determined that the revised standard does not improve the safety of the consumer product and that CPSC is retaining the existing standard. If the Commission does not take this action, the revised voluntary standard will be considered a consumer product safety standard issued under section 9 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2058), effective 180 days after the Commission received notification of the revision (or a later date specified by the Commission in the **Federal Register**). 15 U.S.C. 2056a(b)(4)(B).

Under this authority, in 2016 the Commission issued a mandatory safety rule that incorporated by reference ASTM F1235–15, Standard Consumer Safety Specification for Portable Hook-On Chairs, codified at 16 CFR part 1233 (81 FR 17065, March 28, 2016). This mandatory standard included performance requirements and test methods, as well as requirements for warning labels and instructions, to address hazards to children.

In 2018, ASTM notified CPSC that it had issued a revised voluntary standard for portable hook-on chairs. In accordance with the procedures set out in section 104(b)(4)(B) of the CPSIA, this revised standard became the new mandatory standard for portable hook-on chairs (83 FR 48219, September 24, 2018). The mandatory standard currently incorporates by reference this standard (ASTM F1235–18).

On January 20, 2026, ASTM notified the Commission that it had approved and published another revised version of the voluntary standard, ASTM F1235–25. CPSC is assessing the revised voluntary standard to determine, consistent with section 104(b)(4)(B) of the CPSIA, its effect on the safety of portable hook-on chairs subject to 16 CFR part 1233. The Commission invites public comment to inform CPSC staff's assessment and subsequent Commission consideration of the revisions in ASTM F1235–25.

The currently incorporated voluntary standard (ASTM F1235–18) and the revised voluntary standard (ASTM F1235–25) are available for review in several ways. A read-only copy of the existing, incorporated standard (ASTM F1235–18) is available for viewing, at no cost, on the ASTM website at: *https://www.astm.org/READINGLIBRARY/.* A read-only copy of the revised standard (ASTM F1235–25), including red-lined versions that identify the changes from the 2018 to the 2025 version, is available, at no cost, on ASTM's website at *https://www.astm.org/CPSC.htm.* Interested parties can also download copies of the standards by purchasing them from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; phone: 610–832–9585; *https://www.astm.org.* Alternatively, interested parties can schedule an appointment to inspect copies of the standards at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, telephone: 301–504–7479.

Comments must be received by February 12, 2026. Because of the short statutory time frame Congress established for the Commission to consider revised voluntary standards under section 104(b)(4) of the CPSIA, CPSC will not consider comments received after this date.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2026–01776 Filed 1–28–26; 8:45 am]

BILLING CODE 6355–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2025–1443; FRL–13173–01–R4]

Determination of Attainment by the Attainment Date for the Louisville Moderate Area for the 2015 Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing action related to the attainment date for the Kentucky portion of the Louisville, Kentucky-Indiana area (hereinafter referred to as the ''Louisville, KY-IN Area'' or ''Area''). The Kentucky portion of this Area is classified as ''Moderate'' nonattainment for the 2015 ozone National Ambient Air Quality Standard (NAAQS), and the Indiana portion of this Area has been redesignated to attainment for this NAAQS. EPA is proposing to determine, with the consideration of exceptional events, that the Kentucky portion of the Louisville, KY-IN Area attained the standard by the applicable August 3, 2024, attainment date. This action, if finalized, will fulfill EPA's statutory obligation to determine whether the Kentucky portion of the Louisville, KY-IN Area attained the 2015 8-hour ozone NAAQS by the Moderate attainment date. As part of this rulemaking, EPA also proposes to take final agency action on the portion of an exceptional events request submitted by the Louisville Metro Air Pollution Control District (LMAPCD) on June 11, 2025, addressing six days in June 2023. EPA concurred on these six days on August 12, 2025. The proposed determination by the attainment date is based on EPA's partial concurrence on the exceptional events demonstration. This action is being taken under the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before March 2, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2025–1443 at *regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* 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. 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, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Weston Freund, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8773. Mr. Freund can also be reached via electronic mail at *freund.weston@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview and Basis of Proposal

A. Overview of the Proposed Action

Sections 179(c)(1) and 181(b)(2)(A) of the CAA require EPA to determine whether an ozone nonattainment area attained the ozone standard by the applicable attainment date. EPA is required to issue this determination within six months of the attainment date. EPA's determination of attainment by the attainment date for the 2015 ozone NAAQS is based on a

nonattainment area's design value (DV) [1] as of the attainment date. The 2015 ozone NAAQS is met at an EPA regulatory monitoring site when the DV does not exceed 0.070 parts per million (ppm).

