

into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM or other Official Patrol, defined as a federal, state, or local law enforcement agency on scene to assist the Coast Guard in enforcing the regulated area. Additionally, each person who receives notice of a lawful order or direction issued by the PATCOM or Official Patrol shall obey the order or direction. The PATCOM or Official Patrol may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: December 13, 2021.

**Taylor Q. Lam,**

*Captain, U.S. Coast Guard, Captain of the Port, San Francisco.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 141

[EPA-HQ-OW-2021-0255; FRL-5423.1-04-OW]

RIN 2040-AG15

### Review of the National Primary Drinking Water Regulation: Lead and Copper Rule Revisions (LCRR)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notification of conclusion of review.

**SUMMARY:** On June 16, 2021, the U.S. Environmental Protection Agency (EPA) published the agency's decision to delay the effective and compliance dates of the National Primary Drinking Water Regulations: Lead and Copper Rule Revisions (LCRR), published on January 15, 2021, to allow time for EPA to review the rule in accordance with Presidential directives issued on January 20, 2021, to the heads of Federal agencies to review certain regulations, and conduct important consultations with affected parties. EPA has completed its review. The agency's review included a series of virtual public engagements to hear directly from a diverse set of stakeholders. This document describes the comments conveyed by stakeholders, EPA's decision to proceed with a proposed

rule that would revise certain key sections of the LCRR while allowing the rule to take effect, and other non-regulatory actions that EPA and other Federal agencies can take to reduce exposure to lead in drinking water.

**DATES:** The effective date of the LCRR published on June 16, 2021, in the **Federal Register** (86 FR 31939), continues to be December 16, 2021, and the compliance date continues to be October 16, 2024. Primacy revision applications are due on December 18 2023. See **SUPPLEMENTARY INFORMATION** for further information.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2021-0255. 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 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:** Jeffrey Kempic, Standards and Risk Management Division, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Mail Code 4607M, Washington, DC 20460; telephone number: (202) 564-4880 (TTY 800-877-8339); email address: [kempic.jeffrey@epa.gov](mailto:kempic.jeffrey@epa.gov). For more information visit <https://www.epa.gov/dwreginfo/lead-and-copper-rule>.

#### SUPPLEMENTARY INFORMATION:

#### Executive Summary

EPA's lead drinking water rules are a critical part of reducing the lead exposure for consumers of tap water in the United States. Lead poses serious health risks to both children and adults. Because lead in drinking water primarily results from leaching of lead from plumbing in homes and from lead service lines (lead pipes connecting homes to the water distribution system), and portions of lead service lines may be owned by the water system or homeowner, the drinking water rules intended to reduce the amount of lead in tap water have been complex and controversial. The latest version of those rules, the Lead and Copper Rule Revisions (LCRR), published in January 2021, is no exception.

In compliance with the Biden Administration executive order to review rules issued in the past

Administration, EPA undertook an extensive review of the LCRR and delayed the effective and compliance dates in the rule during the review period. To get comprehensive input, EPA talked with states, tribes, water utilities, as well as people who have been underrepresented in past rule-making efforts. EPA sought input from communities disproportionately impacted by lead in drinking water, especially lower-income people and communities of color, to learn from their experiences. The broad range of thoughtful input EPA received provided valuable insights on ways to improve the LCRR, and more generally, other available tools to address lead in drinking water.

Based upon EPA's evaluation and stakeholder feedback, the agency has concluded that EPA actions to protect the public from lead in drinking water should consider the following policy objectives: Replacing 100 percent of lead service lines (LSLs) is an urgently needed action to protect all Americans from the most significant source of lead in drinking water systems; equitably improving public health protection for those who cannot afford to replace the customer-owned portions of their LSLs; improving the methods to identify and trigger action in communities that are most at risk of elevated drinking water lead levels; and exploring ways to reduce the complexity of the regulations.

To achieve these policy objectives, EPA intends to take the following regulatory and non-regulatory actions: First, EPA intends to propose for public comment a new rule to revise the LCRR to advance the goals described above while balancing stakeholder interests and incorporating required economic, environmental justice, and other analyses. A regulatory framework that addresses these considerations, combined with the other actions described in this document, has the potential to permanently eliminate the most significant source of lead contamination, better target other actions to reduce lead exposure where the highest risks are presented, and provide equitable protections to all Americans. At the same time, because the LCRR provides additional protections relative to the pre-existing rule and contains components (such as the LSL inventory) that supports any future rule, EPA is not further extending the effective date of the LCRR. Therefore, as explained herein, compliance with certain key provisions of the LCRR will not be delayed while the rulemaking is underway.

Because regulatory actions alone may not be adequate to achieve these policy objectives, this document also discusses important non-regulatory actions EPA intends to take, including programs to provide technical assistance and infrastructure funding.

## I. Why EPA Reviewed the LCRR

### *Executive Order 13390 on Protecting Public Health*

On January 15, 2021, EPA published the “National Primary Drinking Water Regulation: Lead and Copper Rule Revisions” in the **Federal Register** (86 FR 4198) (LCRR). On January 20, 2021, President Biden issued the “Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.” (86 FR 7037, January 25, 2021) (Executive Order 13990). Section 1 of Executive Order 13990 states that it is “the policy of the Administration to listen to the science, to improve public health and protect our environment, to ensure access to clean air and water . . . and to prioritize both environmental justice and the creation of the well-paying union jobs necessary to deliver on these goals.” Executive Order 13990 directs the heads of all Federal agencies to immediately review regulations that may be inconsistent with, or present obstacles to, the policy it establishes. On June 16, 2021, EPA published the National Primary Drinking Water Regulations: Lead and Copper Rule Revisions; Delay of Effective and Compliance Dates (86 FR 31939), which delayed the LCRR effective date until December 16, 2021, and the compliance date until October 16, 2024. During EPA’s review, while the LCRR was delayed, EPA engaged with stakeholders to better understand their thoughts and concerns about the LCRR.

