

substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

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

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address “disproportionately high and adverse human health or environmental effects” of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.” EPA further defines the term fair treatment to mean that “no group of people should bear a disproportionate burden of

environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.”

Under the CAA, 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 review state choices, and approve those choices if they meet the minimum criteria of the Act. Accordingly, this final action is finalizing a limited approval and limited disapproval of state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law.

The State did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 4, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements.

Dated: May 26, 2023.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends Part 52, chapter I, title 40 of the Code of Federal Regulations 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 F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(202)(i)(B)(3) and (c)(520)(i)(B)(2) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(202) * * *

(i) * * *

(B) * * *

(3) Previously approved on July 20, 1999, in paragraph (c)(202)(i)(B)(1) of this section and now deleted with replacement in (c)(520)(i)(B)(2): Rule 425.3, adopted on October 13, 1994.

* * * * *

(520) * * *

(i) * * *

(B) * * *

(2) Rule 425.3, “Portland Cement Kilns (Oxides of Nitrogen),” amended on March 8, 2018.

* * * * *

[FR Doc. 2023–11850 Filed 6–2–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2022–0321, FRL–10144–02–R2]

Approval and Promulgation of Implementation Plans; New York; Particulate Matter Control Strategy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the New York State Implementation Plan (SIP) for the purposes of implementing controls of air pollution by particulate matter (PM). The SIP revision consists of amendments to existing regulations outlined within

New York's Codes, Rules, and Regulations (NYCRR) that impose control measures for sources of PM. This action is being taken in accordance with the requirements of the Clean Air Act.

DATES: This final rule is effective July 5, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA-R02-OAR-2022-0321. All documents in the docket are listed on the <http://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 electronically through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Fausto Taveras, Environmental Protection Agency, Region 2, Air Programs Branch, 290 Broadway, New York, New York 10007-1866, at (212) 637-3378, or by email at Taveras.Fausto@epa.gov.

SUPPLEMENTARY INFORMATION: The **SUPPLEMENTARY INFORMATION** section is arranged as follows:

- I. What is the background for these actions?
- II. What comments were received in response to the EPA's proposed action?
- III. What action is the EPA taking?
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. What is the background for these actions?

On September 20, 2022, the EPA published a Notice of Proposed Rulemaking that proposed to approve revisions to the New York SIP submitted by the State of New York on March 26, 2021. *See* 87 FR 57429. This SIP revision includes revisions to an existing regulation, Title 6 of the New York Codes, Rules, and Regulations (NYCRR) Subpart 227-1, "Stationary Combustion Installations," with a State effective date of February 25, 2021. These revisions are applicable statewide and establish PM emission standards for existing and new stationary combustion installations.¹

New York's revisions to Subpart 227-1 include additional control strategies that will reduce PM emissions from

major sources throughout the State. The EPA is approving New York's SIP submittal which applies to major sources of PM, as a SIP-strengthening measure for New York's SIP.

The specific details of New York's SIP submittals and rationale for the EPA's proposed approval are explained in the EPA's proposed rulemaking and are not restated in this final action. For this detailed information, the reader is referred to the EPA's September 20, 2022, proposed rulemaking. *See* 87 FR 57429.

II. What comments were received in response to the EPA's proposed action?

In response to EPA's September 20, 2022, proposed rulemaking on New York's SIP revisions, the EPA received four comments during the 30-day public comment period. The specific comments may be viewed under Docket ID Number EPA-R02-OAR-2022-0321 on the <https://regulations.gov> website. The first two comments, received on October 17, 2022, and October 19, 2022, were supportive of EPA's proposed action to approve New York's revisions of NYCRR Subpart 227-1, "Stationary Combustion Installations," into New York's SIP. A summary of the remaining two comments and the EPA's response are provided in this section.

Comment 3: The third comment, received on October 20, 2022, was submitted by an anonymous commenter from the University of Washington School of Law. The commenter voices support by stating that ". . . the EPA proposal to approve revisions to the New York State Implementation Plan (SIP) is tailored enough in this situation . . . under the SIP, we see a careful and deliberate plan of limiting PM emissions for oil and solid fuel fired stationary combustion installations." The commenter also provides suggestions to New York's SIP, like including a list of all the stationary combustion installations that will be applicable to this regulation. The commenter is also supportive of EPA's proposal to incorporate by reference the revisions made to 6 NYCRR Subpart 227-1 into New York's SIP by stating that ". . . materials like Stationary Combustion Installations available online and through [regulations.gov](http://www.regulations.gov) website will continue to ensure that these proposed rules will be seen by the public." The commenter also mentions that it is important for EPA in future actions to note whether a rule that is finalized will not have a direct cost on tribal governments or preempt tribal law.