For areas classified as Moderate nonattainment for the 2015 ozone NAAQS, the attainment date was August 3, 2024. Because the DV is based on the three most recent, complete calendar years of data, attainment must occur no later than December 31 of the year prior to the attainment date (*i.e.,* December 31, 2023, in the case of Moderate nonattainment areas for the 2015 ozone NAAQS). As such, EPA's proposed determination for the Kentucky portion of the Louisville, KY-IN Area is based upon the complete, quality-assured, and certified ozone monitoring data from calendar years 2021, 2022, and 2023.

On June 11, 2025, LMAPCD submitted a request to exclude data associated with exceptional event claims for ozone data influenced by Canadian wildfires for nine days in June through August 2023. EPA reviewed the request and determined it adequately demonstrated that long-range transport of smoke from the Canadian wildfires caused exceedances of the NAAQS measured at the Cannons Lane ambient monitor in Louisville for six days and determined that all of the criteria of the Exceptional Events Rule found in 40 CFR 50.14 and 51.930 for those six days were met. Therefore, on August 12, 2025, EPA sent a letter to LMAPCD concurring with their exceptional event claim for these six regulatorily significant days, all in June 2023, that resulted in the DV for the Louisville KY-IN Area being reduced from 0.072 ppm to 0.070 ppm.[2] [3] EPA proposes to find that the Kentucky portion of the Louisville, KY-IN Area attained by the attainment date based on the Area's 2021–2023 DV, which does not exceed 0.070 ppm. EPA also proposes to take final agency action on the portion of LMAPCD's exceptional events request addressing the six days in June 2023.

B. Background for Proposed Action

On October 26, 2015, EPA issued its final action to revise the NAAQS for ozone to establish new 8-hour standards. *See* 80 FR 65452 (October 26, 2015). In that action, EPA promulgated identical, tighter primary and secondary ozone standards designed to protect public health and welfare that specified an 8-hour ozone level of 0.070 ppm. Specifically, the standards require that the 3-year average of the annual fourth highest daily maximum 8-hour average ozone concentration not exceed 0.070 ppm.

Under EPA regulations at 40 CFR part 50, appendix U, the 2015 ozone NAAQS is attained at a site when the 3-year average of the annual fourth highest daily maximum 8-hour average ambient air quality ozone concentration (*i.e.,* DV) does not exceed 0.070 ppm. When the DV does not exceed 0.070 ppm at each ambient air quality monitoring site within the area, the area is deemed to be attaining the ozone NAAQS. The rounding convention in Appendix P dictates that concentrations shall be reported in ''ppm'' to the third decimal place, with additional digits to the right being truncated. Thus, a computed 3-year average ozone concentration of 0.071 ppm is greater than 0.070 ppm and would exceed the standard, but a DV of 0.0709 is truncated to 0.070 and attains the 2015 ozone NAAQS.

EPA's proposed determination of attainment by the attainment date is based on data that have been collected and quality-assured in accordance with 40 CFR part 58 and recorded in EPA's Air Quality System (AQS) database.[4] Ambient air quality monitoring data for the 3-year period preceding the attainment date (2021–2023 for the 2015 ozone NAAQS Moderate nonattainment areas) must meet the data completeness requirements in Appendix U.[5] The completeness requirements are met for the 3-year period at a monitoring site if daily maximum 8-hour average concentrations of ozone are available for at least 90 percent of the days within the ozone monitoring season, on average, for the 3-year period, and no single year has less than 75 percent data completeness. Additionally, any exceptional events requests that are concurred upon by EPA are reflected in the DVs found in AQS.

