

HIGHLIGHTS OF THIS ISSUE

These synopses are intended only as aids to the reader in identifying the subject matter covered. They may not be relied upon as authoritative interpretations.

INCOME TAX

Rev. Rul. 2012-32, page 762.

Interest rates; underpayment and overpayments. The rates for interest determined under section 6621 of the Code for the calendar quarter beginning January 1, 2013, will be 3 percent for overpayments (2 percent in the case of a corporation), 3 percent for the underpayments, and 5 percent for large corporate underpayments. The rate of interest paid on the portion of a corporate overpayment exceeding \$10,000 will be 0.5 percent.

Notice 2012-54, page 773.

Qualified plug-in electric drive motor vehicle credit; update of Notice 2009-89. This notice modifies Notice 2009-89, 2009-2 C.B. 714, by changing the address to which a manufacturer (or, in the case of a foreign manufacturer, its domestic distributor) sends certifications and quarterly reports under Notice 2009-89. Notice 2009-89 modified.

Notice 2012-65, page 773.

The notice invites public comments regarding guidance to be provided to governmental and financial entities (applicable entities) described under section 6050P(c) of the Code, who discharge indebtedness and may be required to furnish Form 1099-C information returns pursuant to section 6050P and Treasury regulations section 1.6050P.

EMPLOYEE PLANS

T.D. 9602, page 746.

Final regulations under sections 4375, 4376, and 4377 of the Code provide guidance on determining which health insurance

policies and self-insured health plans and arrangements are subject to fees for the Patient-Centered Outcomes Research Trust Fund, and also on the requirements for calculating, reporting, and paying the fees.

Notice 2012-76, page 775.

This notice contains the 2012 Cumulative List of Changes in Plan Qualification Requirements (2012 Cumulative List) described in section 4 of Rev. Proc. 2007-44, 2007-2 C.B. 54. The 2012 Cumulative List is to be used by plan sponsors and practitioners submitting determination, opinion, or advisory letter applications for plans during the period beginning February 1, 2013 and ending January 31, 2014.

Notice 2012-78, page 785.

Weighted average interest rate update; corporate bond indices; 30-year Treasury securities; segment rates.

This notice contains updates for the corporate bond weighted average interest rate for plan years beginning in December 2012; the 24-month average segment rates; the funding transitional segment rates applicable for December 2012; and the minimum present value transitional rates for November 2012. The rates in this notice reflect certain changes implemented by the Moving Ahead for Progress in the 21st Century Act, Public Law 112-141 (MAP-21).

EXEMPT ORGANIZATIONS

Announcement 2012-49, page 801.

The IRS has revoked its determination that Amani Foundation of Aurora, CO; Excalibur Foundation of Sparks, NV; and The Play Institute of Horseshoe Bay, TX, qualify as organizations described in sections 501(c)(3) and 170(c)(2) of the Code.

(Continued on the next page)

Finding Lists begin on page ii.
Index for July through December begins on page iv.



Announcement 2012–50, page 802.

This document updates Announcement 2012–25, 2012–26 I.R.B. 1054, by extending the time for businesses to comply with the proper treatment of service charges as specified in Q&A 1 of Rev. Rul. 2012–18, 2012–26 I.R.B. 1032., from January 1, 2013 to January 1, 2014. Announcement 2012–25 amplified.

EMPLOYMENT TAX

REG–130074–11, page 790.

Proposed regulations under section 3101 of the Code provide guidance on the Additional Hospital Insurance Tax on wages, compensation, and self-employment income above threshold amounts (“Additional Medicare Tax”), as added by the Affordable Care Act. Specifically, these proposed regulations provide guidance for employers and individuals relating to the implementation of Additional Medicare Tax, relating to the requirement to file a return reporting Additional Medicare Tax, the employer process for making adjustments of underpayments and overpayments of Additional Medicare Tax, and the employer and employee processes for filing a claim for refund for an overpayment of Additional Medicare Tax. A public hearing is scheduled for April 4, 2013.

SELF-EMPLOYMENT TAX

REG–130074–11, page 790.

Proposed regulations under section 3101 of the Code provide guidance on the Additional Hospital Insurance Tax on wages, compensation, and self-employment income above threshold amounts (“Additional Medicare Tax”), as added by the Affordable Care Act. Specifically, these proposed regulations provide guidance for employers and individuals relating to the implementation of Additional Medicare Tax, relating to the requirement to file a return reporting Additional Medicare Tax, the employer process for making adjustments of underpayments and overpayments of Additional Medicare Tax, and the employer and employee processes for filing a claim for refund for an overpayment of Additional Medicare Tax. A public hearing is scheduled for April 4, 2013.

EXCISE TAX

T.D. 9602, page 746.

Final regulations under sections 4375, 4376, and 4377 of the Code provide guidance on determining which health insurance policies and self-insured health plans and arrangements are subject to fees for the Patient-Centered Outcomes Research Trust Fund, and also on the requirements for calculating, reporting, and paying the fees.

T.D. 9604, page 730.

Final regulations provide guidance under section 4191 of the Code on the excise tax on sales of certain medical devices. The tax is effective for sales after December 31, 2012. The final regulations provide a regulatory definition for a “taxable medical device,” and standards for determining if a device is not a taxable medical device because it is generally purchased by the general public at retail for individual use. The final regulations also provide guidance for calculating the tax on lease or installment sale payments where the payments are made on or after January 1, 2013, under a pre-2013 contract. The final regulations will affect medical device manufacturers and importers.

Notice 2012–77, page 781.

This notice provides interim guidance relating to the excise tax on medical devices imposed by section 4191 (the “medical device excise tax”) of the Code. Section 4191 was enacted by section 1405 of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)), in conjunction with the Patient Protection and Affordable Care Act, Public Law 111–148 (124 Stat. 119 (2010)).

ADMINISTRATIVE

Notice 2012–65, page 773.

The notice invites public comments regarding guidance to be provided to governmental and financial entities (applicable entities) described under section 6050P(c) of the Code, who discharge indebtedness and may be required to furnish Form 1099–C information returns pursuant to section 6050P and Treasury regulations section 1.6050P.

The IRS Mission

Provide America's taxpayers top-quality service by helping them understand and meet their tax responsibilities and en-

force the law with integrity and fairness to all.

Introduction

The Internal Revenue Bulletin is the authoritative instrument of the Commissioner of Internal Revenue for announcing official rulings and procedures of the Internal Revenue Service and for publishing Treasury Decisions, Executive Orders, Tax Conventions, legislation, court decisions, and other items of general interest. It is published weekly and may be obtained from the Superintendent of Documents on a subscription basis. Bulletin contents are compiled semiannually into Cumulative Bulletins, which are sold on a single-copy basis.

It is the policy of the Service to publish in the Bulletin all substantive rulings necessary to promote a uniform application of the tax laws, including all rulings that supersede, revoke, modify, or amend any of those previously published in the Bulletin. All published rulings apply retroactively unless otherwise indicated. Procedures relating solely to matters of internal management are not published; however, statements of internal practices and procedures that affect the rights and duties of taxpayers are published.

Revenue rulings represent the conclusions of the Service on the application of the law to the pivotal facts stated in the revenue ruling. In those based on positions taken in rulings to taxpayers or technical advice to Service field offices, identifying details and information of a confidential nature are deleted to prevent unwarranted invasions of privacy and to comply with statutory requirements.

Rulings and procedures reported in the Bulletin do not have the force and effect of Treasury Department Regulations, but they may be used as precedents. Unpublished rulings will not be relied on, used, or cited as precedents by Service personnel in the disposition of other cases. In applying published rulings and procedures, the effect of subsequent legislation, regulations,

court decisions, rulings, and procedures must be considered, and Service personnel and others concerned are cautioned against reaching the same conclusions in other cases unless the facts and circumstances are substantially the same.

The Bulletin is divided into four parts as follows:

Part I.—1986 Code.

This part includes rulings and decisions based on provisions of the Internal Revenue Code of 1986.

Part II.—Treaties and Tax Legislation.

This part is divided into two subparts as follows: Subpart A, Tax Conventions and Other Related Items, and Subpart B, Legislation and Related Committee Reports.

Part III.—Administrative, Procedural, and Miscellaneous.

To the extent practicable, pertinent cross references to these subjects are contained in the other Parts and Subparts. Also included in this part are Bank Secrecy Act Administrative Rulings. Bank Secrecy Act Administrative Rulings are issued by the Department of the Treasury's Office of the Assistant Secretary (Enforcement).

Part IV.—Items of General Interest.

This part includes notices of proposed rulemakings, disbarment and suspension lists, and announcements.

The last Bulletin for each month includes a cumulative index for the matters published during the preceding months. These monthly indexes are cumulated on a semiannual basis, and are published in the last Bulletin of each semiannual period.

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Part I. Rulings and Decisions Under the Internal Revenue Code of 1986

Section 1401.—Rate of Tax

A Notice of Proposed Rulemaking (NPRM) notes that the applicable threshold amounts for the tax imposed by section 1401(b)(2)(A) are reduced (but not below zero) by the amount of wages taken into account in determining the tax imposed under section 3101(b)(2) with respect to the taxpayer. Section 3101(b)(2) was enacted by section 9015 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111–148 (124 Stat. 119 (2010)), and amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)) (collectively, the “Affordable Care Act”). The Affordable Care Act added section 1401(b)(2) to describe the extent to which an individual who has self-employment income is liable for the tax imposed by section 3101(b)(2). See REG-130074-11, page 790.

Section 3102.—Deduction of Tax From Wages

A Notice of Proposed Rulemaking (NPRM) notes that in the case of any tax imposed by section 3101(b)(2) the withholding rules for employers described in section 3102(a) apply only to the extent that an employee receives wages from the employer in excess of \$200,000 in a calendar year. Section 3101(b)(2) was enacted by section 9015 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111–148 (124 Stat. 119 (2010)), and amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)) (collectively, the “Affordable Care Act”). The Affordable Care Act added section 3102(f) to describe an employer’s withholding requirements for the tax imposed by section 3101(b)(2) (effective for wages paid after December 31, 2012). See REG-130074-11, page 790.

A Notice of Proposed Rulemaking (NPRM) describes the liability of an employer and employee for the tax imposed by section 3101(b)(2) to the extent that the tax is not withheld by the employer. See REG-130074-11, page 790.

Section 3202.—Deduction of Tax From Compensation

A Notice of Proposed Rulemaking (NPRM) provides that in the case of any tax imposed by section 3101(b)(2) the withholding rules for employers described in section 3202(a) apply, but only to the extent that an employee receives wages from the employer in excess of \$200,000 in a calendar year. Section 3101(b)(2) was enacted by section 9015 of the

Patient Protection and Affordable Care Act (PPACA), Public Law 111–148 (124 Stat. 119 (2010)), and amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)) (collectively, the “Affordable Care Act”). See REG-130074-11, page 790.

A Notice of Proposed Rulemaking (NPRM) describes the liability of an employer and employee subject to the withholding rules of section 3202(a) for the tax imposed by section 3101(b)(2) to the extent that the tax is not withheld by the employer. See REG-130074-11, page 790.

Section 4191.—Medical Devices

26 CFR 48.4191–1: Imposition and rate of tax.

T.D. 9604

DEPARTMENT OF THE TREASURY Internal Revenue Service 26 CFR Part 48

Taxable Medical Devices

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance on the excise tax imposed on the sale of certain medical devices, enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act. The final regulations affect manufacturers, importers, and producers of taxable medical devices.

DATES: *Effective Date:* These regulations are effective on December 7, 2012.

Applicability Date: These regulations are applicable to sales of taxable medical devices after December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Natalie Payne, Michael Beker, or Stephanie Bland, at (202) 622–3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations that provide guidance on the excise tax imposed on the sale of certain medical devices under section 4191 (the medical device excise tax) of the Internal Revenue Code (Code), enacted by section 1405 of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)), in conjunction with the Patient Protection and Affordable Care Act, Public Law 111–148 (124 Stat. 119 (2010)) (jointly, the ACA).

On February 7, 2012, the IRS and the Treasury Department published a notice of proposed rulemaking (REG–113770–10, 2012–13 I.R.B. 587) (the proposed regulations) in the **Federal Register** (77 FR 6028). The IRS and the Treasury Department received numerous written comments from the public in response to the proposed regulations. A public hearing was held on May 16, 2012. After consideration of the public written comments and hearing comments, the IRS and the Treasury Department are finalizing the proposed regulations with the changes described in this preamble.

Public comments on the proposed regulations identified two issues that the IRS and the Treasury Department will study further and on which the IRS and the Treasury Department have requested additional comments. Those issues are discussed later in this preamble. Comments with regard to those issues should be submitted in writing and can be mailed to the Office of Associate Chief Counsel (Passthroughs and Special Industries), Re: REG–113770–10, CC:PSI:B7, Room 5314, 1111 Constitution Avenue, NW, Washington, DC 20224. All comments received will be available for public inspection at <http://www.regulations.gov> (IRS REG–113770–10).

Explanation of Provisions and Summary of Comments

I. Definition of a “Taxable Medical Device”

Section 4191(b)(1) provides that, in general, a “taxable medical device” is any device, as defined in section 201(h) of the Federal Food, Drug & Cosmetic Act (FFDCA) (codified as amended at 21 U.S.C. 301 *et seq.* (2006)) that is intended for humans.

A. Proposed Regulations

The proposed regulations provide that for purposes of the medical device excise tax, a device defined in section 201(h) of the FFDCA that is intended for humans means a device that is listed as a device with the Food and Drug Administration (FDA) under section 510(j) of the FFDCA and 21 CFR part 807, pursuant to FDA requirements. The proposed regulations further provide that if a device is not listed with the FDA, but the FDA later determines that the device should have been listed as a device, the device will be deemed to have been listed as a device with the FDA as of the date the FDA notifies the manufacturer or importer in writing that corrective action with respect to listing is required.

B. Public Comments and the Final Regulations

Listing requirement

One commenter suggested that the listing rule is overbroad because it includes virtually all types of medical devices in the tax base. The commenter requested that the final regulations narrow the definition of a taxable medical device so that the excise tax is imposed only on devices that Congress specifically intended to subject to the tax.

The final regulations do not adopt this suggestion. Congress linked the definition of a taxable medical device to the definition of a “device” under section 201(h) of the FFDCA. In general, the FDA requires a device defined in section 201(h) of the FFDCA that is intended for humans to be listed as device with the FDA under section 510(j) of the FFDCA and 21 CFR part 807, subject to certain limited exceptions.

The final regulations track this FDA requirement by defining a taxable medical device as a device that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR part 807. This provides taxpayers with greater certainty as to which devices are subject to the tax.

Biologic Devices

Several commenters requested that the final regulations clarify that the definition of a taxable medical device does not include the category of products reviewed as devices by the FDA Center for Biologics Evaluation and Research (CBER).

In general, CBER licenses biologics, such as *in vitro* diagnostic tests for blood donor screening, after the filing of a Biologics License Application (BLA) under the Public Health Service Act. Biologics are listed with the FDA under 21 CFR part 607.

Under the final regulations a taxable medical device is a device that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR part 807, pursuant to FDA requirements. Therefore, devices that CBER regulates that are listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807 are taxable medical devices. Devices that CBER regulates that are not listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807, such as biologics that are listed under 21 CFR part 607, are not taxable medical devices.

Devices “intended for humans”

A number of commenters suggested that certain devices, such as sterilization process indicators, software, and containers used to hold or transport medical products and specimens, should be excluded from the definition of a taxable medical device on the basis that they are not “intended for humans.” Commenters argued that even if the FDA requires certain such devices to be listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807, the devices should not be taxable medical devices because they are not used in the direct treatment, diagnosis, or monitoring of a patient.

Section 4191 links the definition of a taxable medical device to the definition of a device in section 201(h) of the FFDCA. Section 201(h) of the FFDCA provides

generally that the term “device” means an instrument, apparatus, etc., that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and that does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and that is not dependent upon being metabolized for the achievement of its primary intended purposes. Section 201(h) of the FFDCA includes devices intended for “man” and devices intended for “other animals.” Thus, the phrase “intended for humans” included in section 4191(b) limits the definition of a taxable medical device to the devices defined in section 201(h) of the FFDCA that are intended for “man” (intended for humans) and excludes from the section 201(h) definition the devices that are intended for “other animals.”

There is no support in the statute, or in either the legislative history or the Joint Committee on Taxation’s General Explanation (Joint Committee on Taxation General Explanation of Tax Legislation Enacted in the 111th Congress (JCS–2–11), March 2011, at 365–367) (JCT General Explanation) for the proposition that Congress included the statutory phrase “intended for humans” in section 4191(b) to distinguish between devices defined in section 201(h) of the FFDCA that are intended for use directly on patients or directly in patient care from other devices defined in section 201(h) of the FFDCA that are otherwise used in human medicine. Accordingly, the final regulations do not adopt this suggestion.