### *Stakeholder Concerns*

EPA heard significant concerns from many drinking water stakeholders about the LCRR. These concerns included whether the rule will adequately protect public health, the confusion it might create about drinking water safety, and the implementation burden that will be placed on systems and states. Stakeholders also expressed concerns that EPA did not provide adequate opportunities for a public hearing in the development of the LCRR that was published on January 15, 2021 (86 FR 4198), and did not provide a complete or reliable evaluation of the costs and benefits of the proposed LCRR. The delay in the effective date of the LCRR enabled the Agency to engage meaningfully with the public regarding

this important public health regulation before it took effect.

### *Lead Exposure Health Risks*

Lead exposure is a critical public health issue. Its adverse effects on children and the general population are serious and well known. Lead has acute and chronic impacts on the body. Lead exposure causes damage to the brain and kidneys and may interfere with the production of red blood cells that carry oxygen to all parts of the body.<sup>1</sup> The most susceptible life-stages are the developing fetus, infants, and young children. The Centers for Disease Control and Prevention (CDC) states that “no safe blood lead level in children has been identified.”<sup>2</sup> Because they are growing, children’s bodies absorb more lead than adults do, and their brains and nervous systems are more sensitive to its damaging effects. As a result, even low-level lead exposure is of particular concern to children.

The association between lead and adverse cardiovascular effects, renal effects, reproductive effects, immunological effects, neurological effects, and cancer has been documented in the EPA 2013 Integrated Science Assessment for Lead,<sup>3</sup> the U.S. Department of Health and Human Services (HHS) National Toxicology Program (NTP) Monograph on Health Effects of Low-Level Lead,<sup>4</sup> and the Agency for Toxic Substances and Disease Registry (ATSDR) 2020 Toxicological Profile for Lead.<sup>5</sup> EPA’s Integrated Risk Information System (IRIS) Chemical Assessment Summary provides additional health effects information on lead.

### *Disproportionate Exposure to Lead*

The environmental justice analysis for the final LCRR found that minority and low-income populations appear to be disproportionately exposed to the risks of lead in drinking water delivered by community water systems.<sup>6</sup> LSLs are typically the primary source of lead in drinking water,<sup>7</sup> meaning their presence

is likely a driver of this disproportionate exposure given that these populations tend to live in older housing where LSLs are more likely to have been installed. Because of disparities in the quality of housing, community economic status, and access to medical care, lower-income people are also disproportionately affected by lead from other media. For example, children of color and children in low-income communities are more likely to live in proximity to lead-emitting industries and to live in urban areas, which are more likely to have contaminated soils, contributing to their overall exposure (Leech et al., 2016<sup>8</sup>). Additionally, non-Hispanic black people are more than twice as likely as non-Hispanic whites to live in moderately or severely substandard housing, which is more likely to present risks from deteriorating lead-based paint (Leech et al., 2016; White et al., 2016).<sup>9</sup> The disparate exposure to all sources of environmental lead experienced by low-income people and communities of color may be exacerbated because of their more limited resources for remediating LSLs, which can be a significant source of lead exposure. In addition, a higher incidence of rental housing in these communities creates an additional barrier to lead service line replacement (LSLR) where the property owner does not consent to full replacement.

EPA reviewed the LCRR in light of the serious stakeholder concerns about it; the adverse health effects of lead; and the potential environmental justice issues associated with lead exposure. For a more detailed explanation of the decision to review the LCRR, see “National Primary Drinking Water Regulations: Lead and Copper Rule Revisions; Delay of Effective and Compliance Dates” (86 FR 31939) (June 16, 2021); “National Primary Drinking Water Regulations: Lead and Copper Rule Revisions; Delay of Effective and Compliance Dates” (86 FR 14063) (March 12, 2021); and “National Primary Drinking Water Regulations: Lead and Copper Rule Revisions; Delay of Effective Date” (86 FR 14003) (March 12, 2021).

<sup>1</sup> CDC. 2020. ATSDR Toxicological Profile for Lead. Atlanta, GA.

<sup>2</sup> CDC. 2018. Lead. Atlanta, GA. <https://www.cdc.gov/nceh/lead/default.htm>.

<sup>3</sup> USEPA. 2013. Integrated Science Assessment for Lead. Office of Research and Development. (EPA/600/R-10/075F). Research Triangle Park, NC.

<sup>4</sup> HHS. 2012. NTP Monograph on Health Effects of Low-Level Lead. Durham, NC.

<sup>5</sup> CDC. 2020. ATSDR Toxicological Profile for Lead. Atlanta, GA.

<sup>6</sup> See Chapter 8, section 8.11, of the USEPA Economic Analysis for the Final Lead and Copper Rule Revisions, December 2020.

<sup>7</sup> AwwaRF (now the Water Research Foundation). 2008. Contribution of Service Line and Plumbing Fixtures to Lead and Copper Rule Compliance Issues. 978-1-60573-031-7.

<sup>8</sup> Leech, T.G., E.A. Adams, T.D. Weathers, L.K. Staten, and G.M. Filippelli. 2016. Inequitable chronic lead exposure. *Family & Community Health* 39(3):151-159.

<sup>9</sup> White, B.M., H.S. Bonilha, and C. Ellis. 2016. Racial/ethnic differences in childhood blood lead levels among children <72 months of age in the United States: A systematic review of the literature. *Journal of Racial and Ethnic Health Disparities* 3(1):145-153.

## II. E.O. 13990 Review Process

### *EPA's Process for Engagement*

EPA hosted a series of virtual engagements from April to August 2021 to obtain public input on the review of the LCRR. EPA also opened a docket, from April 5, 2021 to July 30, 2021, to accept written comments, suggestions, and data from the public. Summaries of these engagements, including summaries of the meetings and written comments, can be found in the docket, EPA-HQ-OW-2021-0255 at <https://www.regulations.gov/>. Recordings of the public listening sessions and community, tribal, and national stakeholder association roundtables can also be found in the docket. The virtual engagement meetings included two public listening sessions, ten community roundtables, a tribal roundtable, a national stakeholder association roundtable, a national co-regulator meeting, and a meeting with organizations representing elected officials. A diverse group of individuals and associations provided feedback through these meetings and the docket, including people from communities impacted by lead in drinking water, local governments, water utilities, tribal communities, public health organizations, environmental groups, environmental justice organizations, and co-regulators.