Effective on August 3, 2018, EPA designated 52 areas throughout the country, including the Louisville, KY-IN Area, as nonattainment for the 2015 ozone NAAQS. *See* 83 FR 25776 (June 4, 2018). The bi-state Louisville, KY-IN area was classified as a Marginal nonattainment area. *Id.* In a separate action, EPA assigned classification thresholds and attainment dates based on the severity of an area's ozone problem determined by the area's DV. *See* 83 FR 10376 (March 9, 2018). EPA established the attainment date for Marginal and Moderate nonattainment areas as three years and six years, respectively, from the effective date of the final designations. *Id.* Thus, the attainment date for Marginal nonattainment areas for the 2015 ozone NAAQS was August 3, 2021, and the attainment date for Moderate nonattainment areas was August 3, 2024.

The Louisville, KY-IN Area did not attain by the Marginal attainment date of August 3, 2021, and therefore, the Area was reclassified from Marginal to Moderate for the 2015 ozone NAAQS. *See* 87 FR 21842 (April 13, 2022). Indiana, through the Indiana Department of Environmental Management, submitted a request for redesignation to attainment for the Indiana portion of the Louisville, KY-IN area on February 21, 2022, and was redesignated to attainment on July 5, 2022. *See* 87 FR 39750 (July 5, 2022). The Kentucky portion of the Louisville, KY-IN area is still designated as nonattainment.[6] In this notice, EPA is proposing to determine that the Kentucky portion of the Louisville, KY-IN Area attained the 2015 ozone NAAQS by the Moderate attainment date of August 3, 2024. As noted above, the Indiana portion of this Area has already been redesignated to attainment for the 2015 Ozone NAAQS.

[1] A DV is a statistic used to compare data collected at an ambient air quality monitoring site to the applicable NAAQS to determine compliance with the standard. The data handling conventions for calculating DVs for the 2015 ozone NAAQS are specified in appendix U to 40 CFR part 50. The DV for the 2015 ozone NAAQS is the 3-year average of the annual fourth highest daily maximum 8-hour average ozone concentration. The DV is calculated for each air quality monitor in an area, and the DV for an area is the highest DV among the individual monitoring sites located in the area.

[2] See Section I.C. of this notice of proposed rulemaking for additional discussion regarding exceptional events.

[3] This DV is the overall DV for the Louisville, KY-IN Area. Specific DVs for individual air monitors are included in Table 1 of this notice of proposed rulemaking.

[4] EPA maintains AQS, a database that contains ambient air quality monitoring data collected by EPA, state, local, and tribal air pollution control agencies. AQS also contains meteorological data, descriptive information about each monitoring station (including its geographic location and its operator) and quality assurance/quality control information. AQS data is used to (1) assess air quality, (2) assist in attainment/non-attainment designations, (3) evaluate SIPs for non-attainment areas, (4) perform modeling for permit review analysis, and (5) prepare reports for Congress as mandated by the CAA. Access is through the website at *https://www.epa.gov/aqs.*

[5] *See* 40 CFR part 50, appendix U, section 4(b).

[6] After the Indiana portion of the Louisville, KY-IN Area was redesignated to attainment, Kentucky submitted a request to redesignate its portion of the Area to attainment. While Kentucky's redesignation request was pending, the Area violated the NAAQS. Thus, the Kentucky portion of the Louisville, KY-IN Area has not been redesignated to attainment, and EPA is taking a separate action on Kentucky's redesignation request. This proposed determination of attainment by the attainment date does not constitute a proposal to redesignate the Kentucky portion of the Area to attainment under CAA section 107(d)(3).

