such as for exceptional circumstances) in accordance with the regulations adopted in this FC.

• Ensure the methodology can be applied effectively to both service categories with higher and lower copayment limits.

CMS's overall goal in soliciting comments is to consider recommendations for how we can best mitigate disruption from changing copayment limits to ensure copayment limits do not become substantially different than the actuarially equivalent value to the coinsurance standard under this FC, while also striking a balance between protecting beneficiaries (especially vulnerable populations with higher-cost health care conditions) from excessive cost sharing and the costs experienced by MA organizations in providing the benefits. Commenters may also include recommendations regarding how CMS can simplify the rules and policies adopted here through future rulemaking to ensure beneficiaries have access to MA plans that meet the goals and objectives outlined in this FC as the basis for finalizing § 422.100(f)(6), (f)(7), (f)(8), and (j). Specific recommendations for how CMS can best evaluate MA compliance with the cost sharing standards adopted in this FC may also be provided in response to this solicitation. Comments regarding other cost sharing standards that CMS should consider for potential future rulemaking may also be submitted.

In responding to this comment solicitation, we request that all respondents provide complete, clear, and concise comments that include, where practicable, data and specific examples of how we may maintain or calculate updated copayment limits for these benefits in future years. If the proposals involve novel legal questions, analysis regarding our authority is welcome for our consideration. Language illustrating the suggested approach is also welcome so that CMS may understand more precisely the parameters of the suggestions. We are soliciting comment on all of the considerations discussed in this section.

This FC contains a request for comment. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We note that this request for comment is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. This request for comment does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this request for comment and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this request for comment; all costs associated with responding to this request for comment will be solely at the interested party's expense. We note that not responding to this request for comment does not preclude participation in any future procurement or rulemaking, if conducted. It is the responsibility of the potential respondents to monitor this request for comment announcement for additional information pertaining to this request. In addition, we note that we will not respond to questions about the policy issues raised in this request for comment.

We will actively consider all input as we develop future plans and policies. We may or may not choose to contact individual respondents. Such communications would be for the sole purpose of clarifying statements in the respondents' written responses. Contractor support personnel may be used to review responses to this request for comment. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this request for comment may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This request for comment should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

IV. Collection of Information Requirements

The February 2020 proposed rule solicited public comment on our proposed information collection requirements (ICRs), burden, and assumptions for 17 provisions. We also solicited public comment on the provisions without ICRs and stated that those provisions did not propose any new or revised collection of information requirements and/or burden and, therefore, are not subject to the requirements of the Paperwork Reduction Act (PRA). We received no disagreement from the public commenters on this approach for the two provisions being implemented in this FC: (1) Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101); and (2) Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113).

In this FC we make some modifications to the proposals, including the addition of a transition period to implement the range of cost sharing limits for professional service categories (as discussed in section II.B.5.b. of this FC) and adjusting the percentage of ESRD costs to incorporate into the MOOP and inpatient hospital cost sharing limits for 2023 (as discussed in sections II.A.4.c. and II.B.5.c. of this FC), however these changes do not impose new or revised information collection requirements for these two provisions.

Consequently, we are finalizing that the two provisions do not impose any new or revised collection of information requirements and/or burden. In making this assertion we note that the finalized provisions codify and update current guidance governing MA organization bid requirements,[63] which are currently approved by OMB under control number 0938–0763 (CMS–R–262). This FC codifies general subregulatory guidance that we issued in past years about how benefits must be provided by MA plans (including MOOP and cost sharing guidance); because CMS annually reviews all bids, we are certain that there has been plan compliance with our current practice.

This FC also updates certain longstanding requirements and modifies the way that MOOP limits and cost sharing limits have been set by adopting

[63] The CMS–R–262 PRA package may be accessed at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.*

specific methodologies but does not change how CMS evaluates compliance with MOOP and cost sharing limits as part of bid review. However, MA organizations are already submitting supporting documentation (for contract year 2022 and prior years) in order to demonstrate compliance. Similarly, CMS intends to continue providing annual instructions on bid documentation through subregulatory guidance.

Additionally, we received no PRA-related public comments for the provisions implemented in this FC.

Consequently, since there is no additional burden over and above the annual bid-review guidance and plan responses, we are finalizing our estimate of no impact without creating or modifying active ICR(s).

We note that the two MOOP and cost sharing provisions mentioned in this section are the only proposed provisions that are being finalized in this FC. The remaining proposed provisions from the February 2020 proposed rule were finalized in the June 2020 and January 2021 final rules.

V. Regulatory Impact Analysis

A. Statement of Need

The provisions in this FC codify and update current subregulatory guidance governing MA organization bid requirements. This includes changes to MOOP limits and inpatient hospital cost sharing limits consistent with section 17006 of the 21st Century Cures Act (Cures Act), which amended section 1851(a)(3) of the Act to allow Medicare eligible beneficiaries with diagnoses of ESRD to choose an MA plan for Medicare coverage starting January 1, 2021, without the limits on such enrollment that currently apply. Prior to contract year 2021, we excluded the projected out-of-pocket spending for beneficiaries with diagnoses of ESRD, which we are also referring to in this FC as ''ESRD costs,'' from the data used to set MOOP and cost sharing limits. After publication of the February 2020 proposed rule, we announced that we would incorporate a portion of ESRD costs into the data used to set and calculate MOOP and inpatient hospital cost sharing limits for contract year 2021.[64] In addition, we maintained these MOOP and cost sharing limits for contract year 2022.[65] [66] This FC sets a specific schedule to incorporate the remaining ESRD costs into the MOOP and cost sharing limits. MOOP and inpatient hospital cost sharing limits will be calculated using the most recent Medicare FFS data based on the population with access to the MA program in order to be consistent with CMS's historical approach of uniformly spreading the burden of medical costs across all potential MA enrollees. This spreading of costs across all enrollees serves to ensure access to affordable and sustainable benefit packages for all eligible beneficiaries and is also consistent with how benefits must be covered uniformly with uniform cost sharing and premiums by MA plans.

This FC introduces a third MOOP limit as well as changes to cost sharing requirements, including how cost sharing limits will be set for professional services and updating the limits for emergency services. As noted in the February 2020 proposed rule, the percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer group waiver plans that limit enrollment to employer group members and D–SNPs) offering a voluntary MOOP amount and the proportion of total enrollees in a voluntary MOOP plan have decreased considerably from contract year 2011 to contract year 2019. Based on plan data from March 2021, this trend has continued through contract year 2021 with approximately 18.5 percent of plans (21.5 percent of enrollees) having an in-network MOOP amount within the range of the prior voluntary MOOP limit (at or below $3,400), as shown in Table 1. This percentage access increases to 23.3 percent of plans (24.8 percent of enrollees) for contract year 2021 after taking into consideration the increase to the lower MOOP limit for that year (at or below $3,450). Consequently, we expect this trend to continue without intervention. A factor that may further spur this trend is that beneficiaries with diagnoses of ESRD are increasingly enrolling in the MA program because of their typical high health care costs, which the MA organization is financially responsible for after the ESRD enrollee reaches the MOOP amount. To abate this trend and incentivize MA organizations to offer lower MOOP amounts and/or lower or comparable cost sharing, this FC makes cost sharing limits for various service categories dependent on three distinct MOOP types. This FC reduces the cost sharing limits for professional services over a transition period from 50 percent to either 40 percent or 30 percent coinsurance (and actuarially equivalent copayments) for MA plans that use an intermediate or mandatory MOOP type and is a substantive change from longstanding practice. In proposing these changes, CMS also included a methodology to make updates to the cost sharing limits (for example, annually updating the copayment limits for professional services to actuarially equivalent values to align with the coinsurance standard based on the most recent Medicare FFS data projections) and a requirement for MA organizations to comply with cost sharing requirements in a particular manner (for example, using the MA plan total financial liability for a benefit to determine a copayment amount that reflects the coinsurance limit in cases where CMS has not calculated an actuarially equivalent copayment limit).

This rule also codifies the longstanding policy by CMS to calculate MOOP and cost sharing limits for specific service categories by calculating limits based on the most recent Medicare FFS data projections. More specifically, CMS is codifying: (1) That CMS will use Medicare FFS data projections that, with modifications from past practice, incorporate data on the out of pocket costs of beneficiaries with diagnoses of ESRD over a specific schedule; (2) the percentiles used to calculate MOOP limits; (3) the 50 percent cost sharing limit for basic benefits covered by MA plans (which are Part A and B benefits excluding hospice and the costs of kidney acquisition for transplants); (4) the methodology CMS uses to calculate inpatient hospital acute and psychiatric cost sharing limits; (5) applying the cost sharing under original Medicare as a cost sharing limit to several service categories in MA; and (6) codifying that an MA plan's cost sharing for categories of basic benefits in the aggregate must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. In codifying the general policies and approaches used in the past, CMS is also adopting some specific changes from its longstanding policy, including provisions regarding how updates to the MOOP and cost sharing limits are made each year and adopting the range of cost sharing flexibilities tied to using three MOOP

[64] See the HPMS memorandum titled ''Final Contract Year 2021 Part C Benefits Review and Evaluation,'' issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021.

[65] See the HPMS memorandum titled ''Final Contract Year 2022 Part C Benefits Review and Evaluation,'' issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

[66] These HPMS memoranda may be accessed through the HHS guidance repository at: HHS Guidance Submissions | Guidance Portal and individuals and organizations may request placement on the HPMS listserv at *https://hpms.cms.gov/app/ng/home/*.

limits. This FC, including the requirement to base MOOP and cost sharing limits on the most recent Medicare FFS data projections, is a significant improvement over the approach used in prior years, which did not have a specific methodology to recalibrate limits.

In response to comments on the February 2020 proposed rule, the timing of this FC, updated Medicare FFS data projections, and the potential impact of the COVID–19 pandemic since the February 2020 proposed rule, we are also finalizing several changes from the proposals, to smooth the transition to the new MOOP and cost sharing limit regulations. The major vehicle for smoothing this change is the use of multiyear transitions. With these multiyear transitions, we aim to avoid potentially disruptive cost sharing changes, such as sudden and substantive changes in cost sharing from the prior contract year and copayment limits that fluctuate up and down over short periods of time, for enrollees and plan designs.

These new multiyear transitions are used in the following provisions that are finalized in this rule: (1) The coinsurance and copayment limits for professional service categories; (2) the cost sharing limits for emergency services; and (3) and copayment limits for service categories for which cost sharing must not exceed cost sharing under original Medicare. This rule also finalizes (with modifications) the proposed multiyear transition for ESRD costs for MOOP limits and inpatient hospital cost sharing limits.

In the past, CMS set MOOP limits by striking a balance between limiting beneficiary out-of-pocket costs and potential impact to plan design and costs and set cost sharing limits for specific benefits at amounts that CMS believed exceeding would be discriminatory for beneficiaries with high health needs. MA plans were required to have MOOP amounts and cost sharing at or below these limits set by CMS. This FC finalizes regulations with more specific rules for how the limits will be set to achieve the same and other similar program goals. We expect the finalized methodology to update cost sharing limits will be an improvement from prior years. Some of the contract year 2022 copayment limit amounts for professional service categories and benefits for which cost sharing must not exceed cost sharing under original Medicare have been in place for a number of years. Our proposed methodology to calculate copayment limits at actuarially equivalent values to the coinsurance standards being adopted in this rule is, in effect, a recalibration of these copayment limits by using a methodology adjusted from longstanding policy and the most recent Medicare FFS data projections available. Similarly, our proposed methodology to update copayment limits for emergency services considered updated Medicare FFS cost projections that MA organizations are expected to incur in providing these benefits. We expect that updating these copayment limits over several years to reflect the updated Medicare FFS data projections will be a significant improvement in how professional cost sharing standards are applied to MA plans compared to prior years. For example, these updates will incorporate costs resulting from medical inflation and new treatments that became available after the current copayment limits were originally set. Without an actuarially acceptable and structured process to update copayment limits, the standards applied to MA plans could quickly become outdated and discourage MA organizations from establishing copayments over coinsurance structures in their plan designs. As noted in the February 2020 proposed rule, this would not be an ideal outcome as enrollees generally find copayment amounts more predictable and less confusing than coinsurance. CMS expects that this methodology will ultimately result in stable benefit packages by ensuring cost sharing limits are calculated following established actuarial methods, using the most recent Medicare FFS data projections available, and by keeping copayment limits aligned with coinsurance limits.

The regulatory impact statements for the provisions implemented in this FC are included in this section under the appropriate headings.

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 Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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: (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 must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). This rule is economically significant under Executive Order 12866. The Office of Information and Regulatory Affairs has designated this rule as a major rule pursuant to the Congressional Review Act, 5 U.S.C. 804(2).

Section 202 of UMRA 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 2022, that threshold is approximately $165 million. This FC is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of $158 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this FC does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this FC, then we should estimate the cost associated with regulatory review. As of

April 2021, there are 700 MA contracting organizations with CMS (which includes MA and MA–PD plans).[67] We also expect a variety of other organizations, such as advocacy groups, to review these regulations as well as MA organizations. We expect that each organization will designate two people to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this FC is $114.24 per hour, allowing 100 percent increase for fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for each person to review this entire FC. For each entity that reviews this FC, the estimated cost is therefore $900 (8 hours × $114.24). Therefore, we estimate that the maximum total cost of reviewing this entire FC is $1.8 million ($900 × 2,000 reviewers).

We note that this analysis assumed two readers per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we expect it is more reasonable to estimate review time based on the number of contracting MA organizations because a parent organization might have local reviewers assessing potential region-specific effects from this FC.

In accordance with the provisions of Executive Order 12866, this FC was reviewed by OMB.

C. Impact on Small Businesses—Regulatory Flexibility Analysis (RFA)

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA). If a rule may have a significant economic impact on a substantial number of small entities, then that rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a ''significant'' impact to be 3 to 5 percent or more of the affected entities' costs or revenues.

For purposes of the RFA, we estimate that many affected payers are small entities as that term is used in the RFA, either by being nonprofit organizations or by meeting the SBA definition of a small business. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The North American Industry Classification System (NAICS) is used to classify businesses by industry and is used by the United States, Canada, and Mexico. While there is no distinction between small and large businesses among the NAICS categories, the SBA develops size standards for each NAICS category. Note that the most recent update to the NAICS classifications went into effect for the 2017 reference year. The latest size standards are for 2019.The policies being implemented in this FC are: (1) Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101), and (2) Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113). These policies codify, modify, and update current guidance governing MA organization bid requirements.