Veterinary Devices

One commenter stated that the listing requirement is insufficient to distinguish medical devices for human use from those intended for use in veterinary medicine for purposes of applying the medical device excise tax. The commenter suggested that subjecting devices to the medical device excise tax because the device is listed with the FDA under section 510(j) of the FFDCA disadvantages certain manufacturers. Specifically, the commenter noted that medical device manufacturers selling devices for both human use and veterinary

use must pay the excise tax on sales into the veterinary market. The commenter requested that the final regulations provide that devices that are labeled “not for human use” or “veterinary use only” are not taxable medical devices.

The definition of a device in section 201(h) of the FFDCA includes devices used in veterinary medicine. Section 4191 limits the definition of a taxable medical device to devices described in section 201(h) of the FFDCA that are intended for humans, but does not provide that the device must be intended exclusively for humans. Under existing FDA regulations, a device intended for use exclusively in veterinary medicine is not required to be listed as a device with the FDA, whereas a device intended for use in human medicine is required to be listed as a device with the FDA even if the device may also be used in veterinary medicine. Thus, the FDA’s listing requirement effectively tracks those devices that are intended for humans within the meaning of section 4191. Accordingly, the final regulations retain the definition of a taxable medical device from the proposed regulations. Therefore, a device defined in section 201(h) of the FFDCA that is intended for humans means a device that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR part 807, pursuant to FDA requirements. Because devices that are intended for use exclusively in veterinary medicine are not listed as devices under section 510(j) of the FFDCA and 21 CFR part 807, they are not taxable medical devices within the meaning of section 4191.

Devices that Have Medical and Non-Medical Applications (“Dual Use” Devices)

The IRS and the Treasury Department received public comments and several informal inquiries on dual use devices. These comments suggested that the sale of a device defined in section 201(h) of the FFDCA that is listed as a device with the FDA under 21 CFR part 807 but that is used for a non-medical purpose should not be subject to the medical device excise tax. One commenter recommended that the sale of a taxable medical device be exempt where the manufacturer or importer can provide evidence that the product was

purchased specifically for use in non-medical applications.

One commenter noted that because it sells directly to the end user and installs its devices at the end user’s facilities, it can easily identify when it sells a device for a non-medical purpose, as opposed to a medical purpose. The commenter also noted that it must list a device with the FDA even if it makes only some sales of that device for a medical purpose. Accordingly, all of the commenter’s sales will be subject to tax, while sales of the same device by competitors who sell the device only for non-medical purposes, and thus do not have to list their devices with the FDA, will not be subject to tax.

The final regulations do not adopt the commenters’ suggestions. The language of section 4191 does not limit the definition of a taxable medical device to a device that is intended exclusively for medical purposes. Whether or not a given device is a taxable medical device depends upon whether it is a device defined in section 201(h) of the FFDCA. Although section 4191 provides a number of exemptions, the statute does not provide an exemption based on whether a given end user intends to use a particular device for a medical purpose or a non-medical purpose.

Humanitarian Use Devices

One commenter asked that the final regulations clarify that Humanitarian Use Devices (HUDs) for which the FDA has approved a Humanitarian Device Exemption (HDE) are exempt from the medical device excise tax.

A HUD is a device within the meaning of section 201(h) of the FFDCA that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. 21 CFR 814.3(n). A manufacturer must obtain an approved HDE from the FDA to market a HUD. HUDs that are marketed under an HDE exemption are not exempt from the FDA’s listing requirements.

There is no statutory basis for excluding HUDs from the definition of taxable medical device. Therefore, the final regulations do not distinguish HUDs from other taxable medical devices, and a HUD that is marketed under an HDE exemption is

a taxable medical device unless it falls within one of the statutory exemptions to the tax in section 4191(b)(2), such as the retail exemption.

Software Upgrades

Two commenters asked that the final regulations provide that sales of software upgrades are not taxable. One commenter noted that software upgrades should not be subject to the medical device excise tax where the software itself is not listed but is merely a component part of a listed device. A second commenter suggested that the final regulations should differentiate between a listed software product and software updates.

Under the final regulations, a taxable medical device is a device that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR part 807. Accordingly, software and software updates that are not required to be separately listed with the FDA do not fall within the definition of a taxable medical device, and sales of such software and software updates are not subject to the tax.

Devices that Should Have Been Listed with the FDA

Two commenters objected to the rule in the proposed regulations that deems a device to have been listed on the date the FDA provides written notice to the manufacturer or importer that corrective action with respect to listing is required. One commenter suggested that the rule be clarified so that a device is not deemed to be listed until the FDA delivers *final* written notice to the manufacturer or importer that corrective action with respect to listing is required.

The final regulations do not adopt this suggestion. If the FDA initially notifies a manufacturer that corrective action with respect to listing is required but later determines that the device is not required to be listed, a credit or refund may be available for tax paid on sales of the device during the intervening period. See section 6416(a) and the regulations under section 6416(a) for rules regarding the requirements for filing a claim for credit or refund.

Devices that Are Not Required to be Listed with the FDA

The IRS received several informal inquiries on the tax consequences of listing a product as a device with the FDA when the FDA does not require the product to be listed.

If a manufacturer lists a device with the FDA, but the device was not required to be listed, a credit or refund may be available for tax paid on sales of the device once the device has been de-listed. See section 6416(a) and the regulations under section 6416(a) for rules regarding the requirements for filing a claim for credit or refund.

II. The Retail Exemption

Section 4191(b)(2) provides that the term taxable medical device does not include eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use (the retail exemption).

A. Proposed Regulations

The proposed regulations provide a facts and circumstances approach to evaluating whether a medical device is of a type that is generally purchased by the general public at retail for individual use. Under the proposed regulations, a device is considered to be of a type generally purchased by the general public at retail for individual use if (i) the device is regularly available for purchase and use by individual consumers who are not medical professionals, and (ii) the device's design demonstrates that it is not primarily intended for use in a medical institution or office, or by medical professionals.

The proposed regulations provide a non-exclusive list of factors to be considered in determining whether a device is regularly available for purchase and use by individual consumers who are not medical professionals. Those factors are (i) whether consumers who are not medical professionals can purchase the device through retail businesses that also sell items other than medical devices, including drug stores, supermarkets, and similar vendors; (ii) whether consumers who are not medical professionals can safely and

effectively use the device for its intended medical purpose with minimal or no training from a medical professional; and (iii) whether the device is classified by the FDA under Subpart D of 21 CFR part 890 (Physical Medicine Devices) (referred to collectively herein as the "positive factors").

The proposed regulations also provide a non-exclusive list of factors to be considered in determining whether the design of a device demonstrates that it is primarily intended for use in a medical institution or office, or by medical professionals, and therefore not intended for purchase and use by individual consumers. The factors are (i) whether the device generally must be implanted, inserted, operated, or otherwise administered by a medical professional; (ii) whether the cost to acquire, maintain, and/or use the device requires a large initial investment and/or ongoing expenditure that is not affordable for the average consumer; (iii) whether the device is a Class III device under the FDA system of classification; (iv) whether the device is classified by the FDA under certain enumerated parts or subparts of 21 CFR; and (v) whether the device qualifies as durable medical equipment (DME), prosthetics, orthotics, and supplies (collectively, DMEPOS) for which payment is available exclusively on a rental basis under the Medicare Part B payment rules and is an "item requiring frequent and substantial servicing" as defined in 42 CFR 414.222 (referred to collectively herein as the "negative factors").

To provide greater certainty, the proposed regulations also include a safe harbor provision that identifies certain categories of medical devices that the IRS and the Treasury Department have determined fall within the retail exemption. The safe harbor includes (i) devices that are identified in the FDA's IVD Home Use Lab Tests (Over-the-Counter Tests) database, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm>; (ii) devices described as "OTC" or "over the counter" devices in the relevant FDA classification regulation heading; and (iii) devices that are described as "OTC" or "over the counter" devices in the FDA's product code name, the FDA's device classification name, or the "classification name" field in

the FDA's device registration and listing database, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/rl.cfm>. The safe harbor also includes devices that qualify as DMEPOS (as described in Subpart C of 42 CFR part 414 (Parenteral and Enteral Nutrition) and Subpart D of 42 CFR part 414 (Durable Medical Equipment and Prosthetic and Orthotic Devices)) for which payment is available on a purchase basis under Medicare Part B payment rules (in accordance with the fee schedule published by Centers for Medicare and Medicaid Services (CMS)), and are (i) "prosthetic and orthotic devices," as defined in 42 CFR 414.202, that do not require implantation or insertion by a medical professional; (ii) "parenteral and enteral nutrients, equipment, and supplies" as defined in 42 CFR 411.351 and described in 42 CFR 414.102(b); (iii) "customized items" as described in 42 CFR 414.224; (iv) "therapeutic shoes," as described in 42 CFR 414.228(c); or (v) supplies necessary for the effective use of DME, as described in section 110.3 of chapter 15 of the Medicare Benefit Policy Manual (Centers for Medicare and Medicaid Studies Publication 100-02).

B. Public Comments and the Final Regulations

1. Sales for Use in a Professional Medical Setting

One commenter asked that the regulations clarify that the mere fact that a particular device is sold for use in medical offices and institutions is not determinative of whether the device falls within the retail exemption.

As the regulations make clear, whether or not a device falls within the retail exemption is based on all relevant facts and circumstances. Therefore, the mere fact that an individual device is sold for use in a professional setting is not determinative of whether that type of device falls within the retail exemption.

2. Facts and circumstances test

Nonexclusivity of factors

Several commenters requested that the final regulations confirm that the factors enumerated in the facts and circumstances

test for the retail exemption are non-exclusive, and that other factors may also be relevant in determining whether a particular device qualifies for the retail exemption. Commenters also asked for clarification that a device need not meet every positive factor, and that the fact that a device meets a negative factor is not determinative of whether a device qualifies for the retail exemption.

The final regulations retain the facts and circumstances approach to determining whether a particular device falls within the retail exemption. The facts and circumstances approach requires a balancing of factors enumerated in §48.4191-2(b)(2). No one factor is determinative. Thus, a device may qualify for the retail exemption without meeting all of the positive factors listed under paragraph §48.4191-2(b)(2)(i). Additionally, a device may qualify for the retail exemption even if it meets one or more negative factors under paragraph §48.4191-2(b)(2)(ii).

Accordingly, the final regulations state that there may be facts and circumstances that are relevant in evaluating whether a device is of a type generally purchased by the general public at retail for individual use in addition to those described as factors in §48.4191-2(b)(2)(i) and (ii). In addition, the final regulations include seven additional examples that illustrate the process for determining whether a device falls within the retail exemption, including examples that illustrate the balancing of different factors for a particular device.

Purchase at retail

Several commenters suggested that internet sales should be included in the factor described in §48.4191-2(b)(2)(i)(A) that looks to whether consumers who are not medical professionals can purchase the device at certain retail businesses. Other commenters suggested that the fact that consumers who are not medical professionals can purchase a device over the internet should be a factor that indicates that a device is “regularly available for purchase and use by individual consumers,” regardless of whether the internet site is associated with a bricks and mortar store.

Several commenters also suggested that retail sales should include those made over the telephone.

In addition, several commenters suggested that the retail businesses identified in §48.4191-2(b)(2)(i)(A) should explicitly include medical supply stores and retailers that primarily sell medical devices (for example, specialty medical stores).

The final regulations adopt all of these suggestions. Under the final regulations, the factor in §48.4191-2(b)(2)(i)(A) provides that consumers who are not medical professionals can purchase the device in person, over the telephone, or over the internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell medical devices (for example, specialty medical stores, DMEPOS suppliers, and similar vendors).

Minimal or no training

One commenter requested that final regulations remove the factor that looks to whether consumers who are not medical professionals can use the device safely and effectively for its intended medical purpose with minimal or no training from a medical professional. The commenter reasoned that many taxable medical devices that would otherwise qualify for the retail exemption require at least some basic level of training. The commenter then noted that the suggestion that training would cause a taxable medical device to no longer qualify for the retail exemption is not appropriate.

The final regulations do not adopt the commenter’s suggestion. The IRS and the Treasury Department believe that whether more than minimal training from a medical professional is required to safely and effectively use a device is a relevant consideration. At the same time, however, the factor that considers training is only one of many factors to be considered in determining whether a device falls within the retail exemption, and it is possible that a device could qualify for the retail exemption even if it does not satisfy this factor.

Administered by a medical professional

One commenter requested clarification that the phrase “administered by a medical professional” in the factor described in §48.4191-2(b)(2)(ii)(A) does not include the initial and periodic fitting or adjustment with respect to an orthotic or prosthetic device that is not implanted.

The final regulations provide a safe harbor for certain devices that fall under the retail exemption. Prosthetic and orthotic devices, as defined in 42 CFR 414.202, that do not require implantation or insertion by a medical professional, fall under the retail exemption safe harbor described in §48.4191-2(b)(2)(iii)(D)(I). Accordingly, prosthetic and orthotic devices within the meaning of 42 CFR 414.202 that do not require implantation or insertion by a medical professional are considered to be of a type generally purchased by the general public at retail for individual use, without regard to whether they require initial or periodic fitting or adjustment.

A prosthetic or orthotic device that is not in the safe harbor may qualify for the retail exemption based on an application of the facts and circumstances test. The final regulations include an example of a prosthetic device that falls within the retail exemption.

Cost

Two commenters suggested that the factor enumerated in §48.4191-2(b)(2)(ii)(B) that considers a device’s cost should not be included in the final regulations. One commenter stated that whether or not a device is affordable depends on the consumer’s insurance coverage and cost alternatives.

The final regulations do not adopt this suggestion. The final regulations take a facts and circumstances approach to the retail exemption. The facts and circumstances test is comprised of a number of non-exclusive factors; each factor is one of several to be considered in determining whether a device falls within the retail exemption. Devices used in hospitals, doctors offices and other medical institutions, such as x-ray machines, magnetic resonance imaging (MRI) systems, and computed tomography (CT scan) or computed axial tomography (CAT scan) equipment, would likely be prohibitively expensive for an average individual user. Accordingly, the factor that considers cost is meaningful in determining whether a type of device is primarily for use in a medical institution or office or by a medical professional.

Class III devices

Several commenters requested that the final regulations not include classification as a Class III device as a factor, because the JCT General Explanation noted that the retail exemption is not limited by device class.

The final regulations do not adopt this suggestion. Although the JCT General Explanation notes that the retail exemption is not limited by device class, it does not state that classification in Class I, Class II, or Class III is irrelevant to the determination of whether a device falls within the retail exemption. The IRS and the Treasury Department, in consultation with FDA, have determined that the vast majority of Class III types of devices are not devices that are of a type generally purchased by the general public at retail for individual use. Accordingly, the factor that considers whether a device is a Class III type of device is meaningful in determining whether a type of device is primarily for use in a medical institution or office or by a medical professional.

FDA classification categories

Two commenters suggested that 21 CFR part 868 (Anesthesiology Devices) should not be included in the list of FDA classification categories in §48.4191–2(b)(2)(ii)(D) that suggest that a device is primarily for use in a medical institution or office or by a medical professional. The commenters noted that certain portable oxygen systems are classified in 21 CFR part 868.

One commenter requested that 21 CFR part 876 (Gastroenterology-Urology Devices) be removed from the list of FDA classification categories in §48.4191–2(b)(2)(ii)(D) because 21 CFR part 876 contains many devices, such as ostomy supplies, that would otherwise fall within the retail exemption.

The final regulations do not remove any FDA classification categories from those enumerated in §48.4191–2(b)(2)(ii)(D). The IRS and the Treasury Department have determined, after consultation with the FDA, that the overwhelming majority of devices that fall within these regulatory categories are not of a type generally purchased by the general public at retail for

individual use. Further, classification in one of the enumerated parts or subparts is not determinative of whether a device falls within the retail exemption. Devices in these categories must be evaluated in light of all relevant facts and circumstances.

The final regulations include an example that weighs the facts and circumstances with respect to a portable oxygen concentrator, including the fact that it is a device under 21 CFR part 868, and concludes that the portable oxygen concentrator falls within the retail exemption. The final regulations also include an example that illustrates that a urinary ileostomy bag, which is a device under 21 CFR part 876, is included in the safe harbor set forth in §48.4191–2(b)(2)(iii)(D)(1).

Packaging and labeling

Several commenters suggested that the final regulations include a factor that considers whether a device's packaging and labeling suggests that the device is intended for use by individuals who are not medical professionals. One commenter noted that product labeling that is easy for someone who is not a medical or health care professional to understand suggests that the device is regularly available for purchase and use by individual consumers who are not medical professionals.

The final regulations do not adopt this suggestion. Device manufacturers determine the packaging and labeling of a device. Manufacturers may package and label a device in a consumer-friendly manner, even if the device is of a type that is primarily intended for use in a medical institution or office, or by medical professionals. Therefore, the IRS and the Treasury Department have determined that a device's packaging and labeling are not instructive as to whether a device is generally purchased by the general public at retail for individual use.

Documents submitted for FDA notification or approval

One commenter requested that the final regulations include a factor that looks to whether documents submitted to the FDA, such as a Premarket Notification (510(k)) or application for Premarket Approval (PMA), state that the device is intended for individual use.