C. Exceptional Events Demonstration

Congress has recognized that it may not be appropriate for EPA to use certain monitoring data collected by the ambient air quality monitoring network and maintained in EPA's AQS database in certain regulatory determinations. Thus, in 2005, Congress provided the statutory authority for the exclusion of data influenced by ''exceptional events'' meeting specific criteria by adding section 319(b) of the CAA and granted EPA the authority to propose regulations to review and manage air quality monitoring data influenced by exceptional events.[7]

On March 22, 2007, EPA promulgated the 2007 Exceptional Events Rule to implement this 2005 CAA amendment. *See* 72 FR 13560. The 2007 Exceptional Events Rule created a regulatory process codified at 40 CFR 50.1, 50.14, and 51.930. These regulatory sections, which superseded EPA's previous guidance on handling data influenced by exceptional events, contain definitions, procedural requirements, requirements for air agency demonstrations, criteria for EPA's approval of the exclusion of the event-affected air quality data from the data set used for regulatory decisions, and requirements for air agencies to take appropriate and reasonable actions to protect public health from exceedances and violations of the NAAQS. On October 3, 2016, EPA promulgated a comprehensive revision to the 2007 Exceptional Events Rule. *See* 81 FR 68216. The 2016 Exceptional Events Rule revision included the requirement that, if a State demonstrates to the Administrator's satisfaction that emissions from a wildfire smoke event cause a specific air pollution concentration in excess of the NAAQS at a particular air quality monitoring location and otherwise satisfies the requirements of 40 CFR 50.14, EPA must exclude that data from use in determinations of exceedances and violations.[8]

The CAA provides for the exclusion of air quality monitoring data from DV calculations when there are NAAQS exceedances caused by events, such as wildfires, that meet the criteria for an exceptional event identified in EPA's Exceptional Events Rule at 40 CFR 50.1, 50.14, and 51.930. For the purposes of this proposed action, on June 11, 2025, LMAPCD submitted an exceptional events demonstration to show that the maximum daily 8-hour average ozone concentration recorded at the Cannons Lane monitor (AQS Site ID #21–111–0067) was influenced by Canadian wildfires in June through August 2023. EPA concurred on six regulatory significant days in the demonstration on August 12, 2025.

EPA found that six days in LMAPCD's demonstration met the Exceptional Events Rule criteria and had regulatory significance for purposes of calculating the Area's 2021–2023 recent design value to make a determination of attainment by the attainment date for the 2015 ozone NAAQS. As such, EPA proposes to take final regulatory action on the concurred dates, as exceptional events to be removed from the dataset used for regulatory purposes. The rationale of EPA's exceptional events proposal is detailed in the docket. For this proposed action, EPA will rely on the calculated design values that exclude the exceptional event influenced data for the purpose of demonstrating attainment of the 2015 ozone NAAQS by the attainment date. Further details on LMAPCD's analyses and EPA's concurrence, including the exceptional events initial notification, exceptional events demonstration, and EPA's response to the initial notification, can be found in the docket for this proposed action.

While EPA has concurred with six exceptional events days in LMAPCD's request to exclude event-influenced air quality monitoring data from regulatory decisions, those regulatory actions require EPA to provide an opportunity for public comment on these six exceptional event days and all supporting data prior to EPA taking final agency action. This proposed action provides the public with an opportunity to comment on the six exceptional event days, all supporting documents, and EPA's partial concurrence with LMAPCD's request.

II. EPA's Proposal and Its Rationale

EPA is proposing this action to fulfill its statutory obligation under CAA sections 179(c)(1) and 181(b)(2) to determine whether the Kentucky portion of the Louisville, KY-IN Area attained the 2015 ozone NAAQS by the attainment date of August 3, 2024. EPA evaluated air quality monitoring data submitted by the appropriate state and local air agencies to determine the attainment status as of the applicable Moderate nonattainment area attainment date.

EPA is proposing to determine, in accordance with CAA sections 179(c)(1) and 181(b)(2)(A) and the provisions of the 2015 Ozone NAAQS SIP Requirements Rule, that the Kentucky portion of the Louisville, KY-IN Area attained the 2015 ozone NAAQS by the Moderate nonattainment area attainment date of August 3, 2024, based on the Area's 2021–2023 DV of 0.070 ppm.