This rule has several affected stakeholders. They include: (1) MA organizations offering MA plans such as HMOs, local and regional PPOs, MSAs, and PFFS plans; (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies; and (3) enrollees. Note that cost plans are specifically excluded from the provisions of this rule and that the rule only affects Part A and B benefits (not Part D benefits) covered by MA plans. Some descriptive data on these stakeholders are as follows:

- Pharmacies and Drug Stores, NAICS 446110, have a $30 million threshold for ''small size'' with 88 percent of pharmacies, those with under 20 employees, considered small.
- Direct Health and Medical Insurance Carriers, NAICS 524114, have a $41.5 million threshold for ''small size,'' with 75 percent of insurers having under 500 employees meeting the definition of small business. Several Medicare Advantage plans (about 30–40 percent) are not-for-profit resulting in a ''small entity'' status.
- Ambulatory Health Care Services, NAICS 621, including about 2 dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from $8 to $35 million (Dialysis Centers, NAICD 621492, have a $41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed $34 million.
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, Specialty Hospitals have a $41.5 million threshold for small size, with half of the hospitals (those with between 20–500 employees) considered small.
- Skilled Nursing Facilities (SNFs), NAICS 623110, have a $30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

The costs to MA organizations to cover Part A and B benefits for their enrollees are funded by the Federal government through the bidding process and the resulting capitated payments. Therefore, there is no significant burden on MA organizations to fund these benefits. We discuss the details of this immediately below in this section. This discussion will establish that there is no significant burden to a significant number of entities from this proposed rule for these provisions. Each year, MA plans submit a bid for furnishing Medicare Part A and B benefits (excluding hospice and the costs of acquisition of kidneys for transplant) as provided in section 1852 of the Act. The entire bid amount is paid by the government to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary enrolled in the plan pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark and the enrollees in those MA plans must also pay an MA basic premium to the MA plan in addition to their Medicare Part B premium; however, this percentage of plans is not ''significant'' as defined by the RFA and as justified below).

Under 42 CFR 422.100(c)(2) and 422.102, MA plans can also offer supplemental benefits that are not covered under Medicare Parts A, B and D. These supplemental benefits are paid for through enrollee premiums, extra government payments, or a combination

[67] This information is publicly available and updated at the following website: *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2021-04.*

of these. Under the statutory payment formula, if the bid submitted by a MA plan for furnishing covered Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a beneficiary rebate. The beneficiary rebate must be used by the MA plan to provide supplemental benefits and or/lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

To the extent that the government's total payments to plans, for the bid, risk adjustment, and the rebate, exceeds costs in Original Medicare, those additional payments put upward pressure on the Part B premium which is paid by all Medicare beneficiaries, including those in Original Medicare who do not have the enhanced coverage available in many MA plans.

Part D plans, including MA–PD plans, submit bids and those amounts are paid to plans through a combination Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries Part D plans receive special government payments to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by MA and Part D plans is funded by a variety of government funding and in some cases by enrollee premiums. As a result, MA and Part D plans are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA regulations, such as those in this FC, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either—(1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

Thus, there is a cost to plans bidding above the benchmark that is not funded by government payments. Additionally, if an MA plan bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees a premium for that amount. Table 29 reports the percent of the plans bidding above the benchmark along with the percent of affected enrollees in recent years. The table reports aggregates of proprietary bid data collected by the Office of the Actuary. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. As shown in Table 29, both the percentage of plans and the percentage of affected enrollees is decreasing and below this 3–5 percent threshold. Consequently, we may conclude that the number of plans bidding above the benchmark is not considered substantial for purposes of the RFA.

TABLE 29: PERCENTAGE OF PLANS BIDDING ABOVE BENCHMARK BY YEAR

Year	Number of Unique Bid IDs	Projected Enrollment (Member Months)	Number of Unique Bid IDs	Projected Enrollment (Member Months)	Bid ID Percentage	Enrollment Percentage
2020	100	2,108,026	4,270	231,754,722	2.3%	0.9%
2021	66	1,167,779	4,837	259,609,169	1.4%	0.4%
2022	30	328,621	5,298	288,151,395	0.6%	0.1%

The preceding analysis shows that meeting the direct cost of this FC does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

Additionally, this FC is not expected to have impacts because: (1) Several of its provisions are codifications of long-standing practices which CMS knows plans have complied with because of annual bid reviews; and (2) section 1852(a)(1)(B) of the Act requires MA plans to cover Part A and B benefits with cost sharing that is, in the aggregate, actuarially equivalent to cost sharing in the Original Medicare program.

There are certain indirect consequences of these provisions which also create impact. We have already explained that at least 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal government. However, the government additionally pays the plan a ''beneficiary rebate'' amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also partially be paid by enrollee premiums.) However, as previously noted, the number of plans bidding above the benchmark to whom this burden applies do not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this FC would otherwise cause bids to increase, plans will reduce their profit margins, rather than substantially change their benefit package. This may be in part due to market forces; a plan lowering supplemental benefits even for 1 year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it can be advantageous to the plan to temporarily reduce profit margins, rather than reduce supplemental benefits.

We next examine in detail each of the other stakeholders and explain how they can bear cost. Each of the following are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees for: (1) Pharmacies and Drug Stores, NAICS 446110; (2) Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) SNFs, NAICS 623110. Whether these providers are contracted or, in the case of PPOs and PFFS, not contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments. For non-contracted providers, § 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act require that a non-contracted provider accept payment that is at least what they would have been paid had the services been furnished in a fee-for-service setting. For contracted providers, § 422.520 requires that the payment is governed by a mutually agreed upon contract between the provider and the plan. CMS is prohibited from requiring MA plans to contract with a particular healthcare provider or to use a particular price structure for payment under the plan by section 1854(a)(6)(B)(iii) of the Act. Consequently, for these providers, there is no additional cost burden above the already existing burden in original Medicare.

Based on the above considerations, the Secretary has certified that this FC will not have a significant impact on a substantial number of small entities.

In addition, Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. With regard to the section 1102(b) requirements for hospitals, while this rule does have a provision relating to inpatient hospital cost sharing limits, this rule imposes a burden neither on rural or non-rural hospitals because this FC applies only to enrollee cost sharing and does not require any changes in the amounts paid to hospitals. For example, after the MOOP amount is reached, hospitals are paid in full (by the plan or secondary insurance) with the enrollee paying nothing out of pocket. Consequently, the Secretary has certified that this FC does not impost a burden on hospitals.

D. Executive Order 13132 (Federalism)

Executive Order 13132, ''Federalism,'' establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts state law, or otherwise has Federalism implications. The Department has determined that this FC will not impose such costs or have any Federalism implications.

E. Consultation and Coordination With Indian Tribal Governments

We have analyzed this FC in accordance with the principles set forth in Executive Order 13175. We have determined that this FC does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

F. National Environmental Policy Act (NEPA)

We have determined that this FC will not have a significant impact on the environment.

G. Anticipated Effects of Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101) and Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

This FC is identified as economically significant which corresponds to the observation that certain groups of beneficiaries may have significant savings or losses. Nevertheless, for three reasons, we expect no aggregate impact to enrollees from the MOOP limit and Cost Sharing provisions adopted in this FC. First, there is a statutory requirement for submitted bids to be actuarially equivalent to coverage in original Medicare, implying that plans can shift costs, but not create additional out of pocket costs for enrollees compared to the original Medicare program. Even if there are shifts in enrollee out of pocket costs, in aggregate there will be no dollar impact. This is operationalized through an actuarial equivalence test that is a projection that MA cost sharing under each MA plan equals Medicare FFS cost sharing. At the time that the actuarially equivalent cost sharing amounts are calculated, the expectation is that there will be no costs or savings for the policy year in question.

Second, many provisions in this FC are codifications of long-standing policies. CMS is confident that this codification will not result in dollar impact, because CMS annually reviews bids, and has observed compliance with the bid requirements.

Third, an analysis of plan bid changes from contract year 2020 to 2021 provides supportive quantitative evidence that plans, for marketing reasons and because of the principles and incentives inherent in managed care, are not (in most cases) establishing the highest allowable MOOP amount. We note the $6,700 in-network mandatory MOOP limit calculated for contract year 2020 has been longstanding and we used this as a baseline to determine if MOOP amounts were being substantially increased under the new, higher MOOP limits. For example, based on March 2021 MA and MA–PD plan data, after CMS increased MOOP limits for contract year 2021 (using Medicare FFS data with 40 percent of ESRD costs), approximately 63 percent of plans established a MOOP amount below $6,700 (compared to approximately 65 percent with a MOOP amount below $6,700 for contract year 2020). This example highlights how MA organizations typically offer benefits with lower enrollee cost sharing responsibility than the annual limits published by CMS.

MOOP and cost sharing limits are important beneficiary protections and integral to ensuring that MA enrollees who need extensive or expensive health care services because of their health status do not face discrimination. While the overall statutory requirement that cost sharing in an MA plan must be at least actuarially equivalent to cost sharing in original Medicare limits the overall costs that MA plans must cover in their bids and overall out-of-pocket costs for enrollees, the ability to change or set cost sharing for different benefits at different levels could potentially be used by MA plans to discourage enrollment by beneficiaries with high health needs or specific types of health needs (for example, specific specialist services). Requiring MOOP and cost sharing limits in MA plan design in addition to the statutorily required MOOP limits for regional MA plans is necessary in order not to discourage enrollment by individuals who utilize

higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act). Such considerations have been the basis for CMS to set specific MOOP limits and cost sharing limits under existing regulations over the past several years. We proposed adopting transparent rules to govern how those MOOP and cost sharing limits for local and regional plans are set each year, including rules for incorporating out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD (''ESRD costs'' in this discussion) into the methodology for calculating MOOP limits and cost sharing standards, to provide stability for MA organizations and plan enrollees. Prior to this FC, we calculate MOOP and cost sharing limits annually and this process will continue as codified.

In preparing plan bids for contract year 2023 and future years to which this FC is applicable, we expect MA organizations may, as a result of the provisions of this FC, make adjustments to their benefit design, for example, increasing the MOOP amount and/or specific service category cost sharing. However, as indicated at the beginning of this section, which presents three arguments, we do not expect these changes will have a significant aggregate impact.

A substantive change of this FC from the February 2020 proposed rule is inclusion of multiyear transitions to adjust cost sharing limits for: (1) Professional service categories; (2) emergency services; and (3) benefits for which cost sharing must not exceed cost sharing under original Medicare. For example, we finalized a multiyear transition from the 50 percent professional cost sharing limit to a range of cost sharing limits (30, 40, and 50 percent) based on the MOOP type. We expect that a multiyear implementation schedule will be helpful to: (1) Mitigate potentially disruptive changes based on the projected increases to certain service category copayment limits resulting from using the Medicare FFS data projections; and (2) be responsive to commenter requests to provide time for MA organizations and enrollees to adjust to updated cost sharing limits.

We also proposed a multiyear transition schedule of incorporating costs related to Medicare-eligible enrollees with diagnoses of ESRD into the methodology we use to calculate MOOP and inpatient hospital acute and psychiatric cost sharing limits. We proposed to complete this transition by factoring in the ESRD costs into the methodology through an ESRD cost differential (which was generally finalized as proposed as a specific way to measure ESRD costs and factor them into the data used for calculating the MOOP and cost sharing limits). We proposed to transition the ESRD cost differential for both MOOP and inpatient hospital acute and psychiatric cost sharing limits as follows: 60 percent in 2022; 80 percent in 2023; and 100 percent in 2024. As discussed in sections II.A. and B. of this FC, we are finalizing the multiyear transition of ESRD costs into MOOP and cost sharing limits to complete in contract year 2024 as proposed, but given the delay in releasing a final rule for these provisions we are adjusting the ESRD cost differential percentage for contract year 2023 from 80 to 70 percent. The MOOP and cost sharing limits were maintained for contract year 2022 in the absence of a final rule for these provisions; we did not incorporate 60 percent of the ESRD cost differential in contract year 2022 as proposed. We expect judiciously adjusting the percent of ESRD cost differential in contract year 2023, while maintaining the final date by which the multiyear transition is completed (2024), will mitigate the risk of potential increased premiums or decreased benefits that may be associated with the migration of ESRD beneficiaries from Medicare FFS to the MA program and minimize disruption to beneficiaries. Under the finalized methodology, the ESRD cost differential is incorporated as follows: For 2023, 70 percent and for 2024, 100 percent. As discussed in the February 2020 proposed rule, we recognize incorporating ESRD costs would increase all in-network and combined MOOP limits for local and regional MA plan types, but including ESRD costs is an important and necessary step to ensure that plan designs are not discriminatory and protect beneficiaries from high and unreasonable financial costs regardless of the MA plan. We coordinated the MOOP and cost sharing proposals in sections VI.A. and B. of the February 2020 proposed rule in an effort to prevent substantial increases in MOOP limits, cost sharing limits, and premiums to protect beneficiaries, and proposed reasonable updates and flexibilities for MA organizations to offer sustainable MA plans with stable benefit designs.

As discussed in the February 2020 proposed rule, CMS expects transitioning ESRD costs into the data used to calculate MOOP and cost sharing limits may result in a combination of savings and costs for MA organizations. Depending upon an individual's health status and health care coverage selections, some enrollees may experience increased costs while others may experience decreased costs. CMS is not able to quantify these potential impacts precisely.

Accordingly, we provide background and a qualitative discussion to share our rationale. The cost to the MA organization of having a MOOP amount and reduced cost sharing is captured as a supplemental benefit in the bid pricing tool if the MA organization's decision about how to establish MOOP and cost sharing amounts for its plan design results in overall aggregate cost sharing for Medicare-covered benefits for that MA plan to be less than actuarially equivalent to cost sharing in original Medicare. With a higher MOOP limit or cost sharing (as a result of incorporating ESRD costs and/or using the most recent Medicare FFS data to calculate copayment limits), the cost of the MOOP limit and benefits are lower to the MA organization which allows additional rebate dollars to be spent elsewhere (for example, for cost sharing reductions or additional benefits). From an actuarial perspective, on average, the MA enrollee is receiving the same level of benefits in total (of course, individual impacts will vary). MA organizations can continue to structure their PBP to be actuarially equivalent to FFS (without supplemental benefits) through the cost sharing flexibilities that this FC includes. As a result, we expect the MOOP and Cost Sharing provisions will have no material aggregate impact.

