(8) The rate of tax per cubic yard determined by the California Debris Commission applicable to the particular mine; and

(9) The amount of tax due and payable (cubic yards mined multiplied by the rate of tax per cubic yard).

(c) *Supporting statement.* With each return there must be submitted a supporting statement of the person who made the surveys at the mine for the mining season covered by the return (see § 50.6), stating that such surveys were made in accordance with requirements prescribed by the California Debris Commission.

(d) *Verification of return and supporting statement.* The return and the supporting statement shall be verified by written declarations that they are made under the penalties of perjury.

§ 50.8 Due date and place for filing returns and paying tax.

The return for a taxable year shall be filed with, and the tax shall be paid to, the district director at San Francisco, California, on or before September 30 of the calendar year in which the taxable year ends. The tax is due and payable on such date without assessment by, or notice from, the district director.

PART 51—BRANDED PRESCRIPTION DRUG FEE

Sec.

AUTHORITY: 26 U.S.C. 7805; sec. 9008, Public Law 111–347 (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).

SOURCE: T.D. 9544, 76 FR 51249, Aug. 18, 2011, unless otherwise noted.

§ 51.1T Overview (temporary).

(a) The regulations in this part 51 are designated ''Branded Prescription Drug Fee Regulations.''

(b) The regulations in this part 51 provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111–148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111–152 (124 Stat. 1029 (2010)). All references in these regulations to section 9008 are references to section 9008 of the ACA, as amended by section 1404 of HCERA. Unless otherwise indicated, all other section references are to sections in the Internal Revenue Code. All references to ''fee'' in these regulations are references to the fee imposed by section 9008.

(c) Section 9008(b)(4) sets an applicable fee amount for each year, beginning with 2011, that will be apportioned among covered entities with aggregate branded prescription drug sales of over $5 million to government programs or pursuant to coverage under such programs. Generally, each covered entity is liable for a fee in each fee year that is based on its sales of branded prescription drugs in the sales year that corresponds to the fee year in an amount determined by the Internal Revenue Service (IRS) under the rules of this part.

§ 51.2T Explanation of terms (temporary).

(a) *In general.* This section explains the terms used in this part for purposes of the fee imposed by section 9008 on branded prescription drugs.

(b) *Agencies.* The term *agencies* means—

(1) The Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS);

(2) The Department of Veterans Affairs (VA); and

(3) The Department of Defense (DOD).

(c) *Branded prescription drug*—(1) *In general.* The term *branded prescription drug* means—

(i) Any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)); or

(ii) Any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(2) *Prescription drug.* The term *prescription drug* means any drug that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(d) *Branded prescription drug sales.* The term *branded prescription drug sales* means sales of branded prescription drugs to any government program or pursuant to coverage under any such government program. However, the term does not include sales of orphan drugs.

(e) *Covered entity*—(1) *In general.* The term *covered entity* means any manufacturer or importer with gross receipts from branded prescription drug sales including—

(i) A single-person covered entity; or

(ii) A controlled group.

(2) *Single-person covered entity.* The term *single-person covered entity* means a covered entity that is not affiliated with any other covered entity.

(3) *Controlled group.* The term *controlled group* means 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).

(4) *Special rules for controlled groups.* For purposes of paragraph (e)(3) of this section (related to controlled groups)—

(i) A foreign entity subject to tax under section 881 is included within a group under section 52(a) or 52(b); and

(ii) A covered entity is treated as being a member of a controlled group if it is a member of the group on the end of the day on December 31st of the sales year.

(f) *Designated entity*—(1) *In general.* The term *designated entity* means the person that acts for a controlled group regarding the fee by—

(i) Filing Form 8947, ''Report of Branded Prescription Drug Information'';

(ii) Receiving IRS communications about the fee for the group;

(iii) Filing an error report for the group, if applicable, as described in § 51.7T; and

(iv) Paying the fee to the IRS.

(2) *Selection of designated entity*—(i) *Choice of controlled group.* Unless the controlled group is an affiliated group that filed a consolidated return for Federal income tax purposes, the controlled group may select a person as the designated entity by filing Form 8947 in accordance with the form instructions. Among other requirements, the designated entity must state that all the manufacturers or importers of branded prescription drugs that are members of the group have consented to the selection of the designated entity.

(ii) *Requirement for affiliated groups; common parent.* If the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B), is also an affiliated group that filed a consolidated return for Federal income tax purposes, the designated entity is the common parent of the affiliated group as identified on the tax return filed for the sales year. The covered entities in an affiliated group must name the common parent as the designated entity on Form 8947.

(iii) *IRS selection of a designated entity.* If a controlled group does not select a designated entity, the IRS will select a member of the controlled group as the designated entity for the controlled group.

(g) *Fee year.* The term *fee year* means the calendar year in which the fee for a particular sales year must be paid to the government.

(h) *Government programs.* The term *government programs* (collectively ''Programs''), means—

(1) The Medicare Part B program;

(2) The Medicare Part D program;

(3) The Medicaid program;

(4) Any program under which branded prescription drugs are procured by the Department of Veterans Affairs;

(5) Any program under which branded prescription drugs are procured by the Department of Defense; and

(6) The TRICARE retail pharmacy program.

(i) *Manufacturer or importer*. The term *manufacturer or importer* means the person identified in the Labeler Code of the National Drug Code (NDC) for a branded prescription drug.

(j) *NDC*. The term *NDC* means the National Drug Code. The NDC is an identifier assigned by the Food and Drug Administration (FDA) to a branded prescription drug, as well as other drugs. The Labeler Code is the first five numeric characters of the NDC or the first six numeric characters when the available five-character code combinations are exhausted.

(k) *Orphan drugs*—(1) *In general*. Except as provided in paragraph (k)(2) of this section, the term *orphan drug* means any branded prescription drug for which any person claimed a section 45C credit and that credit was allowed for any taxable year.

