[4830-01-p]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 51

[REG-123286-14]

RIN 1545-BM26

Branded Prescription Drug Fee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the branded prescription drug fee. This fee was enacted by section 9008 of the Patient Protection and Affordable Care Act, as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, and the Health Care and Reconciliation Act of 2010 (collectively the ACA). The proposed regulations modify the definition of controlled group for purposes of the branded prescription drug fee. The proposed regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs. The text of the temporary regulations also serves as the text of the proposed regulations.

DATES: Comments and requests for a public hearing must be received by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-123286-14), room 5205, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered to: CC:PA:LPD:PR Monday through Friday

between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-123286-14), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC, or sent electronically via the Federal eRulemaking Portal at www.regulations.gov (IRS REG-123286-14).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Celia Gabrysh, (202) 317-6855; concerning submissions of comments and request for a hearing, Oluwafunmilayo Taylor, (202) 317-6901 (not toll-free calls).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend §§51.2(e)(3) and 51.11(c) of the Branded Prescription Drug Fee Regulations, 26 CFR Part 51. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendment.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory flexibility assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. Because these regulations do not impose a collection of information on small entities, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking has

been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the "Addresses" heading. Comments are requested on all aspects of the proposed regulations. All comments will be available at www.regulations.gov or upon request. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Celia Gabrysh, Office of 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.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 51 is proposed to be amended as follows:

PART 51--BRANDED PRESCRIPTION DRUGS

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

Authority: Authority: 26 U.S.C. 7805; sec. 9008, Public Law 111-347 (124 Stat. 119).

* * * * *

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

§51.2 Explanation of terms.

* * * * *

(e) * * *

(3) [The text of proposed §51.2(e)(3) is the same as the text of §51.2T(e)(3) published elsewhere in this issue of the **Federal Register**.]

Par. 3. Section 51.11 is amended by revising paragraph (c) to read as follows:

§51.11 Effective/applicability date.

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(c) [The text of proposed §51.11(c) is the same as the text of §51.11T(c) published elsewhere in this issue of the **Federal Register**.]

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

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