Response 3: The EPA acknowledges the commenter's support of the EPA's proposed rule. To address the

commenter's suggestion to have New York's SIP include a list of all stationary combustion installations applicable, the EPA reviewed NYSDEC's SIP revision to examine if similar comments were addressed during the Department's assessment of public comments received on the proposal of Subpart 227-1. During the assessment period, representatives from private businesses also submitted a comment requesting NYSDEC to provide an estimate of the number of sites the revised regulation would likely impact. NYSDEC responded to the comment by stating that the Department has issued permits or registrations to 51 facilities throughout New York State that employ 76 wood fired emission sources. New York also states that these sources range in size from 1.4 mmBTU/HR heat input to 855 mmBTU/HR heat input; they burn wood chips, hogged wood fuel, and wood pellets. The Department also provides the following breakdown in their response: (1) 5 facilities with 8 emission sources were issued Title V permits, (2) 15 facilities with 31 emission sources were issued State Facility permits, and (3) 31 facilities with 37 emission sources were issued registrations. NYSDEC affirms that the Regulatory Impact Statement (RIS) and the Regulatory Flexibility Analysis for Small Business and Local Governments (RFASBLG) will also include these emission source data. Also, NYSDEC is not able to accurately predict the number of future installations that may be impacted by this regulation until that facility applies for a permit or registration from the Department. Therefore, containing a list of applicable sources under Subpart 227-1 may not be accurate over time once facilities retire these emission sources or apply for new permits. The EPA plans to ensure that the incorporation by reference materials for New York's SIP revision of 6 NYCRR Subpart 227-1, "Stationary Combustion Installations," will be available through <http://www.regulations.gov> and physically at the EPA Region 2 Office.

Comment 4: The fourth public comment, received on October 19, 2022, was submitted by a New Jersey resident and Rutgers University Human Ecology undergraduate. The commenter acknowledges the prospective benefits from the EPA's intervention in New York's SIP. However, the commenter voices concern over Sections 227-1.3 and Section 227-1.4 of New York's revision to 6 NYCRR Subpart 227-1. Regarding Section 227-1.3, the commenter mentions that ". . . there should be more maintenance

¹ The attendant revisions to 6 NYCRR Part 200, "General Provisions," section 200.9, "Referenced material," Table 1, for 6 NYCRR Subpart 227-1 has been addressed under a separate rulemaking at 87 FR 52337, effective September 26, 2022.

requirements besides providing an annual tune-up of equipment. Bi-annual or quarterly checks would be a stronger form of preventative maintenance that could lead to less repair costs from continuous use of stationary combustion installation.” Thus, the commenter requests that EPA considers issuing a Federal Implementation Plan (FIP) to “. . . execute more stringent regulations concerning monitoring practices in applicable sites.”

Regarding Section 227–1.4, the commenter mentions that “. . . even with the inclusion of Continuous Opacity Monitoring Systems (COMS), 27% opacity limit for 6 minutes per hour is not a feasible attainment plan when considering the proximity of non-attainment industries that contribute to PM emissions in New York . . . the compounding impacts of multiple industries operating at this increased level can have substantial effects on primary and secondary standards over time.” The commenter also mentions that EPA should consider researching what the additional reductions in emission there would be if there were no 27% opacity limits for a 6-minute period every hour.

Response 4: In this action, EPA is approving New York’s SIP submission that revises existing provisions in rules the State’s statewide SIP as a SIP-strengthening measure. In this action, EPA is not determining whether these provisions satisfy specific nonattainment planning obligations under the CAA for purposes of the PM_{2.5} NAAQS. Rather, EPA is approving these New York regulations into the SIP pursuant to CAA section 110(k)(3), which states that EPA “shall approve [a SIP] submittal as a whole if it meets all the applicable requirements of this chapter.” Because this SIP revision relates to emission controls for criteria pollutants and strengthens the preexisting requirements in the New York SIP, EPA has determined it is appropriate to approve the SIP revision.

The EPA does not agree with the commenter that more maintenance requirements besides providing an annual tune-up of equipment are necessary. In its own response to comments, NYSDEC noted that the manufacturer specifications outline that boilers require an annual inspection and periodic maintenance, regardless of how frequently those boilers are monitored. The Department concluded that the annual tune-up requirement will satisfy the manufacturer’s recommended annual inspection and maintenance procedures and ensure that those procedures are followed and performed by the owner or operators of these

impacted units. Therefore, the EPA finds no basis to disapprove New York’s SIP submittal solely on grounds that boilers should have more maintenance requirements besides annual tune-up of equipment.