EPA specifically sought engagement with communities that have been disproportionately impacted by lead in drinking water, especially lower-income people and communities of color that have been underrepresented in past rule-making efforts. EPA hosted roundtables with individuals and organizations from Pittsburgh, PA; Newark, NJ; Malden, MA; Washington, DC; Newburgh, NY; Benton Harbor and Highland Park, MI; Flint and Detroit, MI; Memphis, TN; Chicago, IL; and Milwaukee, WI. These geographically-focused roundtables included a range of participants including local government entities, community organizations, environmental groups, local public water utilities, and public officials. EPA worked with community representatives to develop meeting agendas that reflected community priorities. Each community roundtable included a presentation by local community members. EPA held a separate roundtable with representatives from tribes and tribal communities. Participants in all roundtables were invited to share diverse perspectives with the agency through verbal discussion and a chat feature. EPA obtained detailed, valuable feedback from these engagements, which often

focused on the lived experiences of people impacted by lead in drinking water.

### *Public Comments Received by EPA*

Many commenters, in their statements at virtual engagements and in their written materials provided to the docket, expressed concern that the LCRR would not provide equitable public health protections and would be difficult to implement. Commenters also provided many suggestions beyond the LCRR to reduce drinking water lead exposure.

While commenters provided feedback on all aspects of the LCRR, most comments focused on LSLR, the action level (AL) and trigger level (TL), tap sampling, public education, and sampling for lead in schools and child-care facilities. Each of these topics are discussed in more detail below.

**Lead Service Line Replacement:** Nearly all commenters expressed support for the goal of full replacement of all the nation's lead service lines. Many commenters raised concerns regarding LSLR and the financial and public health burdens placed on communities. Some participants noted the frequent split ownership of LSLs between water systems and property owners and that the LCRR does not prohibit partial replacements in which the private LSL remains in place if a customer is unwilling or unable to replace the private-side LSL. Partial replacements can cause elevated lead levels due to the physical disturbance associated with the practice as well as the potential for galvanic corrosion with the new portion of the service line. Frequent suggestions included: A regulatory requirement for water systems to proactively replace all LSLs over a defined time period (e.g., 10–15 years) regardless of drinking water lead levels, a ban on all or certain partial replacements, and increased financial support for LSLR coordinated across Federal agencies. One participant also suggested the use of opportunity zone funds to provide tax incentives for replacement. Some commenters did not support a complete ban on partial LSLR, stating that there are some situations where they are necessary and that risk mitigation steps can reduce lead levels associated with partial replacements while maintaining water service for drinking, basic sanitation, and fire suppression purposes. Many commenters expressed that individual homeowners should not be asked to pay for the replacement of any part of an LSL. Many commenters also expressed the need for equitable distribution of funding for LSLR, noting that low-

income people and communities of color are disproportionately served by LSLs and lack the resources to replace them. Commenters expressed the need for state and federal assistance, cautioning that funding LSLR by rate revenue could disproportionately affect low-income households given potential impacts on water rates. Some commenters also discussed potential barriers to private-side replacement, including local or state ordinances that may limit water system access to private property, restrictions on using rate revenue for such projects, or the possibility that customers may decline replacement even when available at no cost to them. Many commenters also observed that renters lack the ability to compel the replacement of the portions of LSLs that are owned by their landlords. Additionally, a few commenters cautioned that only conducting LSLR in conjunction with existing planned infrastructure projects may result in LSLs remaining in communities that have experienced historic disinvestment, particularly communities of color. Several commenters also expressed support for strengthening the LSL inventory requirements, including setting a deadline for identifying service line material and including lead connectors in the definition of a LSL for purposes of the inventory.

**Action Level (AL):** Most commenters expressed concern that the LCRR did not lower the lead AL. Some requested that EPA reconsider setting a Maximum Contaminant Level (MCL) for lead at 5 parts per billion (ppb) and that the agency reduce the AL (e.g., 10, 5, or 1 ppb) if an MCL is not set. These commenters stated that the MCL or AL should be lowered to compel more systems to take actions to reduce drinking water lead exposure. Several commenters suggested removing the TL and reducing the AL to 10 ppb, noting that the use of two regulatory values would create confusion and be onerous to implement. These commenters noted that adding a TL that compels similar but different actions for LSLR, corrosion control, and public education creates confusion regarding which actions systems must take. Some commenters noted that the TL and AL also create confusion regarding health risks since neither is a health-based number. Some commenters discussed high childhood blood lead levels in their communities, noting that health impacts occur at levels much lower than the AL. Others did not support reducing the AL from 15 ppb, citing feasibility and the burden on water systems.

*Tap Sampling:* Many commenters expressed support for requiring first and fifth liter samples in homes served by LSLs and using the samples with the highest levels of lead in 90th percentile calculations. Commenters emphasized the need to prioritize the most at-risk populations in tap sample site selection. Several commenters recommended allowing water systems to maintain existing compliance tap sampling schedules.

*Public Education Materials:* A common recommendation was that the LCRR should require accessible public education materials and outreach to residents about lead risk. EPA was urged to ensure that public education information is provided in multiple languages and appropriate for people with different reading levels. Many commenters also called for more proactive communication about lead in drinking water and for clarity in general communications from water systems regarding the potential for lead in drinking water. Multiple commenters emphasized the need for public education targeted specifically towards renters. Commenters suggested that regulators and water systems should partner with local trusted messengers and organizations to conduct community outreach. There were also many commenters who expressed concerns with the number of public education and notification requirements. Some recommended streamlining the requirements and reducing certifications to primacy agencies.

*Water Testing in Schools and Child-Care Facilities:* Some commenters identified the inherent shortcomings of the LCRR's schools and child-care lead testing requirement given the statutory limitations of the Safe Drinking Water Act. Commenters recommended that more coordination between the water system and relevant entities, such as child-care facilities and state or local licensing entities, could improve outcomes. Many commenters recommended expansion of the requirements for water system-conducted lead testing in schools and child-care facilities. These recommendations included requiring sampling all elementary and secondary schools, more frequent sampling at more taps, making results public, and requiring remediation measures or installation of filters. Other commenters expressed concern regarding the ability of schools and child-care facilities to address lead issues given the potential associated financial, technical, and staff burdens. Some commenters also requested that EPA allow previous

school and child-care sampling efforts to count towards the LCRR requirement while a few others stated that water systems should not be responsible for sampling in schools and child-care facilities.