The final regulations do not adopt this suggestion. After consultation with the FDA, the IRS and the Treasury Department have determined that documents submitted to the FDA, such as 510(k) documents and PMA applications, are not consistently reliable indicators of whether a device is of a type that is generally purchased by the general public for individual use.

3. Safe Harbor

Durable Medical Equipment, Prosthetics, Orthotics and Supplies

One commenter suggested that the retail exemption safe harbor defined in §48.4191–2(b)(2)(iii)(D) be expanded to include all devices that fall under the definition of DMEPOS in 42 CFR 414.202.

The final regulations do not adopt this suggestion. However, devices that fall within the definition of DMEPOS that are not included in the retail exemption safe harbor in §48.4191–2(b)(2)(iii)(D), such as oxygen equipment and other rental durable medical equipment devices, may qualify for the retail exemption by application of the facts and circumstances test. The final regulations provide an example that evaluates whether a portable oxygen concentrator falls within the retail exemption based upon an evaluation of such a device under the facts and circumstances test.

Capped rental devices

One commenter suggested that the safe harbor defined in §48.4191–2(b)(2)(iii)(D) be expanded to include "capped rental" devices, within the meaning of 42 CFR 414.229, for which title transfers to the individual user (the Medicare beneficiary) at the end of the rental term.

The category of capped rental DME consists of DME that is not subject to the payment provisions set forth in 42 CFR 414.220 through 42 CFR 414.228. Medicare pays for capped rental DME other than complex rehabilitation power-driven wheelchairs on a rental basis. See 42 CFR 414.229. Payment is made on a rental basis, not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made,

the supplier must transfer title to the equipment to the Medicare beneficiary. See 42 CFR 414.229(f)(2). Medicare also pays for complex rehabilitation power-driven wheelchairs on a capped rental or lump-sum purchase basis. The supplier of the complex rehabilitation power-driven wheelchair must offer Medicare beneficiaries the option to purchase the complex rehabilitation power-driven wheelchair at the time the equipment is initially furnished. See 42 CFR 414.229(h). If the beneficiary does not elect to purchase the complex rehabilitation power-driven wheelchair, payment is made on a capped rental basis in accordance with the rules described above for other capped rental DME. See 42 CFR 414.229(f).

The IRS and the Treasury Department, in consultation with the Center for Medicare and Medicaid Services (CMS), have determined that, in most instances, the rental period of a capped rental device terminates before the transfer of title. Further, information on the capped rental devices for which title has transferred to the individual user does not suggest a pattern of title transfer for specific types of devices. Accordingly, capped rental devices cannot be categorically said to qualify as devices that are generally purchased by the general public at retail for individual use. They may, however, qualify for the retail exemption by an application of the facts and circumstances test. Therefore, safe harbor treatment is not appropriate for capped rental devices, and the final regulations do not adopt the commenter's suggestion.

Prosthetics and orthotics

One commenter noted that 42 CFR 414.202 excludes from the definition of prosthetic and orthotic devices medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by a Home Health Agency (HHA) as part of home health services under 42 CFR 409.40(e). The commenter asked that the final regulations address the significance, if any, of the exclusion of products furnished by an HHA on the breadth of the safe harbor in §48.4191-2(b)(2)(iii)(D)(I) for prosthetic and orthotic devices as defined in 42 CFR 414.202.

The IRS and the Treasury Department, in consultation with CMS, have determined that the HHA language in 42 CFR 414.202 is a provision that clarifies that when individual devices are furnished by an HHA, they are payable as home health services under 42 CFR 409 subpart E. The HHA language in 42 CFR 414.202 does not exclude any type of device from the definition of prosthetic and orthotic devices and, therefore, has no impact on the retail exemption safe harbor in §48.4191-2(b)(2)(iii)(D).

4. *“Of a type”*

Section 4191(b)(2) provides that the term taxable medical device does not include eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use. Several commenters requested that final regulations define a “type” of device to include all devices that are categorized in the same FDA product code.

The final regulations do not adopt this suggestion. In consultation with the FDA, the IRS and the Treasury Department determined that the breadth and variety of devices within a particular product code and across product codes can vary greatly. Therefore, the product code designation is generally too broad to be useful in determining which devices fall within the retail exemption.

5. *Components of exempt devices*

One commenter noted that the FDA requires some components of devices to be separately listed as devices. The commenter suggested that the final regulations exempt listed components that are ultimately used as component parts of a device that is exempt under section 4191(b) and §48.4191-2(b), such as component parts of certain completed prosthetic or orthotic devices.

The safe harbor provision in §48.4191-2(b)(2)(iii)(D) includes some components of prosthetic and orthotic devices. The IRS and the Treasury Department request public comments to help identify listed components of devices that are exempt under section 4191(b) and §48.4191-2(b) that are not included in a safe harbor or that do not otherwise fall

within the retail exemption by an application of the facts and circumstances test.

6. *Dental Devices*

Several commenters suggested that dental devices that are customized for an individual patient, such as crowns, bridges, and braces, should qualify for the retail exemption because they are sold directly to individual consumers. Further, one commenter noted that the factor described in §48.4191-2(b)(2)(ii)(A), which considers whether a device “generally must be implanted, inserted, operated, or otherwise administered by a medical professional,” creates an unnecessary distinction between devices that an individual can insert and remove, and devices that a dentist must embed or affix within the patient's mouth.

The final regulations do not create a special rule for dental devices. The final regulations take a facts and circumstances approach to the retail exemption. The facts and circumstances test is comprised of a number of non-exclusive factors. A customized dental device will qualify for the retail exemption if, based on the totality of the facts and circumstances, the device is of a type that is generally purchased by the general public at retail for individual use.

III. *Combination products*

A. *Proposed Regulations*

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. See 21 CFR 3.2(e). The proposed regulations tie the definition of taxable medical device to the FDA's listing requirements for devices. Therefore, under the proposed regulations, a combination product that is listed as a device with the FDA under section 510(j) of the FDCA and 21 CFR part 807 and that does not fall under a statutory exemption, such as the retail exemption, is subject to the medical device excise tax.

B. *Public Comments and the Final Regulations*

Several commenters requested that the final regulations provide that a manufacturer will not be required to pay the medical device excise tax on a combination product that is taken into account in

computing the branded prescription drug (BPD) fee enacted under section 9008 of the ACA.

The final regulations do not adopt this suggestion. The ACA enacted both the medical device excise tax and the BPD fee, but provided no coordination between the provisions. Therefore, there is no statutory basis for providing an exclusion from the tax under section 4191 for a combination product with both a device component and a drug component, even if the combination product is taken into account for purposes of computing the BPD fee. Moreover, the comments did not raise any likely scenarios in which both the BPD fee and the medical device excise tax apply to the same product. Based on consultation with the FDA, the IRS and the Treasury Department anticipate that few, if any, combination products will be subject to both the medical device excise tax and the BPD fee. Accordingly, under the final regulations, a combination product that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR part 807 is a taxable medical device.

IV. *Manufacturers Excise Taxes*

The ACA added section 4191 to chapter 32, subtitle D of the Code, which relates to taxes imposed on the sales of taxable articles by manufacturers, producers, and importers (commonly referred to as “manufacturers excise taxes”). Accordingly, the preamble to the proposed regulations states that the existing chapter 32 rules apply to the medical device excise tax.

Definition of a “manufacturer”

One commenter requested that the final regulations include a presumption that a manufacturer who lists a device with the FDA is the manufacturer of the device for excise tax purposes.

The final regulations do not adopt this suggestion. There are longstanding rules with respect to the definition of “manufacturer” or “importer” for chapter 32 purposes. These rules are contained in statutory and regulatory provisions, and they have been developed further through other published guidance and case law. Therefore, the definitions of manufacturer and importer under chapter 32 apply to section 4191; whether a person is considered

a manufacturer or importer for FDA purposes is not relevant.

Sale price

Numerous commenters suggested that the IRS apply the constructive sale price rules with flexibility and sensitivity to data limitations that medical device companies face. The IRS and the Treasury Department recognize that the medical device industry will likely face some implementation issues when the medical device excise tax goes into effect on January 1, 2013, and the IRS intends to work with stakeholders on compliance-related issues, such as the determination of price.

Numerous commenters requested that the final regulations extend the principle of Revenue Ruling 80-273, 1980-2 C.B. 315, to taxable medical devices. Rev. Rul. 80-273 holds that when a manufacturer or importer sells a taxable article directly to an unrelated end user at retail, the excise tax may be based on a sale price of 75 percent of the retail sale price, after any adjustments under section 4216(a), such as for containers, packing, and transportation charges. The holding applies only to the excise taxes imposed under the Code sections explicitly listed in the revenue ruling. Commenters also requested that the final regulations clarify that sales “at retail” in the medical device context include sales to hospitals and other medical service providers. Although the final regulations do not adopt this suggestion, the IRS and the Treasury Department will issue separate interim guidance along with these regulations to address sale price issues and have considered these comments in the context of such guidance.

One commenter requested that the final regulations provide that taxpayers can use transfer pricing under section 482 to determine the taxable sale price of a taxable medical device.

The final regulations do not adopt the commenter’s suggestion. Because the standards are not the same under the section 482 regulations and section 4216, an arm’s length result determined under section 482 is not an appropriate proxy for the constructive sale price or fair market price under section 4216. While in certain circumstances facts used to support a transfer price for purposes of section 482 may be relevant to determining the sale

price under section 4216, transfer pricing documentation or studies developed for purposes of section 482 or section 6662(e) will not be conclusive.

Finally, the IRS received several informal inquiries about whether the 2.3% medical device excise tax may be excluded from the sale price upon which the medical device excise tax is imposed. Section 4216(a) provides that in determining the price for which an article is sold there should be excluded the amount of tax imposed, whether or not stated as a separate charge. See section 4216(a) and §48.4216(a)-2(a) of the Manufacturers and Retailers Excise Tax Regulations for the rules regarding the exclusion of tax from sale price.

Installment sales, leases, and long-term contracts

Several commenters requested transition relief for installment sales and leases of taxable medical devices where the contract is entered into prior to the effective date of the tax on January 1, 2013.

The final regulations do not provide transition relief for all contracts entered into prior to January 1, 2013. However, the final regulations do provide transition relief for contracts entered into prior to March 30, 2010, the date the ACA was enacted. More specifically, the final regulations provide that payments made on or after January 1, 2013, pursuant to a written binding contract for the lease, installment sale, or sale on credit of a taxable medical device that was in effect prior to March 30, 2010, are not subject to tax under section 4191 unless the contract is materially modified on or after March 30, 2010. For purposes of this transition relief, a material modification includes only a modification that materially affects the property to be provided under the contract, the terms of payment under the contract, or the amount payable under the contract. A material modification does not include a modification to the contract required by applicable Federal, State, or local law.

Payments made pursuant to a contract that was entered into on or after March 30, 2010, are subject to tax under section 4191 and the existing provisions of sections 4216(c) and 4217, and §§48.4216(c)-1 and 48.4217-2 apply.

Several commenters requested that the final regulations specifically provide that the following are not taxable uses where the manufacturer receives no direct benefit in the form of money, services, or other property: (i) demonstration products used for health care professionals and product awareness, such as samples used to demonstrate the type of device to be implanted in a patient; (ii) evaluation products provided to help health care professionals determine whether and when to use, order, purchase, or recommend the device; (iii) loaned devices to facilitate procedures utilizing a sold taxable medical device, such as instruments specifically designed to implant a particular orthopedic joint; (iv) testing and development products; and (v) product donations and charitable contributions.

The final regulations do not adopt this suggestion because it is necessary to have consistent rules for all manufacturers excise taxes. Section 4218 generally imposes a tax on certain uses of an article by the article's manufacturer. In general, under §48.4218-1(b), if the manufacturer of a taxable article uses the article for any purpose other than in the manufacture of another taxable article, then the manufacturer is liable for tax on the article as if the manufacturer had sold it.

With regard to demonstration products, the provision or use of a taxable medical device as a demonstration product may constitute a taxable use, depending on the facts and circumstances of the arrangement. See Rev. Rul. 60-290, 1960-2 C.B. 331, and Rev. Rul. 72-563, 1972-1 CB 568.

With regard to evaluation and testing products, Rev. Rul. 76-119, 1976-1 C.B. 345, holds that if a manufacturer uses a taxable article in the testing of another article of its own manufacture, the use of the taxable article is not a taxable use.

The existing chapter 32 rules do not specifically address whether a donation of a taxable article to charity constitutes a taxable use under section 4218. However, the IRS and the Treasury Department will issue separate interim guidance along with these regulations to address donations of taxable medical devices.

Several commenters requested that the final regulations provide manufacturers with the option of excluding from the sale price a reasonable estimate of purchase price adjustments for rebates, with a later true-up based on the actual rebate amounts. These commenters suggest that manufacturers have reliable historical data on past rebate performance, so they are able to project rebate amounts with reasonable certainty.

The final regulations do not adopt this suggestion. Section 48.4216(a)-3(c) provides that a manufacturer may take a rebate into account in determining sale price only to the extent the rebate is made prior to the close of the quarter during which the sale associated with the rebate is made. In addition, if the manufacturer subsequently allows a rebate for taxable articles on which tax has been paid, the manufacturer may make a claim for credit or refund of that portion of the tax that is proportionate to the part of the price that is rebated.

Software sold together with services

One commenter requested clarification with respect to the taxability of software that is sold together with services and/or maintenance contracts.

Section 48.4216(a)-1(e) provides that where a taxable article and a nontaxable article are sold by the manufacturer as a unit, the tax attaches to that portion of the manufacturer's sale price of the unit that is properly allocable to the taxable article. Because the definition of a taxable medical device is tied to the FDA's device listing requirements, if the software and service bundle is not listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807 (in other words, if the entire bundle is not a taxable medical device), the medical device excise tax attaches only to the sale of the devices within the bundle that are listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807.

Refurbished and remanufactured medical devices

Several commenters requested guidance on how the medical device excise tax will apply to sales of refurbished and remanufactured medical devices. One

commenter requested that the definition of manufacturer in §48.0-2(a)(4) be clarified to ensure that repairing, refurbishing, or rebuilding an already taxed medical device does not create another taxable medical device and is not considered manufacturing.

The final regulations do not adopt these suggestions. Under existing chapter 32 rules, remanufacturing or refurbishing constitutes manufacture if the remanufacturing or refurbishing process produces a new and different taxable article. See Rev. Rul. 86-130, 1986-2 C.B. 179, Rev. Rul. 83-149, 1983-2 C.B. 186, Rev. Rul. 68-40, 1968-1 C.B. 452, Rev. Rul. 64-202, 1964-2 C.B. 431, and Rev. Rul. 58-586, 1958-2 C.B. 806. If a remanufacturer or refurbisher produces a new and different taxable article, the tax is imposed upon the sale or use of the remanufactured or refurbished article.

Replacement parts

Two commenters suggested that parts used to replace an existing part or component in a taxable medical device should not be subject to the tax, even if the part or component is listed separately as a device with the FDA.

The final regulations do not adopt this suggestion. Under existing law, if a taxable article is returned to the manufacturer under a warranty and the manufacturer provides a replacement article free or at a reduced price, the tax on the replacement article is computed on the actual amount, if any, paid to the manufacturer for the replacement article. See §48.4216(a)-3(b) and Rev. Rul. 75-272, 1975-2 C.B. 421.

With regard to replacements that are not made under warranty, replacement parts that are listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807 are taxable medical devices, and their sale by the manufacturer is generally subject to tax.

Licensing of software

One commenter requested clarification on whether the licensing of software that is a taxable medical device is a taxable event.

Under existing chapter 32 rules, the manufacturers excise tax generally attaches upon the sale or use of a taxable article by the manufacturer. The lease of a

taxable article by the manufacturer is considered a sale. Neither the existing chapter 32 rules nor the final regulations address the issue of whether the licensing of a taxable article is a taxable event. However, the IRS and the Treasury Department will issue separate interim guidance along with these regulations to address this issue.

Consolidated filing of Form 720

The medical device excise tax is reported on Form 720, *Quarterly Federal Excise Tax Return*. Several commenters requested that the IRS and the Treasury Department permit manufacturers and importers of taxable medical devices who are members of a affiliated group for income tax purposes to file Form 720 on a consolidated basis.

The final regulations do not adopt this suggestion. Section 1501 provides generally that an affiliated group of corporations shall have the privilege of making a consolidated return with respect to the income tax imposed by chapter 1 for the taxable year in lieu of separate returns. There is no similar provision that applies to excise tax. Thus, the privilege to file consolidated returns applies only to income tax returns and not to excise tax returns. Accordingly, for excise tax purposes, each business unit that has or is required to have a separate employer identification number is treated as a separate person with separate tax liability, and each such business unit must file a separate Form 720.

Consolidated Form 637 registration

Registration through the Form 637 application process is necessary to effectuate tax-free sales. Several commenters requested that final regulations allow one entity in an affiliated group to register on behalf of the group with respect to intra-group sales.

