EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP—Continued

State citation	Title/subject	State submittal/effective 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.

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(j) *Revisions to the Arkansas Pollution Control and Ecology Commission's (APC&EC) Rule No. 19, Chapter 15.* Revisions to 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

[1] 85 FR 76666 (Nov. 30, 2020).

[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).

2020 Final Rule was extended to January 1, 2023.[3]

Subsequently, Congress extended this effective date three times: (i) section 90006 of the Infrastructure Investment and Jobs Act, Public Law 117–58, prohibited implementation, administration, or enforcement of the regulatory revisions established by the 2020 Final Rule prior to January 1, 2026; (ii) section 13101 of the Bipartisan Safe Communities Act, Public Law 117–159, extended the moratorium on implementation, administration, or enforcement until January 1, 2027; and (iii) section 11301 of the Inflation Reduction Act of 2022, Public Law 117–169, further extended the moratorium on implementation, administration, or enforcement of the 2020 Final Rule until January 1, 2032.

II. Final Rule

This final rule stays the amendments made to the safe harbor regulations through the 2020 Final Rule, specifically the new paragraphs added at 42 CFR 1001.952(h)(5)(viii), 42 CFR 1001.952(h)(6)–(9), 42 CFR 1001.952(cc), and 42 CFR 1001.952(dd). Pursuant to the most recent congressional mandate in section 11301 of the Inflation Reduction Act of 2022, Public Law 117–169, the 2020 Final Rule's revisions to the safe harbor regulations will be stayed until January 1, 2032.

III. Regulatory Impact Statement

As set forth below, we have examined the impact of this final rule as required by the Administrative Procedure Act, Executive Order 12866, the Regulatory Flexibility Act of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132.

A. Administrative Procedure Act

To the extent that 5 U.S.C. 553 applies to this action, implementation of this action without opportunity for public comment is based on the good cause exception in 5 U.S.C. 553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The postponement of the effective date, until January 1, 2032, is required by law. Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the orderly issue and implementation of regulations.

B. Executive Order 12866 and the Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act do not apply. Furthermore, this document does not meet the criteria for a significant regulatory action as specified in Executive Order 12866.

C. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or Tribal Governments in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation). We believe that this final rule will not impose any mandates on State, local, or Tribal Governments or the private sector that would result in an expenditure of $100 million or more (adjusted for inflation) in any given year, and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

D. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has federalism implications. In reviewing this final rule under the threshold criteria of Executive Order 13132, Federalism, we have determined that this final rule would not significantly limit the rights, roles, and responsibilities of State or local governments. We have determined, therefore, that a full analysis under Executive Order 13132 is not necessary.

IV. Paperwork Reduction Act

In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are required to solicit public comments, and receive final approval from the Office of Management and Budget, on any information collection requirements set forth in rulemaking. This final rule will not impose any information collection burden or affect information currently collected by OIG.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Social Security.

For the reasons set forth above, the following provisions of 42 CFR part 1001 are stayed as set forth below:

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302; 1320a–7; 1320a–7b; 1395u(j); 1395u(k); 1395w–104(e)(6), 1395y(d); 1395y(e); 1395cc(b)(2)(D), (E), and (F); 1395hh; 1842(j)(1)(D)(iv), 1842(k)(1), and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. In § 1001.952, paragraphs (h)(5)(viii), (h)(6) through (9), (cc), and (dd) are stayed until January 1, 2032.

Dated: December 26, 2023.

Xavier Becerra,

Secretary.

[FR Doc. 2023–28775 Filed 12–28–23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 30 and 150

[Docket No. USCG–2022–0327]

RIN 1625–AC73

2022 Liquid Chemical Categorization Updates

Correction

In rule document 2023–25026, appearing on pages 81184 through 81234 in the issue of Tuesday, November 21, 2023, make the following corrections:

§ 30.25–1 Cargoes carried in vessels certificated under the rules of this subchapter. [Corrrected]

■ 1. On page 81188, in the second column, on the fourth line from the bottom, ''(≤75%)'' should read ''(>75%)''.

■ 2. On the same page, in the same column, on the third and second lines from the bottom, ''(≤85%)'' should read ''(>85%)''.

■ 3. On page 81189, in the table, in the eighteenth row, ''(≤75%)'' should read ''(>75%)''.

■ 4. On the same page, in the same table, in the nineteenth row, ''(≤85%)'' should read ''(>85%)''.

■ 5. On the same page, in the same table, following the twenty-fourth row,

[3] See *Pharmaceutical Care Management Association* v. *United States Department of Health & Human Services et al.,* No. 1:21–cv–00095 (D. D.C. Jan. 30, 2021) (order granting joint stipulation and postponing effective date), Doc. No. 19; *see also* 86 FR 7815 (Feb. 2, 2021), 86 FR 10181 (Feb. 19, 2021), and 86 FR 15132 (Mar. 22, 2021).