The EPA also reviewed NYSDEC’s SIP revision of 6 NYCRR Subpart 227–1, “Stationary Combustion Installations,” to examine if similar comments regarding the commenter’s opacity concerns arose during the Department’s assessment of public comments. Following that review, the EPA identified that no other comments were submitted that urged the Department to incorporate more stringent opacity limits than those adopted within the revision. Within New York’s SIP submittal, the Department indicated that the purpose of this SIP revision is to impose stringent particulate matter emission limits on existing and new stationary combustion installations that either predate, or are not subject to, a federal New Source Performance Standard (NSPS) and/or National Emission Standards for Hazardous Air Pollutants (NESHAP). Essentially, the purpose of this revision to Subpart 227–1 is to impose particulate matter and opacity standards on a larger universe of stationary combustion installations that are not currently subject to any federal NSPS or NESHAP. To address the commenter’s concern regarding the opacity limits adopted in this rule, the EPA reviewed the opacity requirements listed within various NSPS and NESHAPs that also applied to stationary combustion installation sources applicable to New York’s rule. The EPA reviewed these federal opacity standards and compared them with the opacity limits outlined within Subpart 227–1 to determine if the opacity requirements included in this SIP would meet or exceed those already enforced on a federal standard.

In EPA’s review, existing federal NSPS impose similar opacity requirements for Electric Utility Steam Generating Units and for Industrial-Commercial-Institutional Steam Generating Units.² New York’s revised Subpart 227–1 contains a lower applicability threshold and thus imposes the opacity and PM standards on a larger universe of sources. The lower applicability threshold will

² Owners or operators of affected units subject to either 40 CFR part 60 subpart Da and Db shall not cause to be discharged into the atmosphere any gases which exhibit greater than 20 percent opacity (6-minute average), except for one 6-minute period per hour of not more than 27 percent opacity. See <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-60/subpart-Da> and <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-60/subpart-Db>.

impose the PM limits on more stationary combustion installations than previous versions of the regulation. The EPA is approving New York’s revisions to Subpart 227–1 as a SIP-strengthening measure, since this revision extends the applicability of these opacity and PM standards to more existing and new stationary combustion installations than previous iterations of the rule. On May 22, 2001, the EPA finalized approval of additional administrative changes that New York made to Subpart 227–1. In this action, the EPA incorporated by reference those administrative changes, which included similar opacity limits as for the purpose of enforcing New York’s SIP. See 66 FR 28059.

Since 1972, New York has developed and submitted SIP provisions that have allowed the New York-N. New Jersey-Long Island, NY-NJ-CT area to demonstrate attainment of the primary and secondary PM_{2.5} National Ambient Air Quality Standards (NAAQS). See 80 FR 2206. New York’s revision to Subpart 227–1 will continue to ensure that stringent PM emission limits and monitoring requirements apply to owners or operators of stationary combustion installations to further reduce emissions of the precursors of PM_{2.5}, to help New York State continue to maintain the current 24-hour and Annual PM_{2.5} NAAQS.

This concludes our response to the comments received. No changes have been made to the proposed rule as a result of the comments received.

III. What action is the EPA taking?

The EPA is approving New York’s SIP revision submission, dated March 26, 2021, making revisions 6 NYCRR Subpart 227–1, “Stationary Combustion Installations,” as SIP-strengthening. This approval of the revisions will extend the requirements of 6 NYCRR Subpart 227–1 to a broader universe of sources by changing the applicability criteria of the existing SIP emission limits. EPA has already addressed related revisions New York made to 6 NYCRR Part 200, “General Provisions,” section 200.9, “Referenced material,” Table 1, for 6 NYCRR Subpart 227–1 in a separate rulemaking (see 87 FR 52337, effective September 26, 2022). These revisions include changes to the applicability threshold and PM emission limits that will reduce PM_{2.5} emissions statewide and provide support for New York State to continue to maintain the current 24-hour and Annual PM_{2.5} NAAQS. The EPA finds that this submission strengthens New York’s existing SIP.

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of 6 NYCRR Subpart 227–1, “Stationary Combustion Installations”, the regulation described in the amendments to 40 CFR part 52 as discussed in Section I. and III. of this preamble. The EPA has made and will continue to make these materials generally available through <http://regulations.gov> and at the EPA Region 2 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in New York’s SIP, have been incorporated by reference by EPA into that SIP, and are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA’s approval, and will be incorporated by reference in the next update to the SIP compilation.³

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. See 42 U.S.C. 7410(k); see also 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA’s role is to approve state choices, provided they meet the criteria of the CAA. Accordingly, this 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 final action:

- Is not a “significant regulatory action” subject to review by the Office of Management and Budget under Executive Order 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 this action does not involve technical standards.