TABLE 1—2021–2023 OZONE DESIGN VALUES FOR AIR MONITORING SITES IN THE LOUISVILLE, KY-IN AREA

AQS site ID	County, state	Local site name	2021–2023 design value (ppm)
18–019–0008	Clark, IN	Charlestown State Park	0.066
18–043–0008	Floyd, IN	New Albany	0.066
21–029–0006	Bullitt, KY	Shepherdsville	0.067
21–111–0051	Jefferson, KY	Watson Lane	0.068
21–111–0067	Jefferson, KY	Cannons Lane	[9] 0.070
21–111–0080	Jefferson, KY	Carrithers Middle School	0.070
21–111–1041	Jefferson, KY	Algonquin Parkway	[10] ND

[7] Under CAA section 319(b), an exceptional event means an event that: (i) affects air quality; (ii) is not reasonably controllable or preventable; (iii) is an event caused by human activity that is unlikely to recur at a particular location or a natural event; and (iv) is determined by EPA under the process established in regulations promulgated by EPA in accordance with section 319(b)(2) to be an exceptional event. For the purposes of section 319(b), an exceptional event does not include: (i) stagnation of air masses or meteorological inversions; (ii) a meteorological event involving high temperatures or lack of precipitation; or (iii) air pollution relating to source noncompliance.

[8] *See* 40 CFR 50.14(b)(4).

[9] As discussed above, EPA partially concurred on LMAPCD's request to exclude exceptional event influenced data for this monitor, which resulted in the 2021–2023 DV being reduced from 0.072 ppm to 0.070 ppm. A copy of EPA's concurrence letter and the associated Technical Support Document are available in the docket for this proposed action.

[10] The Algonquin Parkway monitoring site (AQS ID: 21–111–1041) does not have a valid 2021–2023 ozone design value because ozone monitoring at the site started in March 2023.

TABLE 1—2021–2023 OZONE DESIGN VALUES FOR AIR MONITORING SITES IN THE LOUISVILLE, KY-IN AREA—Continued

AQS site ID	County, state	Local site name	2021–2023 design value (ppm)
21–185–0004	Oldham, KY	Buckner	0.065

III. Proposed Action

EPA is proposing to determine that the Kentucky portion of the Louisville, KY-IN Area attained the 2015 ozone NAAQS by the Moderate attainment date. This proposed determination is based on complete, quality-assured, quality-controlled, and certified ambient air monitoring data for the 2021–2023 monitoring period, including EPA's concurrence on six exceptional events days in LMAPCD's June 11, 2025, exceptional events request. If finalized, this action will address EPA's obligation under CAA sections 179(c) and 181(b)(2) to determine whether the Kentucky portion of the Louisville, KY-IN Area attained the 2015 ozone NAAQS by the August 3, 2024, attainment date.

If EPA finalizes this proposed determination, the Kentucky portion of the Louisville, KY-IN Area will remain designated as nonattainment and will retain its current classification. A determination of attainment by the attainment date does not have the effect of redesignating a nonattainment area to attainment under CAA section 107(d)(3). Redesignation of a nonattainment area to attainment requires, among other things, that all applicable requirements of CAA section 110 and Part D have been met, EPA has approved a maintenance plan to ensure continued attainment of the standard for 10 years following redesignation as provided under CAA section 175A, and EPA has approved a redesignation request.[11]

EPA also proposes to take final agency action on the portion of LMAPCD's exceptional events request submitted by LMAPCD on June 11, 2025, addressing the six days in June 2023 concurred on by EPA on August 12, 2025.

EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This proposed action is not expected to be an Executive Order 14192 action because this proposed action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This proposed action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

I certify that this proposed action will not have a significant economic impact on a substantial number of small entities under the RFA. This proposed action will not impose any requirements on small entities. The proposed determinations of attainment do not in and of themselves create any new requirements beyond what is mandated by the CAA. Instead, this rulemaking only makes factual determinations and does not directly regulate any entities.