*Additional Comments:* EPA also received comments on other areas of the LCRR, including corrosion control treatment (CCT) related requirements, "find-and-fix" (see below), and small system flexibility. On CCT, commenters requested:

- More flexibility in CCT requirements;
- Additional oversight of CCT decisions;
- Additional water quality parameter (WQP) monitoring; and
- More frequent monitoring after source or treatment changes.

Multiple commenters expressed support for the intention of find-and-fix provisions, which require water systems to follow up with customers where tap sampling was conducted to identify the cause of a lead sample exceeding 15 ppb. Some commenters raised potential implementation challenges for find-and-fix requirements including cases of repeat exceedances and customer inability or unwillingness to address lead in premise plumbing. Commenters supported limiting the flexibility provided by the small system options. Many commenters also requested timely guidance on a range of rule topics, including LSL inventory development, tap sampling site selection, CCT, and find-and-fix.

Most commenters requested that EPA revise the LCRR, citing inadequate health protection. However, some commenters urged EPA to implement the LCRR as finalized, and requested that if the agency makes further revisions that it suspend compliance dates, citing regulatory uncertainty.

### III. Outcome of LCRR Review

Based upon EPA's evaluation and stakeholder feedback, EPA has determined that there is a range of potential regulatory and non-regulatory actions the agency can take to further reduce drinking water lead exposure.

EPA finds that although the LCRR improves public health protection in comparison to the previous version of the rule, there are significant opportunities to further improve upon it to achieve increased protection of communities from lead exposure through drinking water. Specifically, after hearing from stakeholders, including during the engagements that took place over the last nine months, the agency has concluded that regulations and other non-regulatory actions to

protect the public, from lead in drinking water, should consider: The urgent need to replace LSLs as quickly as possible to protect all Americans from the most significant source of drinking water lead; equitably improving public health protection for those who cannot afford to replace the customer-owned portions of their LSLs; and improving the methods to identify and trigger action in communities that are most at risk of elevated drinking water lead levels. A framework including regulatory and nonregulatory actions to address these considerations has the potential to permanently eliminate the most significant sources of drinking water lead contamination, better target other actions to reduce lead exposure to where the highest risks are presented, and provide equitable protections to all Americans. Accordingly, EPA intends to propose for public comment a rulemaking to revise the LCRR as part of its overall strategy to advance these policy goals while balancing stakeholder interests, and incorporating required economic, environmental justice, and other analyses, and to take other steps towards these goals. And, as with any rulemaking, EPA will maintain an open mind and looks forward to receiving comments on its proposed new rule. Each of these considerations is discussed more fully below.

First, our review impressed upon the agency the urgency of fully removing all lead service lines using any and all regulatory and non-regulatory tools available to EPA and its federal partners. Leaving millions of LSLs in place would result in generations of Americans being at risk of significant lead exposure through their drinking water. Where present, LSLs are the most significant source of drinking water lead exposure.<sup>10</sup> These LSLs present a risk of sustained lead exposure through drinking water, which presents a risk of damage to the brains of children and the kidneys and other critical functions of adults. EPA estimates that the LCRR would result in replacements of only approximately five percent of LSLs over a 35-year period. Our review leads the agency to believe that there are opportunities to do significantly more to address this urgent public health risk. EPA plans to seek comment on how revisions to the LCRR could advance the Administration's priority of removing 100 percent of LSLs.

Second, based on EPA's review of the LCRR, the agency believes there are significant potential opportunities to

<sup>10</sup> AwwaRF. 2008. Contribution of Service Line and Plumbing Fixtures to Lead and Copper Rule Compliance Issues. 978-1-60573-031-7.

revise the LCRR to ensure that it equitably improves public health protection for all, regardless of their economic status, to avoid exacerbating existing health and economic inequalities. To reach this goal, EPA will explore potential regulatory revisions in combination with financial assistance programs and partnerships targeted to disadvantaged consumers, regardless of whether they are homeowners, in an effort to direct limited community resources towards low-income households that have been historically underserved. Communities such as Newark, New Jersey, and Flint, Michigan have shown that full LSLR can be equitably achieved when there is both a regulatory requirement and a commitment to prioritize funding.

Third, EPA's review of the LCRR leads the agency to conclude that there are opportunities to better identify the communities that are most at risk of elevated drinking water lead levels and explore ways to compel action before consumers have been put at risk, rather than only after a lead action level exceedance. Specifically, EPA is considering potential revisions to the LCRR to expeditiously compel steps to replace lead service lines and ensure that the higher tap sampling result is used for measuring compliance, including levels found in the service line or in plumbing fixtures inside homes. In addition, EPA is considering potential revisions to the LCRR to reduce complexity from the lead action and trigger levels in particular and ensure that the rule is easily understandable and triggers appropriate and feasible corrective actions.

#### IV. Planned Actions To Address Lead in Drinking Water

To protect public health and fully and equitably meet the requirements of the Safe Drinking Water Act, the agency intends to propose for comment revisions to the Lead and Copper Rule and to undertake non-regulatory actions. This section describes the potential improvements to the LCRR that EPA plans to explore through a notice and comment rulemaking and additional actions EPA is contemplating to ensure greater public health protection from lead in drinking water.

##### A. New Regulation: Lead and Copper Rule Improvements

EPA intends to immediately begin to develop a proposed National Primary Drinking Water Regulation: Lead and Copper Rule Improvements (LCRI) to address the issues identified in the E.O. 13990 review. EPA will follow all Safe Drinking Water Act (SDWA) and other

relevant statutory and E.O. requirements in proposing the LCRI and taking final action on the proposal, including all necessary economic and environmental justice analyses and the consideration of alternatives and public comment. EPA intends to take final action on the LCRI proposal prior to the October 16, 2024 compliance date of the existing regulations (*i.e.*, the LCRR); the implications for compliance and primacy applications under the LCRR are discussed in detail below in Section IV.B. This schedule ensures that as little time as possible is lost before the improved public health protections of the LCRR and the LCRI can be realized in communities across the country.