The final regulations do not adopt this suggestion. The IRS and the Treasury Department have determined that it is necessary in the interest of effective tax administration to require each entity with a separate employer identification number to apply for registration under *Application for Registration (For Certain Excise Tax Activities)* (Form 637) to verify the activity for which the entity seeks registration. Once an entity is registered for a particular activity, the registration does not ex-

pire. Therefore, for most entities, the initial application process is the extent of the entity's obligation with respect to registration.

Form 720 filing requirements

One commenter suggested that the quarterly reporting requirement is unduly burdensome on small medical device manufacturers. The commenter suggested that the final regulations initially require only annual reporting for small medical device manufacturers to enable those taxpayers to become familiar with the excise tax rules and implement the proper accounting practices and procedures.

The final regulations do not adopt this suggestion. The ACA added section 4191 to chapter 32. Therefore, the existing rules governing chapter 32 apply. Manufacturers excise taxes, including the medical device excise tax, are reported on Form 720. In general, Form 720 must be filed on a quarterly basis. For more information about reporting requirements, see §40.6011(a)-1(a).

Semimonthly deposits

Several commenters suggested that the semimonthly deposit requirements under section 6302 are burdensome to medical device manufacturers because device manufacturers have little or no experience with returning and paying federal excise taxes and because manufacturers need time to develop their systems to implement these final regulations. Some of those commenters requested that final regulations specifically carve out taxable medical devices from the deposit rules set forth in section 6302 and the regulations thereunder. Other commenters requested that the IRS and the Treasury Department waive on a reasonable cause basis any tax penalty applicable to the failure to deposit the correct amount of tax.

The final regulations do not carve taxable medical devices out of the semimonthly deposit rules. Therefore, medical device manufacturers will generally be required to make semimonthly deposits of tax unless the manufacturer's net tax liability does not exceed \$2,500 for the quarter. See section 6302 and the regulations thereunder for the rules regarding semimonthly deposits.

The IRS and the Treasury Department recognize that the application of the manufacturers excise tax rules, particularly with regard to sale price, may present certain challenges. The IRS and the Treasury Department further recognize that manufacturers and importers in the medical device industry may not have prior experience complying with the rules regarding semimonthly deposits. Given that the tax goes into effect on January 1, 2013, the IRS and the Treasury Department will issue separate interim guidance along with these regulations that addresses penalties under section 6656.

Disregarded entities

One commenter requested that the IRS and the Treasury Department amend the regulations under section 7701 to allow entities that are disregarded as separate from their owners for income tax purposes to be similarly disregarded for excise tax purposes.

The final regulations do not adopt this suggestion because it is necessary to have a consistent rule for all excise taxes. Specifically, §1.1361-4(a)(8) and §301.7701-2(c)(2)(v) treat a qualified subsidiary and a single-owner eligible entity that is disregarded as an entity separate from its owner under §301.7701-2 as a separate entity for purposes of excise taxes imposed by chapter 32 of the Code. These rules were adopted because of the difficulties that arise from the interaction of the disregarded entity rules and the federal excise tax rules. For example, the manufacturers excise tax rules rely on state law, rather than Federal law, to determine attachment of a tax. See §48.0-2(b) (providing that excise taxes attach when title to an article passes to the purchaser, which is based on the laws of the local jurisdiction where the sale is made in the absence of express intention of the parties to the sale). Accordingly, a Form 720 reporting the medical device excise tax imposed on sales of taxable medical devices by the manufacturer or importer after December 31, 2012, must be filed under the name and employer identification number of the entity rather than under the name and EIN of the disregarded entity's owner.

Penalties for failure to file and failure to pay tax; Accuracy-related penalties

Several commenters highlighted the compliance challenges associated with implementation of the medical device excise tax. These commenters requested that the IRS and the Treasury Department temporarily waive all tax penalties relating to the filing of Form 720.

The final regulations do not adopt this suggestion. Section 6651(a) imposes penalties for failure to file any return required under subchapter A of chapter 61 and for failure to pay the amount shown as tax on any such return, unless it is shown that the failure is due to reasonable cause and not willful neglect. Under §301.6651-1(c), a taxpayer may avoid penalties under section 6651 for the failure to file a tax return or pay tax if the taxpayer makes an affirmative showing of all facts necessary to establish a reasonable cause for the taxpayer's failure to file a return or pay tax on time. If the taxpayer exercised ordinary business care and prudence but was nevertheless unable to file the return within the prescribed time, then the delay is due to a reasonable cause. A failure to pay will be considered to be due to a reasonable cause to the extent the taxpayer has made a satisfactory showing that the taxpayer exercised ordinary business care and prudence in providing for payment of the taxpayer's tax liability and was nevertheless either unable to pay the tax or would suffer an undue hardship (as described in §1.6161-1(b)) if the taxpayer paid on the due date.

Section 6662 imposes an accuracy-related penalty for, among other things, negligence or disregard of the rules or regulations. Under section 6662(c), the term "negligence" includes any failure to make a reasonable attempt to comply with the provisions of the Code, and the term "disregard" includes any careless, reckless, or intentional disregard.

The IRS and the Treasury Department recognize that the application of the manufacturers excise tax rules may present certain implementation challenges. The IRS and the Treasury Department also recognize that manufacturers and importers in the medical device industry may not have prior experience with filing a Form 720. However, the IRS and the Treasury

Department believe that the existing reasonable cause provisions under section 6651(a) and §301.6651-1(c) and the negligence standard in section 6662 provide taxpayers with an appropriate mechanism for relief. If a penalty is assessed under section 6651 or section 6662, the IRS encourages taxpayers to call the telephone number on the penalty notice to discuss abatement options.

V. Kits

Under the proposed regulations, a taxable medical device is a device that is listed as a device with the FDA under section 510(j) of the FFDCa and 21 CFR part 807. Therefore, under the proposed regulations, a listed kit is a taxable medical device. The proposed regulations define a "kit" as a set of two or more articles packaged in a single bag, tray, or box for the convenience of the end user. In addition, the proposed regulations provide that if a kit is a taxable medical device, then the use of other taxable medical devices in the assembly of the kit constitutes "further manufacture" within the meaning of section 4221(a)(1) of the Code by the person who produces the kit.

The IRS and the Department of Treasury received numerous public comments regarding kits. Several commenters noted that taxing the kit will result in taxing items contained in the kit that, standing alone, are not taxable medical devices.

Some public comments pointed to certain FDA rules governing kits as evidence that kits should receive a different tax treatment than other devices that are listed with the FDA under section 510(j) of the FFDCa and 21 CFR part 807. The commenters suggested that kits should receive special tax treatment because many kits are not subject to FDA premarket notification requirements.

Additionally, several commenters suggested that the producer of a kit is not a "manufacturer" within the meaning of section 48.0-2(a)(4)(i). Other commenters requested that the final regulations exclude kits from the definition of "further manufacture" within the meaning of section 4221(a)(1), so that the sale of a kit is not subject to the medical device excise tax.

The final regulations do not explicitly provide that the use of other taxable medical devices in the assembly of the

kit constitutes further manufacture, within the meaning of section 4221(a)(1), by the person who produces the kit. The IRS and the Treasury Department will issue separate interim guidance along with these regulations on the treatment of kits for purposes of the medical device excise tax.

Several commentators requested that the final regulations confirm that the use of a kit by a hospital or medical institution that produced the kit is not a taxable use within the meaning of section 4218.

Hospitals or medical institutions that produce kits for their own use are known as self-kitters. Self-kitters are exempt from the FDA's registration and listing requirements. See 21 CFR 807.65(f). Therefore, under the definition of a taxable medical device in both the proposed regulations and the final regulations, a kit produced by a hospital or medical institution for its own use would not be a "taxable medical device." Accordingly, the use of the self-produced kits by the hospital or medical institution would not be a taxable use under the rules of section 4218.

Availability of IRS Documents

The IRS final regulations and revenue rulings cited in this preamble are published in the Internal Revenue Cumulative Bulletin and are available from the Superintendent of Documents, P.O. Box 979050, St. Louis, MO 63197-9000.

Special Analyses

It has been determined that this Treasury Decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory 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, and because these regulations do not impose a collection of information on small entities, the provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking that preceded these 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.

Drafting Information

The principal authors of these regulations are Natalie Payne and Stephanie Bland, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

* * * * *

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 48 is amended as follows:

PART 48—Manufacturers and Retailers Excise Taxes

Paragraph 1. The authority citation for part 48 is amended by adding entries in numerical order to read in part as follows:

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

Section 48.4191-1 also issued under 26 U.S.C. 4191.

Section 48.4191-2 also issued under 26 U.S.C. 4191(b)(2).

48.0-1 [Amended]

Par. 2. The fourth sentence of §48.0-1 is amended by removing the language “and sporting goods” and adding “sporting goods, and taxable medical devices” in its place.

Par. 3. Subpart L, consisting of §§48.4191-1 and 48.4191-2 is added to read as follows:

Subpart L — Taxable Medical Devices

48.4191-1 Imposition and rate of tax.
48.4191-2 Taxable medical device.

§48.4191-1 Imposition and rate of tax.

(a) *Imposition of tax.* Under section 4191(a), tax is imposed on the sale of any taxable medical device by the manufacturer, producer, or importer of the device. For the definition of the term *taxable medical device*, see §48.4191-2.

(b) *Rate of tax.* Tax is imposed on the sale of a taxable medical device at the rate of 2.3 percent of the price for which the device is sold. For the definition of the term *price*, see section 4216 and §§48.4216(a)-1 through 48.4216(e)-3.

(c) *Liability for tax.* The manufacturer, producer, or importer making the sale of a taxable medical device is liable for the tax imposed by section 4191(a). For rules relating to the determination of who the manufacturer, producer, or importer is for purposes of section 4191, see §48.0-2(a)(4). For the definition of the term *sale*, see §48.0-2(a)(5). For rules relating to the lease of an article by the manufacturer, producer, or importer, see section 4217 and §48.4217-1 through §48.4217-2. For rules relating to the use of an article by the manufacturer, producer, or importer, see section 4218 and §48.4218-1 through §48.4218-5.

(d) *Procedural rules.* For the procedural rules relating to section 4191, see part 40 of this chapter.

(e) *Tax-free sales for further manufacture or export.* For rules relating to tax-free sales of taxable medical devices for further manufacture or export, see section 4221 and §48.4221-1 through §48.4221-3.

(f) *Payments made on or after January 1, 2013, pursuant to lease, installment sale, or sale on credit contracts.* For rules relating to the taxability of payments made on or after January 1, 2013, pursuant to a lease, installment sale, or sale on credit contract entered into on or after March 30, 2010, see §48.4216(c)-1(e)(1). For rules relating to the taxability of payments made on or after January 1, 2013, pursuant to a lease, installment sale, or sale on credit contract entered into before March 30, 2010, see §48.4216(c)-1(e)(2).

(g) *Effective/applicability date.* This section applies to sales of taxable medical devices on and after January 1, 2013.

§48.4191-2 Taxable medical device.

(a) *Taxable medical device—(1) In general.* A taxable medical device is any device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA), that is intended for humans. For purposes of this section, a device defined in section 201(h) of the FFDCA that is intended for humans means a device that is listed as a device with the Food and Drug Administration (FDA) under section 510(j) of the FFDCA and 21 CFR part 807, pursuant to FDA requirements.

(2) *Devices that should have been listed with the FDA.* If a device is not listed

as a device with the FDA but the FDA determines that the device should have been listed as a device, the device will be deemed to be listed as a device with the FDA as of the date the FDA notifies the manufacturer or importer in writing that corrective action with respect to listing is required.

(b) *Exemptions—(1) Specific exemptions.* The term *taxable medical device* does not include eyeglasses, contact lenses, and hearing aids.

(2) *Retail exemption.* The term *taxable medical device* does not include any device of a type that is generally purchased by the general public at retail for individual use (the retail exemption). A device will be considered to be of a type generally purchased by the general public at retail for individual use if it is regularly available for purchase and use by individual consumers who are not medical professionals, and if the design of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional. Whether a device is of a type described in the preceding sentence is evaluated based on all the relevant facts and circumstances. Factors relevant to this evaluation are enumerated in paragraphs (b)(2)(i) and (ii) of this section. Further, there may be facts and circumstances that are relevant in evaluating whether a device is of a type generally purchased by the general public at retail for individual use in addition to those described in paragraphs (b)(2)(i) and (ii) of this section. The determination of whether a device is of a type that qualifies for the retail exemption is made based on the overall balance of factors relevant to the particular type of device. The fact that a device is of a type that requires a prescription is not a factor in the determination of whether or not the device falls under the retail exemption.

(i) *Regularly available for purchase and use by individual consumers.* The following factors are relevant in determining whether a device is of a type that is regularly available for purchase and use by individual consumers who are not medical professionals:

(A) Whether consumers who are not medical professionals can purchase the device in person, over the telephone, or over the internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily

sell devices (for example, specialty medical stores, durable medical equipment, prosthetics, orthotics, and supplies (DME-POS) suppliers and similar vendors);

(B) Whether consumers who are not medical professionals can use the device safely and effectively for its intended medical purpose with minimal or no training from a medical professional; and

(C) Whether the device is classified by the FDA under Subpart D of 21 CFR part 890 (Physical Medicine Devices).

(ii) *Primarily for use in a medical institution or office or by a medical professional.* The following factors are relevant in determining whether a device is designed primarily for use in a medical institution or office or by a medical professional:

(A) Whether the device generally must be implanted, inserted, operated, or otherwise administered by a medical professional;

(B) Whether the cost to acquire, maintain, and/or use the device requires a large initial investment and/or ongoing expenditure that is not affordable for the average individual consumer;

(C) Whether the device is a Class III device under the FDA system of classification;

(D) Whether the device is classified by the FDA under—

(1) 21 CFR part 862 (Clinical Chemistry and Clinical Toxicology Devices), 21 CFR part 864 (Hematology and Pathology Devices), 21 CFR part 866 (Immunology and Microbiology Devices), 21 CFR part 868 (Anesthesiology Devices), 21 CFR part 870 (Cardiovascular Devices), 21 CFR part 874 (Ear, Nose, and Throat Devices), 21 CFR part 876 (Gastroenterology — Urology Devices), 21 CFR part 878 (General and Plastic Surgery Devices), 21 CFR part 882 (Neurological Devices), 21 CFR part 886 (Ophthalmic Devices), 21 CFR part 888 (Orthopedic Devices), or 21 CFR part 892 (Radiology Devices);

(2) Subpart B, Subpart D, or Subpart E of 21 CFR part 872 (Dental Devices);

(3) Subpart B, Subpart C, Subpart D, Subpart E, or Subpart G of 21 CFR part 884 (Obstetrical and Gynecological Devices); or

(4) Subpart B of 21 CFR part 890 (Physical Medicine Devices); and

(E) Whether the device qualifies as durable medical equipment, prosthetics, orthotics, and supplies for which payment is available exclusively on a rental basis under the Medicare Part B payment rules, and is an “item requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

(iii) *Safe Harbor.* The following devices will be considered to be of a type generally purchased by the general public at retail for individual use:

(A) Devices that are included in the FDA’s online IVD Home Use Lab Tests (Over-the-Counter Tests) database, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm>.

(B) Devices that are described as “OTC” or “over the counter” devices in the relevant FDA classification regulation heading.

(C) Devices that are described as “OTC” or “over the counter” devices in the FDA’s product code name, the FDA’s device classification name, or the “classification name” field in the FDA’s device registration and listing database, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/rl.cfm>.

(D) Devices that qualify as durable medical equipment, prosthetics, orthotics, and supplies, as described in Subpart C of 42 CFR part 414 (Parenteral and Enteral Nutrition) and Subpart D of 42 CFR part 414 (Durable Medical Equipment and Prosthetic and Orthotic Devices), for which payment is available on a purchase basis under Medicare Part B payment rules, and are—

(1) “Prosthetic and orthotic devices,” as defined in 42 CFR 414.202, that do not require implantation or insertion by a medical professional;

(2) “Parenteral and enteral nutrients, equipment, and supplies” as defined in 42 CFR 411.351 and described in 42 CFR 414.102(b);

(3) “Customized items,” as described in 42 CFR 414.224;

(4) “Therapeutic shoes,” as described in 42 CFR 414.228(c); or

(5) Supplies necessary for the effective use of durable medical equipment (DME), as described in section 110.3 of chapter 15 of the Medicare Benefit Policy Manual

(Centers for Medicare and Medicaid Studies Publication 100–02).

(iv) *Examples.* The following examples illustrate the rules of this paragraph (b)(2).

Example 1. X manufactures non-sterile absorbent tipped applicators. X sells the applicators to distributors Y and Z, which, in turn, sell the applicators to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of non-sterile absorbent tipped applicators to list the applicators as a device with the FDA. The applicators are classified by the FDA under 21 CFR part 880 (General Hospital and Personal Use Devices) and product code KXF.

