



[4830-01-p]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 51

[TD 9684]

RIN 1545-BJ39

Branded Prescription Drug Fee; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment

SUMMARY: This document contains corrections to final regulations (TD 9684) that were published in the **Federal Register** on Monday, July 28, 2014 (79 FR 43631). The final regulations provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing branded prescription drugs.

DATES: This correction is effective **[INSERT DATE OF PUBLICATION OF THIS DOCUMENT IN THE FEDERAL REGISTER]** and applicable beginning July 28, 2014.

FOR FURTHER INFORMATION CONTACT: Celia Gabrysh, at (202) 317-6855 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9684) that are the subject of this correction is under section 9008 of the Patient Protection and Affordable Care Act.

Need for Correction

As published, the final regulations (TD 9684) contains errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 51

Drugs, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 51 is corrected by making the following correcting amendments:

PART 51—BRANDED PRESCRIPTION DRUG FEE

Paragraph 1. The authority citation for part 51 continues to read in part as follows:

Authority: 26 U.S.C. 7805 ***

Par. 2. Section 51.4 is corrected by revising paragraphs (b)(2)(i)(A) and (B) (b)(2)(ii) through (iv), and (c)(4)(i)(D) to read as follows:

§51.4 Information provided by the Agencies.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(A) Any direct and indirect remuneration (DIR) (within the meaning of paragraph (b)(2)(ii) of this section), which includes any DIR reported on the PDE records at the

point of sale and any DIR reported on a Detailed DIR Report (within the meaning of a paragraph (b)(2)(iii) of this section); and

(B) Any coverage gap discount amount (within the meaning of paragraph (b)(2)(iv) of this section).

(ii) Direct and indirect remuneration. For purposes of paragraph (b)(2)(i)(A) of this section, the term direct and indirect remuneration (DIR) has the same meaning as found in the definition of actually paid in 42 CFR 423.308.

(iii) Detailed DIR Report. For purposes of paragraph (b)(2)(i)(A) of this section, the term Detailed DIR Report means the report containing any DIR (within the meaning of paragraph (b)(2)(ii) of this section) that is collected yearly from Part D sponsors at the NDC level.

(iv) Coverage gap discount amount. For purposes of paragraph (b)(2)(i)(B) of this section, the term coverage gap discount amount means a 50-percent manufactured-paid discount on certain drugs under the Coverage Gap Discount Program described in section 1860D-14A of the Social Security Act.

(c) * * *

(4) * * *

(i) * * *

(D) Those entities (if any) identified in paragraph (c)(4)(i)(C) of this section that are manufacturing branded prescription drugs assigned to the HCPCS code.

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