##### EPA's Intent To Propose LCR Improvements

EPA intends to propose changes to the LCRR to address the main opportunities for improvement identified in our review, as well as consider other potential improvements. These are described below.

##### 1. Replacement of LSLs

First, there is a significant opportunity to improve the LCRR with regard to replacement of LSLs. Under the LCRR, water systems are only required to replace a small percentage of their LSLs and only after their customers are exposed to high lead levels. Water systems serving more than 10,000 people with more than 10 percent of samples above the action level of 0.015 mg/L need only replace 3 percent of their LSLs per year. These systems may stop their LSLR programs in as little as two years if the system meets the action level in four consecutive 6-month monitoring periods. Large systems with 90th percentile lead concentrations above the trigger level of 0.010 mg/L are only required to replace LSLs at a goal rate approved by the state. EPA projected that goal rate would likely be lower than 3 percent (USEPA, 2020).<sup>11</sup> Systems may stop these goal-based LSLR programs in as little as one year if the system meets the trigger level in two consecutive 6-month monitoring periods. Ultimately, most systems would be required to replace only a small portion of the LSLs in their distribution system: EPA projected that only 339,000 to 555,000 LSLs (out of 6.3 to 9.3 million LSLs) would be replaced over the 35-year period of analysis for the rulemaking (USEPA, 2020). This Administration believes it is an urgent

priority to eliminate all LSLs to improve the health of our people. President Biden has called for replacement of all LSLs in the nation, which will improve public health while putting Americans to work.<sup>12</sup> To help achieve this goal, the recently enacted Bipartisan Infrastructure Law (BIL) provides \$15 billion in funding over the next five years for LSLR.

Given the serious risks of lead exposure through drinking water, replacing all LSLs is an important policy goal. The States of Michigan, Illinois, and New Jersey have recently passed laws requiring all of their water systems to proactively replace lead service lines. These are three of the five states with the highest estimated numbers of LSLs according to a 2016 national survey (Cornwell 2016).<sup>13</sup> Cornwell 2016 reported that the sum of the estimated number of LSLs in these three states is just over one-fourth of the remaining estimated number of LSLs in the country.

EPA is mindful however, that the existing LCRR requirements and action by selected states and federal funding incentives may not be sufficient to achieve 100 percent replacement of LSLs and reduce risks to families living in the homes served by these lines without additional actions. Therefore, EPA intends to propose for comment requirements that, along with other, non-regulatory actions, would result in the replacement of all LSLs as quickly as is feasible. EPA's proposal will fully consider the agency's statutory authority and required analyses, including an economic and environmental justice analysis.

Second, there are important opportunities to ensure that public health is protected equitably. The cost of replacing the customer-portion of an LSL may leave the most vulnerable Americans disproportionately exposed to lead if they cannot afford the expense of replacement. In the Economic Analysis for the final LCRR (USEPA, 2020), EPA estimated that between 21 and 28 percent of the anticipated LSLRs under the LCRR would be customer-initiated replacements. Those are replacements where the system replaces the public portion of an LSL after being notified that a homeowner has replaced the private portion of the service line. The remaining LSLR predicted under the LCRR would be done by systems that exceed the action level or trigger

<sup>12</sup> <https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/31/fact-sheet-the-american-jobs-plan/>.

<sup>11</sup> USEPA. 2020. Economic Analysis for the Final Lead and Copper Rule Revisions. December 2020. Office of Water.

<sup>13</sup> Cornwell, D.A et al., National Survey of Lead Service Line Occurrence, Journal AWWA, April 2016, at E182.

level. To meet the LCRR's mandatory 3 percent replacement or state-approved goal rate, some systems may focus on replacing lines where the customer could pay to replace their portion of the line.

To address both of these issues, EPA intends to propose for comment rule revisions to advance the policy goal to prioritize distributional impacts. For instance, EPA intends to explore how to replace LSLs in a manner that prioritizes historically disadvantaged communities. Through the regulatory development process, EPA will also evaluate options to partner and provide financial assistance and prioritize the removal of LSLs in communities disproportionately impacted by lead in drinking water. EPA is also committing to partnering on a number of non-regulatory actions to address this issue of the cost of LSLR on consumers (see Section IV.C of this document).

The goal of these potential LSLR regulatory improvements and non-regulatory actions is to equitably improve public health protection and remove the most significant source of lead in drinking water.

## 2. Compliance Tap Sampling and Action/Trigger Levels

There are also significant potential opportunities to identify the communities that are most at risk of experiencing elevated levels of lead in drinking water and compel actions sufficient to reduce the health risks in those communities. At sites with LSLs, the LCRR requires a fifth liter sample to be analyzed for lead to better characterize the lead which has been introduced while the water was in contact with the LSL, as opposed to the building premise plumbing. It also requires a first liter sample to be analyzed for copper when copper is also being monitored at those sites. For non-lead LSL sites, a first liter sample is analyzed for both lead and copper. The State of Michigan revised its Lead and Copper Rule in 2018 to require the first and fifth liter samples to be analyzed for lead at sites with LSLs, with the higher of the two results used for the 90th percentile calculation. The Association of State Drinking Water Administrators, in their May 21, 2021 comments, summarized data from the initial round of sampling in Michigan. Using the highest number from the first and fifth liters, 31 systems had an action level exceedance. When just the fifth liter results were used, only 22 systems had an action level exceedance. EPA will explore these and other available data in developing potential revisions to

strength compliance tap sampling in the forthcoming LCRI proposal.

In the forthcoming proposed LCRI, EPA also intends to evaluate options for utilities to address lead contamination at lower levels and improve sampling methods to provide better health protection and more effective implementation of the rule. The agency will evaluate options to consolidate and potentially lower the LCRR's action and trigger levels. Stakeholders participating in the virtual engagement identified the action level/trigger level concept as the central regulatory variable that drives system and state action to reduce elevated lead levels in drinking water and many stakeholders commented that the action level should be lower to require more systems to take corrective action to protect public health from the adverse effects of lead. In the forthcoming proposed LCRI, the agency will explore options to address these concerns, including whether to eliminate the trigger level and lower the action level to compel action by water systems sooner to reduce the health risks in more communities. The agency will also evaluate whether the trigger level requirements of the LCRR would still be necessary if improved proactive LSLR and a more aggressive lower action level are adopted.