Absorbent tipped applicators do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the absorbent tipped applicators are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals can regularly purchase the absorbent tipped applicators at drug stores, supermarkets, cosmetic supply stores or other similar businesses, and can use the applicators safely and effectively for their intended medical purpose without training from a medical professional. Further, the absorbent tipped applicators do not need to be implanted, inserted, operated, or otherwise administered by a medical professional, do not require a large investment and/or ongoing expenditure, are not a Class III device, are not classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

Thus, the applicators have multiple factors under paragraph (b)(2)(i) of this section that tend to show they are regularly available for purchase and use by individual consumers and none of the factors under paragraph (b)(2)(ii) of this section tend to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the applicators are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 2. X manufactures adhesive bandages. X sells the adhesive bandages to distributors Y and Z, which, in turn, sell the bandages to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of adhesive bandages to list the bandages as a device with the FDA. The adhesive bandages are classified by the FDA under 21 CFR part 880 (General Hospital and Personal Use Devices) and product code KGX.

Adhesive bandages do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the adhesive bandages are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals can regularly purchase the adhesive bandages at drug stores, supermarkets, or other similar businesses, and can use the adhesive bandages safely and effectively for their intended medical purpose

without training from a medical professional. Further, the adhesive bandages do not need to be implanted, inserted, operated, or otherwise administered by a medical professional, do not require a large investment and/or ongoing expenditure, are not Class III devices, are not classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

Thus, the adhesive bandages have multiple factors under paragraph (b)(2)(i) of this section that tend to show they are regularly available for purchase and use by individual consumers and none of the factors under paragraph (b)(2)(ii) of this section tend to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the adhesive bandages are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 3. X manufactures snake bite suction kits. X sells the snake bite suction kits to distributors Y and Z, which, in turn, sell the kits to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of snake bite suction kits to list the kits as a device with the FDA. The FDA classifies the snake bite suction kits under 21 CFR part 880 (General Hospital and Personal Use Devices) and product code KYP.

Snake bite suction kits do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the snake bite suction kits are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals can regularly purchase the snake bite suction kits at sporting goods stores, camping stores, or other similar retail businesses, and can use the kits safely and effectively for their intended medical purpose without training from a medical professional. Further, the snake bite suction kits do not need to be implanted, inserted, operated, or otherwise administered by a medical professional, do not require a large investment and/or ongoing expenditure, are not Class III devices, are not classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

Thus, the snake bite suction kits have multiple factors under paragraph (b)(2)(i) of this section that tend to show they are regularly available for purchase and use by individual consumers and none of the factors under paragraph (b)(2)(ii) of this section tend to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the snake bite suction kits are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 4. X manufactures denture adhesives. X sells the denture adhesives to distributors Y and Z, which, in turn, sell the adhesives to dental offices and retail businesses. The FDA requires manufacturers of denture adhesives to list the adhesive as a device with the FDA. The FDA classifies the denture adhesives under 21 CFR part 872 (Dental Devices) and product code KXX.

The denture adhesives do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the denture adhesives are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals can regularly purchase the denture adhesives at drug stores, supermarkets, or other similar businesses, and can use the adhesives safely and effectively for their intended medical purpose with minimal or no training from a medical professional. Further, the denture adhesives do not need to be implanted, inserted, operated, or otherwise administered by a medical professional, do not require a large investment and/or ongoing expenditure, are not Class III devices, are not classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

Thus, the denture adhesives have multiple factors under paragraph (b)(2)(i) of this section that tend to show they are regularly available for purchase and use by individual consumers and none of the factors under paragraph (b)(2)(ii) of this section tend to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the denture adhesives are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 5. X manufactures mobile x-ray systems. X sells the x-ray systems to distributors Y and Z, which, in turn, sell the systems generally to medical institutions and offices, as well as medical professionals. The FDA requires manufacturers of mobile x-ray systems to list the systems as a device with the FDA. The FDA classifies the mobile x-ray systems under 21 CFR part 892 (Radiology Devices) and product code IZL.

Mobile x-ray systems do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the mobile x-ray systems are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals can regularly purchase the mobile x-ray systems over the internet. However, individual consumers cannot use the x-ray systems safely and effectively for their intended medical purpose without training from a medical professional. Although the mobile x-ray systems are not Class III devices and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222, they need to be operated by a medical professional, may require a large investment and/or ongoing expenditure, and are classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section (21 CFR part 892 (Radiology Devices)).

Thus, with regard to the factors under paragraph (b)(2)(i) of this section, the mobile x-ray systems have one factor that tends to show they are regularly available for purchase and use by individual consumers and one factor that tends to show that they are not regularly available for purchase and use by individual consumers. With regard to the factors

under paragraph (b)(2)(ii) of this section, the mobile x-ray systems have multiple factors that tend to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the mobile x-ray systems are not devices that are of a type generally purchased by the general public at retail for individual use.

Example 6. X manufactures pregnancy test kits. X sells the kits to distributors Y and Z, which, in turn, sell the pregnancy test kits to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of pregnancy test kits to list the kits as a device with the FDA. The FDA classifies the kits under 21 CFR part 862 (Clinical Chemistry and Clinical Toxicology Devices) and product code LCX.

The pregnancy test kits are included in the FDA’s online IVD Home Use Lab Tests (Over-the-Counter Tests) database. Therefore, the over the counter pregnancy test kits fall within the safe harbor set forth in paragraph (b)(2)(iii)(A) of this section. Further, the FDA product code name for LCX is “Kit, Test, Pregnancy, HCG, Over The Counter.” Therefore, the pregnancy test kits also fall within the safe harbor set forth in paragraph (b)(2)(iii)(C) of this section. Accordingly, the pregnancy test kits are devices that are of a type generally purchased by the general public at retail for individual use.

Example 7. X manufactures blood glucose monitors, blood glucose test strips, and lancets. X sells the blood glucose monitors, test strips, and lancets to distributors Y and Z, which, in turn, sell the monitors, test strips, and lancets to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of blood glucose monitors, test strips, and lancets to list the items as devices with the FDA. The FDA classifies the blood glucose monitors under 21 CFR part 862 (Clinical Chemistry and Clinical Toxicology Devices) and product code NBW. The FDA classifies the test strips under 21 CFR part 862 (Clinical Chemistry and Clinical Toxicology Devices) and product code NBW. The FDA classifies the lancets under 21 CFR part 878 (General and Plastic Surgery Devices) and product code FMK.

The blood glucose monitors and test strips are included in the FDA’s online IVD Home Use Lab Tests (Over-the-Counter Tests) database. Therefore, the blood glucose monitors and test strips fall within the safe harbor set forth in paragraph (b)(2)(iii)(A) of this section. Further, the FDA product code name for NBW is “System, Test, Blood Glucose, Over the Counter.” Therefore, the blood glucose monitors and test strips also fall within the safe harbor set forth in paragraph (b)(2)(iii)(C) of this section.

In addition, the lancets are supplies necessary for the effective use of DME as described in chapter 15 of the Medicare Policy Benefit Manual. Therefore, the lancets fall within the safe harbor set forth in paragraph (b)(2)(iii)(D)(5) of this section.

Accordingly, the blood glucose monitors, test strips, and lancets are devices that are of a type generally purchased by the general public at retail for individual use.

Example 8. X manufactures single axis endoskeletal knee shin systems, which are used in the manufacture of prosthetic legs. X sells the knee shin systems to Y, a business that makes prosthetic

legs. The FDA requires manufacturers of knee shin systems and prosthetic legs to list the items as devices with the FDA. The FDA classifies prosthetic leg components, including knee shin systems, as external limb prosthetic components under Subpart D of 21 CFR part 890.3420 and product code ISH. The FDA classifies prosthetic legs as an external assembled lower limb prosthesis under 21 CFR part 890.3500 and product code ISW / KFX. In addition, the Centers for Medicare and Medicaid Services have assigned the knee shin systems Healthcare Procedure Coding System code L5810.

Prosthetic legs and certain prosthetic leg components, including single axis endoskeletal knee shin systems, fall within the safe harbor for prosthetic and orthotic devices that do not require implantation or insertion by a medical profession that is set forth in paragraph (b)(2)(iii)(D)(1) of this section. Accordingly, both the single axis endoskeletal knee shin systems manufactured by X and the prosthetic legs made by Y are devices that are of a type generally purchased by the general public at retail for individual use.

Example 9. X manufactures mechanical and powered wheelchairs. X sells the wheelchairs to distributors Y and Z, which, in turn, sell the wheelchairs to medical institutions and offices, medical professionals, nursing homes, and retail businesses. The FDA requires manufacturers of manual and powered wheelchairs to list the items as devices with the FDA. The FDA classifies the manual and powered wheelchairs under Subpart D of 21 CFR part 890 (Physical Medicine Devices). The FDA classifies mechanical wheelchairs under product code IOR. The FDA classifies powered wheelchairs under product code ITI.

Mechanical and powered wheelchairs do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the mechanical and powered wheelchairs are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals can regularly purchase the wheelchairs in drug stores, medical specialty stores, or DME suppliers, as well as over the internet. In addition, individual consumers can use the wheelchairs safely and effectively for their intended medical purpose with minimal or no training from a medical professional, and the wheelchairs are classified by the FDA under Subpart D of 21 CFR part 890 (Physical Medicine Devices). Further, although the wheelchairs may require a large initial investment and/or ongoing expenditure, they do not need to be implanted, inserted, operated, or otherwise administered by a medical professional, are not Class III devices, are not classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

Thus, the wheelchairs have multiple factors under paragraph (b)(2)(i) of this section that tend to show they are regularly available for purchase and use by individual consumers and, at most, only one factor under paragraph (b)(2)(ii) of this section tends to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances,

the mechanical and powered wheelchairs are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 10. X manufactures portable oxygen concentrators. X sells the portable oxygen concentrators to distributors Y and Z, which, in turn, sell the portable oxygen concentrators to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of portable oxygen concentrators to list the items as devices with the FDA. The FDA classifies the oxygen regulators under 21 CFR part 868 (Anesthesiology Devices) and product code CAW.

Portable oxygen concentrators do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the oxygen concentrators are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals can regularly purchase the portable oxygen concentrators in retail pharmacies, medical specialty stores, or DME suppliers, as well as over the internet. In addition, individual consumers can use the portable oxygen concentrators safely and effectively for their intended medical purpose with minimal or no training from a medical professional. Further, although the portable oxygen concentrators are classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, they do not need to be implanted, inserted, operated, or otherwise administered by a medical professional, do not require a large investment and/or ongoing expenditure, are not Class III devices, and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

Thus, the portable oxygen concentrators have multiple factors under paragraph (b)(2)(i) of this section that tend to show they are regularly available for purchase and use by individual consumers and only one factor under paragraph (b)(2)(ii) of this section tends to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the portable oxygen concentrators are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 11. X manufactures urinary ileostomy bags. X sells the urinary ileostomy bags to distributors Y and Z, which, in turn, sell the urinary ileostomy bags to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of urinary ileostomy bags to list the items as devices with the FDA. The FDA classifies the urinary ileostomy bags under 21 CFR part 876 (Gastroenterology — Urology Devices) and product code EXH.

The urinary ileostomy bags are “Prosthetic and orthotic devices,” as defined in 42 CFR 414.202, that do not require implantation or insertion by a medical professional. Therefore, the urinary ileostomy bags fall within the safe harbor set forth in paragraph (b)(2)(iii)(D)(1) of this section. Accordingly, the urinary ileostomy bags are devices that are of a type generally purchased by the general public at retail for individual use.

Example 12. X manufactures nonabsorbable silk sutures. X sells the nonabsorbable silk sutures to

distributors Y and Z, which, in turn, sell the nonabsorbable silk sutures to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of nonabsorbable silk sutures to list the items as devices with the FDA. The FDA classifies the nonabsorbable silk sutures under 21 CFR part 878 (General and Plastic Surgery Devices) and product code GAP.

Nonabsorbable silk sutures do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the nonabsorbable silk sutures are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals can regularly purchase the nonabsorbable silk sutures over the internet. However, individual consumers cannot use nonabsorbable silk sutures safely and effectively for their intended medical purpose with minimal or no training from a medical professional. Further, although the nonabsorbable silk sutures do not require a large investment and/or ongoing expenditure, are not Class III devices, and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222, the nonabsorbable silk sutures are classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, and they need to be administered by a medical professional.

Thus, with regard to the factors under paragraph (b)(2)(i) of this section, the nonabsorbable silk sutures have one factor that tends to show they are regularly available for purchase and use by individual consumers and one factor that tends to show that they are not regularly available for purchase and use by individual consumers. With regard to the factors under paragraph (b)(2)(ii) of this section, the nonabsorbable silk sutures have multiple factors that tend to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the nonabsorbable silk sutures are not devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 13. X manufactures nuclear magnetic resonance imaging (NMRI) systems (also known as magnetic resonance imaging (MRI) systems). X sells the NMRI systems to distributor Y, which, in turn, sells the systems to medical institutions. The FDA requires manufacturers of NMRI systems to list the systems as a device with the FDA. The FDA classifies the magnetic resonance diagnostic device under 21 CFR part 892 (Radiology Devices) and product code LNH.

NMRI systems do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the NMRI systems are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals may be able to regularly purchase the NMRI systems over the internet. However, individual consumers cannot use the NMRI systems safely and effectively for their intended medical purpose without training from a medical professional. Although the NMRI systems are not Class III devices and are not “items requiring frequent and substantial

servicing” as defined in 42 CFR 414.222, they need to be operated by a medical professional, and are of a type classified by the FDA under 21 CFR part 892 (Radiology Devices). Further, the cost to acquire, maintain, and/or use the NMRI systems requires a large initial investment and/or ongoing expenditure that is not affordable for the average consumer.

Thus, with regard to the factors under paragraph (b)(2)(i), the NMRI systems have, at most, one factor that tends to show that they are regularly available for purchase and use by individual consumers and at least one factor that tends to show that they are not regularly available for purchase and use by individual consumers. With regard to the factors under paragraph (b)(2)(ii), the NMRI systems have multiple factors that tend to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the NMRI systems are not devices that are of a type generally purchased by the general public at retail for individual use.

Example 14. X manufactures therapeutic AC powered adjustable home use beds. X sells the beds to distributors Y and Z, which, in turn, sell the beds to retail businesses. The FDA requires manufacturers of therapeutic AC powered adjustable home use beds to list the items as devices with the FDA. The FDA classifies the therapeutic AC powered adjustable home use beds under 21 CFR part 880 (General Hospital Devices) and product code LLI.

Therapeutic AC powered adjustable home use beds do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the beds are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Although the beds may require a large initial investment and/or ongoing expenditure, individual consumers who are not medical professionals can regularly purchase the beds in medical specialty stores or from DME suppliers, as well as over the internet. In addition, individual consumers can use the beds safely and effectively for their intended medical purpose with minimal or no training from a medical professional. Further, the beds are not classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, do not need to be implanted, inserted, operated, or otherwise administered by a medical professional, are not Class III devices, and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

Thus, the therapeutic AC powered adjustable home use beds have multiple factors under paragraph (b)(2)(i) of this section that tend to show they are regularly available for purchase and use by individual consumers and, at most, only one factor under paragraph (b)(2)(ii) of this section that tends to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the therapeutic AC powered adjustable home use beds are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 15. X manufactures powered flotation therapy beds. X sells the beds to distributors Y and Z, which, in turn, sell the beds to medical institutions

and offices, and medical professionals. The FDA requires manufacturers of powered flotation therapy beds to list the items as devices with the FDA. The FDA classifies the powered flotation therapy beds under 21 CFR part 890 (Physical Medicine Devices) and product code IOQ.

Powered flotation therapy beds do not fall within a retail exemption safe harbor set forth in paragraph (b)(2)(iii) of this section. Therefore, the determination of whether the beds are devices of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis.

Individual consumers who are not medical professionals may be able to regularly purchase the beds over the internet. However, individual consumers cannot use the beds safely and effectively for their intended medical purpose with minimal or no training from a medical professional. Although the powered flotation therapy beds are not Class III devices and are not “items requiring frequent and substantial servicing” as defined in 42 CFR 414.222, they need to be operated or otherwise administered by a medical professional. Further, the cost to acquire, maintain, and/or use the powered flotation therapy beds requires a large initial investment and/or ongoing expenditure that is not affordable for the average consumer.

Thus, with regard to the factors under paragraph (b)(2)(i) of this section, the powered flotation therapy beds have, at most, one factor that tends to show they are regularly available for purchase and use by individual consumers and at least one factor that tends to show they are not regularly available for purchase and use by individual consumers. With regard to the factors under paragraph (b)(2)(ii) of this section, the powered flotation therapy beds have multiple factors that tend to show they are designed primarily for use in a medical institution or office or by medical professionals. Based on the totality of the facts and circumstances, the powered flotation therapy beds are not devices that are of a type that are generally purchased by the general public at retail for individual use.

(c) *Effective/applicability date.* This section applies to sales of taxable medical devices on and after January 1, 2013.

Par. 4. Section 48.4216(c)–1 is amended by adding paragraphs (e)(1), (e)(2), and (e)(3) to read as follows:

§48.4216(c)–1 Computation of tax on leases and installment sales.