Enrollment impacts from section 17006 of the 21st Century Cures Act are addressed in sections III.A., VII.B.3., and VIII.D.1. of the June 2020 final rule (85 FR 33796). Before the amendments made by the 21st Century Cures Act were effective for contract year 2021, individuals diagnosed with ESRD could not enroll in an MA plan, subject to limited exceptions. Generally, those exceptions included the following circumstances: An individual that developed ESRD while enrolled in an MA plan could remain in that plan; an ESRD individual enrolled in a plan which terminated or discontinued had a one-time opportunity to join another plan; or, an individual could enroll in a special needs plan that had obtained a waiver to be open for enrollment to individuals with ESRD. CMS calculated separate payment rates to address the higher costs MA plans may experience when managing care for enrollees with ESRD, and has been continuing to do so after Medicare beneficiaries with diagnoses of ESRD were allowed to enroll in MA plans in greater numbers.

MA organizations have been aware of the program change to allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA since section 17006 of the Cures Act was enacted in December 2016. Accordingly, CMS expects MA organizations have planned and prepared for this program change by conducting business activities, such as evaluating plan benefits, provider contracting with network providers, developing case management programs, and addressing reinsurance arrangements as applicable. Following the 21st Century Cures Act, the OACT projected the number of individuals with diagnoses of ESRD that may enroll in MA.[68] In the February 2020 proposed rule we referenced this projection; OACT expected ESRD enrollment in MA plans to increase by 83,000 as a result of the Cures Act provision.[69] The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021. Based on actual 2021 enrollment data, the OACT continues to project that 83,000 beneficiaries with diagnoses of ESRD will enroll in the MA program over 6 years.

CMS notes that MA organizations are in a competitive market and design their plan bids to manage risk, encourage enrollment, and satisfy Medicare coverage requirements. CMS does not require MA organizations to disclose these strategies, and as such, cannot quantitatively project what savings or costs MA organizations may incur from the changes in MOOP and cost sharing limits. CMS's goal is to provide predictable and transparent MOOP limits and cost sharing standards and to calculate limits at a level that should not result in significant new costs for MA organizations or enrollees. By taking the program changes from section 17006 of the 21st Century Cures Act into account within our existing process to calculate and update MOOP limits and cost sharing standards, we are protecting MA enrollees against high out-of-pocket costs and sudden changes in those costs.

As discussed in the February 2020 proposed rule, CMS believes the MOOP limit in the MA program provides a protection to MA enrollees from high out-of-pocket costs. CMS notes beneficiaries with diagnoses of ESRD previously enrolled in Medicare FFS with or without Medigap coverage may experience different cost sharing and out-of-pocket costs if they switch to an MA plan. For example, a Medicare beneficiary with a diagnosis of ESRD enrolled in Medicare FFS (without Medigap or employer coverage) may experience higher out-of-pocket costs annually if their annual health care treatment out-of-pocket costs go above the MOOP limit required for MA plans.

CMS cannot precisely project the individual cost impacts for enrollees and MA organizations in its proposed MOOP and cost sharing limit changes because potential savings and costs are largely influenced by—

- The rate of transition for Medicare beneficiaries with diagnoses of ESRD into the MA program;
- Enrollee cost sharing information including how many individuals (with and without ESRD) reach the MOOP, variability in reaching the MOOP by year, and frequency of utilization of services both below the MOOP and above the MOOP; and
- The mechanisms MA organizations choose to address this programmatic change, such as provider contracting, case management, plan benefit designs, and benefit flexibilities including Special Supplemental Benefits for the Chronically Ill, MA uniformity flexibility, and the proposed MOOP limits and cost sharing flexibilities, while additionally making sure the plan bid remains actuarially equivalent to original Medicare.

By implementing more than two levels of MOOP limits and providing increased flexibility in calculating cost sharing amounts for MA organizations with lower MOOP limits, we expect to encourage plan offerings with favorable benefit designs for Medicare beneficiaries to choose from. We note that beneficiaries consider the MOOP limit and cost sharing structure when choosing an MA plan, however we do not expect them to face more complex plan options due to our regulatory changes. From a beneficiary's perspective, the individual will have the ability to review the same volume of information about MOOP limits and cost sharing structures as currently available. We also do not expect MA organizations to necessarily offer more plan options than they currently do as a result of this change. MA organizations can already create different MOOP amount and cost sharing structures based on a number of market factors that may, or may not, be related to beneficiaries with ESRD diagnoses being able to enroll in MA plans. Additionally, CMS will continue evaluations and enforcement of its current authority prohibiting plans from misleading beneficiaries in their marketing and communication materials and continue efforts to improve plan offerings and plan comparison tools and resources (for example, Medicare & You and 1–800–MEDICARE). Consistent with statutory requirements, CMS will not approve a plan bid if its proposed benefit design substantially discourages enrollment in that plan for certain Medicare-eligible individuals.

We did not receive any comments that specifically referenced the cost impact of the MOOP and cost sharing proposals.

H. Alternatives Considered

In this section, CMS includes discussions of Alternatives Considered to implement the provisions to which they are applicable. We note a more detailed discussion of the finalized implementation approach and the mechanics of operationalizing it for the policies discussed in this section is available in sections II.A. and B. of this FC. When considering the alternative transition scenarios presented in this section, the actuarial equivalence tests are still upheld, implying that in aggregate the expected enrollee cost sharing expenses will remain the same for those enrollees in MA and for those enrollees in FFS. Consequently, there are no expected changes to the Medicare Trust Fund expenditures since aggregate enrollee cost sharing remains unchanged under the alternative scenario(s). Additionally, several provisions of this FC codify long-standing existing polices used by CMS in annual bid reviews, implying that no additional dollar impact across the program as a whole will occur.

Throughout section V.H.1. and 2. of this FC we list alternatives, including multiyear transitions, for each or for combinations of the provisions. The multiyear transitions considered are generally consistent with the transition methodology proposed to incorporate ESRD costs into MOOP and inpatient hospital cost sharing limits. At a high level, all alternatives considered sought to strike a balance between: (1) Finalizing policies that would incentivize MA organizations to establish lower MOOP amounts; and (2) protecting enrollees from potential disruption that may result from

[68] The Fiscal Year President's Budgets may be accessed at *https://www.govinfo.gov/app/collection/BUDGET/* and the annual Advance Notice and Rate Announcements may be accessed at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[69] The estimated cost per year to the Medicare Trust Fund based on this enrollment projection of beneficiaries with diagnoses of ESRD is available in Table 7 on page 33887 in section VIII.D.1. of the June 2020 final rule (85 FR 33796) *https://www.federalregister.gov/documents/2020/06/02/2020-11342/medicare-program-contract-year-2021-policy-and-technical-changes-to-the-medicare-advantage-program.*

substantially shifting MOOP and copayment limits within 1 year.

Throughout this section, each alternative would result in a terminal year in which MOOP limits and cost sharing standards are at 100 percent of what we proposed, with one exception for the ''Part B drugs—other'' service category (as explained in detail in sections II.B.5.e. and V.H.2. of this FC). The main difference between the alternatives is the length of time in which the finalized provisions are not fully in effect. In the February 2020 proposed rule, CMS developed the proposals to apply to contract year 2022 and future years. However, we did not finalize these provisions in advance of the contract year 2022 bid deadline. Consequently, we needed to delay implementation of the provisions in this FC to contract year 2023 and future years. This led us to use the MOOP limits and cost sharing standards that were set for contract year 2022 as the baseline (as shown in Tables 30, 31, and 33 through 37) for comparing the proposed and finalized policies. The level to which the provisions are in effect during the transitional period described in each alternative is described as a percentage in most cases. For example, 100 percent signifies that the transitional period has concluded and the provisions are fully implemented as finalized in this FC.

These transitions are examined through tables and narratives indicating consequences. While we project that there is no dollar impact to the Medicare Trust Fund from any of these alternatives, certain transitions may have unintended adverse beneficiary and marketing impacts. More specifically, a transition that is implemented too quickly may have an unintended effect of increasing cost sharing for certain services too quickly (based on the most recent Medicare FFS data projections available at the time of this FC). Such sudden increases would be expected to—

- Result in beneficiary concern;
- Potentially affect the ''total beneficiary cost''; and
- Potentially steer certain sets of beneficiaries away from enrolling in the MA program or to different plans (this might have quantitative adverse impact, but we have no way of knowing how each group of beneficiaries would react nor how many are involved).

Similarly, a transition that is too slow is not useful or protective to enrollees. This delay would contradict the very purpose of using updated Medicare FFS data projections to calculate MOOP limits and cost sharing limits for inpatient services; this might result in MA organizations making other changes to their bid design, such as increasing premiums or reducing benefits. However, we have no way to quantify the potential adverse effects this may cause.

To avoid repetitive text, throughout this section we reference potential disruption generally instead of repeating the preceding paragraphs. Specifically, references to potential disruption include one or more of the adverse consequences listed previously in this section. Our goal in considering these alternatives in implementation is to achieve a balance in the transition, not too fast and not too slow for the stakeholders involved (namely, enrollees and MA organizations). Details of the projected MOOP and cost sharing limits that would result from the various alternatives (which motivated CMS in choosing a final implementation approach) are available in the tables and discussions in sections V.H.1. and 2. of this FC.

1. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

CMS considered two alternatives to finalize the ESRD cost transition into the methodology CMS uses to calculate MOOP limits at specific percentiles of beneficiary out of pocket costs in the Medicare FFS program. We note this part of the MOOP provision makes substantive changes to existing policy. Specifically, we considered alternatives in the rate and length of the ESRD cost transition due to all the following:

- Timing of this FC.
- Potential for enrollee disruption and impacts of further delays in integrating ESRD costs.
- Public comments on the MOOP limit proposals (as summarized in section II.A.4. of this FC).

The transition schedule we proposed incorporated the ESRD cost differential as follows: 60 percent in 2022; 80 percent in 2023 or the next year; and 100 percent in 2024 or the final year of transition. In addition, our proposal included guardrails to pause the incorporation of the ESRD cost differential if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs increased or decreased too much (as defined in the February 2020 proposed rule as a difference of more than 2 percentiles above or below the 85th and 95th percentile) from the prior year. We note other schedules to phase in ESRD costs are possible and we expect each unique transition would have different beneficiary and marketing impacts through its completion. Our goal, as indicated in the introduction of this section, is to minimize disruption.

The projections from the OACT in the February 2020 proposed rule on expected enrollment of 83,000 Medicare beneficiaries with diagnoses of ESRD into the MA program appear to align with actual enrollment based on 2021 enrollment data. As such, the delay of this FC resulted in the proposed 60 percent of the ESRD cost differential not being incorporated into contract year 2022 MOOP limits while enrollment of beneficiaries with diagnoses of ESRD in MA is projected to increase. Finally, as summarized in section II.A. of this FC, we received some public comments requesting changes to the proposed transition, including an accelerated transition of ESRD costs into the methodology CMS uses to calculate MOOP limits. As a result, CMS considered the following alternatives:

Alternative 1: We considered finalizing the ESRD transition as proposed for contract years 2023 and 2024 (that is, incorporating 80 percent of the ESRD cost differential for contract year 2023 and 100 percent for contract year 2024 if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs did not increase or decrease more than 2 percentiles above or below the 85th and 95th percentile from the prior year) to minimize the changes from the proposal to only address the delay of the final rule release. Table 30 illustrates the impact of this alternative on contract year 2023 in-network MOOP limits in comparison to the other alternatives and baseline limits described in this section. Table 31 demonstrates the same comparison for contract year 2023 total catastrophic (combined) MOOP limits.

As shown in Tables 30 and 31, finalizing 80 percent of the ESRD cost differential for contract year 2023 would increase the MOOP limits at a greater rate than illustrated in the February 2020 proposed rule (using updated projections based on Medicare FFS data from 2017–2021). For example, in the February 2020 proposed rule the highest allowable in-network mandatory MOOP limit for contract year 2023 was projected to be $7,950 and this alternative implemented with updated projections based on 2017–2021 Medicare FFS data increased this amount to $8,700 (a $750 increase) as shown in Table 30. We also note this would reflect a $1,150 increase from the highest allowable in-network mandatory MOOP limit of $7,550 in contract year 2022. The increases to the MOOP limits resulting from this alternative shown in Table 30 (and by extension based on how the total catastrophic MOOP limits

are calculated, Table 31) also reflect implementing the proposed guardrails to pause the incorporation of the ESRD cost differential if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs increased or decreased too much (as defined in the February 2020 proposed rule). For example, the projected 95th percentile of projected Medicare FFS costs increased from $8,468 to $9,111 between contract year 2022 and 2023, in comparison the 97th percentile of projected Medicare FFS costs (for contract year 2022) was $11,837. As the projected contract year 2023 95th and 85th percentiles did not increase or decrease more than 2 percentiles above or below the contract year 2022 95th and 85th percentiles, the cap of a 10 percent change from the prior year's MOOP limit was not applied (as proposed) in Tables 30 and 31.

We considered these higher projected increases in relation to actual contract year 2021 plan MOOP changes, potential impacts of further delays in integrating ESRD costs, and feedback from public commenters in determining the final ESRD cost transition as further described in this section. Ultimately, we expect that transitioning from 40 percent of the ESRD cost differential (initially incorporated for contract year 2021 and maintained for 2022) to 80 percent for contract year 2023 would have a greater potential to produce disruptive consequences (such as, greater disenrollment from the MA program as a result of potential plan benefit design changes) than reducing the percentage of ESRD costs that are incorporated for contract year 2023. As a result, we declined to adopt the ESRD cost transition exactly as proposed for contract year 2023 as we believe that another approach would better protect against potential enrollee disruption and be responsive to public commenters.

Alternative 2: Second, we considered extending the proposed ESRD cost transition schedule by 1 year (that is, incorporating 60 percent of the ESRD cost differential for contract year 2023, 80 percent for contract year 2024, and 100 percent for contract year 2025) and implementing the guardrails to pause the incorporation of the ESRD cost differential if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs increased or decreased too much (as defined in the February 2020 proposed rule) as generally proposed (applied to each year of the transition). We believe this is another approach to minimize the changes from the February 2020 proposed rule, provide MA organizations with adequate time to prepare for these changes, and to avoid potentially disruptive changes for enrollees. Table 30 provides the projected impact of finalizing this alternative on contract year 2023 in-network MOOP limits in comparison to the other alternatives and baseline limits described in this section. Table 31 demonstrates the same comparison for the total catastrophic MOOP limits.