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 any substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address “disproportionately high and adverse human health or environmental effects” of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.” EPA further defines the term fair treatment to mean that “no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences.”

The NYSDEC did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for

people of color, low-income populations, and Indigenous peoples.

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. 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 August 4, 2023. 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, Incorporation by Reference, Particulate matter, Reporting and recordkeeping requirements.

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

Lisa Garcia,
Regional Administrator, Region 2.

For the reasons set forth in the preamble, 40 CFR part 52 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 HH—New York

- 2. In § 52.1670 the table in paragraph (c) is amended by revising the entry “Title 6, Part 227, Subpart 227–1” to read as follows:

³ 62 FR 27968 (May 22, 1997).

§ 52.1670 Identification of plan.

(c) * * *

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EPA-APPROVED NEW YORK STATE REGULATIONS AND LAWS

State citation	Title/subject	State effective date	EPA approval date	Comments
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Title 6, Part 227, Subpart 227-1	Stationary Combustion Installations.	2/25/2021	6/5/2023	• EPA approved finalized at [insert Federal Register citation].
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

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[FR Doc. 2023-11684 Filed 6-2-23; 8:45 am]
BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, and 494

[CMS-3415-F, CMS-3414-F, CMS-3401-F]

RIN 0938-AU75, 0938-AU57, 0938-AU33

Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements

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

ACTION: Final rule.

SUMMARY: This final rule removes expired language addressing staff and patient COVID-19 testing requirements for LTC Facilities issued in the interim final rule with comment “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” published in the September 2, 2020 **Federal Register**. The rule also finalizes requirements for these facilities to provide education about COVID-19 vaccines and to offer

COVID-19 vaccines to residents, clients, and staff. In addition, the rule withdraws the regulations in the interim final rule with comment (IFC) “Omnibus COVID-19 Health Care Staff Vaccination” published in the November 5, 2021 **Federal Register**, and finalizes certain provisions of the “COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff” IFC, published in the May 13, 2021 **Federal Register**.

DATES: The regulations in this final rule are effective on August 4, 2023.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: CMS Office of Communications, Department of Health and Human Services, *press@cms.hhs.gov*.

For technical inquiries: CMS Center for Clinical Standards and Quality, Department of Health and Human Services, (410)786-6633.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the “coronavirus disease 2019” (COVID-19) outbreak caused by “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2) a “Public Health Emergency of International Concern.” On January 31, 2020, pursuant to section 319 of the Public Health Service Act (PHSA) (42 U.S.C. 247d), the Secretary of the Department of Health and Human Services (Secretary) determined that a public health emergency (PHE) exists for the United States. On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. The President of the United States declared the COVID-19 pandemic a national emergency on March 13, 2020. Pursuant to section 319 of the

PHSA, the determination that a PHE continues to exist may be renewed at the end of each 90-day period.¹ The initial determination that a PHE for COVID-19 exists and had existed since January 27, 2020, lasted for 90 days, and was renewed by the Secretary on April 21, 2020; July 23, 2020; October 2, 2020; January 7, 2021; April 15, 2021; July 19, 2021; October 15, 2021; January 14, 2022; April 12, 2022; July 15, 2022; October 13, 2022; January 11, 2023; and February 9, 2023.² The COVID-19 PHE expired on May 11, 2023.

COVID-19 has had significant negative health effects on individuals, communities, and the nation as a whole. Over a year ago, in September 2021, COVID-19 overtook the 1918 influenza pandemic as the deadliest disease in American history.³ According to the Centers for Disease Control and Prevention (CDC), just over 6 million patients admitted to hospitals in the United States have been confirmed positive with COVID-19 infection since August 1, 2020, and approximately 1.1 million COVID-19 deaths have been reported in the United States as of April 14, 2023. In light of our responsibility to protect the health and safety of individuals receiving care and services from Medicare- and Medicaid-certified providers and suppliers, and CMS’ statutory authority, as outlined in section I.E. of this final rule, to establish health and safety regulations, we have been compelled to act throughout the COVID-19 pandemic. While a comprehensive discussion of CMS’ regulatory responses during the PHE is outside the scope and purpose of this final rule, we note that CMS issued several interim final rules with comment periods (IFCs) during the COVID-19 PHE to help minimize the

¹ <https://aspr.hhs.gov/legal/PHE/Pages/Public-Health-Emergency-Declaration.aspx>.

² <https://aspr.hhs.gov/legal/PHE/Pages/default.aspx>.

³ <https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/>.