* * * * *

(e) *Contracts for the lease, installment sale, or sale on credit, of a taxable medical device.*

(1) *General rule.* Payments made on or after January 1, 2013, pursuant to a contract for the lease, installment sale, or sale on credit of a taxable medical device that was entered into on or after March 30, 2010, are subject to tax under section 4191,

and the provisions of paragraphs (a), (b), and (c) of this section apply.

(2) *Exception for payments made on or after January 1, 2013, pursuant to written binding contracts entered into prior to March 30, 2010.* Payments made on or after January 1, 2013, pursuant to a written binding contract for the lease, installment sale, or sale on credit of a taxable medical device that was in effect prior to March 30, 2010, are not subject to tax under section 4191. This exception includes payments made on or after January 1, 2013, if they are made pursuant to a written binding contract that was entered into prior to March 30, 2010. This exception does not apply to payments made under any contract that is materially modified on or after March 30, 2010. For this purpose, a material modification includes only a modification that materially affects the property to be provided under the contract, the terms of payment under the contract, or the amount payable under the contract. Notwithstanding the foregoing, a material modification does not include a modification to the contract required by applicable Federal, State, or local law.

(3) *Effective/applicability date.* This section applies on and after January 1, 2013.

Par. 5. Section 48.4221–1 is amended by adding paragraph (a)(2)(vii) to read as follows:

§48.4221–1 Tax-free sales; general rule.

(a) * * *

(2) * * *

(vii) The exemptions under section 4221(a)(3) through (a)(6) do not apply to the tax imposed by section 4191 (medical device tax).

* * * * *

Par. 6. Section 48.6416(b)(2)–2 is amended by adding paragraph (a)(4) to read as follows:

§48.6416(b)(2)–2 Exportations, uses, sales and resales included.

(a) * * *

(4) Beginning on January 1, 2013, sections 6416(b)(2)(B), (C), (D), and (E) do not apply to any tax paid under section 4191 (medical device tax).

* * * * *

Steven T. Miller,
Deputy Commissioner for
Services and Enforcement.

Approved November 30, 2012.

Mark J. Mazur,
Assistant Secretary
of the Treasury (Tax Policy).

(Filed by the Office of the Federal Register on December 5, 2012, 8:45 a.m., and published in the issue of the Federal Register for December 7, 2012, 77 F.R. 72924)

Section 4375.—Health Insurance

26 CFR 40.0–1: Introduction.

T.D. 9602

DEPARTMENT OF THE TREASURY Internal Revenue Service 26 CFR Parts 40, 46, and 602

Fees on Health Insurance Policies and Self-Insured Plans for the Patient-Centered Outcomes Research Trust Fund

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that implement and provide guidance on the fees imposed by the Patient Protection and Affordable Care Act on issuers of certain health insurance policies and plan sponsors of certain self-insured health plans to fund the Patient-Centered Outcomes Research Trust Fund. These final regulations affect the issuers and plan sponsors that are directed to pay those fees.

DATES: *Effective Date:* These regulations are effective December 6, 2012.

Applicability Date: These regulations apply to policy and plan years ending on or after October 1, 2012, and before October 1, 2019.

FOR FURTHER INFORMATION CONTACT: R. Lisa Mojiri-Azad at (202)

622–6080 (regarding self-insured health arrangements) or Rebecca L. Baxter at (202) 622–3970 (regarding health insurance policies).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–2238. The collections of information in these final regulations are in §46.4375–1(c)(2)(iv) (use of the snapshot method to calculate the fee under section 4375); §46.4375–1(c)(2)(v) (use of the National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit to calculate the fee under section 4375); §46.4375–1(c)(2)(vi) (use of certain state forms to calculate the fee under section 4375); §46.4376–1(b)(2)(G) (identification or designation of a plan sponsor under the governing plan document for certain applicable self-insured health plans); §46.4376–1(c)(2)(iv) (use of snapshot method to calculate the fee under section 4376); and §46.4376–1(c)(2)(v) (use of the Form 5500, “Annual Return/Report of Employee Benefit Plan,” or Form 5500-SF, “Short Form Annual Return/Report of Employee Benefit Plan” to calculate the fee under section 4376).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains final amendments to 26 CFR part 40 (Excise Tax Procedural Regulations) and 26 CFR part 46 (relating to excise taxes imposed on policies issued by foreign insurers and obligations not in registered form) to implement the requirements under sections

4375 through 4377 of the Internal Revenue Code (Code). The Treasury Department and the IRS issued proposed regulations under sections 4375 through 4377 on April 17, 2012 (77 FR 22,691). Sections 4375 and 4376 of the Code impose fees on issuers of specified health insurance policies and plan sponsors of applicable self-insured health plans, and section 4377 contains special rules that apply to these issuers and plan sponsors with respect to these fees. Sections 4375, 4376, and 4377 were added to the Code by section 6301 of the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148 (124 Stat. 119 (2010)).

The Affordable Care Act provides for the establishment of the private, nonprofit corporation, the Patient-Centered Outcomes Research Institute (the “Institute”). Through research, the Institute will assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence-based medicine through the synthesis and dissemination of comparative clinical effectiveness research findings. The statute specifically prohibits the Secretary of Health and Human Services (HHS) from using the evidence or findings of the research conducted in determining coverage, reimbursement, or incentive programs unless it is through an iterative and transparent process which includes public comment and considers the effect on subpopulations. Nothing under this provision allows the Secretary of HHS to deny coverage of items or services solely on the basis of comparative clinical effectiveness research. The statute provides that the Institute will not develop a dollars-per-quality-life-year estimate as a threshold to establish effective or recommended care.

Section 6301 of the Affordable Care Act amended the Code by adding new section 9511 to establish the Patient-Centered Outcomes Research Trust Fund (the “Trust Fund”), which is the funding source for the Institute. Section 6301 of the Affordable Care Act also added new Code sections 4375, 4376, and 4377 to provide a funding source for the Trust Fund that is to be financed, in part, by fees to be paid by issuers of specified health insurance policies and sponsors of applicable self-insured health plans.

Statutory Provisions

Section 4375 imposes a fee on an issuer of a specified health insurance policy for each policy year ending on or after October 1, 2012, and before October 1, 2019. Under section 4375(a), the fee is two dollars (one dollar in the case of policy years ending before October 1, 2013) multiplied by the average number of lives covered under the policy. Under section 4375(d), for policy years ending on or after October 1, 2014, the fee is increased based on increases in the projected per capita amount of National Health Expenditures. Section 4375(b) provides that the fee imposed by section 4375(a) shall be paid by the issuer of the policy.

Section 4375(c) defines a *specified health insurance policy* as any accident or health insurance policy (including a policy under a group health plan) issued with respect to individuals residing in the United States. Section 4375(c)(2) excludes from a specified health insurance policy any insurance if substantially all of its coverage is of excepted benefits described in section 9832(c). Section 4375(c)(3) provides that a specified health insurance policy includes any prepaid health coverage arrangement described in section 4375(c)(3)(B). An arrangement is described in section 4375(c)(3)(B) if, under the arrangement, fixed payments or premiums are received as consideration for a person's agreement to provide or arrange for the provision of accident or health coverage to residents of the United States, regardless of how the coverage is provided or arranged to be provided.

Section 4376 imposes a fee on a plan sponsor of an applicable self-insured health plan for each plan year ending on or after October 1, 2012, and before October 1, 2019.¹ Under section 4376(a), the fee is two dollars (one dollar for plan years ending before October 1, 2013) multiplied by the average number of lives covered under the plan. Under section 4376(d), for plan years ending on or after October 1, 2014, the fee is increased based on increases in the projected *per capita* amount of National Health Expenditures. Section 4376(b)(1) provides that the fee

imposed by section 4376(a) shall be paid by the plan sponsor.

Section 4376(b)(2) defines a *plan sponsor* as the employer in the case of a plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization. Section 4376(b)(2) also provides that, in the case of (1) a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, (2) a multiple employer welfare arrangement, or (3) a voluntary employees' beneficiary association described in section 501(c)(9), the plan sponsor is the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan. Section 4376(b)(2) further provides that in the case of a plan established or maintained by a rural electric cooperative (as defined in section 3(40)(B)(iv) of the Employee Retirement Income Security Act of 1974 (ERISA)) or rural telephone cooperative association (as defined in section 3(40)(B)(v) of ERISA), the plan sponsor is the cooperative or association that established or maintained the plan.

Section 4376(c) defines an *applicable self-insured health plan* as any plan for providing accident or health coverage if any portion of the coverage is provided other than through an insurance policy, and the plan is established or maintained (1) by one or more employers for the benefit of their employees or former employees, (2) by one or more employee organizations for the benefit of their members or former members, (3) jointly by one or more employers and one or more employee organizations for the benefit of employees or former employees, (4) by a voluntary employees' beneficiary association described in section 501(c)(9), (5) by any organization described in section 501(c)(6), or (6) if not previously described, by a multiple employer welfare arrangement (as defined in section 3(40) of ERISA), a rural electric cooperative (as defined in section 3(40)(B)(iv) of ERISA), or a rural telephone cooperative association (as defined in section 3(40)(B)(v) of ERISA).

Section 4377 includes definitions and special rules that apply for purposes of sections 4375 and 4376. Section 4377(a)(1) defines *accident and health coverage* as any coverage that, if provided by an insurance policy, would cause the policy to be a specified health insurance policy (as defined in section 4375(c)).

Section 4377(b)(1)(B) provides that "[n]otwithstanding any other law or rule of law, governmental entities shall not be exempt from" the fees imposed by sections 4375 and 4376 unless the policy or plan is an exempt governmental program. Section 4377(b)(3) defines an *exempt governmental program* as (1) any insurance program established under title XVIII of the Social Security Act (42 U.S.C. 1395 *et. seq.*) (Medicare), (2) the medical assistance program established by title XIX (42 U.S.C. 1396 *et. seq.*) (Medicaid) or title XXI of the Social Security Act (42 U.S.C. 1397aa *et. seq.*) (Children's Health Insurance Program), (3) any program established by Federal law for providing medical care (other than through insurance policies) to individuals (or the spouses and dependents thereof) by reason of such individuals being members of the Armed Forces of the United States or veterans, and (4) any program established by Federal law for providing medical care (other than through insurance policies) to members of Indian tribes (as defined in section 4(d) of the Indian Health Care Improvement Act, 25 U.S.C. 1603). Under these special rules, a governmental entity (including a federally recognized Indian tribal government) that is the plan sponsor of an applicable self-insured health plan that does not meet the definition of an exempt governmental program must pay the fee imposed by section 4376.

Section 4377(c) provides that the fees imposed by sections 4375 and 4376 are treated as taxes for purposes of subtitle F of the Code (sections 6001 through 7874 that set forth the rules of federal tax procedure and administration).

Notice 2011–35 and Proposed Regulations

On June 8, 2011, the IRS released Notice 2011–35, 2011–25 I.R.B. 879, which requested comments on how the fees

¹ The Department of Labor has advised that, because the fee is imposed on the plan sponsor under section 4376 (instead of the plan), paying the PCORI fee generally does not constitute a permissible expense of the plan for purposes of Title I of the Employee Retirement Income Security Act (ERISA), although special circumstances may exist in limited situations. The Department of Labor will provide guidance in the near future on PCORI fee payments under Title I of ERISA on its website, www.dol.gov/ebsa.

imposed under sections 4375 and 4376 (referred to collectively as the PCORI fee) should be calculated and paid, including possible rules and safe harbors. The Treasury Department and the IRS received numerous comments in response to Notice 2011–35 and considered all comments in issuing proposed regulations under sections 4375, 4376, and 4377 (77 FR 22,691). The Treasury Department and the IRS received 26 written comments on the proposed regulations. After consideration of the comments, these final regulations adopt the provisions of the proposed regulations with certain modifications, the most significant of which are highlighted in the Summary of Comments and Explanation of Revisions. See §601.601(d)(2).

Summary of Comments and Explanation of Revisions

I. Health insurance policies subject to the PCORI fee

Section 4375(a) imposes a fee on an issuer of a specified health insurance policy for each policy year ending on or after October 1, 2012, and before October 1, 2019. Section 46.4375–1(b)(1) of these regulations defines a *specified health insurance policy* as any accident and health insurance policy (including a policy under a group health plan) issued with respect to individuals residing in the United States. Section 46.4375–1(b)(1)(ii) provides exceptions to the term *specified health insurance policy*. Section 4375(c)(2) and §46.4375–1(b)(1)(ii)(A) provide an exclusion for any insurance if substantially all of its coverage is of excepted benefits described in section 9832(c). While §46.4376–1(b)(ii)(B) excludes from the definition of applicable self-insured health plan an employee assistance program (EAP), disease management program, or wellness program, if the program does not provide significant benefits in the nature of medical care or treatment, no similar exclusion was included in the proposed regulations for a specified health insurance policy.

One commentator explained that California and Nevada regulate EAPs that provide for four or more counseling, treatment, or therapy visits as insurance thereby requiring the issuance of an insurance policy. The commentator argued

that in any other state, identical EAPs would be excluded from the definition of applicable self-insured plan and not subject to the PCORI fee. In recognition of the unique California and Nevada requirements that certain employee assistance plans be treated as insurance, the commentator asked that an exception be added to the definition of specified health insurance policy to exclude those EAPs. In response to this comment, these final regulations provide that the definition of a *specified health insurance policy* does not include any insurance policy to the extent that the policy provides for an EAP, disease management program, or wellness program, if the program does not provide significant benefits in the nature of medical care or treatment. No inference is intended whether the specific health benefits cited by the commentator constitute insignificant benefits.

II. Retiree coverage and retiree-only plans

As noted in the preamble to the proposed regulations, sections 4375 and 4376 may apply to a retiree-only plan because, although group health plans that have fewer than two participants who are current employees (such as retiree-only plans) are excluded from the requirements of chapter 100 (setting forth requirements applicable to group health plans such as portability, nondiscrimination, and market reform requirements), this exclusion does not apply to sections 4375 and 4376 because these sections are in chapter 34. In addition, section 4376(c)(2)(A) states explicitly that an applicable self-insured health plan includes a plan established or maintained by one or more employers for the benefit of their employees or former employees. Some commentators requested that the final regulations exempt from the PCORI fee retiree coverage on public policy grounds, but generally agreed that a retiree-only insured plan or retiree coverage under an applicable self-insured health plan may be subject to the PCORI fee. Consistent with the statutory language, the final regulations apply the PCORI fee to specified health insurance policies or applicable self-insured health plans that provide accident and health coverage to retirees, including retiree-only policies and plans.

III. COBRA coverage

Commentators requested clarification of whether sections 4375 and 4376 apply to continuation coverage required under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) or similar continuation coverage under other federal law or under state law (referred to collectively as “continuation coverage”) and asked that the final regulations explicitly exclude continuation coverage from application of those sections. If the coverage provided under the continuation coverage arrangement is accident and health coverage, there is no basis to exclude the arrangement from the PCORI fee. The requirements of sections 4375 and 4376 apply to specified health insurance policies that provide accident and health coverage and plans that are applicable self-insured health plans, regardless of whether provided through the individual market, to an active employee as part of a group health plan, or as continuation coverage to an active employee, former employee, or otherwise qualifying beneficiary. In response to comments, these final regulations state explicitly that continuation coverage must be taken into account in determining the PCORI fee, unless the arrangement is otherwise excluded.

IV. Lives taken into account in calculating the fee

The fee imposed on an issuer of a specified health insurance policy under section 4375 is based on the average number of lives covered under the policy during the policy year. The fee imposed on a plan sponsor of an applicable self-insured health plan under section 4376 is based on the average number of lives covered under the plan during the plan year.

Commentators acknowledged that separate fees are imposed by sections 4375 and 4376, but argued that this only reflects congressional intent for the PCORI fee to extend to both insured and self-insured arrangements. Several commentators requested that the final regulations provide that the PCORI fee does not apply multiple times if accident and health coverage is provided to one individual through more than one policy or self-insured arrangement (for example, where an individual is covered by a fully-insured ma-

for medical insurance policy and a self-insured prescription arrangement). Commentators also requested that the final regulations clarify that the issuer or plan sponsor is required to pay only once with respect to each covered life under the specified health insurance policy or applicable self-insured health plan.

The final regulations do not adopt the requested change that the fee apply only once with respect to each covered life because it would be contrary to the explicit statutory language applying the fee to each specified health insurance policy or applicable self-insured health plan. For example, for an employee covered by both a group insurance policy and a health reimbursement arrangement (HRA), the group insurance policy falls within the definition of a specified health insurance policy to which section 4375 applies a fee, and the HRA falls within the definition of an applicable self-insured health plan, to which section 4376 applies a fee to the plan sponsor. Because there are no allocation rules or other method of applying the fee on an aggregated basis in the statute or legislative history, there is no evidence that the statutory provisions were intended to be applied in a manner that aggregated these separate arrangements for a single covered individual and allocated the fee between them. However, in response to comments, the final regulations permit an applicable self-insured health plan that provides accident and health coverage through fully-insured options and self-insured options to determine the fee imposed by section 4376 by disregarding the lives that are covered solely under the fully-insured options. (See also discussion under section V of this preamble relating to the special rule for plan sponsors that establish or maintain multiple self-insured arrangements with the same plan year and section VI of this preamble relating to special rules for health reimbursement arrangements and flexible spending arrangements). Except as otherwise provided, the final regulations do not permit an issuer or plan sponsor to disregard a covered life merely because that individual is also covered under another specified health insurance policy or applicable self-insurance plan.