## 3. Other Areas of the Rule Where EPA Is Considering Improvements

EPA intends to primarily focus its rulemaking process on proposing approaches aimed at the policy goal of proactive and equitable LSLR, as well as proposals to address compliance tap sampling improvements; re-evaluation of the action and trigger levels; and consideration of prioritizing protections for historically disadvantaged communities. The agency also received stakeholder input suggesting improvements to a number of additional components of the LCRR. EPA will also be considering these suggestions and other options to equitably improve public health protection and improve implementation of the rule to ensure that it prevents adverse health effects of lead to the extent feasible. These additional components may include the LCRR provisions for small system flexibility, school and child-care sampling, risk communication, and corrosion control treatment. EPA will also consider addressing these issues through non-regulatory actions such as the development of implementation tools, guidance, and other federal programs.

## B. Implementation of the Lead and Copper Rule Revisions

The final agency action, National Primary Drinking Water Regulations: Lead and Copper Rule Revisions; Delay of Effective and Compliance Dates (published on June 16, 2021 in the **Federal Register** (86 FR 31939)), delayed the effective date of the LCRR until December 16, 2021 and the compliance date until October 16, 2024. Following the LCRR review, EPA has decided to not delay the effective date any further. At this time, EPA is also not planning to further change the compliance dates for the LCRR. EPA will consider any such changes through its forthcoming rulemaking. While EPA has identified components of the LCRR for potential revision to improve public health protection, the agency has also determined that the LCRR includes advancements that should proceed in order to ensure continued progress toward reducing drinking water lead exposure.

## Compliance Deadlines

The current compliance deadline for the LCRR is thus October 16, 2024. EPA intends to propose, in the LCRI, revisions to the compliance deadlines only for components of the rule that the agency will propose to significantly revise. At this time, EPA does not expect to propose changes to the requirements for information to be submitted in the initial LSL inventory or the associated October 16, 2024 compliance date. Continued progress to identify LSLs is integral to lead reduction efforts regardless of potential revisions to the rule. The inventory provides critical information on the locations of potentially high drinking water lead exposure within and across public water systems, which will allow for quick action to reduce exposure. By preparing an LSL inventory, water systems will be able to target communication to residents in homes with LSLs about the actions they can take to reduce their lead exposure. Preparing the initial inventory will allow systems to assess the extent of the LSLs within their system, better identify sampling locations, and begin planning for LSLR actions, including applying for state and federal grants and loans. LSL inventories will allow water systems, states, tribes, and the Federal government to determine the prevalence of these lead sources and to target lead risk communication and lead removal programs where they are needed most. With the development of these initial inventories nationwide over the next three years, EPA anticipates that water

systems, states and tribes will be prepared to quickly implement the other LCRR requirements, as well as any improvements made through the planned LCRI rulemaking that may be adopted to further reduce drinking water lead levels, and be well-positioned to apply for any available grants or loans for LSLR.

There are two other actions that water systems currently must complete by the LCRR's October 16, 2024 compliance date: the LSLR plan and the tap sampling plan. The LSLR plan would describe the procedure for systems to conduct lead service line replacements in accordance with the LCRR and the tap sampling plan would identify the locations and procedures for systems to conduct tap sampling in accordance with the LCRR. Because EPA intends to propose changes to the LSLR and tap sampling requirements, however, the agency also expects to propose to delay the October 16, 2024 deadline for submitting LSLR and tap sampling plans so that systems can incorporate any potential revisions made through LCRI rulemaking. While EPA expects to complete that rulemaking prior to the 2024 compliance date, EPA recognizes that this announcement of the forthcoming proposal creates some uncertainty for water systems and states regarding the deadline for completion of these plans. EPA plans to continue to engage with states, tribes, water systems, and all other stakeholders as the agency proposes the LCRI and takes final action on the proposal. In those engagements, which include a notice and comment process, EPA will seek input on a number of issues including whether current LCRR deadlines should be changed. As part of those discussions, EPA will consider concerns expressed by some commenters that further delays in compliance dates for some LCRR provisions may delay public health improvements. EPA also intends to seek comment on whether it would be practicable for water systems to implement any of the proposed LCRI requirements earlier than three years from the date of final action on the proposed LCRI, consistent with SDWA section 1412(b)(10).

#### Primacy Deadlines

SDWA section 1413(a)(1) and 40 CFR 142.12(b), require states and tribes with primary enforcement authority (primacy) to submit final requests for approval of primacy program revisions to adopt new or revised EPA regulations two years after promulgation. As noted above, the LCRR is taking effect on December 16, 2021. EPA is not withdrawing the LCRR or further

delaying its effective date because, among other reasons, it is critical for states and tribes to begin working with water systems to implement the initial LSL inventory provisions of the LCRR and because some other provisions of the LCRR, which advance protections from lead in drinking water, may not be revised as part of the forthcoming LCRI rulemaking. As explained in the final rule delaying the effective and compliance dates for the LCRR, EPA interprets the primacy revision application deadline in 40 CFR 142.12(b)(1) to be calculated using this publication date, December 17, 2021. As a result, primacy revision applications are due on December 18, 2023. However, a state or tribe may apply for an extension of the deadline for up to two years in accordance with 40 CFR 142.12(b)(2).

As further stated in this document, EPA anticipates completing its LCRI rulemaking prior to October 16, 2024. The forthcoming proposed regulatory changes under the LCRI, if finalized, would also result in states and tribes having to submit a primacy application for that regulation two years after it is promulgated. States and tribes will have greater clarity with respect to the primary enforcement (primacy) application revisions process and relevant timeframes when the LCRI is proposed. Accordingly, states and tribes that are concerned about submitting two successive primacy applications may request an extension of their LCRR primacy application deadline to be able to group the program revisions for the LCRR and LCRI into a single primacy application in accordance with 40 CFR 142.12(b)(2)(i)(C).

