

imminence of the effective date, seeking prior notice and the opportunity for public comment on this delay is impractical. Specifically, if prior notice and opportunity for public comment are required to delay the effective date to February 16, 2025, this final rule will not be issued prior to February 16, 2024. As a result, the current final rule will become effective February 16, 2024, and ambulance providers without contracts in place would be subject to those payment methodologies until contracts have been implemented. For those entities engaged in the contracting process, this is likely to cause confusion and uncertainty.

VA also finds that prior notice and opportunity for comment would be contrary to the public interest because it could adversely impact veteran care or result in veterans being billed directly for services. Under the new regulation, VA will pay the lesser of actual charge associated with an air ambulance service, or the CMS ambulance fee schedule rate for that service, unless a separate rate has been established based on local contracts between air ambulance providers and local VA medical centers. As discussed above, since publication of the final rule, VA has received feedback that more time is necessary to accommodate unforeseen difficulties in air ambulance broker contracting, which relate to air ambulance brokers requiring a contract or subcontract in place with all potential air ambulance providers that covers emergency, non-VA initiated trips. The negotiation and implementation of these contracts will not be completed by February 16, 2024. As a result, absent the delayed effective date, the current final rule will go into effect on February 16, 2024, and ambulance providers would be subject to those payment methodologies until contracts have been implemented. This could be especially concerning for those entities whose negotiated rates could be higher than the applicable CMS ambulance fee schedule rate in the event VA determines it may be justified based on local considerations, such as for rural areas. Air ambulance providers contend that the Medicare reimbursement rate that would apply absent a contract is unsustainable for their business operations, potentially leading to reduction in the availability of air ambulance services for veterans. While VA is not aware that veterans are currently receiving preferential treatment from air ambulance providers by virtue of VA paying billed charges, or that such preferential treatment would stop were VA to pay CMS

ambulance fee schedule rates in the absence of a contract, VA acknowledges that there is a risk that veterans could be billed directly for the difference between the Medicare rate that VA pays for emergency, non-VA initiated trips and the amount billed by the ambulance provider. For these reasons, VA finds that good cause exists to dispense with the prior notice and public comment procedures for this final rule, as it concludes that such procedures are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(B).

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on December 22, 2023, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2023-28726 Filed 12-28-23; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R06-OAR-2022-0907; FRL-11174-02-R6]

Air Plan Approval; Arkansas; Revisions to Rule 19 of the Arkansas Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is approving portions of the revisions to the Arkansas State Implementation Plan (SIP) including revisions to the Arkansas Pollution Control and Ecology Commission's ("Commission" or APC&EC) Rule No. 19, *Rules of the Arkansas Plan of Implementation for Air Pollution Control* submitted by the Arkansas Department of Energy and Environment, Division of Environmental Quality (DEQ) via the Arkansas Governor's Office on June 22, 2022. Most of the revisions are administrative in nature and make the SIP current with Federal rules.

DATES: This rule is effective on January 29, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R06-OAR-2022-0907. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet. Publicly available docket materials are available electronically through <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Clovis Steib, EPA Region 6 Office, Infrastructure and Ozone Section, 214-665-7566, steib.clovis@epa.gov. Please call or email the contact listed above if you need alternative access to material indexed but not provided in the docket.

SUPPLEMENTARY INFORMATION: Throughout this document "we," "us," and "our" means the EPA.

I. Background

The background for this action is discussed in detail in our August 22, 2023, proposal (88 FR 57014) and the accompanying Technical Support Document (TSD), available in the docket for this rule. In our August 2023 proposal we proposed to approve portions of the revisions to the Arkansas State Implementation Plan (SIP) including revisions to the Arkansas Pollution Control and Ecology Commission's Regulation No. 19, *Rules of the Arkansas Plan of Implementation for Air Pollution Control* submitted by the Arkansas Department of Energy and Environment, Division of Environmental Quality (ADEQ) via the Arkansas Governor's Office on June 22, 2022. The proposal included revisions to remove certain outdated provisions and update other provisions that are incorporated into Regulation 19. Specific provisions to be partially repealed are those in Chapter 10 of APC&EC Regulation 19 regarding the control of volatile organic compounds (VOC) from certain source categories in Pulaski County, and provisions repealed from the Clean Air Interstate Rule (CAIR) in Chapter 14, and informational provisions regarding sources eligible or subject to best available retrofit technology (BART) requirements for Regional Haze in Chapter 15. All of the repealed provisions were either superseded by other rules or otherwise no longer necessary. One of the revisions restructured the regulations and organized them as "rules," such that "Regulation No. 19" became "Rule No. 19," *Rules of the Arkansas Plan of*

Implementation for Air Pollution Control, with corresponding chapters and appendices. Most of the revisions are administrative in nature and make the Arkansas SIP current with applicable Federal Rules. We did not receive any comments during the requisite comment period regarding our August 2023 proposal.