V. Lives covered under multiple policies or plans

Section 46.4376-1(b)(1)(iii) of the proposed regulations provided that for purposes of section 4376, two or more arrangements established or maintained by the same plan sponsor that provide for accident and health coverage other than through an insurance policy and that have the same plan year may be treated as a single applicable self-insured health plan for purposes of calculating the fee imposed by section 4376.

A few commentators described self-insured arrangements that are coordinated with an underlying health plan, including a plan of an unrelated entity. Commentators pointed to collectively bargained arrangements under which the union sponsors a prescription-only or premium-only plan that is tied to an insured health plan of the employers that have entered into a collective bargaining agreement between the employee representatives and one or more employers. These commentators requested that the final regulations include special rules that exempt from the PCORI fee certain applicable self-insured health plans that are established or maintained by a union because the lives covered under the union plan are taken into account for the fee imposed on the employer, if the employer's plan is also an applicable self-insured health plan, or the issuer, if the employer's plan is an insured plan. One commentator requested that the final regulations permit collectively bargained plans to be aggregated with the employer's plan, without regard to whether they have the same sponsor or plan year, for purposes of determining the fee with respect to the same lives covered.

One commentator pointed out that the Medical Loss Ratio (MLR) Interim Final Rule issued by HHS allows affiliated issuers to report their premiums and expenditures on an aggregate basis if one issuer provides in-network coverage and the second provides out-of-network coverage for one group health plan. The commentator requested the same approach provided in §46.4376-1(b)(1)(iii) (permitting two or more applicable self-insured health plans with the same plan sponsor and same plan year to be treated as a single applicable self-insured health plan) be provided for group health plans that

provide separate benefits to a participant or beneficiary during the same plan year under two or more insurance policies or through a self-insured plan and an insured plan. Specifically, the commentator suggested that if insurance policies covering the same individual qualify for aggregation under the MLR rebate reporting rules, the IRS should allow issuers to aggregate their policies for purposes of the PCORI fee.

Sections 4375 and 4376 specifically apply the PCORI fee to, respectively, an issuer of a specified health insurance policy and to the sponsor of an applicable self-insured health plan (subject to certain exceptions). The commentators have shown no statutory basis for combining arrangements involving different issuers or different plan sponsors. The statute specifically contemplated that different arrangements having different plan sponsors would be subject to separate fees imposed by section 4376. See section 4376(b)(2) (naming the different types of plan sponsors for different types of applicable self-insured health plans). Commentators, however, point to the proposed rule, adopted in these final regulations, permitting a plan sponsor to treat two different applicable self-insured health plans with the same plan year and plan sponsor as one plan as the basis for adopting the suggested change. There is no significant difference between that arrangement and a single plan, or "umbrella" plan containing both self-insured arrangements. In contrast, if the two arrangements are sponsored by two different plan sponsors, there is no single plan equivalent. Accordingly, this suggestion is not adopted in the final regulations.

VI. Health reimbursement arrangements (HRAs) and flexible spending arrangements (FSAs)

Section 46.4376-1(b)(1)(ii) of the proposed regulations defined an applicable self-insured health plan to include HRAs (as described in Notice 2002-45, 2002-2 C.B. 93) and health flexible spending arrangements (as described in section 106(c)(2)) (FSAs) that do not satisfy the requirements to be treated as an excepted benefit (within the meaning of section 9832(c) and §54.9831-1(c)(3)(v)). The proposed regulations also provided additional rules that permitted the plan sponsor

sor to assume one covered life for each employee with an HRA and for each employee with an FSA that is not an excepted benefit. The final regulations retain these rules. See §601.601(d)(2).

Commentators requested that the definition of applicable self-insured health plan be revised to exclude all HRAs, or alternatively that the final regulations exclude from the definition HRAs that are “integrated” with coverage under a self-insured or fully-insured arrangement. One commentator requested that the final regulations exempt from the definition of applicable self-insured health plan premium-only HRAs for Medicare-eligible retirees. As discussed in the preamble to the proposed regulations, an HRA is not subject to a separate fee under section 4376 if the plan sponsor also maintains a separate applicable self-insured health plan with a calendar year (referred to as the other plan). In such circumstances, the plan sponsor is permitted to treat the HRA and other plan as a single applicable self-insured health plan for purposes of section 4376 and therefore determine and pay the PCORI fee once with respect to each life covered under the HRA and other plan. Because the statutory structure provides that the fee imposed by section 4375 is separate from the fee imposed by section 4376, these regulations do not permit a plan sponsor to treat the HRA and a fully-insured plan as a single plan or arrangement for purposes of the PCORI fee, and these final regulations include additional examples to clarify the application of the PCORI fee to an HRA, including an HRA and other plan.

For the same reasons, the final regulations do not adopt the request to provide that the PCORI fee does not apply to an employee’s FSA that does not meet the requirements for being an excepted benefit if the employee is covered by a major medical plan.

VII. *Determination of whether an individual is residing in the United States*

The term *specified health insurance policy* includes only an accident and health insurance policy that is issued with respect to an individual residing in the United States. The final regulations adopt the rule in the proposed regulations that provides that if the address on file with the issuer

or plan sponsor for the primary insured is outside of the United States, the issuer or plan sponsor may treat the primary insured and the primary insured’s spouse, dependents, or other beneficiaries covered under the policy as having the same place of abode and not residing in the United States. For this purpose, the term *primary insured* refers to the individual covered by the policy whose eligibility for coverage was not due to his or her status as a spouse, dependent, or other beneficiary of another insured individual. Also as provided in the proposed regulations, these final regulations clarify that for purposes of the PCORI fee, “an individual residing in the United States” means an individual who has a place of abode in the United States.

Two commentators suggested that an issuer or plan sponsor should be permitted to find that a primary insured who is on a temporary U.S. visa does not have a place of abode in the United States. The commentators argued that because many (if not most) health insurance issuers offering expatriate plans request, for compliance purposes, an overview of citizenship and visa status from an employee covered under an employer-sponsored international plan, visa information and citizenship information should be available to them and can be relied upon in determining whether the employee’s place of abode is the United States or elsewhere.

The final regulations do not adopt this requested change. To exclude covered individuals who are residing in the United States would be contrary to Congressional intent that the PCORI fee applies to policies and plans that cover individuals residing in the United States. An individual on a temporary U.S. visa who has a place of abode in the United States is residing in the United States. For purposes of sections 4375, 4376, and 4377, the determination of place of abode is based on the most recent address on file with the issuer or plan sponsor.

VIII. *Self-insured expatriate plans*

As in the proposed regulations, these final regulations provide that the term *specified health insurance policy* does not include any group policy issued to an employer if the facts and circumstances show that the group policy was designed and issued specifically to cover primarily em-

ployees who are working and residing outside of the United States. One commentator requested clarification that similar self-insured plans are also excepted for purposes of the fee under section 4376. The final regulations clarify that the term *applicable self-insured health plan* does not include a self-insured plan if the facts and circumstances show that the self-insured plan was designed specifically to cover primarily employees who are working and residing outside of the United States.

IX. *Additional rules for determining the applicable fee*

Under the proposed regulations, issuers and plan sponsors were permitted to use alternative methods for determining the average number of lives for the year. Issuers could choose any of four alternative methods to determine the average number of lives covered under policies that it issues for purposes of the fee imposed by section 4375: (1) the actual count method, (2) the snapshot method, (3) the member months method, or (4) the state form method. While the actual count and snapshot methods count lives covered on the policy-by-policy basis for each policy having a policy year that ends in the reporting period (which is based on the calendar year), the member months or state form methods count all lives covered during the calendar year for all policies in effect during the calendar year irrespective of when actual policy years end. Plan sponsors could use one of three alternative methods to determine the average number of lives covered under a plan for purposes of the fee imposed by section 4376: (1) the actual count method, (2) the snapshot method, or (3) the Form 5500 method.

One of the permitted methods — the “snapshot method” — would have required issuers and plan sponsors to determine the average lives by adding the number of lives covered on one date (or an equal number of dates) in each quarter during the plan year or policy year and dividing that sum by the number of dates on which the count was made. Commentators suggested that issuers and plan sponsors using the snapshot method should not be required to use the same date for each quarter, but should be permitted to use different dates to determine the number of lives covered during a quarter to address

holidays, weekend days, or other similar issues. The Treasury Department and the IRS recognize the need for flexibility but also the need to avoid permitting issuers and plan sponsors to pick the most advantageous dates (that is, the dates on which the number of lives covered is the lowest so that under the facts and circumstances the snapshot method does not fairly approximate the average number of lives covered for the applicable year). In response to these comments, the final regulations require an issuer or a plan sponsor that uses the snapshot method to determine the counts used based on a date during the first, second, or third month of each quarter (or more dates in each quarter if an equal number of dates is used for each quarter). Each date used for the second, third, and fourth quarters must be within three days of the date in that quarter that corresponds to the date used for the first quarter, and all dates used must fall within the same policy year or plan year. If an issuer or plan sponsor uses multiple dates for the first quarter, the issuer or plan sponsor must use dates in the second, third, and fourth quarters that correspond to each of the dates used for the first quarter or are within three days of such corresponding dates, and all dates used must fall within the same policy year or plan year. The 30th and 31st day of a month are treated as the last day of the month for purposes of determining the corresponding date for any month that has fewer than 31 days (for example, if either March 30 or 31 are used as snapshot dates for a calendar year plan, June 30 is the corresponding date for the second quarter). Thus, for example, under the final regulations, if a plan sponsor uses the snapshot method to determine the average number of lives covered under an applicable self-insured health plan with a calendar year plan year and uses Monday, January 7, 2013, as the counting date for the first quarter, the plan sponsor may use any date beginning with Thursday, April 4, 2013, and ending with Wednesday, April 10, 2013, as the counting date for the second quarter (because all of those days are within three days of April 7, 2013, the date that corresponds to the January 7, 2013 counting date for the first quarter).

One commentator stated that the actual count and snapshot methods may pose significant operational challenges for many issuers. Because these methods require a

determination of the number of lives covered by reference to the policy year for each health insurance policy that is subject to the fee, the commentator anticipates that issuers with a significant number of insurance policies that have policy years that begin at different dates during a calendar year will have difficulty implementing this approach. The commentator suggested that, regardless of the actual policy year, issuers who choose to use the actual count method should be permitted to measure lives covered on all days of a calendar year and then divide the result by 365. The commentator also suggested that, regardless of the actual policy year, issuers who choose to use the snapshot method should be permitted to measure lives covered using calendar year quarters and then average the results.

The final regulations do not adopt this requested change. The fee imposed by section 4375 applies to policies based on their policy year. For administrative ease and to facilitate the use of available information that is compiled by issuers, these regulations provide the member months method and the state form method as alternatives for all policies in effect during a calendar year. Under each of these alternatives, the data permitted to be used is already reported by the issuer based on the calendar year. Issuers may use calendar year information in lieu of policy year information only if they use the member months method or the state form method.

The member months data and the data reported on state forms are based on the calendar year. To adjust for the fee being applicable to policy years ending after September 30, 2012, but before January 1, 2013, and after December 31, 2018, but before October 1, 2019, these final regulations adopt the *pro rata* approach set out in the proposed regulations for calculating the average number of lives covered using the member months method or the state form method for 2012 and 2019. For example, the member months number for 2012 is divided by 12 and the resulting number is multiplied by one-quarter to arrive at the average number of lives covered for October through December 2012. The proposed regulations further treated the amount calculated under this *pro rata* approach as the average number of lives covered for policies with policy years that end on or after October 1,

2012, and before January 1, 2013. Similar rules are provided for 2019.

Commentators suggested that the special *pro rata* approach for calculating the average number of lives covered using the member months method or the state form method for 2012 and 2019 should be applied to all years the fee is in effect, to appropriately reflect the change in the fee during each of such intervening years. One commentator argued that this revision is needed to prevent issuers that use these methods from being unfairly penalized by paying the rate determined as of December 31 of each year, resulting in an unanticipated higher liability for an issuer using those methods.

The final regulations do not adopt this requested change. The special *pro rata* approach for calculating the average number of lives covered was the least administratively burdensome way for the first and last policy years to which the fee applies to incorporate data from the NAIC annual report and similar state reporting requirements with the applicability dates for the PCORI fee related to policy years ending in 2012 and 2019. Other years are not affected by the applicability date issues. In addition, issuers are not required to use the member months or state form method and can use another permissible method.

X. Plan years subject to the PCORI fee

The fee imposed by section 4376 applies to plan years ending on or after October 1, 2012, and before October 1, 2019. Under the proposed regulations, an applicable self-insured health plan was required to determine the fee using the applicable dollar amount that applies for the plan year and the average number of lives covered during the plan year. Unlike the section 4375 fee, which is based on policy years, the application and amount of the section 4376 fee is based on the applicable dollar amount under section 4376 that is in effect on the last day of the plan year. One commentator requested additional examples illustrating the plan years covered by the fee, including the first plan year to which the PCORI fee applies. In response, §46.4376-1(a) of the final regulations includes examples illustrating the plan years (calendar and fiscal years) subject to the PCORI fee and the applicable dollar amount that must be used to deter-

mine the section 4376 fee for that plan year.

XI. Reporting and payment deadline

Consistent with the proposed regulations, these final regulations require an issuer of a specified health insurance policy and plan sponsor of an applicable self-insured health plan to report and pay the PCORI fee for a policy year or plan year no later than July 31 of the year following the last day of the policy or plan year.

One commentator asked that the final regulations provide that the reporting and payment due date for a plan sponsor that uses the Form 5500 method to determine the PCORI fee be the due date (including extensions) for the plan's Form 5500. The extended due date for a Form 5500 for a plan with a calendar year plan year is generally October 15 of the following year. As discussed earlier in this preamble, the Institute is funded in part from the PCORI fee. Under current rules, the PCORI fee ceases to apply after the end of the last policy and plan year ending before October 1, 2019, (with a due date of July 31, 2020) and funding for the Institute terminates on September 30, 2019. This lag between the last year of the PCORI fee (policy and plan years ending before October 1, 2019) and the proposed due date for the fee for the last year (July 31, 2020) means that the PCORI fee collected for the last year will not be available to the Institute. A delay for policy or plan years ending in years before 2019, as requested, would permit the PCORI fee for the policy or plan year ending during 2018 to be paid after September 30, 2019, and result in the Institute losing an additional year of funding. Accordingly, the Treasury Department and IRS have determined that delaying the proposed due date would result in additional complications and burdens for the Institute. Thus, these final regulations retain the proposed rule set forth in §40.6071(a)-1(c) that all plan sponsors and issuers report and pay the PCORI fee no later than July 31 of the calendar year following the last day of the policy or plan year.

XII. Correction and amendments of Form 720

One commentator requested that the final regulations provide that plan sponsors

may correct, without penalty, inadvertent errors if correction is within a specified period or if the error is *de minimis*. These final regulations do not adopt this change and, therefore, do not explicitly address corrections. As discussed in the preamble to the proposed regulations, the PCORI fee must be reported and paid on the Form 720, "Quarterly Federal Excise Tax Return."

The applicable penalties related to late filing of the applicable form or late payment of the applicable fee, however, may be waived or abated if the issuer or plan sponsor has reasonable cause and the failure was not due to willful neglect. See §301.6651-1(c) relating to rules for showing of reasonable cause. Issuers and plan sponsors may use Form 720X, "Amended Quarterly Federal Excise Tax Return," to make adjustments to liabilities reported on a previously filed Form 720, including adjustments that result in an overpayment.

XIII. Special rules for first year fee is in effect

The Treasury Department and the IRS recognized when issuing the proposed regulations that in certain instances the policy or plan year to which the PCORI fee would apply had already commenced, and therefore that transition relief was appropriate for purposes of counting lives covered under the policy or plan during the period before the issuance of the proposed regulations. Two commentators requested additional transition relief, including extending the good faith compliance period provided under the proposed regulations. These final regulations do not adopt this request because the Treasury Department and IRS have determined that the relief provided in the proposed regulations is sufficient.

Accordingly, consistent with the proposed regulations, these final regulations provide that an issuer using the actual count method for determining the average number of lives covered under a policy with a policy year that ends on or after October 1, 2012, could begin counting lives covered under a policy as of May 14, 2012 (30 days after the date that the proposed regulations were published in the **Federal Register**), rather than the first day of the policy year, and divide by the appropriate number of days remaining in the policy year. Similarly, for policy years that end on or after October 1, 2012, but that began

before May 14, 2012, these regulations provide that issuers using the snapshot method could use counts from quarters beginning on or after May 14, 2012, to determine the average number of lives covered under the policy. These final regulations also permit a plan sponsor to use any reasonable method to determine the average number of lives covered under an applicable self-insured health plan for a plan year beginning before July 11, 2012 (90 days after the date that the proposed regulations were published in the Federal Register), and ending on or after October 1, 2012.