#### C. Additional EPA Actions To Address Lead in Drinking Water

EPA's review of the LCRR and information received during the engagements process led the agency to conclude that EPA should take a number of additional actions outside of the SDWA regulatory framework to achieve the agency's policy objectives. These actions include:

- Developing and partnering on plans to ensure the equitable distribution of funds for reducing lead in drinking water;
- Encouraging cabinet level commitments for federal collaboration to address school and child-care lead in drinking water;
- Committing to target oversight and technical assistance for communities impacted by high lead levels;
- Improving risk communication through additional EPA guidance and tool development;

- Supporting water systems in meeting LSL Inventory requirements through the issuance of guidance; and
- Encouraging full LSL replacement and strongly discouraging partial LSL replacement.

#### 1. Financing and Grant Programs

Funding is key to a community's ability to accelerate both voluntary and required LSLR programs. EPA collaborates with states and tribes to provide opportunities for below-market interest rate loans and grants through the Drinking Water State Revolving Fund (DWSRF) and the Water Infrastructure Finance and Innovation Act (WIFIA) loan program. To support LSLR programs, special financing terms are available through the DWSRF for disadvantaged communities to help address affordability and the impacts of past disinvestment. EPA will encourage states to use their disadvantaged community programs to their fullest extent to provide subsidies and other assistance to support LSLR in vulnerable communities.

Since 2018, EPA has also developed and implemented three grant programs<sup>14</sup> under the Water Infrastructure Improvements for the Nation (WIIN) Act to fund grants to small and disadvantaged communities. More than \$175 million has been provided to date for: developing and maintaining compliance with national primary drinking water regulations (NPDWRs); lead reduction projects; and support for voluntary testing of drinking water in schools and child-care facilities. Funding from these programs can continue to be used to support actions to reduce lead in drinking water in addition to regulatory actions. Specifically, EPA has determined that there are multiple lead reduction activities that these grant programs authorize the use of funds for:

- Developing LSL inventories;
- Replacing full LSLs (including replacing the customer-owned portion of an LSL);
- Installing or improving corrosion control treatment;
- Supporting voluntary lead drinking water testing programs for schools and child-care facilities; and

<sup>14</sup> The 2016 Water Infrastructure Improvements for the Nation Act (WIIN Act) addresses, supports, and improves America's drinking water infrastructure and included three new drinking water grants that promote public health and the protection of the environment. These include: (1) Section 2104: Small, Underserved, and Disadvantaged Communities; (2) Section 2105: Reducing Lead in Drinking Water; and (3) Section 2107: Lead Testing in School and Child Care Program Drinking Water.

- Remediating lead in school and child-care drinking water.

EPA learned during the LCRR virtual engagements that many small and historically disadvantaged communities face challenges accessing these EPA funding opportunities. Many lack the capacity to develop competitive funding applications and have not applied for DWSRF loans or other infrastructure grants in the past. EPA will seek opportunities to provide technical assistance to small and disadvantaged communities. The agency will also promote awareness of the availability of these programs to address lead in drinking water, including, for LSL replacement, regardless of ownership of the LSLs. EPA will also highlight case studies from communities that have successfully addressed concerns regarding the use of public funds for private-side LSLR. To the extent possible, expanded, or new funding programs under future legislation will also be directed to similar projects.

States can direct funds available under the American Rescue Plan (ARP) Act to water infrastructure, and specifically lead reduction. States could also use ARP funds to address lead in schools and child-care facilities and to accelerate voluntary LSLR programs.

## 2. Ensuring Equity in the Distribution of Funds for Reducing Lead in Drinking Water

Through E.O. 14008, President Biden established the Justice 40 initiative—setting a goal that 40 percent of the overall benefits of certain Federal investments flow to disadvantaged communities that have been historically marginalized and overburdened by pollution and underinvestment in housing, transportation, water and wastewater infrastructure, and health care. This initiative is a critical part of the Administration's whole-of-government approach to advancing equity and environmental justice. Two EPA programs central to EPA's goal to accelerate LSLR are pilot programs under the Justice 40 initiative: The DWSRF and the WIIN Reduction in Lead via Drinking Water Exposure Grant. EPA is engaging with stakeholders and exploring opportunities to maximize the benefits of these programs in disadvantaged communities, including their specific application to LSLR projects.

EPA will partner with states, tribes, and other stakeholders to collaborate with disadvantaged communities to build their capacity to better compete for and access water infrastructure funding. EPA will develop tools to share information, improve transparency and

accountability. EPA is committed to improving public education and outreach on the availability of funding opportunities and the tools and resources to support accessing these dollars.

One of EPA's priorities is to ensure that entities receiving federal financial assistance from the agency comply with the federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, sex and age, including Title VI of the Civil Rights Act of 1964. Federal civil rights laws protect many of the populations that have been exposed to disproportionate levels of harmful environmental, quality of life, and health impacts from pollution and environmental contamination. These populations are also more likely to be exposed to lead in drinking water. Many states and water systems receive some form of federal funding under the Safe Drinking Water Act and have an affirmative obligation to ensure their actions comply with civil rights laws. States and water systems receiving federal funds have an affirmative obligation to implement effective non-discrimination compliance programs. EPA intends to carefully evaluate the provisions of the rule, including the LSLR provisions, and implementation of EPA financial assistance programs to ensure compliance with these laws.

## 3. Bipartisan Infrastructure Law

The recent Bipartisan Infrastructure Law (BIL)<sup>15</sup> provides an additional \$11.713 billion in general DWSRF funding and \$15 billion specifically targeted to communities for the identification and replacement of LSLs through the DWSRF. Each funding provision is scheduled over the next five years. The BIL authorizes \$500 million for the WIIN Reduction in Lead Program over the next five years, emphasizing LSL replacement and corrosion control treatment in disadvantaged communities. BIL also authorizes \$200 million for lead testing and remediation in school and child-care drinking water and authorizes \$10 million for a new grant program for LSLR in communities with existing inventories. EPA will work with its state and tribal partners, communities, and other stakeholders to identify potentially high impact but underutilized authorities that would allow states and tribes to fund full LSL replacement. The agency will also significantly increase federal, state, and tribal outreach and engagement efforts

to communities to support LSLR activities. Additionally, EPA will update funding program guidance to provide examples of best state practices for addressing disproportionate and adverse health and environmental impacts experienced by communities, including communities of color and low-income communities.

