



[4830-01-p]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 51

[TD 9823]

RIN 1545-BM26

Branded Prescription Drug Fee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that define the term controlled group for purposes of the branded prescription drug fee. The final regulations supersede and adopt the text of temporary regulations that define the term controlled group. The final regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs.

DATES: Effective Date: The final regulations are effective **July 24, 2017**.

Applicability Date: For dates of applicability, see §51.11(b) of the final regulations.

FOR FURTHER INFORMATION CONTACT: Rachel S. Smith at (202) 317-6855 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The branded prescription drug fee was enacted by section 9008 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as

amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (collectively the ACA). Section 9008 did not amend the Internal Revenue Code (Code) but cross-references specific Code sections.

On July 28, 2014, temporary regulations (TD 9684) relating to the fee on branded prescription drugs were published in the **Federal Register** (79 FR 43631) (2014 temporary regulations). A notice of proposed rulemaking (REG-123286-14) cross-referencing the temporary regulations was published in the **Federal Register** on the same day (79 FR 43699). The 2014 temporary regulations provided a definition of the term controlled group that was broader than the definition of the term controlled group in §51.2T(e)(3) of the temporary regulations (TD 9544) published in the **Federal Register** (76 FR 51245) on August 18, 2011 (2011 temporary regulations).

Neither the Department of the Treasury (Treasury Department) nor the Internal Revenue Service (IRS) received any written comments with respect to the notice of proposed rulemaking and no public hearing was requested or held. The final regulations adopt the proposed regulations without change and the 2014 temporary regulations are removed.

Explanation of Provisions

The 2011 temporary regulations defined the term controlled group to mean a group of at least two covered entities that are treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code. The 2014 temporary regulations defined the term controlled group more broadly to mean a group of two or more persons, including at least one person that is a covered entity, that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code. These final

regulations adopt the definition of controlled group contained in the 2014 temporary regulations without change.

The broader definition of the term controlled group in the 2014 temporary regulations and these final regulations is supported by the statutory language and is consistent with the way in which controlled group rules based on similar statutory language are applied, including how the term controlled group is defined in §57.2(c)(1) for purposes of the health insurance providers fee under section 9010 of the ACA. Consistent with the preamble to the 2014 temporary regulations, the Treasury Department and the IRS continue to expect that the broader definition of the term controlled group in the final regulations will primarily affect the scope of joint and several liability for the fee and will not otherwise affect the administration of the fee.

The 2014 temporary regulations applied beginning on January 1, 2015 (i.e., starting with 2015 sales years), and are effective until July 24, 2017. These final regulations apply on and after **July 24, 2017**. Because both the 2014 temporary regulations and these final regulations provide the same definition of controlled group for purposes of section 9008 of the ACA, that definition applies continuously beginning with the 2015 sales year and 2017 fee year.

Special Analyses

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. Because the final regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the

Code, the notice of proposed rulemaking that preceded the final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business. No comments were received on the proposed regulations.

Drafting Information

The principal author of these final regulations is Rachel S. Smith, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 51

Drugs, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 51 is amended as follows:

PART 51 – BRANDED PRESCRIPTION DRUG FEE

Paragraph 1. The authority citation for part 51 is revised to read as follows:

Authority: 26 U.S.C. 7805; sec. 9008, Pub. L. 111-148, 124 Stat. 119.

Section 51.8 also issued under 26 U.S.C. 6302(a).

Section 51.6302-1 also issued under 26 U.S.C. 6302(a).

Par. 2. Section 51.2 is amended by revising paragraph (e)(3) to read as follows:

§51.2 Explanation of terms.

* * * * *

(e) * * *

(3) Controlled group. The term controlled group means a group of two or more persons, including at least one person that is a covered entity, that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o).

* * * * *

§51.2T [Removed]

Par. 3. Section 51.2T is removed.

Par. 4. Section 51.11 is amended by revising the section heading and paragraph (b) and removing paragraph (c) to read as follows:

§51.11 Applicability date.

* * * * *

(b) Section 51.2(e)(3) applies on and after **July 24, 2017**.

§51.11T [Removed]

Par. 5. Section 51.11T is removed.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: July 17, 2017.

Tom West,

Tax Legislative Counsel.