As shown in Table 30, finalizing 60 percent of the ESRD cost differential for contract year 2023 would increase the highest allowable in-network mandatory MOOP limit to $8,350, an increase of $400 from the illustrative $7,950 amount in the February 2020 proposed rule using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). This $8,350 amount also reflects a $800 increase from the highest allowable in-network mandatory MOOP limit of $7,550 in contract year 2022. In comparison, the highest allowable in-network mandatory MOOP limit increased from $6,700 to $7,550 ($850) from contract year 2020 to 2021 as a result of the Medicare FFS data percentile projections (based on 2015–2019 Medicare FFS data) and 40 percent of the ESRD cost differential being incorporated.

For the same reasons as discussed in the first alternative of this section, the increases to the MOOP limits resulting from this alternative do not reflect the application of a 10 percent change cap from the prior year's MOOP limit because the updated 95th and 85th percentiles did not increase or decrease more than 2 percentiles above or below the 95th and 85th percentiles from the prior year. Given this potential increase, we reviewed the changes MA plans made in establishing their contract year 2021 MOOP amounts and determined that most MA organizations were not utilizing the full flexibility from the increased MOOP limits. Comparing contract year 2020 and 2021, we found that approximately 35 percent of all MA and MA–PD plans established the highest allowable MOOP amount ($6,700) for contract year 2020 and approximately 37 percent of all MA and MA–PD plans chose to establish a MOOP amount at or above $6,700 for contract year 2021. This indicates a modest increase in the percent of plans with the highest allowable MOOP amount from the prior contract year on an aggregate basis. This data does not suggest that incorporating a greater percentage of the ESRD cost differential is likely to result in most MA organizations substantially increasing their MOOP amounts for contract year 2023 (as they already could increase their MOOP amounts further and chose not to for contract year 2021). However, we acknowledge that our data are limited to comparing the change between contract year 2020 and 2021. As a result, we cannot make a definitive prediction on how MA organizations may utilize the available flexibility in establishing their plan MOOP amounts for future years.

Feedback from public commenters (as summarized and responded to in section II.A. of this FC) included requests for an accelerated transition of ESRD costs into the methodology CMS uses to calculate MOOP limits given the potential for faster growth of ESRD enrollment in the MA program and geographic variations. In addition, the delay of this FC resulted in no increased ESRD cost adjustments in calculating contract year 2022 MOOP limits while enrollment of beneficiaries with diagnoses of ESRD in MA is projected to increase. Extending the ESRD cost transition would effectively produce changes that are contrary to commenter feedback, are not consistent with the increased costs MA organizations may experience based on enrollment projections, and are not sufficiently supported by the number of plans using the existing level of flexibility in MOOP limits. As a result, we rejected this alternative ESRD cost transition schedule because the data and public commenter feedback summarized previously did not suggest that an extended transition of ESRD costs in the methodology to calculate MOOP limits was justified or necessary to protect against potential enrollee disruption.

Alternative 3 (Finalized): We are finalizing most of our proposals to codify and update the methodology CMS uses to calculate MOOP limits, except we are modifying the multiyear transition of ESRD costs and not finalizing the provision that would delay (or toll) the incorporation of ESRD costs into the data used to calculate the MOOP limits. The finalized schedule judiciously modifies the transition of ESRD costs into the methodology to calculate MOOP limits by incorporating 70 percent of the ESRD cost differential for contract year 2023 (instead of the proposed 80 percent). In addition, we are finalizing the timing of the conclusion of the ESRD cost transition as proposed with 100 percent of the ESRD cost differential incorporated for contract year 2024. In addition, beginning for contract year 2023 we are finalizing a modified version of the proposed 10 percent change cap from the prior year's MOOP limit to prevent increases greater than 10 percent, without the additional requirements of

meeting the two percentiles change threshold. In finalizing this ESRD cost transition schedule we are especially considerate of the potential impact of further delays in integrating ESRD costs, comments on the proposed transition schedule, and the possibility of enrollee disruption. Table 5 contains the final contract year 2023 MOOP limits and Table 9 contains illustrative contract year 2024 MOOP limits, which were developed using the methodology finalized in this FC. The calculations of the MOOP limits in Tables 5 and 9 using the methodology finalized in this FC and projections of 2017–2021 Medicare FFS data are in Tables 2–4 and 6–8.

The proportion of ESRD cost differential incorporated into the MOOP limits for contract year 2023 was finalized at 70 percent instead of 80 percent as proposed. The impact of incorporating 80 percent (with the requirement that to apply the 10 percent cap on changes to the MOOP limit the respective percentiles of Medicare FFS costs would need to exceed two percentiles from the prior contract year) using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data) is addressed in our discussion of the first alternative in this section and illustrated in Tables 29 and 30. In comparison, as shown in Table 30, this finalized approach increased the highest allowable in-network mandatory MOOP limit for contract year 2023 from the $7,950 illustrative amount in the February 2020 proposed rule to $8,300 (a $350 increase) using projections of Medicare FFS costs based on 2017–2021 Medicare FFS data. The $8,300 amount also reflects a $750 increase from the highest allowable in-network mandatory MOOP limit of $7,550 in contract year 2022. This increase to the mandatory MOOP limit was calculated using the contract year 2022 mandatory MOOP limit plus 10 percent of that amount and applying the rounding rules at § 422.100(f)(4)(iii) as the 10 percent cap on increases was met (without the requirement to exceed two percentiles from the prior contract year as described in section II.A.4. of this FC). The delay of this FC resulted in no increased ESRD cost adjustments in calculating contract year 2022 MOOP limits (versus the 20 percent increase proposed) while ESRD enrollment in MA is projected to increase in 2022. As a result, we considered changes to the ESRD cost transition to reduce the potential disruption from transitioning to 80 percent of the ESRD cost differential in 1 year (from 40 percent that was incorporated in contract year 2021 and maintained for contract year 2022). While the proportion of MA plans with mandatory MOOP amounts did not significantly change between contract year 2020 and 2021 (approximately 2 percent as discussed previously in this section) this trend may not continue if MOOP limits do not fully reflect ESRD costs as ESRD enrollment in the MA program continues to increase. For example, as indicated in our discussion of disruption in section V.H. of this FC, delaying the ESRD cost transition may result in MA organizations choosing to use the maximum level of flexibility that is available (increasing the MOOP amount to the maximum MOOP limit to a greater extent than prior years) or making other changes to their plan benefit designs (increasing premiums or cost sharing amounts) in order to compensate for the additional costs they would be covering.

In addition, feedback from public commenters (as summarized and responded to in section II.A. of this FC) included requests for an accelerated transition of ESRD costs into the methodology CMS uses to calculate MOOP limits given the potential for faster growth of ESRD enrollment in the MA program and geographic variations. While the finalized approach does not accelerate the timeframe to fully integrate ESRD costs into MOOP limits, as some commenters requested, the transition schedule as finalized strikes a balance between curbing more significant increases to MOOP limits from contract year 2022 and helping ensure that MA organizations are able to continue offering all plan enrollees, regardless of their ESRD status, high-quality care and service while keeping premiums and out-of-pocket costs at non-discriminatory levels. By striking this balance and continuing our longstanding practice of calculating MOOP limits based on Medicare FFS data projections, CMS expects the finalized transition schedule will also mitigate the risk of increased premiums or decreased benefits that may be associated with the migration of beneficiaries with diagnoses of ESRD from Medicare FFS to the MA program.

As noted in section V.G. of this FC, because of multiple factors affecting bids and our longstanding actuarially equivalent plan bid requirements, we have not estimated a cost to this provision and acknowledged a possible combination of savings and costs for individual MA organizations and enrollees. Similarly, we would not be able to quantify potential impacts from these alternatives. However, potential impacts from the alternatives are noted previously in this section.

TABLE 30: ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED MOOP LIMIT METHODOLOGY ON HIGHEST ALLOWABLE CONTRACT YEAR 2023 IN-NETWORK MOOP LIMITS BASED ON PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

ESRD Cost Transition Methodology	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	$3,450	N/A	$7,550
Alternative 1: Incorporate 80% of the ESRD Cost Differential	$3,700	$6,200	$8,700
Alternative 2: Incorporate 60% of the ESRD Cost Differential	$3,600	$5,950	$8,350
Alternative 3 (Finalized): Incorporate 70% of the ESRD Cost Differential	$3,650	$6,000	$8,300

TABLE 31: ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED MOOP LIMIT METHODOLOGY ON HIGHEST ALLOWABLE CONTRACT YEAR 2023 (COMBINED) TOTAL CATASTROPHIC MOOP LIMITS BASED ON PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

ESRD Cost Transition Methodology	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	$5,150	N/A	$11,300
Alternative 1: Incorporate 80% of the ESRD Cost Differential	$5,550	$9,300	$13,100
Alternative 2: Incorporate 60% of the ESRD Cost Differential	$5,400	$8,950	$12,500
Alternative 3 (Finalized): Incorporate 70% of the ESRD Cost Differential	$5,450	$8,950	$12,450

2. Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

Similar to our approach for the MOOP limit provision, CMS developed several alternatives to finalizing the specific proposals on Cost Sharing that make substantive updates to existing policy. These proposals include the following:

- Range of Cost Sharing Limits for Certain Outpatient and Professional Services (§ 422.100(f)(6)(iii)).
- Emergency/Post-Stabilization Services and Urgently Needed Services (§ 422.113(b)(2)(v) and (vi)).
- Services No Greater Than Original Medicare (§ 422.100(j)(1))

We considered alternatives due to all of the following:

- Timing of this FC.
- Potential for enrollee disruption.
- Public comments on the Cost Sharing proposals (as summarized in section II.B.5. of this FC).

After the February 2020 proposed rule was released, we received updated Medicare FFS projections for service category cost sharing amounts from the OACT that were not available at the time of drafting the February 2020 proposed rule (for example, updated average and median allowed amount Medicare FFS data projections based on 2017 through 2021 Medicare FFS data). We evaluated the potential enrollee disruption resulting from the use of these updated amounts to calculate actuarially equivalent copayment limits. Finally, as summarized in section II.B. of this FC, we received public comments requesting changes to our proposals, including applying a transition to the range of cost sharing limits for professional services and delays to increases to cost sharing for emergency services.

In this section we address the consequences of alternatives that were considered in response to the factors and feedback discussed previously. While each cost sharing proposal, such as the ones for emergency services or the ones for the copayment limits for professional services, had unique aspects, we present the narrative discussing the alternatives for all of these proposals in one section (as the approach is generally the same for each provision). However, the tables in this section show how each alternative would uniquely impact the copayment limits that are subject to a particular policy (either §§ 422.100(f)(6)(iii), (j)(1), or 422.113(b)(2)(v)).

The following tables contain the projected impact of finalizing each of the alternatives discussed in this section on contract year 2023 cost sharing limits for particular service categories:

- Table 33: Physical therapy and speech-language pathology.
- Table 34: Partial hospitalization.
- Table 35: Emergency services.
- Table 36: Part B drugs—chemotherapy/radiation drugs.
- Table 37: Part B drugs—other.

A more complete discussion of the data analyses completed to reach the actuarially equivalent values of the copayment limits in Tables 33 through 37 is available in the February 2020 proposed rule and section II.B.5 of this FC. In addition, the cost sharing limits in Tables 33 through 37 for Alternative 3 are final amounts resulting from CMS applying the regulations using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). In addition, the specific emergency services cost sharing limits in Table 35 for Alternative 3 in section V.H.2.c. of this FC are codified in § 422.113(b)(2)(v) for contract year 2023. We note that no additional Medicare FFS data projections were used to calculate the cost sharing limits for emergency services during the transition in Table 35 (all amounts were based on the specified dollars limits from the February 2020 proposed rule). A complete list of final contract year 2023 in-network cost sharing limits calculated following the methodology in this FC is available in Table 28.

Alternative 1: We considered finalizing the three cost sharing proposals (in §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v)) for use of the proposed coinsurance percentages and use of actuarially equivalent copayment limits to begin immediately for contract year 2023 as an approach to minimize the changes from the February 2020 proposed rule and to incentivize MA organizations to establish lower MOOP amounts. This alternative would result in the most substantial increases to the contract year 2023 cost sharing limits, as shown in Tables 33 through 37 in comparison to the other alternatives discussed in this section. We ultimately rejected this alternative to be responsive to public comments and apply another approach that would better protect enrollees from potential disruption that may result from substantially shifting copayment limits within 1 year.

As shown in Table 33, finalizing the range of cost sharing limits for contract year 2023 would increase the physical therapy and speech-language pathology copayment limit for a plan that establishes a lower MOOP amount to $90, a $5 increase from the illustrative amount in the February 2020 proposed rule (using contract year 2023 Medicare FFS data projections based on 2017–2021 Medicare FFS data). This $90 amount also reflects a $50 increase from the contract year 2022 copayment limit for this service category. Similarly, as shown in Table 34, this alternative would increase the partial hospitalization copayment limit for a plan that establishes a lower MOOP amount to $135. This $135 amount reflects a $80 increase from the contract year 2022 copayment limit for this service category.

As shown in Table 35, finalizing the proposed emergency services cost sharing limits for contract year 2023 would increase the cost sharing limit for a plan that establishes a lower MOOP amount from $120 in contract year 2022 to $150 for contract year 2023 and future years (an increase of $30) as generally illustrated in the February 2020 proposed rule. These specific cost sharing limits would apply unless cost

sharing established by the MA plan if the emergency services were provided through the MA organization is lower.

As shown in Table 36, the 20 percent coinsurance limit (cost sharing under original Medicare) for the Part B drugs—chemotherapy/radiation drugs service category remains consistent with the cost sharing standards CMS has used since 2012. In addition, using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data) for the Part B drugs—chemotherapy/radiation drugs service category, an actuarially equivalent copayment value based on 20 percent coinsurance would be $280. As a result, if this first alternative were finalized, beginning in contract year 2023 MA organizations could establish a $280 copayment (a $205 increase from the $75 copayment limit for Part B drugs—chemotherapy/radiation drugs for contract year 2022) which would be potentially disruptive to enrollees.