## 4. Cabinet Level Commitments for Federal Collaboration To Address School and Child-Care Lead in Drinking Water

Children spend a significant portion of their time at places of learning, so it is critical to reduce lead in drinking water in schools and child-care facilities. This is a challenging problem. EPA's authority to regulate actions by schools and child-care centers that may be necessary to address lead in drinking water is limited. Moreover, due to resource constraints, schools and child-care facilities may choose not to participate in voluntary efforts to sample for lead in drinking water if funding for remediation is not available. Some commenters representing facilities with lead in drinking water indicated they need financial support to address lead. Finally, schools and child-care facilities that serve low-income communities are less likely to have the resources necessary to identify and address lead issues.

EPA currently advances efforts to address lead in schools and child-care facilities through two vehicles: (a) The Memorandum of Understanding on Reducing Lead Levels in Drinking Water in Schools and Child-Care Facilities (MOU), which includes 14 federal and non-federal partners; and (b) funding under grant programs like the Lead Testing in School and Child-care Drinking Water Grant and the Reducing Lead in Drinking Water Grant. While these efforts assist schools and child-care facilities to develop and implement lead testing programs, EPA recognizes the urgency of a more comprehensive federal approach to address this issue.

To address these critical concerns, EPA is pursuing deeper partnerships with a range of Federal agencies to make progress on reducing lead in drinking water from schools and child-care facilities. EPA will explore funding that may be available from Federal agencies that could be used towards remediation of lead in drinking water in these facilities, with a particular focus on communities at risk of multiple forms of lead exposure. Collaboration at the federal level has the potential to further the reduction of lead in drinking water at schools and child-care facilities than

<sup>15</sup> Public Law 117–58. <https://www.congress.gov/117/bills/hr/3684/BILLS-117hr3684enr.pdf>.

could be achieved by reliance on regulatory requirements alone.

#### 5. Targeted Technical Assistance to Communities With High Drinking Water Lead Levels

While EPA will propose important changes to the regulation of lead in drinking water, it is critical for systems to conduct proper sampling for lead and maintain the water chemistry needed to minimize lead corrosion under existing rules. EPA will collaborate with states to provide oversight of these critical provisions as well as provide assistance to low income and other historically disadvantaged communities experiencing high levels of lead in their drinking water because they are disproportionately served by LSLs. Communities impacted by lead in drinking water participating in the LCRR virtual engagements emphasized the need for financial and technical assistance. In collaboration with our state and tribal coregulators, EPA intends to provide targeted technical assistance to community water systems to reduce lead exposure.

#### 6. Improving Risk Communication Tools

Throughout the LCRR virtual engagements, EPA received feedback that risk communication about lead in drinking water must be improved and that water utilities need support to develop effective communication materials. EPA intends to develop guidance and templates to assist states, tribes, and water systems in the communication of lead risk to households and communities. Additionally, EPA intends to propose revisions to the Consumer Confidence Report Rule (40 CFR 141, subpart O) which will include requirements related to providing information on corrosion control efforts and on lead action level exceedances when corrective action is needed.

#### 7. Providing Guidance on How To Create a Lead Service Line Inventory

To further advance the proactive replacement of LSLs, EPA will pursue research to use data analytics and other methods to accelerate and improve the process of identifying LSLs. EPA intends to publish inventory development guidance to assist water systems, states, and tribes by providing best practices, case studies, and templates. The guidance will address issues raised by commenters including the use of statistical models to help determine LSL locations, classification of unknowns, goosenecks, and galvanized plumbing, best practices for service line material verification,

inventory form and format, inventory accessibility, tools to support inventory development and data tracking, and how LSL identification may be prioritized. EPA is also updating the Safe Drinking Water Information System, including all relevant components, to support state and tribal data management needs for LSL inventories.

#### 8. Discourage Partial LSLR and Encourage Full LSLR

Partial LSLRs can cause short-term elevation of lead concentrations in drinking water and further extend lead health risk from service lines because a portion of the lead line remains in service. EPA strongly discourages water systems from conducting partial LSLR. EPA recommends systems proactively implement full LSLR programs. The agency also expects water systems to effectively inform and engage customers during LSLR and provide outreach and filters to residents with LSLs for six months following replacements. EPA also recommends that LSLR programs prioritize the most vulnerable populations by focusing on schools, child-care facilities, homes where children are living, other locations where children are present, and households of those who historically have been disproportionately exposed to lead from water and other media.

EPA will provide training and guidance on LSLR program development and available methods for replacing LSL as safely and efficiently as possible. EPA also will provide tools, best practices, and case studies for systems to set up voluntary LSLR programs and to implement required ones. The agency will update the document *Funding and Technical Resources for Lead Service Line Replacement in Small and Disadvantaged Communities*,<sup>16</sup> and promote awareness of funding and financing that can be used for LSLR, including the replacement of the customer-owned portion of the service line. All the agency's communications will describe the risks posed by partial LSLR and mitigation measures to reduce elevated water lead concentrations.

**Michael S. Regan,**

*Administrator.*

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**BILLING CODE 6560-50-P**

<sup>16</sup> [https://www.epa.gov/sites/default/files/2020-12/documents/ej\\_slr\\_funding\\_sources-final.pdf](https://www.epa.gov/sites/default/files/2020-12/documents/ej_slr_funding_sources-final.pdf).

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 447

[CMS-2482-CN]

RIN 0938-AT82

### Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States; Correction

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects technical errors in the final rule that appeared in the November 19, 2021 **Federal Register** entitled, "Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States."

**DATES:** Effective December 20, 2021.

**FOR FURTHER INFORMATION CONTACT:** Christine Hinds, (410) 786-4578.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In FR Doc. 2021-25009 (86 FR 64819), the final rule entitled, "Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States" there were technical errors that are identified and corrected in this correcting document. These corrections are applicable as of December 16, 2021.

##### **II. Summary of Errors**

###### *A. Summary of Errors in the Preamble*

On page 64819 of the Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States final rule, we inadvertently omitted the delayed effective date of the revised definition of "Best price" at § 447.505(a), which was previously published in the December