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; 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 February 19, 2021, this action delays the published effective date of the amendments to 42 CFR 1001.952(h)(5) published November 30, 2020, at 85 FR 76666, and corrected at 86 FR 7815, February 2, 2021, until 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 (6)–(9) to 42 CFR 1001.952(h), 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.[1]

On January 12, 2021, a lawsuit challenging the final rule was filed in the U.S. District Court for the District of Columbia.[2] On January 30, 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 January 1, 2022.[3] Consistent with that order, the Department is taking this action to notify the public that the effective date of the amendments to paragraph 42 CFR 1001.952 (h)(5) in the final rule 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 one-year 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. 2021–03167 Filed 2–18–21; 8:45 am]

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[1] 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, was subsequently delayed until March 22, 2021. 86 FR 7815 (Feb. 2, 2021).

[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).

[3] *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.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, 27, 90

[ET Docket No. 18–295; FCC 20–51; WT Docket No. 17–200; FCC 20–67, FRS 17383]

Unlicensed Use of the 6 GHz Band; Review of the Commission's Rules Governing the 896–901/935–940 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget has approved the information collection requirements associated with the rules and policies adopted in the Federal Communications Commission's 6 GHz Report and Order, FCC 20–51, making 1,200 megahertz of spectrum in the 6 GHz band (5.925–7.125 GHz) available for unlicensed use, and 900 MHz Report and Order, FCC 20–67, establishing rules for broadband license operations in the 897.5–900.5/936.5–939.5 MHz segment of the 900 MHz band (896–901/935–940 MHz), and that compliance with the new requirements is now required.

DATES: *Compliance date:* Compliance with 47 CFR 27.1503 and 27.1505, published at 85 FR 43124 on July 16, 2020, is required on February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Jaclyn Rosen, Mobility Division, Wireless Telecommunications Bureau, at (202) 418–0154 or *Jaclyn.Rosen@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that the Office of Management and Budget (OMB) approved the information collection requirements in 47 CFR 27.1503(b)(1), (b)(2), (b)(3), (c)(1) and 47 CFR 27.1505(a), (b), on December 10, 2020. These rules were adopted in the 6 GHz Order, FCC 20–51, published at 85 FR 31390 on May 26, 2020, and, 900 MHz Report and Order, FCC 20–67, published at 85 FR 43124 on July 16, 2020. Compliance with all new or amended rules adopted in the 6 GHz Order that do not require OMB approval