As shown in Table 37, to be consistent with the February 2020 proposed rule for this alternative, we considered the alternative under which we would apply the range of cost sharing limits (30, 40, and 50 percent) for the ''Part B drugs—other'' service category rather than our longstanding 20 percent coinsurance requirement. This alternative would increase the cost sharing limit for a plan that establishes a lower MOOP amount from $50 or 20 percent coinsurance in contract year 2022 to $800, or 50 percent coinsurance for contract year 2023 (an increase of $750). Specifically, $800 reflects an actuarially equivalent value to 50 percent coinsurance for the ''Part B drugs—other'' service category using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data).

We note that if we instead codified the 20 percent coinsurance limit without a transition, based on the same contract year 2023 Medicare FFS data projections, the actuarially equivalent copayment limit would be $320 for the ''Part B drugs—other'' service category in contract year 2023. Based on these significant projected increases to the ''Part B drugs—other'' copayment limit in comparison to the contract year 2022 limit (as shown in Table 37), we decided to address this service category differently from the other service categories we proposed to be subject to § 422.100(f)(6)(iii) for the rest of this section. Specifically, instead of finalizing a range of cost sharing for this service category, we considered both codifying our longstanding 20 percent coinsurance requirement and applying a multiyear transition to an actuarially equivalent copayment value based on 20 percent coinsurance in the other alternatives discussed in this section.

In relation to the cost sharing limits in Tables 33, 34, 36, and 37, as discussed in section II.B.5. of this FC, if CMS does not calculate a copayment limit for a service category subject to § 422.100(f)(6)(iii) or (j)(1) (which would also be consistent with the February 2020 proposed rule), an MA plan must not establish a copayment that exceeds an actuarially equivalent value to the cost sharing standard. This means the potential outcomes shown in Tables 33, 34, 36, and 37 for this alternative remain essentially the same in the absence of a copayment limit calculated by CMS. For example, if CMS did not set a contract year 2023 partial hospitalization service category copayment limit for MA plans with a lower MOOP amount those plans may still be able to establish up to an $135 copayment under this alternative for contract year 2023 (the same amount shown in Table 34 for this alternative).

As discussed in section II.B. of this FC, calculating copayment limits based on updated Medicare FFS data projections reflects plan costs associated with the variety and expense of services included in the cost sharing limit. In addition, calculating a maximum cost sharing limit of up to 50 percent coinsurance or an actuarially equivalent copayment value for a lower MOOP type is consistent with CMS's longstanding interpretation and application of the anti-discriminatory requirements, which is that cost sharing over 50 percent for services—where there are no other applicable cost sharing limits—is discriminatory to enrollees who need those services. However, our proposed methodology to calculate copayment limits based on specified percentages is, in effect, a recalibration of the copayment limits in one year by using a methodology adjusted from longstanding policy and updated Medicare FFS data projections. As a result, implementing this alternative means that some of the projected copayment limits in Tables 33 through 37 represent substantial disruptive shifts from the prior contract year since enrollees could experience changes in copayments up to those amounts. As discussed in the introduction to section V.H. of this FC, we understand such increases (in conjunction with the other projected increases to MOOP limits as discussed in more detail in section II.A. and V.H.1. of this FC) could have significant disruptive consequences for enrollees, especially if they have limited financial means.

Public comments (as summarized and responded to in section II.B.5. of this FC) were mixed on these three cost sharing proposals (in §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v) and (vi)). In brief, some commenters generally opposed the proposed increases to the cost sharing limits for certain service categories (such as physical therapy and speech-language pathology, emergency services, and dialysis services) as they stated it may prevent MA enrollees from having meaningful access to services and substantial changes to copayment limits from one year to the next should be avoided to reduce disruption in the market and for beneficiaries. Other commenters were supportive as they stated it would provide an incentive for MA organizations to offer plans with lower MOOP amounts. In addition, a commenter requested CMS conduct a multiyear transition from the current cost sharing limits to the range of cost sharing limits proposed given the potential for enrollee disruption (based on the projected changes to cost sharing limits in the February 2020 proposed rule). While we respond to these (and other) comments in section II.B.5. of this FC, we agree that it is important that enrollees do not face unexpected financial hardships in accessing needed health care services. Further, finalizing these proposals for contract year 2023, when the actuarially equivalent copayment limits for some professional service categories have increased to a greater extent than illustrated in the February 2020 proposed rule (using contract year 2023 Medicare FFS data projections based on 2017–2021 Medicare FFS data) would not have fully addressed the concerns raised in those public comments that CMS shared.

In summary, implementing this alternative to finalize as proposed (with the delay of implementation of the three cost sharing proposals from contract year 2022 to 2023) would mean that many of the copayment limits for services categories subject to §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v) and (vi) would substantially increase from the prior contract year. Based on the enrollee's situation, these changes would be disruptive; they could, for example, potentially discourage them from seeking those services with increased cost sharing and/or result in enrollees choosing to disenroll from the plan or the MA program. We rejected this alternative because the data and public commenter feedback summarized previously did not suggest that

implementing these proposals without a transition would sufficiently protect enrollees from potentially significant year over year changes.

Further, CMS has a practice of phasing in changes in the MA program in order to avoid unnecessary disruption and to ensure a smooth transition. For example, CMS began incorporating encounter data into risk score calculations in 2015 as an additional source of diagnoses. Between 2016 and 2022, CMS calculated risk scores for MA organizations using a weighted average of RAPS-based and encounter data-based risk scores, gradually phasing in encounter data in risk score calculation. In 2022, CMS completed the transition to calculating risk scores for payment to MA organizations using only encounter data. Similarly, the 21st Century Cures Act mandated that several changes be made to the Part C risk adjustment model for MA organizations, and that these changes be phased in over a 3-year period, beginning with 2019, with the changes being fully implemented for 2022. CMS began implementing the risk adjustment requirements in the Cures Act in 2019, with a portion of the risk score applied in payments to MA organizations calculated with a risk adjustment model that included new condition categories. CMS continued implementation by calculating an increasing portion of the risk score used for payments for 2020 and 2021 using a model that included additional condition categories and factors that take into account the total number of diseases or conditions of a beneficiary. For 2022 payment to MA organizations, the risk adjustment model that meets Cures Act requirements was fully phased in. This history has demonstrated the value of using transition schedules when incorporating changes into the MA program.

Alternative 2: We considered: (1) Finalizing a 5-year transition to implement the three cost sharing proposals (with one exception for the ''Part B drugs—other'' service category) beginning for contract year 2023; (2) codifying our longstanding requirement of 20 percent coinsurance (the cost sharing under original Medicare) for the ''Part B drugs—other'' service category; (3) calculating copayment limits for the ''Part B drugs—other'' service category consistent with the 5-year transition (rather than immediately using a copayment limit that is actuarially equivalent to the coinsurance limit); and (4) requiring that CMS set copayment limits at an amount that is the lesser of: An actuarially equivalent value to the applicable cost sharing standard or the value resulting from the 5-year actuarially equivalent copayment transition for that service category. In considering these changes our goal is to protect against potential enrollee disruption, provide MA organizations with adequate time to prepare for these changes, and to incentivize MA organizations to establish lower MOOP amounts. This alternative would result in the least substantial increases to the contract year 2023 cost sharing limits as shown in Tables 33 through 37 in comparison to the other alternatives discussed in this section. However, we ultimately rejected this alternative because of potential disruptive consequences resulting from an extended transition as discussed at the beginning of this section and in section V.H. of this FC (for example, MA organizations increasing premiums or reducing benefits).

The detailed aspects of operationalizing a multiyear transition for these proposals is provided in section II.B.5 of this FC. Our goal in this Alternative Considered section is to analyze the individual cost sharing and difficult-to-quantify impacts of various alternatives. However, in order to understand the long-term implications of this alternative, we summarize the coinsurance limits that would be applied for service categories subject to § 422.100(f)(6)(iii) in Table 32. Table 32 is not included in section II.B. of this FC as that section focuses on the finalized methodology (the third alternative in this section). In addition, Table 32 is only relevant to service categories subject to paragraph (f)(6)(iii) as the coinsurance limit for benefits subject to § 422.100(j)(1) would not need to be transitioned (20 percent coinsurance remains consistent with contract year 2022) and the cost sharing limits for emergency services in § 422.113(b)(2)(v) do not include coinsurance limits (before our proposal and as proposed). As shown in Table 32, CMS would maintain the 50 percent coinsurance limit for the lower (previously ''voluntary'') MOOP type and transition the contract year 2022 coinsurance limit of 50 percent for the mandatory MOOP type to the proposed 30 percent coinsurance limit by decreasing the limit 4 percent each year. In addition, as finalized in section II.A. of this FC, the intermediate MOOP limit is a new type of MOOP beginning in contract year 2023. In order to provide consistently differentiated coinsurance limits between the MOOP limits through the 5-year transition, we would set a 48 percent coinsurance limit for contract year 2023 for the intermediate MOOP limit and decrease it by 2 percent each year to reach the proposed 40 percent coinsurance by contract year 2027.

TABLE 32: ALTERNATIVE 2 – A 5-YEAR TRANSITION TO REACH THE RANGE OF COINSURANCE LIMITS BASED ON THE MOOP TYPE FOR SERVICE CATEGORIES SUBJECT TO § 422.100(f)(6)(iii)

MOOP Type	2023	2024	2025	2026	2027 and Future Years
Lower	50%	50%	50%	50%	50%
Intermediate	48%	46%	44%	42%	40%
Mandatory	46%	42%	38%	34%	30%

In implementing the requirement that CMS set copayment limits at an amount that is the lesser of: (1) An actuarially equivalent value to the applicable cost sharing standard; or (2) the value resulting from the 5-year actuarially equivalent copayment transition for that service category, we note the first value would be the actuarially equivalent copayment to the coinsurance limit shown in Table 32. The second value would result from CMS factoring in an increasing percentage of the difference (or differential) between two values: (1) The contract year 2022 copayment limit for the service category; and (2) the actuarially equivalent value for that service category based on the proposed

cost sharing standards. (This is similar to the approach we finalized in § 422.100(f)(8) but using a different schedule.) We note this definition is explained in greater detail in section II.B.5. of this FC (for instance, how CMS would apply it to the copayment limits applicable for MA plans that have an intermediate MOOP limit). Unique to this alternative, this differential would be factored in over 5 years for service categories subject to §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v) by factoring in the differential as follows:

- Contract Year 2023: 20 percent
- Contract Year 2024: 40 percent
- Contract Year 2025: 60 percent
- Contract Year 2026: 80 percent
- Contract Year 2027: 100 percent

By factoring in 100 percent in contract year 2027 CMS would complete the transition to actuarially equivalent copayment values at the same time the range of coinsurance limits are completed in Table 32 (that is, the copayment limits calculated for contract year 2027 would be actuarially equivalent to the coinsurance limits that apply for that year as we proposed for contract year 2022).

As shown in Table 33, finalizing a 5-year transition to the range of cost sharing limits reduces the increase to the physical therapy and speech-language pathology copayment limit for a plan that establishes a lower MOOP amount compared to the first alternative discussed in this section (using Medicare FFS data projections based on 2017–2021 Medicare FFS data). For example, the contract year 2023 copayment limit for the physical therapy and speech-language pathology service category if a plan establishes a lower MOOP amount would be $50 under this alternative. This $50 amount reflects a $35 decrease compared to the $85 illustrative copayment limit in the February 2020 proposed rule. In addition, this $50 amount is a $10 increase from the contract year 2022 copayment limit of $40 for this service category (compared to a $50 increase for the lower MOOP limit if the first alternative discussed in this section was implemented). Similarly, as shown in Table 34, this alternative would result in a $70 contract year 2023 copayment limit for the partial hospitalization service category for a plan that establishes a lower MOOP amount. This $70 amount reflects a $15 increase compared to the contract year 2022 copayment limit of $55 for this service category. The copayment limits in Table 33 and 34 also reflect implementing the ''lesser of'' requirement (for both alternative two and three in this section); each copayment limit calculated from factoring in an increasing percentage of the actuarially equivalent copayment differential over the transition period was less than the amount that would be actuarially equivalent to the coinsurance limit that would apply in contract year 2023 (as listed in Table 32 and described in the third alternative in this section).

As shown in Table 35, applying a 5-year transition would reduce the impact of the increase to the emergency services cost sharing limit for a plan that establishes a lower MOOP amount from $120 in contract year 2022 to $125 for contract year 2023, an increase of $5 from the prior contract year instead of the $30 increase, as illustrated in the February 2020 proposed rule. As no coinsurance limits for emergency services were proposed, the requirement that CMS set copayment limits at an amount that is the lesser of: (1) An actuarially equivalent value to the applicable cost sharing standard; or (2) the value resulting from the actuarially equivalent copayment transition for that service category does not apply to emergency services.

Table 36 illustrates that applying a 5-year transition would reduce the increase to the Part B drugs—chemotherapy/radiation drugs service category copayment limit; the copayment limit would increase from $75 in contract year 2022 to $115 for contract year 2023. This $115 amount reflects an increase of $40 from the prior contract year and a decrease of $165 in comparison to the first alternative in this section (using contract year 2023 Medicare FFS data projections based on 2017–2021 Medicare FFS data). The copayment limits in Table 36 also reflect implementing the ''lesser of'' requirement (for both alternative two and three in this section); each copayment limit calculated from factoring in an increasing percentage of the actuarially equivalent copayment differential over the transition period was less than the amount that would be actuarially equivalent to the coinsurance limit that would apply in contract year 2023 (20 percent, reflecting the cost sharing in original Medicare).

Table 37 shows applying this alternative for the ''Part B drugs—other'' service category produces substantially lower copayment limits than the first alternative discussed in this section (using the same contract year 2023 Medicare FFS data projections). This is because the differential between the contract year 2022 limit and the final cost sharing limits that would be applied in contract year 2027 is reduced from a maximum of $800 (for the lower MOOP limit under the first alternative) to $105 (for all MOOP types under this alternative). Specifically, Table 37 applies a 5-year transition to reach an actuarially equivalent copayment limit to our longstanding 20 percent coinsurance requirement for the ''Part B drugs—other'' service category. For example, under this alternative the contract year 2023 ''Part B drugs—other'' service category copayment limit for a plan that establishes a lower MOOP amount would be $105, an increase of $55 from the $50 contract year 2022 copayment limit. In comparison, the increase from contract year 2022 would be $750 from the first alternative in this section (which would have used a 50 percent coinsurance limit for the lower MOOP type). Finally, the copayment limits shown in Table 37 for both the second and third alternative discussed in this section also reflect implementing the ''lesser of'' requirement; each copayment limit calculated from factoring in an increasing percentage of the actuarially equivalent copayment differential over the transition period was less than the amount that would be actuarially equivalent to the coinsurance limit that would apply in contract year 2023 (20 percent).

