EPA-APPROVED NON-REGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE ARKANSAS SIP—Continued

Name of SIP provision	Applicable geographic or nonattainment area	State submittal/ effective date	EPA approval date	Explanation
Arkansas 2015 O_3 NAAQS Interstate Transport SIP Revision.	Statewide	10/4/2019	3/22/2021 [Insert **Federal Register** citation].	Approval of visibility transport portion of this interstate transport SIP revision that addresses CAA section 110(a)(2)(D)(i)(II) for the following NAAQS: 2006 24-hour $PM_{2.5}$ NAAQS; the 2012 annual $PM_{2.5}$ NAAQS; the 2008 and 2015 eight-hour O_3 NAAQS; the 2010 one-hour NO_2 NAAQS; and the 2010 one-hour SO_2 NAAQS.
Arkansas Regional Haze SO_2 and PM SIP Revision.	Statewide	8/8/2018	3/22/2021 [Insert **Federal Register** citation].	Approval of visibility transport portion of this regional haze SIP revision, as supplemented by the Arkansas 2015 O_3 NAAQS Interstate Transport SIP Revision.

■ 3. In § 52.173, add paragraphs (h) and (i) to read as follows:

§ 52.173 Visibility protection.

* * * * *

(h) *Arkansas Regional Haze Phase III SIP Revision.* The Arkansas Regional Haze Phase III SIP Revision submitted on August 13, 2019, is approved as follows:

(1) The clear weight of evidence determination that the BART alternative for Power Boilers No. 1 and 2 satisfies all of the applicable regional haze provisions set forth in 40 CFR 51.308(e)(2)(i) to (iv) for the Domtar Ashdown Mill with respect to SO_2, NO_X, and PM_{10}.

(2) The regional haze program-specific plantwide conditions 32 to 43 from section VI of Permit #0287–AOP–R22 are approved for Power Boilers No. 1 and 2 for the Domtar Ashdown Mill, which contain SO_2, NO_X, and PM_{10} emission limits and conditions for implementing the BART alternative.

(3) The approval of the withdrawal of the current PM_{10} BART determination of 0.07 lb/MMBtu for Power Boiler No. 1 in the 2008 Arkansas Regional Haze SIP and replacement with the PM_{10} BART alternative limit in the Arkansas Regional Haze Phase III SIP Revision.

(4) The reasonable progress components under 40 CFR 51.308(d)(1) pertaining to the Domtar Ashdown Mill are approved.

(5) The long-term strategy component pertaining to the Domtar Ashdown Mill that includes the emission limits and schedules of compliance component under 40 CFR 51.308(d)(3)(v)(3) is approved.

(6) Consultation and coordination in the development of the SIP revision with the FLMs and with other states with Class I areas affected by emissions from Arkansas sources, as required under 40 CFR 51.308(i)(2) and 40 CFR 51.308(d)(3)(i), is approved.

(i) *Portions of the Arkansas 2015 O_3 NAAQS Interstate Transport SIP Revision and Arkansas Regional Haze SO_2 and PM SIP Revision addressing Visibility Transport.* The portion of the Arkansas 2015 O_3 NAAQS Interstate Transport SIP revision addressing the visibility transport requirements of CAA section 110(a)(2)(D)(i)(II) for Arkansas for the 2006 24-hour $PM_{2.5}$ NAAQS; the 2012 annual $PM_{2.5}$ NAAQS; the 2008 and 2015 eight-hour O_3 NAAQS; the 2010 one-hour NO_2 NAAQS; and the 2010 one-hour SO_2 NAAQS are approved. The visibility transport portion of the Arkansas Regional Haze SO_2 and PM SIP revision, as supplemented by the Arkansas 2015 O_3 NAAQS Interstate Transport SIP revision, is also approved.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0936–AA08

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; Additional Delayed Effective Date

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

ACTION: Final rule; notification of court-ordered delay of effective date.

SUMMARY: As required by an order issued by the U.S. District Court for the District of Columbia, this action provides notice of the delay of the effective date of 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 on November 30, 2020. The new effective date for these certain amendments is January 1, 2023.

DATES: As of March 18, 2021, the January 29, 2021 effective date of the amendments to 42 CFR 1001.952(h)(6)

through (9), (cc), and (dd) published at 85 FR 76666, November 30, 2020, which was delayed to March 22, 2021, pursuant to the rule published at 86 FR 7815, February 2, 2021, is further delayed until January 1, 2023. In addition, the effective date of the corrections published at 86 FR 7815, February 2, 2021, is delayed from March 22, 2021, to January 1, 2023.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 30, 2020, the Department issued a final rule establishing four changes to the regulatory safe harbors to the Federal anti-kickback statute (Social Security Act Section 1128B(b)). Specifically, the final rule: (1) 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; (2) created a new safe harbor at § 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; (3) created a new safe harbor at § 1001.952(dd) for fixed fees that manufacturers pay to pharmacy benefit managers (PBMs) for services rendered to the manufacturers that meet specified criteria; and (4) added new paragraphs (h)(6) through (9) to 42 CFR 1001.952, defining certain terms. The 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.[1] On January 30, 2021, the Court issued an order postponing until January 1, 2023, the effective date of the provisions of the final rule that were scheduled to take effect on January 1, 2022.[2] Consistent with that order, the Department notified the public that the effective date of the amendments to 42 CFR 1001.952(h)(5) in the final rule is now January 1, 2023.[3]

In the **Federal Register** of February 2, 2021, the Department announced that it was undertaking a regulatory review of the interactions between the final rule's various provisions and the overall regulatory framework.[4] To assure adequate time to determine what additional action, if any, would be appropriate, the Department delayed until March 22, 2021, the effective date of the amendments to 42 CFR 1001.952(h)(6) through (9), (cc), and (dd) published at 85 FR 76666, November 30, 2020. In addition, the Department determined that the November 2020 final rule contained a technical error in the amendatory instructions that would have prevented the Office of the Federal Register from properly incorporating the amendments to § 1001.952 into the CFR. The Department's February 2, 2021, **Federal Register** publication therefore announced a technical correction to those instructions that would likewise take effect on March 22, 2021.

On March 15, 2021, the Court issued an order postponing until January 1, 2023, the effective date of all provisions of the final rule that were scheduled to take effect on March 22, 2021.[5] Consistent with that order, the Department is taking this action to notify the public that the effective date of the amendments to 42 CFR 1001.952(h)(6) through (9), (cc), and (dd) in the final rule (inclusive of the technical correction) is now January 1, 2023. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of these amendments is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

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, 2023, is required by court order in accordance with the court's authority to postpone a rule's effective date pending judicial review (5 U.S.C. 705). 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.

Norris Cochran,

Acting Secretary.

[FR Doc. 2021–05903 Filed 3–18–21; 4:15 pm]

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

[2] *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.

[3] 86 FR 10181 (Feb. 19, 2021).

[4] 86 FR 7815 (Feb. 2, 2021).

[5] *Pharmaceutical Care Management Association* v. *United States Department of Health & Human Services et al.,* No. 1:21–cv–00095 (D. D.C .Mar. 15, 2021) (order granting joint stipulation and postponing effective date), Doc. No. 27.