E. Unfunded Mandates Reform Act (UMRA)

This proposed action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–38, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This proposed action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Government

This proposed action does not have tribal implications, as specified in Executive Order 13175, because this proposed action is not approved to apply in any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction, and will not impose direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this proposed action.

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

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. Therefore, this proposed action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. Furthermore, EPA's Policy on Children's Health does not apply to this proposed action.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This proposed action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This proposed action does not involve technical standards.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

[11] As noted above in footnote 6, Kentucky submitted a request under CAA section 107(d)(3) to redesignate its portion of the Louisville, KY-IN Area to attainment and that request is being addressed in a separate action.

Dated: January 20, 2026.

Kevin McOmber,

Regional Administrator, Region 4.

[FR Doc. 2026–01733 Filed 1–28–26; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 482

[CMS–1516–ANPRM]

RIN 0938–AV72

Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This advance notice of proposed rulemaking solicits public comment on potential options we may consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made personal protective equipment and essential medicines to secure our nation's health and safety and to reflect the additional resource costs incurred when procuring these domestically manufactured items. We seek input on a possible new ''Secure American Medical Supplies'' friendly designation that could be earned by hospitals that demonstrate their commitment to domestic procurement. In addition, we seek input on potential ways such a designation could facilitate the creation of new, streamlined payment policies to support hospitals in their efforts. We are also seeking input on a potential new structural quality measure as part of the Hospital Inpatient Quality Reporting (IQR) Program that could promote hospital commitments to invest in domestic procurement to secure our nation's health and safety.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than March 30, 2026.

ADDRESSES: In commenting, please refer to file code CMS–1516–ANPRM.

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 *https://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–1516–ANPRM, P.O. Box 8010, Baltimore, MD 21244–1850.

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–1516–ANPRM, 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:

Ted Oja, (410) 786–4487 or *DAC@cms.hhs.gov.*

Made in America Office, *MadeInAmerica@omb.eop.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: *https://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 commenter will take actions to harm an 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.

I. Background

Sufficient domestic availability of personal protective equipment (PPE) and essential medicines in the health care sector is a critical component of emergency public health preparedness. In spring of 2020, supply chains for PPE faced severe disruptions due to lockdowns that limited production and unprecedented demand spikes across multiple industries. Supply of National Institute for Occupational Safety and Health (NIOSH)-approved® surgical N95® respirators — a specific type of filtering facepiece respirator (FFR) that is a subset of N95 respirators used in some clinical settings under conditions requiring respiratory protection from airborne pathogens and splash protection from exposure to fluids — was one type of PPE that experienced significant supply chain disruptions. So-called ''just-in-time'' supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough PPE to protect health care workers. Similarly, shortages for critical medical products have persisted, with a recent report authored by the Senate Committee on Homeland Security and Government Affairs noting that the average drug shortage lasts about 1.5 years.[1] For pharmaceuticals, nearly two-thirds of hospitals reported more than 20 drug shortages at any one time—from antibiotics used to treat severe bacterial infections to crash cart drugs necessary to stabilize and resuscitate critically ill adults.[2] Shortages of both essential medicines and reliable PPE jeopardize patient safety and health care quality.

In recent years, we have solicited comment and, based on feedback from interested parties, implemented payment adjustments to Medicare participating hospitals to reflect the additional costs of procuring domestically made surgical N95 FFRs and creating buffer stocks of certain essential medicines. In the Calendar Year (CY) 2023 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period (87 FR 72037 through 72047), we implemented payment adjustments under the OPPS and Inpatient Prospective Payment System (IPPS) to support a resilient and reliable domestic supply of NIOSH-approved surgical N95 respirators.. This payment adjustment is based on the IPPS and OPPS shares of the difference in cost between domestic and non-domestic NIOSH-approved surgical N95 FFRs and is available where those costs are separately tracked, reported and

[1] Senate Committee on Homeland Security & Governmental Affairs, Short Supply: The Health and National Security Risks of Drug Shortages, March 2023: *https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.*

[2] Vizient, Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals, June 2019: *https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129.*