If CMS does not set a copayment limit for a service category subject to § 422.100(f)(6)(iii) or (j)(1) (which would also be consistent with the February 2020 proposed rule), an MA plan must not establish a copayment that exceeds an actuarially equivalent value based on the coinsurance limit. In comparison, the contract year 2023 copayment limits that would result from this alternative (and the third alternative in this section) in Tables 33, 34, 36, and 37 are not solely based on being actuarially equivalent to the coinsurance limit, using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). Rather, they are influenced by the contract year 2022 copayment limits through the increasing incorporation of the differential (and the requirement to set the copayment limit using the lesser value) as discussed previously in this section. As a result, if CMS does not set a copayment limit during a multiyear transition period (following this alternative or the third alternative discussed in this section) for a service category subject to paragraph (f)(6)(iii) or (j)(1), the copayments MA organizations may establish for that service category may be higher or lower than the values in Tables 33, 34, 36, and 37. The potential administration burden for each service category for which CMS does not calculate a copayment limit

would remain the same as discussed previously in this section. Further information about how MA organizations may approach preparing supporting documentation for their cost sharing amounts is available in section II.B.5.a. of this FC.

As discussed in section II.B. of this FC, the copayment limits set for some service categories (subject to § 422.100(f)(6)(iii) and (j)(1) in this FC) in past years do not reflect current actuarially equivalent values using contract year 2023 Medicare FFS data projections (based on 2017–2021 Medicare FFS data). In applying a multiyear transition to recalibrate copayment limits and a requirement to set copayment limits at the lower value, enrollees will be better protected from potential disruption and MA organizations will have more time to consider different cost sharing structures and approaches, such as using copayment structures (which may be more transparent for beneficiaries) instead of coinsurance, or using lower cost sharing than the maximum permitted.

However, as indicated in the introduction to this Alternative Section, applying a lengthy multiyear transition to reach the proposed range of cost sharing limits may not provide an incentive for MA organizations to adopt a lower MOOP amount as quickly. In addition, an earlier completion of the transition will: (1) Improve the alignment of copayment limits with the coinsurance limits; (2) increase the flexibility MA organizations have in establishing copayments; (3) may encourage the use of copayments and lower MOOP amounts among MA plans; and (4) mitigate potential premium increases or benefit reductions. Further, MA organizations were able to, and may continue to, establish cost sharing equal to original Medicare for all benefits subject to paragraph (j)(1) and cost sharing up to 50 percent coinsurance for professional service categories subject to § 422.100(f)(6)(iii) in contract year 2022 and prior years through coinsurance structures. Some MA organizations may have chosen to use coinsurance structures in their benefit designs because of geographic variation in health care costs. While CMS is finalizing the policies in this FC in a manner to avoid potentially disruptive changes for enrollees wherever possible, a longer transition schedule for service categories subject to paragraph (j)(1) means that the copayment limits remain out of proportion to the consistent 20 percent coinsurance limit for a longer period of time. If CMS maintained copayment limits at lower than actuarial equivalent amounts for a long period of time, MA organizations may still modify their plan benefit designs in other ways to cover these additional costs.

We rejected this alternative to apply a 5-year transition schedule because we expect a shorter transition schedule is a more reasonable way for MA organizations to absorb the costs of providing these services and in designing plan benefits. In addition, as discussed in section II.B. of this FC, updated Medicare FFS projections since the February 2020 proposed rule show further increases (for service categories applicable to each of the three cost sharing proposals discussed in this section). However, we clarify that the projected increased costs for emergency services (based on contract year 2023 Medicare FFS data projections) are not factored into the transition of cost sharing limits in Table 35 as the proposal for that service category was based on specific amounts.

Alternative 3 (Finalized): This alternative: (1) Shortens the multiyear transition by 1 year (compared to the second alternative discussed in this section); (2) continues to codify the longstanding 20 percent coinsurance limit for the ''Part B drugs—other'' service category (with the same 4-year transition); and (3) requires that CMS set copayment limits at an amount that is the lesser of: An actuarially equivalent value to the applicable cost sharing standard or the value resulting from the 4-year actuarially equivalent copayment transition for that service category. The shorter transition schedule results in increases to the copayment limits for contract year 2023 for the service categories shown in Tables 33 through 37 that are generally greater than the second alternative but less than the first alternative. In addition, applying either this alternative or the second alternative discussed in this section also results in the same cost sharing limits for contract year 2023 for certain service categories and MOOP limits (as shown in Tables 33 through 35). However, the differences in applying this alternative or the second alternative discussed in this section, would result in greater differences in the cost sharing limits in the later years of the multiyear transition schedules in most cases.

Our rational for selecting this finalized approach is multifaceted. It—(1) improves the methodology CMS uses to calculate copayment limits to ultimately reflect actuarially equivalent values based on updated Medicare FFS data projections; (2) helps to mitigate potentially substantial increases to cost sharing or premium, and/or benefit reductions if copayment limits are not adjusted to reflect updated Medicare FFS data projections; (3) incentivizes MA organizations to adopt lower MOOP amounts; and (4) implements changes in a transparent, incremental approach to provide more stability and predictability to the MA program. This rationale and the aspects of operationalizing this transition are discussed in greater detail in section II.B. of this FC (for example, see Table 13 for the annual change in coinsurance limits for service categories subject to § 422.100(f)(6)(iii) for contract years 2023 to 2026 and future years). As shown in Table 33, finalizing a 4-year transition to the range of cost sharing limits results in nominal changes for the physical therapy and speech-language pathology service category compared to the second alternative discussed in this section (using the same contract year 2023 Medicare FFS data projections). Specifically, the coinsurance limit for the intermediate and mandatory MOOP limit is 1 percent less than what would be applied if the second alternative was implemented. This outcome holds true in contract year 2023 for all professional services subject to paragraph (f)(6)(iii) as coinsurance limits are applied consistently across these service categories. As a result of applying a requirement to set copayment limits at the lower value and the rounding rules in paragraph (f)(6)(ii), Table 34 shows that the contract year 2023 partial hospitalization copayment limit for the lower and intermediate MOOP limits changes by $5 between the second and third alternatives.

Finalizing a 4-year transition does not change the emergency services cost sharing limits in comparison to implementing the second alternative discussed in this section for contract year 2023 (as shown in Table 35). This is due to the rounding rules, which are being applied consistent with the February 2020 proposed rule. CMS calculated the proposed and final emergency services cost sharing limits using those same rounding rules. As discussed in relation to the second alternative in this section, the requirement that CMS set copayment limits at an amount that is the lesser of: (1) An actuarially equivalent value to the applicable cost sharing standard; or (2) the value resulting from the actuarially equivalent copayment transition for that service category does not apply to emergency services.

Table 36 shows how finalizing a 4-year transition also reduces the contract year 2023 Part B drugs—chemotherapy/radiation drugs service category copayment limit compared to the first alternative in this section. Specifically, the increase from the $75 copayment

limit for contract year 2022 changes from a $205 increase (resulting from the first alternative) to a $50 increase (this alternative). In addition, the $125 copayment limit resulting from this alternative only reflects an additional increase of $10 in comparison to the second alternative discussed in this section (based on the same contract year 2023 Medicare FFS data projections) as a result of applying a requirement to set copayment limits at the lower value and the rounding rules in paragraph (f)(6)(ii).

Table 37 shows how finalizing a 4-year transition from current copayment limits to copayments that are aligned to the longstanding 20 percent coinsurance limit for the ''Part B drugs—other'' service category significantly reduces the contract year 2023 copayment limit for this service category compared to the first alternative in this section (based on the same contract year 2023 Medicare FFS data projections). Specifically, the increase to the ''Part B drugs—other'' service category copayment limit from the prior year ($50 for contract year 2022) for this alternative is $70 (for all MOOP types) which is significantly lower than an increase of $750 in the first alternative for a plan that establishes a lower MOOP amount). In addition, the $120 copayment limit resulting from this alternative reflects an increase of only $15 in comparison to the second alternative discussed in this section as a result of applying a requirement to set copayment limits at the lower value and the rounding rules in paragraph (f)(6)(ii).

As discussed previously, the potential administration burden for each service category for which CMS does not set a copayment limit would remain the same. As discussed in the second alternative in this section, if CMS does not apply the methodology and rules in § 422.100(f)(6), (f)(7), (f)(8) and (j) to set a copayment limit during the multiyear transition period for a service category subject to paragraph (f)(6)(iii) or (j)(1), MA organizations may establish copayment amounts for that service category that may be higher or lower than the projected values in Tables 33, 34, 36, and 37, depending on the MA organization's calculation of a value that is an actuarially equivalent to the applicable coinsurance limit.

As a result, CMS calculated and set contract year 2023 copayment limits for the majority of service categories that had copayment limits in contract year 2022 (as shown in Tables 25A, 25B, and 28). Specifically, for benefits subject to § 422.100(j)(1), calculating actuarially equivalent copayment limits based the most recent Medicare FFS data projections available to CMS for these service categories ensures that MA cost sharing does not exceed cost sharing in original Medicare for those benefits. This allows CMS to ensure MA organizations comply with these limits and that the plan cost sharing does not discriminate against or discourage enrollment in an MA plan by beneficiaries who have high health care needs.

We acknowledge that a multiyear transition that is shorter than 4 years, but longer than 1 year as described in the first alternative, would result in more substantial increases to the copayment limits for the service categories subject to §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v) compared to the contract year 2022 limits. For example, a $5 increase to the partial hospitalization service category copayment limit for the mandatory MOOP limit in comparison to contract year 2022 (as shown in Table 34 for this alternative) is not necessarily substantial by itself. However, CMS considered the combined potential effect of the increases to MOOP limits and copayment limits across service categories. For example, we were especially aware of the substantial increases to the copayment limits for benefits subject to paragraph (j)(1) from contract year 2022 as a result of calculating actuarially equivalent values to the cost sharing in original Medicare using contract year 2023 Medicare FFS data projections based on 2017–2021 Medicare FFS data (as shown in Tables 36 and 37) could negatively impact enrollees as described in the introduction to section V.H. of this FC. In addition, prior to this FC, CMS has only updated MOOP limits, inpatient hospital, skilled nursing facility, and emergency services cost sharing limits in recent years. Under this FC, we will be updating MOOP limits and cost sharing limits for most service categories each year during the transition period, which reflects more significant changes to our standards compared to recent years, in order to reach the proposed MOOP and cost sharing limits in a reasonable timeframe.

Based on the considerations discussed in this section, we are implementing this alternative to: (1) Codify our longstanding 20 percent coinsurance limit for the ''Part B drugs—other'' service category; (2) apply a 4-year transition to reach the proposed cost sharing standards (for professional services, emergency services, and benefits for which cost sharing must not exceed cost sharing in original Medicare); and (3) require that CMS set copayment limits at an amount that is the lesser of: an actuarially equivalent value to the applicable cost sharing standard or the value resulting from the 4-year actuarially equivalent copayment transition for that service category. We expect implementing the policies based on this alternative will (for the reasons discussed in this section and in section II.B. of this FC: (1) Ensure beneficiary access to affordable and sustainable benefit packages; (2) protect enrollees from discriminatory levels of cost sharing; (3) limit potential rapid cost and benefit changes; (4) encourage MA organizations to establish lower MOOP amounts; and (5) streamline the updates to MOOP limit and cost sharing requirements, which will also provide stability for MA organizations. We reiterate that the copayment limits set for contract year 2022 have been in place for a number of years and that CMS expects that this 4-year transition to the proposed cost sharing limits will ultimately result in stable benefit packages by ensuring limits are calculated following established actuarial methods, using the most recent Medicare FFS data projections available, and by aligning copayment limits with coinsurance limits. In other words, CMS is making the changes necessary to reach actuarially equivalent copayments that reflect plan costs associated with the variety and expense of services included in the cost sharing limit while protecting beneficiaries from discriminatory levels of cost sharing.