II. Final Action

We are approving portions of the revisions submitted by the State of Arkansas on June 22, 2022. We are finalizing the action without changes from our August 2023 proposal. Specifically, we are approving the following submitted revisions to Regulation 19: Revisions to Chapters 1, 2, 3, 4, 5, 6, 7, 9, 11, 13, 15, and Appendices A and B; the partial repeal of Regulation 19, Chapter 10 and repeal of Regulation 19, Chapters 14, and 16; and the new provision of Regulation 19, Chapter 18. Finally, we are approving the revision to rename Regulation 19 as Rule 19. These changes reflect the current organizational structure of ADEQ, remove outdated information, and make non-substantive formatting edits. This action is being taken under section 110 of the Act.

III. Environmental Justice Consideration

The EPA reviewed demographic data for groups of populations living within Pulaski County, Arkansas. The EPA then compared the data to the State of Arkansas and the national average for each of the demographic groups. The result of this analysis is discussed in detail in our proposal; and is provided for informational and transparency purposes.

This final action revises portions of the Arkansas SIP including revisions to Regulation 19 of the Arkansas Plan of Implementation for Air Control. We expect that this action and resulting emissions reductions will generally be neutral or contribute to reduced environmental and health impacts on all populations in the State of Arkansas, including people of color and low-income populations. The revisions provide updates to the SIP and improve clarity in the SIP so that the public can read and understand what is currently in the SIP. Further, there is no information in the record indicating that this action is expected to have disproportionately high or adverse human health or environmental effects on a particular group of people.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes

incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference the revisions to the Arkansas regulations as described in Section II of this preamble, Final Action. The EPA has made, and will continue to make, these materials generally available through www.regulations.gov (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 the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rule of EPA's approval, and will be incorporated in the next update to the SIP compilation.

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- 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 subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

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.”¹ 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.”²

ADEQ 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. The EPA performed an environmental justice analysis, as is described above in the section titled, “Environmental Justice Considerations.” The analysis was done for the purpose of providing additional context and information about this rulemaking to the public, not as a basis of the 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. In addition, there is no information in the record upon which this decision is based inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a

¹ See <https://www.epa.gov/environmentaljustice/learn-about-environmental-justice>.

² <https://www.epa.gov/environmentaljustice/learn-about-environmental-justice>.

tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

This action is subject to the Congressional Review Act, 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).

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 February 27, 2024. 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, Ammonia, Carbon oxides, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: December 19, 2023.

Earthea Nance,
Regional Administrator, Region 6.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 52 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 E—Arkansas

■ 2. In § 52.170, the table in paragraph (c), entitled “EPA-Approved Regulations in the Arkansas SIP,” is amended by revising the heading and entries for “Regulation No. 19: Regulations of the Arkansas Plan of Implementation for Air Pollution Control” to read as follows:

§ 52.170 Identification of plan.

* * * * *
(c) * * *

EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP

State citation	Title/subject	State submission/ef- fective date	EPA approval date	Explanation
Rule No. 19: Regulations of the Arkansas Plan of Implementation for Air Pollution Control				
Chapter 1: Title, Intent and Purpose				
Rule 19.101	Title	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.102	Applicability	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.103	Intent and Construction	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.104	Severability	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.105	Incorporation by Reference	6/22/2022	12/29/2023	[Insert Federal Register citation].
Chapter 2: Definitions				
Chapter 2	Definitions	6/22/2022	12/29/2023	[Insert Federal Register citation].
Chapter 3: Protection of the National Ambient Air Quality Standards				
Rule 19.301	Purpose	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.302	Division Responsibilities	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.303	Regulated Sources Responsibilities.	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.304	Delegated Federal Programs	6/22/2022	12/29/2023	[Insert Federal Register citation].
Chapter 4: Minor Source Review				
Rule 19.401	General Applicability	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.402	Approval Criteria	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.403	Owner/Operator’s Responsibilities	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.404	Required Information	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.405	Action on Application	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.406	Public Participation	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.407	Permit Amendments	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.408	Exemption from Permitting	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.409	[Reserved]	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.410	Permit Revocation and Cancellation.	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.411	General Permits	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.412	Dispersion Modeling	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.413	Confidentiality	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.414	Operational Flexibility—Applicant’s Duty to Apply for Alternative Scenarios.	6/22/2022	12/29/2023	[Insert Federal Register citation].
Rule 19.415	Changes Resulting in No Emissions Increases.	6/22/2022	12/29/2023	[Insert Federal Register citation].

EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP—Continued

State citation	Title/subject	State submission/ef- fective date	EPA approval date	Explanation
Rule 19.416	Permit Flexibility	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.417	Registration	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 5: General Emission Limitations Applicability to Equipment				
Rule 19.501	Purpose	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.502	General Rules	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.503	Visible Emission Rules	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.504	Stack Height/Dispersion Rules	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.505	Revised Emissions Limitation	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 6: Upset and Emergency Conditions				
Rule 19.601	Upset Conditions	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.602	Emergency Conditions	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 7: Sampling, Monitoring, and Reporting Requirements				
Rule 19.701	Purpose	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.702	Air Emissions Sampling	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.703	Continuous Emissions Monitoring	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.704	Notice of Completion	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.705	Record Keeping and Reporting Requirements.	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.706	Public Availability of Emissions Data.	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 9: Prevention of Significant Deterioration				
Rule 19.901	Title	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.902	Purposes	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.903	Definitions	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.904	Adoption of Rules	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 10: Rules for the Control of Volatile Organic Compounds in Pulaski County				
Rule 19.1001	Title	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1002	Purpose	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1003	Definitions	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1004	[Reserved]	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1005	Provisions for Specific Processes	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1006	[Reserved]	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 11: Major Source Permitting Procedures				
Chapter 11	Major Source Permitting Procedures.	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 13: Stage 1 Vapor Recovery				
Rule 19.1301	Purpose	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1302	Applicability	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1303	Definitions	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1304	Exemptions	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1305	Prohibited Activities	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1306	Record Keeping	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1307	Inspections	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1308	Vapor Recovery Systems	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1309	Gasoline Delivery Vessels	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1310	Owner/Operator Responsibility	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1311	Test Methods	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1312	Effective Date	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 14: [RESERVED]				
Chapter 15: Best Available Retrofit Technology				
Rule 19.1501	Purpose	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1502	Definitions	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1503	[Reserved]	6/22/2022	12/29/2023, [Insert Federal Register citation].	

EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP—Continued

State citation	Title/subject	State submission/ef- fective date	EPA approval date	Explanation
Rule 19.1504	[Reserved]	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1505	Best Available Retrofit Technology Requirements.	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1506	Compliance Provisions	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Rule 19.1507	[Reserved]	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Chapter 18: Effective Date				
Rule 19.1801	Effective Date	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Appendix A: Insignificant Activities List				
Appendix A	Insignificant Activities List	6/22/2022	12/29/2023, [Insert Federal Register citation].	
Appendix B: National Ambient Air Quality Standards List				
Appendix B	National Ambient Air Quality Standards List.	6/22/2022	12/29/2023, [Insert Federal Register citation].	
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■ 3. Section 52.173 is amended by adding paragraph (j) to read as follows:

§ 52.173 Visibility protection.

* * * * *

(j) *Revisions to the Arkansas Pollution Control and Ecology Commission’s (APC&EC) Rule No. 19, Chapter 15, submitted on June 22, 2022, are approved.*

[FR Doc. 2023–28497 Filed 12–28–23; 8:45 am]
 BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0936–AA14

Action to Delay Effective Date Consistent With Congressionally Enacted Moratorium

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This action stays certain amendments to the safe harbors to the Federal anti-kickback statute that were promulgated in a final rule (“Fraud And Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in

Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees”) published in the **Federal Register** on November 30, 2020 (the 2020 Final Rule). In response to a moratorium enacted by Congress on implementation of the 2020 Final Rule, most recently in section 11301 of the Inflation Reduction Act of 2022, which extended previous moratoria on implementation, administration, or enforcement of the 2020 Final Rule until January 1, 2032, the new effective date for the amendments set forth in the 2020 Final Rule is January 1, 2032.

DATES: As of December 29, 2023, 42 CFR 1001.952(h)(5)(viii), 42 CFR 1001.952(h)(6) through (9), 42 CFR 1001.952(cc), and 42 CFR 1001.952(dd) are stayed until January 1, 2032.

FOR FURTHER INFORMATION CONTACT: Aaron Zajic, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** published on November 30, 2020, the Department issued the 2020 Final Rule establishing four changes to the regulatory safe harbors to the Federal anti-kickback statute (section 1128B(b) of the Social Security Act).¹ Specifically, the 2020 Final Rule: (i) amended 42 CFR 1001.952(h)(5) to remove safe harbor protection for reductions in price for prescription pharmaceutical products provided to plan sponsors under Part D by making punctuation changes to subparagraphs (5)(vi) and (vii) and adding new subparagraph paragraph

(h)(5)(viii), (ii) added new paragraphs (6)–(9) to 42 CFR 1001.952(h), (iii) created a new safe harbor at 42 CFR 1001.952(cc) for certain point-of-sale reductions in price offered by manufacturers on prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations that meet certain criteria, and (iv) created a new safe harbor at 42 CFR 1001.952(dd) for fixed fees that manufacturers pay to pharmacy benefit managers for services rendered to the manufacturers that meet specified criteria. The 2020 Final Rule was published with an effective date of January 29, 2021, except for the amendments to 42 CFR 1001.952(h)(5), which were to be effective on January 1, 2022.

On January 12, 2021, a lawsuit challenging the final rule was filed in the U.S. District Court for the District of Columbia.² Because of orders in this lawsuit and in response to a Government memorandum regarding postponing effective dates of rules that had not yet taken effect, the effective dates of various sections of these amendments to the safe harbors were extended multiple times between January and March of 2021, and, ultimately, the effective date of the regulatory revisions established by the

² *Pharmaceutical Care Management Association v. United States Department of Health & Human Services et al.*, No. 1:21–cv–00095 (D. DC. filed Jan. 12, 2021).

¹ 85 FR 76666 (Nov. 30, 2020).