



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 [INSERT DATE OF FILING FOR PUBLIC INSPECTION AT THE FEDERAL REGISTER], 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

¹ *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).

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

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: 3/18/2021 4:15 pm; Publication Date: 3/22/2021]

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