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TABLE 33: CONTRACT YEAR 2023 IN-NETWORK PHYSICAL THERAPY AND SPEECH-LANGUAGE PATHOLOGY SERVICE CATEGORY COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COST SHARING LIMITS FOR SERVICE CATEGORIES SUBJECT TO A RANGE OF COST SHARING LIMITS BASED ON MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Range of Cost Sharing Limits Implementation	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	50% / $40	N/A	50% / $40
Alternative 1: Apply range of cost sharing as proposed beginning in contract year 2023	50% / $90	40% / $70	30% / $55
Alternative 2: Apply a 5-year transition to the range of cost sharing limits proposed	50% / $50	48% / $45	46% / $45
Alternative 3 (Finalized): Apply a 4-year transition to the range of cost sharing limits proposed	50% / $50	47% / $50	45% / $45

TABLE 34: CONTRACT YEAR 2023 IN-NETWORK PARTIAL HOSPITALIZATION SERVICE CATEGORY COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COST SHARING LIMITS FOR SERVICE CATEGORIES SUBJECT TO A RANGE OF COST SHARING LIMITS BASED ON MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Range of Cost Sharing Limits Implementation	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	50% / $55	N/A	50% / $55
Alternative 1: Apply range of cost sharing as proposed beginning in contract year 2023	50% / $135	40% / $110	30% / $80
Alternative 2: Apply a 5-year transition to the range of cost sharing limits proposed	50% / $70	48% / $65	46% / $60
Alternative 3 (Finalized): Apply a 4-year transition to the range of cost sharing limits proposed	50% / $75	47% / $70	45% / $60

TABLE 35: CONTRACT YEAR 2023 EMERGERCY SERVICES COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COPAYMENT LIMITS TO PROPOSED COST SHARING LIMITS

Emergency Services Cost Sharing Limits	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	$120	N/A	$90
Alternative 1: Apply cost sharing limits as proposed beginning in contract year 2023	$150	$130	$115
Alternative 2: Apply a 5-year transition to proposed copayment limits	$125	$110	$95
Alternative 3 (Finalized): Apply a 4-year transition to proposed copayment limits	$125	$110	$95

TABLE 36: CONTRACT YEAR 2023 IN-NETWORK PART B DRUGS: CHEMOTHERAPY/RADIATION DRUGS SERVICE CATEGORY COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COPAYMENT LIMITS FOR SERVICE CATEGORIES SUBJECT TO § 422.100(j)(1) TO ACTUARIALLY EQUIVALENT VALUES TO COST SHARING IN ORIGINAL MEDICARE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Services for which Cost Sharing Must Not Exceed Cost Sharing under Original Medicare	All MOOP Limits
Baseline: Contract Year 2022 Limits	20% / $75
Alternative 1: No copayment limits, MA organizations have the burden to determine actuarially equivalent copayment values	20% / $280
Alternative 2: Apply a 5-year transition to actuarially equivalent copayment limits	20% / $115
Alternative 3 (Finalized): Apply a 4-year transition to actuarially equivalent copayment limits	20% / $125

TABLE 37: CONTRACT YEAR 2023 IN-NETWORK PART B DRUGS: OTHER SERVICE CATEGORY COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COPAYMENT LIMITS FOR SERVICE CATEGORIES SUBJECT TO § 422.100(j)(1) TO ACTUARIALLY EQUIVALENT VALUES TO COST SHARING IN ORIGINAL MEDICARE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Services for Which Cost Sharing Must Not Exceed Cost Sharing under Original Medicare	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	20% / $50	N/A	20% / $50
Alternative 1: Apply range of cost sharing as proposed beginning in contract year 2023	50% / $800	40% / $640	30% / $480
Alternative 2: Apply a 5-year transition to copayment limits that are actuarially equivalent to original Medicare	20% / $105	20% / $105	20% / $105
Alternative 3 (Finalized): Apply a 4-year transition to copayment limits that are actuarially equivalent to original Medicare	20% / $120	20% / $120	20% / $120

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I. Accounting Statement

This FC rule finalizes provisions on the coinsurance and copayment limits for professional service categories, the cost sharing limits for emergency services, copayment limits for service categories for which cost sharing must not exceed cost sharing under original Medicare, and presents a multiyear transition for ESRD costs for MOOP limits and inpatient hospital cost sharing limits. As discussed in this RIA section, a combination of three reasons drives the conclusion that in aggregate this FC has no cost: (1) The MA requirement of actuarial equivalence to coverage in original Medicare, implying that plans can shift costs, but not create additional out of pocket costs for enrollees compared to the original Medicare program; (2) many of the provisions of this FC are codifications of existing practice, which because of the annual bid cycle and review, we are confident plans are complying with; and (3) with regard to the MOOP provisions, analysis of bid changes shows that plans in general have not been charging the highest MOOP amount.

As a result, although in aggregate there is no estimated impact, Medicare Advantage plans may shift cost sharing costs provided they do not create additional costs. This is because actuarial equivalence refers to an equivalence with all original Medicare beneficiaries and all services provided by original Medicare. It follows, that a more detailed analysis on particular cohorts of enrollees and particular collections of services may reveal gains or losses to these groups. Because of the challenges with making such an analysis, including the proprietary nature of bids, we are unable to provide quantification in this FC; however, because of the possibility that some of these cohorts might have a gain or loss exceeding the threshold, we have classified this rule as major.

This summary serves as the accounting statement required by Circular A–4.

J. Conclusion

This FC makes policy changes in alignment with federal laws related to the Medicare Advantage (MA or Part C) program from the 21st Century Cures Act (Pub. L. 114–255). The rule also includes regulatory changes to strengthen and improve the Part C program by codifying in regulation several CMS policies previously adopted through the annual Call Letter and other guidance documents to interpret and implement rules regarding benefits in MA plans. The provisions in this FC do not have an aggregate cost impact.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on February 8, 2022.

List of Subjects in 42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

* * * * *

■ 2. Section 422.100 is amended by—

■ a. Adding paragraph headings for paragraphs (f)(1) through (3);

■ b. Revising paragraphs (f)(4) through (6);

■ c. Adding paragraphs (f)(7), (8), and (9); and

■ d. Revising paragraph (j).

The revisions and additions read as follows:

§ 422.100 General requirements.

* * * * *

(f) * * *

(1) *Guidelines.* * * *

(2) *Discrimination.* * * *

(3) *Other requirements.* * * *

(4) *In-network MOOP limit.* Except as provided in paragraph (f)(5) of this section, MA local plans (as defined in § 422.2) must have an enrollee in-network maximum out-of-pocket (MOOP) amount for basic benefits that is no greater than the annual limit calculated by CMS using Medicare Fee-for-Service (FFS) data projections. With respect to a private fee-for-service (PFFS) plan, the in-network MOOP limits specified in this paragraph (f)(4) apply. MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the plan's in-network MOOP amount is reached.

(i) *Medicare FFS data projections in CMS MOOP limit calculations.* For each year beginning on or after January 1, 2023, CMS calculates three MOOP limits using Medicare FFS data projections. For purposes of this paragraph (f)(4) and calculating actuarially equivalent copayments as described in paragraph (f)(7) of this section, the term *Medicare FFS data projections* means the projections of beneficiary out-of-pocket costs for the applicable contract year, based on recent Medicare FFS data, including data for beneficiaries with and without diagnoses of ESRD, that are consistent with generally accepted actuarial principles and practices as outlined in paragraph (f)(7)(i) of this section. The dollar ranges for the three MOOP limits are as follows:

(A) *Mandatory MOOP limit.* One dollar above the intermediate MOOP limit and up to and including the mandatory MOOP limit.

(B) *Intermediate MOOP limit.* One dollar above the lower MOOP limit and up to and including the intermediate MOOP limit.

(C) *Lower MOOP limit.* Between $0.00 and up to and including the lower MOOP limit.

(ii) *MOOP type.* An MA organization that establishes a plan's MOOP amount within the dollar range specified in paragraphs (f)(4)(i)(A) through (C) of this section has the corresponding mandatory, intermediate, or lower MOOP type for purposes of paragraphs (f) and (j) of this section and §§ 422.101(d) and 422.113(b)(2)(v).

(iii) *CMS rounding of MOOP limits.* Each MOOP limit CMS calculates is rounded to the nearest $50 increment and in cases where the MOOP limit is projected to be exactly in between two $50 increments, CMS rounds to the lower $50 increment.

(iv) *MOOP limits for 2023.* For 2023, CMS calculates the MOOP limits as follows, applying paragraph (f)(4)(vi)(A) of this section:

(A) *Mandatory MOOP limit.* $7,175 (the 95th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: The resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the mandatory MOOP limit from the prior year, in which case CMS caps the increase to the mandatory MOOP limit by 10 percent of the prior year's MOOP limit.

(B) *Intermediate MOOP limit.* The numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) of this section and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraphs (f)(4)(iv)(A) and (C) of this section).

(C) *Lower MOOP limit.* $3,360 (the 85th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: The resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the voluntary MOOP limit from the prior year, in which case CMS caps the increase to the lower MOOP limit by 10 percent of the prior year's MOOP limit.

(v) *MOOP limits for 2024 and subsequent years.* For 2024 and subsequent years, CMS annually calculates the MOOP limits as follows, applying paragraph (f)(4)(vi)(B) of this section:

(A) *Mandatory and lower MOOP limits.* The prior year's MOOP limits are increased or decreased for the upcoming contract year to reflect the applicable percentiles (95th for the mandatory MOOP and 85th for the lower MOOP) of the Medicare FFS data projections unless: Either of the resulting MOOP limits reflect an increase greater than 10 percent compared to the same type of MOOP limit from the prior year, in which case CMS caps the increase to the applicable MOOP limit(s) by 10 percent of the prior year's MOOP limit annually until the MOOP limit(s) reflects the applicable percentile(s).

(B) *Intermediate MOOP limit.* Is either maintained at the prior year's limit or if either the mandatory or lower MOOP limit changes from the prior year, updated to the new numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) of this section and after application of the 10-percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraph (f)(4)(v)(A) of this section).

(vi) *CMS calculation of the ESRD cost differential.* For purposes of the ESRD cost transition methodology to calculate annual MOOP limits contained in this section, the *ESRD cost differential* is the difference between, first, for the mandatory MOOP limit, $7,175 and for the lower MOOP limit, $3,360 and second, for the mandatory MOOP limit, the 95th percentile and, for the lower MOOP limit, the 85th percentile of the Medicare FFS data projections for each year between 2023 and 2024. CMS transitions to using the Medicare FFS data projections by factoring in a percentage of the ESRD cost differential on the following schedule:

(A) For 2023, CMS uses projected Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD plus 70 percent of the ESRD cost differential.

(B) For 2024 and subsequent years, CMS uses the Medicare FFS data projections.

(5) *Combined MOOP limit.* With respect to a local PPO plan, the MOOP limits specified under paragraph (f)(4) of this section apply only to use of in-network providers.

(i) *Combined and total catastrophic MOOP limits.* MA local PPO plans must establish a combined enrollee MOOP amount for basic benefits that are provided in-network and out-of-network that is no greater than the total catastrophic limit applicable to regional plans in § 422.101(d)(3).

(ii) *In-network and combined MOOP type.* The type of in-network MOOP limit dictates the type of combined MOOP limit the MA plan may use. MA PPO plans must have the same MOOP type (lower, intermediate, or mandatory) for the in-network MOOP limit and combined limit on in-network and out-of-network out-of-pocket expenditures.

(iii) *MOOP limit attainment.* MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee and must alert enrollees and contracted providers when the combined MOOP amount is reached.

(6) *General cost sharing limits.* Cost sharing for basic benefits specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services. For each year beginning on or after January 1, 2023, a MA organization must establish cost sharing for basic benefits that complies with the cost sharing limits in this paragraph (f)(6), paragraph (j) of this section, and § 422.113(b)(2), which are in addition to any other limits and rules applicable to MA cost sharing, including the requirement in § 422.254(b)(4) that overall MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing. Cost sharing may be a coinsurance or copayment; a cost sharing limit is calculated for a plan benefit package service category or for a reasonable group of benefits covered under the plan. For purposes of cost sharing evaluation, the analysis is completed at the plan (or segment) level. An MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s).

(i) *The 50 percent cap on original Medicare benefits.* For in-network basic benefits that are not specifically addressed in this paragraph (f)(6), paragraph (j)(1) of this section, or § 422.113(b)(2), and for out-of-network basic benefits, MA plans must not establish a cost sharing amount that exceeds 50 percent coinsurance or an actuarially equivalent copayment value (calculated by CMS following the requirements in paragraph (f)(7) of this section or, if CMS does not calculate a copayment limit, based on the average Medicare FFS allowable amount for the plan service area or the estimated total MA plan financial liability for the service category or for a reasonable group of benefits in the PBP for that contract year). The rules in this paragraph (f)(6)(i) apply regardless of

the type of MOOP limit established by the plan.

(ii) *Copayment rounding rules.* The following rounding rules apply in calculating copayment limits and in evaluating compliance with this paragraph (f)(6) and paragraphs (f)(7), (f)(8), and (j)(1) of this section:

(A) For service categories subject to paragraph (f)(6)(i) of this section, professional services subject to paragraph (f)(6)(iii) of this section, and benefits listed in paragraph (j)(1)(i) of this section, the final actuarially equivalent copayment value is rounded to the nearest whole $5.

(B) For inpatient hospital acute and psychiatric and skilled nursing facility cost sharing limits subject to paragraphs (f)(6)(iv) and (j)(1)(i)(C) of this section, the final actuarially equivalent copayment value is rounded to the nearest whole $1.

(C) When the actuarially equivalent copayment value is projected to be exactly between two increments, the final figure is rounded to the lower dollar amount.

(iii) *Cost sharing limits for professional services.* (A) For in-network basic benefits that are professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services, an MA plan must not establish cost sharing that exceeds the limits in this paragraph (f)(6)(iii) for the MOOP limit established by the MA plan.

(B) When calculating copayment limits for purposes of this paragraph, CMS calculates an actuarially equivalent value to the coinsurance limits in this paragraph (f)(6)(iii), subject to the requirements in paragraph (f)(7) of this section and the restrictions on increases to copayment limits in paragraph (f)(8) of this section. If CMS does not calculate a copayment limit for a professional service category, the MA plan must not establish a copayment that exceeds the actuarially equivalent value to the coinsurance limits in this paragraph (f)(6)(iii) based on the estimated total MA plan financial liability for that benefit for that contract year.

(C) For 2023, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 47 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 53 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(D) For 2024, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 40 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 60 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(E) For 2025, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 35 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 65 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 42 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 58 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(F) For 2026 and subsequent years, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 30 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 70 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 40 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 60 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(iv) *Inpatient hospital acute and psychiatric service category cost sharing limits.* (A) For in-network basic benefits that are inpatient hospital acute and psychiatric service categories, an MA plan must not establish cost sharing that exceeds the limits calculated by CMS under paragraph (f)(6)(iv) of this section and subject to paragraph (f)(7) of this section for the MOOP limit established by the MA plan.

(B) Cost sharing limits for inpatient hospital acute and psychiatric service categories are calculated for the following seven length-of-stay scenarios for a period for which cost sharing would apply under original Medicare: Inpatient hospital acute stay scenarios of 3 days, 6 days, 10 days, and 60 days and inpatient hospital psychiatric stay scenarios of 8 days, 15 days, and 60 days.

(C) CMS calculates the inpatient hospital acute and psychiatric service category cost sharing limits annually using projections of Medicare FFS out-of-pocket costs and utilization for the applicable year and length of stay scenario and factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD on the transition schedule described in paragraphs (f)(4)(vi)(A) through (B) of this section and may also use patient utilization information from MA encounter data.

(D) Provided that the total cost sharing for the inpatient benefit does not exceed the MA plan's MOOP limit or overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis, cost sharing applicable to inpatient hospital acute and psychiatric service categories is permitted up to the following limits (based on original Medicare cost sharing for a new benefit period):

(1) Mandatory MOOP limit. Cost sharing must not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario.

(2) Intermediate MOOP limit. Cost sharing must not exceed the numeric midpoint between the cost sharing limits established in paragraphs (f)(6)(iv)(D)*(1)* and *(3)* of this section for the same inpatient hospital length of stay scenario, before application of the

rounding rules in paragraph (f)(6)(ii) of this section.

