



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

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

ACTION: Final rule; delay of effective date; correction.

SUMMARY: In accordance with the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” and given the pendency of litigation, *Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services, et al.*, Civil Action No. 21-95 (JDB) (D.D.C.), challenging the final rule, this action temporarily delays for 60 days from the date of the memorandum the effective date of certain amendments as promulgated by the final rule titled “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 November 30, 2020, **Federal Register**. This document announces that the effective date for the certain provisions of the final rule is delayed until March 22, 2021, the first business day after 60 days from the date of the memorandum. This document also corrects a technical error in the amendatory instructions.

DATES: As of [INSERT DATE OF FILING FOR PUBLIC INSPECTION], 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, is delayed until March 22, 2021.

This correction is effective as of March 22, 2021. The amendatory instructions in FR 2020-25841 (85 FR 76666), published on November 30, 2020 is corrected.

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

SUPPLEMENTARY INFORMATION:

The January 20, 2021 memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” instructed Federal agencies to consider delaying the effective date of rules published in the **Federal Register**, but which have not yet taken effect, for a period of 60 days from the date of the memorandum to permit review of the rule. This action is consistent with that memorandum insofar as the Department has decided to review the rule at issue, and needs time to determine what additional action, if any, is appropriate.

The Department also has good cause to delay this rule’s effective date without advance notice and comment under 5 U.S.C. 553(b)(B) because of the pendency of litigation challenging the final rule, and the Department’s interest in evaluating its position in that litigation. The litigation includes both procedural and substantive challenges to the rule and its effective date. Though the provisions of the rule being delayed by this notice do not fully overlap with the provisions at issue in the pending litigation, the intersections between the rule’s various provisions and the overall regulatory framework are complex. HHS intends to evaluate those interactions as part of its regulatory review process, but needs additional time to do so beyond the current effective date of January 29, 2021.

Accordingly, this final rule delays the effective date of certain portions of the safe harbor regulation concerning discounts for prescription pharmaceutical products at 42 CFR 1001.952. The effective date of new paragraphs (h)(6) through (9), (cc), and (dd) of that rule, which would have been January 29, 2021, is now March 22, 2021. The temporary delay in the effective date of this final rule is necessary to give Department officials the opportunity for further review and consideration of the revisions to paragraphs (h)(5)(vi) and (viii), as well as the addition of new paragraphs (h)(5)(iii), (6) through (9), (cc), and (dd) of 42 CFR 1001.952, consistent with the memorandum of January 20, 2021.

Separately, 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. This document also corrects that error.

In FR 2020-25841 (85 FR 76666), published on November 30, 2020, the following corrections are made:

§ 1001.952 [Corrected]

1. On page 76730, third column, instruction 2 (including a. and b.) is corrected to read as follows:

2. Section 1001.952 is amended by adding paragraphs (h)(6) through (9), (cc), and (dd) to read as follows:

§ 1001.952 [Corrected]

2. On page 76731, first column, § 1001.952 is corrected by removing “(5) * * *”, and the text of paragraphs (vi) through (viii).

§ 1001.952 [Corrected]

3. On page 76731, third column, add amendatory instruction 3 to read as follows:

3. Effective January 1, 2022, § 1001.952 is amended by revising paragraphs (h)(5)(vi) and (vii) and adding paragraph (h)(5)(viii) to read as follows:

§ 1001.952 Exceptions.

* * * * *

(h) * * *

(5) * * *

(vi) Services provided in accordance with a personal or management services contract;

(vii) Other remuneration, in cash or in kind, not explicitly described in this paragraph

(h)(5); or

(viii) A reduction in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law.

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Norris Cochran,
Acting Secretary.

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