(2) *Exclusions*. The term *orphan drug* does not include—

(i) Any drug for which there has been a final assessment or court order disallowing the full section 45C credit taken for the drug; or

(ii) Any drug for any sales year after the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, regardless of whether a section 45C credit was allowed for the drug either before, in the same year as, or after this FDA designation.

(3) *FDA marketing approval for treatment of another rare disease or condition*. If a drug has prior FDA marketing approval for the treatment of a rare disease or condition for which a section 45C credit was allowed, and the FDA subsequently gives the drug marketing approval for the treatment of another rare disease or condition for which another section 45C credit was also allowed, the drug retains its status as an orphan drug provided the FDA has never approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed.

(4) *Examples*. The following examples illustrate the rules of this paragraph (k):

Example 1: Allowance of section 45C credit and later FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition. (i) *Facts.* Drug A is a branded prescription drug that was not on the market before 2008. In 2008, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug A. There was no final IRS assessment or court order that disallowed the full credit for Drug A. In 2009, the FDA approved Drug A for marketing for an indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed and this indication was not for another rare disease or condition for which a section 45C was allowed.

(ii) *Analysis.* In 2008 and 2009, Drug A is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was not a final assessment or court order disallowing the full credit taken for the drug; and third, before 2009, the FDA did not approve the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. However, Drug A is not an orphan drug for the 2010 sales year or later sales years because in 2009 the FDA approved Drug A for marketing for an indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed and this indication was not for treatment of another rare disease or condition for which a section 45C credit was allowed.

Example 2: FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition and later allowance of section 45C credit. (i) *Facts.* Drug B is a branded prescription drug that was not on the market before 2008. In 2008, FDA approved Drug B for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. In 2009, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug B. There was no final IRS assessment or court order that disallowed the full credit for Drug B.

(ii) *Analysis.* In 2008, Drug B is not an orphan drug because no section 45C credit was allowed. In 2009, although the covered entity was allowed a section 45C credit for its qualified clinical testing expenses related to Drug B and there was no final IRS assessment or court order that disallowed the full credit, Drug B still is not an orphan drug because the FDA had approved the drug in 2008 for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed in 2009. Thus, Drug B is not an orphan drug for the 2009 sales year or later sales years.

Example 3: Allowance of section 45C credit and subsequent allowance of section 45C credit with no intervening FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. (i) *Facts.* Drug C is a branded prescription drug that was not on the market before 2007. In 2007, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug C. In 2009, a covered entity claimed an additional section 45C credit for its qualified clinical testing expenses related to Drug C for marketing for the treatment of a rare disease or condition different than the one for which the section 45C credit was claimed in 2007. There was no final IRS assessment or court order that disallowed the full credit for Drug C in 2007 or 2009. The FDA has not approved Drug C for an indication other than the treatment of a rare disease or condition for which a section 45C was allowed.

(ii) *Analysis.* In 2007 and 2008, Drug C is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was not a final assessment or court order disallowing the full credit taken for the drug; and third, FDA had not approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. In 2009, Drug C retains its orphan drug status because another section 45C credit was allowed and the FDA did not approve Drug C for marketing for any indication other than the treatment of another rare disease or condition for which a section 45C credit was allowed. Thus, Drug C is an orphan drug for the 2010 sales year.

(l) *Sales taken into account.* The term *sales taken into account* means branded prescription drug sales after application of the percentage adjustment table in section 9008(b)(2) (relating to annual sales less than $400,000,001). See § 51.5T(a)(3).

(m) *Sales year.* The term *sales year* means the second calendar year preceding the fee year. Thus, for example, for the fee year of 2011, the sales year is 2009.

[T.D. 9544, 76 FR 51249, Aug. 18, 2011; 76 FR 59897, Sept. 28, 2011]

§ 51.3T Information requested from covered entities (temporary).

(a) *In general.* Annually, each covered entity may submit a completed Form 8947, ''Report of Branded Prescription Drug Information,'' in accordance with the instructions for the form. Generally, the form solicits information from covered entities on NDCs, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions.

(b) *Due date.* Form 8947 must be filed by the date prescribed in guidance in the Internal Revenue Bulletin.

§ 51.4T Information provided by the agencies (temporary).

(a) *In general.* For each sales year, the IRS will compile a list of branded prescription drugs by NDC using the data submitted on Forms 8947 and in error reports submitted as part of the dispute resolution process (described in § 51.7T) and, after applying appropriate due diligence, will provide this list to the Agencies. The Agencies will provide data to the IRS on branded prescription drug sales during the sales year by Program and NDC. The Agencies will provide data for use in preparing the preliminary fee calculation (described in §§ 51.5T and 51.6T) and may revise or supplement that data following review of error reports submitted as part of the dispute resolution process. The calculation methodology for calculating the sales amounts for each Program, including any reasonable estimation techniques and assumptions that the Agencies expect to use, is described in this section.

(b) *Medicare Part D.* CMS will aggregate the ingredient cost reported in the ''Ingredient Cost Paid'' field and the units reported in the ''Quantity Dispensed'' field of the Prescription Drug Event (PDE) records at the NDC level for each sales year. Only PDE data that Part D sponsors have submitted by the PDE submission deadline (within 6 months after the end of the sales year) and have been approved for inclusion in the Part D payment reconciliation will be included.

(c) *Medicare Part B*—(1) *In general.* CMS will determine branded prescription drug sales under Medicare Part B using the following two data sources:

(i) CMS will use data reported by manufacturers pursuant to section 1847A(c) of the Social Security Act to calculate the annual weighted average sales price (ASP) for each Healthcare Common Procedure Coding System (HCPCS) code for the sales year.