(3) Lower MOOP limit. Cost sharing must not exceed 125 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length of stay scenario other than the inpatient hospital acute 60-day length-of-stay for MA plans that establish a lower MOOP limit. For inpatient hospital acute 60-day length of stays, MA plans that establish a lower MOOP limit have the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing.

(7) *Using generally accepted actuarial principles and practices.* (i) *Application of generally accepted actuarial principles and practices.* The projections and calculations used in the methodologies described in paragraphs (f)(4), (f)(5), (f)(6), (f)(7)(ii), (f)(8), and (j) of this section and in § 422.101(d)(2) and (3) must be made using generally accepted actuarial principles and practices.

(A) In applying generally accepted actuarial principles and practices, actuarial judgment and discretion may be used, including taking into account information such as changes in legislation (such as changes in Medicare benefits), Medicare payment policy, trends over several years of data, and external variables (such as public health emergencies); selecting among different approaches (such as weighting for utilization and using average or median values); and in selecting data or data samples.

(B) MA organizations must use generally accepted actuarial principles and practices in complying with the regulations in paragraphs (f)(6) and (j) of this section.

(C) CMS applies generally accepted actuarial principles and practices in evaluating MA plan compliance with paragraphs (f)(6) and (j) of this section.

(ii) *CMS calculation of actuarially equivalent copayment limits.* As feasible and appropriate to carry out program purposes, CMS calculates copayment limits for basic benefits in accordance with paragraphs (f)(6)(i) and (iii) and (j)(1) of this section. Beginning January 1, 2023, unless specified otherwise in paragraphs (f)(6) and (j)(1) of this section, CMS calculates these copayment limits at an actuarially equivalent value to the cost sharing standard as follows:

(A) Using Medicare FFS data projections, as defined in paragraph (f)(4)(i) of this section, for the applicable year and service category.

(B) Using patient utilization information from MA encounter data, in addition to the Medicare FFS data projections (including cost and utilization data), if available and where appropriate to consider utilization differences between Medicare FFS beneficiaries and MA enrollees to reach a value that most closely reflects an actuarially equivalent copayment for the benefit and beneficiary population.

(C) Selecting a particular approach to calculate an actuarially equivalent copayment value in situations where there may be multiple or a range of actuarially equivalent copayment values for a service category in order to carry out program purposes, including: Setting copayment limits that most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protecting against discriminatory cost sharing, and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries.

(D) Applying the actuarially equivalent copayment transition in paragraph (f)(8) of this section.

(E) Applying rounding rules in paragraph (f)(6)(ii) of this section.

(iii) *CMS issuance of annual guidance.* CMS issues guidance that specifies the MOOP limits and cost sharing standards for the upcoming contract year (beginning with contract year 2024) that are set and calculated using the methodology and standards in paragraphs (f) and (j) of this section and §§ 422.101(d) and 422.113. This guidance is released prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. Unless a public comment period is impracticable, unnecessary, or contrary to the public interest, CMS provides a public notice and comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year.

(8) *Annual cap on CMS increasing copayment limits during the actuarially equivalent copayment transition.* For 2023 through 2025, CMS sets a copayment limit for a service category subject to paragraph (f)(6)(iii) or (j)(1) of this section at an amount that is the lesser of an actuarially equivalent value to the applicable cost sharing standard (from paragraph (f)(6)(iii) or (j)(1) of this section) or the value resulting from the actuarially equivalent copayment transition in paragraph (f)(8)(ii) of this section for that service category.

(i) CMS *calculation of the actuarially equivalent copayment differential.* For purposes of this section, the actuarially equivalent copayment differential is as follows:

(A) For cost sharing at the mandatory and lower MOOP limits, the difference between, first, the copayment limit set for a plan benefit package service category based on the MOOP type for 2022 and second, the copayment value for the same service category that is actuarially equivalent to the coinsurance limits in paragraphs (f)(6)(iii) and (j)(1) of this section that apply in 2026 based on the MOOP type, using the Medicare FFS data projections that are updated each year to reflect the costs of the contract year for which the copayment limit will apply.

(B) For cost sharing at the intermediate MOOP limit, the difference between, first, the copayment limit set for a plan benefit package service category based on the mandatory MOOP type for 2022 and second, the copayment value for the same service category that is actuarially equivalent to the coinsurance limits in paragraphs (f)(6)(iii) and (j)(1) of this section that apply in 2026 for the intermediate MOOP type, using the Medicare FFS data projections that are updated each year to reflect the costs of the contract year for which the copayment limit will apply.

(ii) *CMS's actuarially equivalent copayment transition.* For service categories subject to the cost sharing standards in paragraphs (f)(6)(iii) and (j)(1) of this section, copayment limits calculated by CMS for 2023 through 2025 are capped at the amounts calculated under this paragraph, unless specified otherwise in paragraph (f)(8) of this section, rounded as provided in paragraph (f)(6)(ii) of this section:

(A) For 2023, CMS uses the copayment limits set for 2022 plus 25 percent of the actuarially equivalent copayment differential.

(B) For 2024, CMS uses the copayment limits set for 2022 plus 50 percent of the actuarially equivalent copayment differential.

(C) For 2025, CMS uses the copayment limits set for 2022 plus 75 percent of the actuarially equivalent copayment differential.

(D) For 2026 and subsequent years, CMS calculates service category copayment limits at the projected actuarially equivalent value to the cost sharing standards in paragraphs (f)(6)(iii)(F) and (j)(1) of this section and subject to paragraph (f)(7) of this section.

(9) *Bundled cost sharing.* Cost sharing (copayments and coinsurance) for basic benefits must reflect the enrollee's entire cost sharing responsibility, inclusive of professional, facility, or provider setting charges, by combining (or bundling) all applicable fees into the cost sharing amount for that particular service(s) and setting(s) and be clearly

reflected as a single, total cost sharing in appropriate materials distributed to beneficiaries for basic benefits.

* * * * *

(j) *Cost sharing and actuarial equivalence standards for basic benefits*—(1) *Specific benefits for which cost sharing may not exceed cost sharing under original Medicare.* (i) *General rule.* For each year beginning on or after January 1, 2023, in-network cost sharing established by an MA plan for the basic benefits listed in this paragraph may not exceed the cost sharing required under original Medicare. When an MA plan uses coinsurance, the coinsurance must not exceed the coinsurance charged in original Medicare. When an MA plan uses copayments, the copayment must not exceed the actuarially equivalent value calculated using the rules in paragraph (j)(1)(ii) of this section. The benefits listed in this paragraph are as follows:

(A) Chemotherapy administration services to include chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen.

(B) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(C) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare, when the MA plan establishes the mandatory MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than $20 per day for the first 20 days of a SNF stay; when the MA plan establishes the intermediate MOOP type, the cost sharing must not be greater than $10 per day for the first 20 days of a SNF stay.

(1) Regardless of the MOOP amount established by the MA plan, the per-day cost sharing for days 21 through 100 must not be greater than one eighth of the projected (or actual) Part A deductible amount.

(2) Total cost sharing for the overall SNF benefit must not be greater than the per member per month actuarially equivalent cost sharing for the SNF benefit in original Medicare.

(D) Home health services (as defined in section 1861(m) of the Act), when the MA plan establishes a mandatory or intermediate MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than 20 percent coinsurance or an actuarially equivalent copayment.

(E) The following specific service categories of durable medical equipment (DME): Equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts when the MA plan establishes the mandatory MOOP limit. For all MOOP limits, total cost sharing for the overall DME benefit must not be greater than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare.

(F) Other drugs covered under Part B of original Medicare (that is, Part B drugs not included in paragraph (j)(1)(i)(A) of this section).

(ii) *Rules for calculating copayment limits.* For 2023 and subsequent years, CMS calculates copayment limits for the basic benefits listed in paragraph (j)(1)(i) of this section subject to the requirements in paragraph (f)(7) of this section and the restrictions on increases to copayment limits in paragraph (f)(8) of this section. If CMS does not calculate a copayment limit for a benefit listed in paragraph (j)(1)(i) of this section, an MA plan must establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare; such actuarially equivalent value must be established in accordance with paragraph (f)(7)(i) of this section and based on the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year.

(2) *Actuarially equivalent cost sharing evaluation for all basic benefits and specific categories of basic benefits in the aggregate.* For each year beginning on or after January 1, 2023, an MA plan's total cost sharing for all basic benefits, excluding out of network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

(i) MA plans must have cost sharing for the following specific benefit categories that does not exceed the cost sharing for those benefit categories in original Medicare on a per member per month actuarially equivalent basis:

(A) Inpatient hospital acute and psychiatric services, defined as services provided during a covered inpatient stay during the period for which cost sharing would apply under original Medicare.

(B) Durable medical equipment (DME).

(C) Drugs and biologics covered under Part B of original Medicare.

(D) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare.

(ii) CMS may extend flexibility for MA plans when evaluating compliance with the requirements in paragraph (j)(2)(i) of this section regarding actuarial equivalent cost sharing for all basic benefits and specific categories of basic benefits to the extent that it is actuarially justifiable provided that the MA plan's cost sharing is based on generally accepted actuarial principles and practices (consistent with paragraph (f)(7) of this section), supporting documentation included in the bid, and the MA plan's cost sharing for specific service categories otherwise satisfies applicable cost sharing standards.

* * * * *

■ 3. Amend § 422.101 by revising paragraphs (d)(2) and (3) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(2) *Catastrophic limit.* For each year beginning on or after January 1, 2023, MA regional plans must do the following:

(i) Establish a catastrophic enrollee MOOP amount for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4).

(ii) Have the same MOOP type (lower, intermediate, or mandatory) for the catastrophic (in-network MOOP) limit and total catastrophic (combined in-network and out-of-network expenditures) limit under paragraph (d)(3) of this section.

(3) *Total catastrophic limit.* For each year beginning on or after January 1, 2023, MA regional plans must establish a total catastrophic (combined in-network and out-of-network expenditures) enrollee MOOP amount for basic benefits that is consistent with this paragraph (d)(3).

(i) The total catastrophic limit may not be used to increase the catastrophic limit described in paragraph (d)(2) of this section.

(ii) CMS calculates the total catastrophic limits by multiplying the respective in-network MOOP limits (before the rounding rules in § 422.100(f)(4)(iii) are applied and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in § 422.100(f)(4)(iv) and (v)) by 1.5 for the relevant year, then applying the rounding rules in § 422.100(f)(4)(iii). The dollar ranges for the three total catastrophic MOOP limits are as follows:

(A) *Mandatory MOOP limit.* One dollar above the in-network intermediate MOOP limit and up to and

including the total catastrophic mandatory MOOP limit.

(B) *Intermediate MOOP limit.* One dollar above the in-network lower MOOP limit and up to and including the total catastrophic intermediate MOOP limit.

(C) *Lower MOOP limit.* Between $0.00 and up to and including the total catastrophic lower MOOP limit.

(iii) An MA organization must establish the total catastrophic MOOP amount (mandatory, intermediate, or lower) within the dollar range specified in paragraphs (d)(3)(ii)(A) through (C) of this section for purposes of paragraph (d) of this section and §§ 422.100(f)(6), (j)(1), and 422.113(b)(2)(v).

* * * * *

■ 4. Section 422.113 is amended by—

■ a. Revising paragraph (b)(2)(v); and

■ b. Adding paragraph (b)(2)(vi).

The revision and addition read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(2) * * *

(v) With a dollar limit on emergency services costs for enrollees that is the lower of—

(A) The cost sharing established by the MA plan if the emergency services were provided through the MA organization; or

(B) A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:

(*1*) For 2023, $95 for a mandatory MOOP limit, $110 for an intermediate MOOP limit, and $125 for a lower MOOP limit.

(*2*) For 2024, $100 for a mandatory MOOP limit, $120 for an intermediate MOOP limit, and $135 for a lower MOOP limit.

(*3*) For 2025, $110 for a mandatory MOOP limit, $125 for an intermediate MOOP limit, and $140 for a lower MOOP limit.

(4) For 2026 and subsequent years, $115 for a mandatory MOOP limit, $130 for an intermediate MOOP limit, and $150 for a lower MOOP limit.

(vi) For each year beginning on or after January 1, 2023, with a cost sharing limit on urgently needed services that does not exceed the limits specified for professional services in § 422.100(f)(6)(iii).

* * * * *

Dated: April 5, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–07642 Filed 4–7–22; 4:15 pm]

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FEDERAL REGISTER

Vol. 87 Thursday,

No. 72 April 14, 2022

Part III

The President

Notice of April 13, 2022—Continuation of the National Emergency With Respect to Specified Harmful Foreign Activities of the Government of the Russian Federation

Federal Register
Vol. 87, No. 72
Thursday, April 14, 2022

Presidential Documents

Title 3—

The President

Notice of April 13, 2022

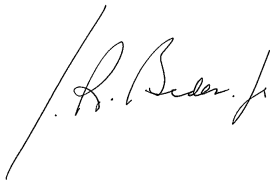
Continuation of the National Emergency With Respect to Specified Harmful Foreign Activities of the Government of the Russian Federation

On April 15, 2021, by Executive Order 14024, I declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by specified harmful foreign activities of the Government of the Russian Federation. On March 8, 2022, I issued Executive Order 14066 to expand the scope of the national emergency declared in Executive Order 14024. On August 20, 2021, March 11, 2022, and April 6, 2022, I issued Executive Orders 14039, 14068, and 14071, respectively, to take additional steps with respect to the national emergency declared in Executive Order 14024.

Specified harmful foreign activities of the Government of the Russian Federation—in particular, efforts to undermine the conduct of free and fair democratic elections and democratic institutions in the United States and its allies and partners; to engage in and facilitate malicious cyber-enabled activities against the United States and its allies and partners; to foster and use transnational corruption to influence foreign governments; to pursue extraterritorial activities targeting dissidents or journalists; to undermine security in countries and regions important to United States national security; and to violate well-established principles of international law, including respect for the territorial integrity of states—continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared in Executive Order 14024, which was expanded in scope by Executive Order 14066, and with respect to which additional steps were taken in Executive Orders 14039, 14068, and 14071, must continue in effect beyond April 15, 2022.

Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 14024.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
April 13, 2022.

[FR Doc. 2022–08244
Filed 4–13–22; 11:15 am]
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