XIV. Third-party or affiliated insurer reporting and payment

The proposed regulations did not permit third-party reporting or payment of the PCORI fee. One commentator requested that the final regulations permit third-party reporting and payment. Another commentator requested that the final regulations permit affiliated insurers to designate an insurer that will be responsible for payment of the section 4375 fee as long as the responsible insurer consents to such designation. Because the PCORI fee ceases to apply to policy years and plan years that end on or after October 1, 2019, the Treasury Department and IRS have determined that the burden and complexity that would have to be addressed by issuers, plan sponsors and the IRS to develop and operate a third-party reporting and payment regime significantly outweigh the benefits of such a regime. Therefore, the final regulations do not permit or include rules for third-party reporting or payment of the PCORI fee.

Applicability Date

These regulations apply to policy and plan years ending on or after October 1, 2012, and before October 1, 2019.

Special Analyses

It has been determined that these final regulations are not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It is hereby certified that these final regulations will not have a significant economic impact

on a substantial number of small entities. This certification is based on the fact that small businesses generally do not have self-insured health plans and that these regulations will therefore primarily affect large corporations. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. The Treasury Department and the IRS specifically solicit comments from any party, particularly affected small entities, on the accuracy of this certification. Pursuant to section 7805(f) of the Code, the proposed regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comments on its impact on small business and no comments were received.

Drafting Information

The principal authors of these regulations are R. Lisa Mojiri-Azad, Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), and Rebecca L. Baxter, Office of Associate Chief Counsel (Financial Institutions & Products). However, other personnel from the Treasury Department and the IRS participated in their development.

* * * * *

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 40, 46, and 602 are amended as follows:

PART 40—EXCISE TAX PROCEDURAL REGULATIONS

Paragraph 1. The authority citation for part 40 continues to read in part as follows:

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

Par. 2. Section 40.0–1 is amended by:

1. Removing from the third sentence in paragraph (a) the language “chapter 34 to taxes imposed on policies issued by foreign insurers” and adding “chapter 34 to taxes imposed on certain insurance policies” in its place.

2. Adding a new sentence after the third sentence in paragraph (a).

The addition reads as follows:

§40.0–1 Introduction.

(a) * * * References in this part to “taxes” also include references to the fees imposed by sections 4375 and 4376. * * *

Par. 3. Section 40.6011(a)–1 is amended by:

1. In paragraph (a)(2)(i), first sentence, the language “paragraph (b) of this section” is removed and the language “paragraphs (b) and (c) of this section” is added in its place.

2. Paragraph (c) is added.

The addition reads as follows:

§40.6011(a)–1 Returns.

* * * * *

(c) *Fees on health insurance policies and self-insured health plans—(1) In general.* A return that reports liability imposed by section 4375 or 4376 is a return for policies or plans with policy or plan years ending in the previous calendar year, and, for issuers that determine the average number of lives covered under a policy for purposes of section 4375 using the member months method under §46.4375–1(c)(2)(v) or the state form method under §46.4375–1(c)(2)(vi) of this chapter, the return is for all policies in effect during the previous calendar year. The second sentence of paragraph (a)(2)(i) of this section (relating to filing quarterly returns regardless of whether liability is incurred) does not apply to a person that files a Form 720, “*Quarterly Federal Excise Tax Return*,” only to report liability imposed by section 4375 or 4376.

(2) *Applicability date.* This paragraph (c) applies to returns that report liability imposed by section 4375 or 4376.

Par. 4. Section 40.6071(a)–1 is amended as follows:

1. Paragraph (c) is revised.

2. Paragraph (d) is added.

The revision and addition read as follows:

§40.6071(a)–1 Time for filing returns.

* * * * *

(c) *Fees on health insurance policies and self-insured health plans—(1) Specified health insurance policies.* A return that reports liability for the fee imposed by section 4375 must be filed by July 31 of the calendar year immediately following

the last day of the policy year. For issuers that determine the average number of lives covered under the policy for section 4375 using the member months method under §46.4375–1(c)(2)(v) or the state form method under §46.4375–1(c)(2)(vi), the return must be filed by July 31 of the immediately following calendar year. Thus, for example, a return that reports liability for the fee imposed by section 4375 for the year ending on December 31, 2012, must be filed by July 31, 2013.

(2) *Applicable self-insured health plans.* A return that reports liability for the fee imposed by section 4376 for a plan year must be filed by July 31 of the calendar year immediately following the last day of the plan year. Thus, for example, a return that reports liability for the fee imposed by section 4376 for the plan year ending on January 31, 2013, must be filed by July 31, 2014.

(d) *Effective/Applicability date.* Paragraphs (a) and (b) of this section apply to returns for calendar quarters beginning on or after October 1, 2001, and paragraph (c) of this section applies to returns that report liability imposed by section 4375 or 4376.

§40.6091–1 Amended

Par. 5. Section 40.6091–1, paragraph (a), is amended by removing the language “paragraph (b) of this section, quarterly returns” and by adding the language “paragraphs (b) and (c) of this section, returns” in its place.

Par. 6. Section 40.6302(c)–1 is amended by revising paragraph (e)(1)(iv) to read as follows:

§40.6302(c)–1 Deposits.

* * * * *

(e) * * *

(1) * * *

(iv) Sections 4375 and 4376 (relating to fees on health insurance policies and self-insured health plans).

* * * * *

PART 46—EXCISE TAX ON CERTAIN INSURANCE POLICIES, SELF-INSURED HEALTH PLANS, AND OBLIGATIONS NOT IN REGISTERED FORM

Par. 7. The authority citation for part 46 continues to read in part as follows:

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

Par. 8. In part 46, the heading is revised to read as set forth above.

§46.0–1 Amended

Par. 9. In §46.0–1, first sentence, the language “policies issued by foreign insurers” is removed and the language “certain insurance policies and self-insured health plans” is added in its place.

§46.0–2 [Removed]

Par. 10. Section 46.0–2 is removed.

Par. 11. In Part 46, subpart C is redesignated as subpart D and a new subpart C is added to read as follows:

Subpart C—Fees on Insured and Self-insured Health Plans

Sec.

46.4375–1 Fee on issuers of specified health insurance policies.

46.4376–1 Fee on sponsors of self-insured health plans.

46.4377–1 Definitions and special rules.

Subpart C—Fees on Insured and Self-insured Health Plans

§46.4375–1 Fee on issuers of specified health insurance policies.

(a) *In general.* An issuer of a specified health insurance policy is liable for a fee imposed by section 4375 for policy years ending on or after October 1, 2012, and before October 1, 2019. Paragraph (b) of this section provides definitions that apply for purposes of section 4375 and this section. Paragraph (c) of this section provides rules for calculating the fee under section 4375. Paragraph (d) of this section provides the applicability date. For rules relating to filing the required return and paying the fee, see §§40.6011(a)–1 and 40.6071(a)–1 of this chapter.

(b) *Definitions.* The following definitions apply for purposes of section 4375 and this section. See also §46.4377–1 for additional definitions.

(1) *Specified health insurance policy*—(i) *In general.* Except as provided in paragraph (b)(1)(ii) of this section and §46.4377–1, *specified health insurance policy* means any accident and health insurance policy (including a policy under a

group health plan) issued with respect to individuals residing in the United States (as defined in §46.4377–1(a)(2)), including prepaid health coverage arrangements described in paragraph (b)(2) of this section. *Specified health insurance policy* also includes any policy that provides accident and health coverage to an active employee, former employee, or qualifying beneficiary, as continuation coverage required under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) or similar continuation coverage under other Federal law or state law.

(ii) *Exceptions.* The term *specified health insurance policy* does not include—

(A) Any insurance policy if substantially all of its coverage is of excepted benefits described in section 9832(c);

(B) Any group policy issued to an employer where the facts and circumstances show that the group policy was designed and issued specifically to cover primarily employees who are working and residing outside of the United States (as defined in §46.4377–1(a)(3));

(C) Any stop loss or indemnity reinsurance policy; or

(D) Any insurance policy to the extent it provides an employee assistance program, disease management program, or wellness program if the program does not provide significant benefits in the nature of medical care or treatment.

(iii) *Stop loss policy.* For purposes of paragraph (b)(1)(ii) of this section, *stop loss policy* means an insurance policy in which—

(A) The insurer that issues the policy to a person establishing or maintaining a self-insured health plan becomes liable for all, or an agreed upon portion of, losses that person incurs in covering the applicable lives in excess of a specified amount; and

(B) The person establishing or maintaining the self-insured health plan retains its liability to, and its contractual relationship with, the applicable lives covered.

(iv) *Indemnity reinsurance policy.* For purposes of paragraph (b)(1)(ii) of this section, *indemnity reinsurance policy* means an agreement between two or more insurance companies under which—

(A) The reinsuring company agrees to accept and to indemnify the issuing company for all or part of the risk of loss under policies specified in the agreement; and

(B) The issuing company retains its liability to, and its contractual relationship with, the applicable lives covered.

(2) *Prepaid health coverage arrangement.* The term *prepaid health coverage arrangement* means an arrangement under which fixed payments or premiums are received as consideration for a person’s agreement to provide or arrange for the provision of accident and health coverage to individuals residing in the United States, regardless of how such coverage is provided or arranged to be provided. For example, any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract is a specified health insurance policy.

(c) *Calculation of fee*—(1) *In general.* The amount of the fee for a policy for a policy year is equal to the product of the average number of lives covered under the policy for the policy year (determined in accordance with paragraphs (c)(2) and (c)(3) of this section) and the applicable dollar amount (determined in accordance with paragraph (c)(4) of this section). For purposes of computing the fee under this paragraph (c), in the case of an issuer that determines the average number of lives covered for all policies in effect during a calendar year using the member months method under paragraph (c)(2)(v) of this section or the state form method under paragraph (c)(2)(vi) of this section, the applicable dollar amount with respect to such issuer’s policies for such calendar year is the applicable dollar amount for policy years ending on December 31 of such calendar year (determined in accordance with paragraph (c)(4) of this section), except that the applicable dollar amount with respect to such an issuer’s policies for calendar year 2019 is the applicable dollar amount for policy years ending on September 30, 2019. For more information, see the examples in paragraphs (c)(2)(iii)(B), (c)(2)(iv)(B), (c)(2)(v)(B), and (c)(2)(vi)(B) of this section.

(2) *Determination of the average number of lives covered under a policy*—(i) *In general.* To determine the average number of lives covered under a specified health insurance policy during a policy year, an issuer must use one of the following methods—

(A) The actual count method (described in paragraph (c)(2)(iii) of this section);

(B) The snapshot method (described in paragraph (c)(2)(iv) of this section);

(C) The member months method (described in paragraph (c)(2)(v) of this section); or

(D) The state form method (described in paragraph (c)(2)(vi) of this section).

(ii) *Consistency requirements.* An issuer must use the same method of calculating the average number of lives covered under a policy consistently for the duration of the year. In addition, for all policies for which a liability is reported on a Form 720, “*Quarterly Federal Excise Tax Return*,” for a particular year, the issuer must use the same method of computing lives covered. An issuer that determines the average number of lives covered by using the actual count method described in paragraph (c)(2)(iii) of this section or the snapshot method described in paragraph (c)(2)(iv) of this section may change its method of computing the average lives covered to the snapshot method or actual count method, respectively, provided that the issuer uses the same method for computing the average lives covered for all policies for which a liability is reported on the Form 720 for that year. For example, an issuer with a policy having a policy year that ends on June 30, Policy A, may determine the average number of lives covered under Policy A for July 1, 2013, to June 30, 2014, using the actual count method if the issuer uses the actual count method for all policies for which a liability will be reported on the Form 720 due by July 31, 2015 (the due date for return that will include the liability for the July 2013 to June 2014 policy year for Policy A). The issuer may change its method for determining the average number of lives covered under Policy A to the snapshot method for the July 1, 2014, to June 30, 2015, policy year, provided that the snapshot method is used for all policies for which a liability will be reported on the Form 720 due by July 31, 2016 (the due date for return that will include the liability for the July 2014 to June 2015 policy year for Policy A). An issuer that determines the average number of lives covered by using the member months method under paragraph (c)(2)(v) of this section or the state form method under paragraph (c)(2)(vi) of this section must use the same method for calculating lives

covered for all policy years for which the fee applies.

(iii) *Actual count method—(A) Calculation method.* An issuer may determine the average number of lives covered under a policy for a policy year by adding the total number of lives covered for each day of the policy year and dividing that total by the number of days in the policy year.

(B) *Example.* The following example illustrates the principles of paragraphs (c)(1) and (c)(2)(iii)(A) of this section:

Example. Insurance Company A issues three policies that are in effect during 2014, Group Health Insurance Policy A, which has a policy year from December 1 to November 30, Group Health Insurance Policy B, which has a policy year from March 1 to February 28, and Group Health Insurance Policy C, which has a policy year from January 1 to December 31. To calculate the average number of lives covered for 2014, Insurance Company A must calculate the average number of lives covered for each of its three policies for the policy year that ends in 2014. Insurance Company A chooses to use the actual count method under paragraph (c)(2)(iii)(A) of this section to determine average lives covered for policies having a policy year that ends in 2014. Insurance Company A calculates the sum of lives covered under Policy A for each day of the policy year ending November 30, 2014, as 3,285,000. The average number of lives covered under Policy A for the policy year ending November 30, 2014, is 3,285,000 divided by 365, or 9,000. Insurance Company A calculates the sum of lives covered under Policy B for each day of the policy year ending February 28, 2014, as 547,500. The average number of lives covered under Policy B for the policy year ending February 28, 2014, is 547,500 divided by 365, or 1,500. Insurance Company A calculates the sum of lives covered under Policy C for each day of the policy year ending December 31, 2014, as 4,380,000. The average number of lives covered under Policy C for the policy year ending December 31, 2014, is 4,380,000 divided by 365, or 12,000. To calculate the section 4375 fee under paragraph (c)(1) of this section for calendar year 2014, Insurance Company A must first determine the applicable dollar amount for each policy under paragraph (c)(4) of this section and multiply that amount by the average number of lives covered for that policy. Insurance Company A then adds the total fees for all three policies to determine the total fee under section 4375 that it must pay for calendar year 2014.

(iv) *Snapshot method—(A) Calculation method.* An issuer may determine the average number of lives covered under a policy for a policy year by adding the totals of lives covered on a date during the first, second, or third month of each quarter (or more dates in each quarter if an equal number of dates is used for each quarter), and dividing that total by the number of dates on which a count is made. For purposes of this paragraph (c)(2)(iv)(A), each date

used for the second, third and fourth quarters must be within three days of the date in that quarter that corresponds to the date used for the first quarter, and all dates used must be within the same policy year. If an issuer uses multiple dates for the first quarter, the issuer must use dates in the second, third, and fourth quarters that correspond to each of the dates used for the first quarter or are within three days of such corresponding dates, and all dates used must be within the same policy year. The 30th and 31st day of a month are treated as the last day of the month for purposes of determining the corresponding date for any month that has fewer than 31 days (for example, if either March 30 or March 31 is used as a counting date for a calendar year policy, June 30 is the corresponding date for the second quarter).

(B) *Example.* The following example illustrates the principles of paragraphs (c)(1) and (c)(2)(iv)(A) of this section:

Example. (i) Insurance Company B issues three policies with 12-month policy years that end in 2014, Group Health Insurance Policy A, which has a policy year from December 1 to November 30, Group Health Insurance Policy B, which has a policy year from March 1 to February 28, and Group Health Insurance Policy C, which has a policy year from January 1 to December 31. To calculate the average number of lives covered for 2014, Insurance Company B must calculate the average number of lives covered for each of its three policies for the policy year that ends in 2014. Insurance Company B chooses to determine the average lives covered using the snapshot method for all policies that have a policy year that ends in 2014 and chooses to count lives covered on a single date of the first month of each quarter of the policy years. Thus, for Policy A, Insurance Company B must count lives covered on a single date falling in each of December 2013, March 2014, June 2014 and September 2014; for Policy B, Insurance Company B must count lives covered on a single date falling in each of March 2014, June 2014, September 2014 and December 2014; and for Policy C, Insurance Company B must count lives covered on a single date falling in each of January 2014, April 2014, July 2014 and October 2014. In addition, the date for each of the second, third, and fourth quarters must fall within three days of the date in such quarter that corresponds to the date used for the first quarter, and must fall within the same policy year.

(ii) On December 6, 2013, Policy A covers 8,900 lives, on March 7, 2014, 9,100 lives, on June 6, 2014, 9,050 lives, and on September 5, 2014, 9,050 lives. Insurance Company B treats the average number of lives covered under Policy A for the policy year ending November 30, 2014, as 36,100 (8,900 + 9,100 + 9,050 + 9,050) divided by 4, or 9,025.

(iii) On March 4, 2013, Policy B covers 1,500 lives, on June 7, 2013, 1,350 lives, on September 6, 2013, 1,400 lives, and on December 6, 2013, 1,550 lives. Insurance Company B treats the average number of lives covered under Policy B for the policy year

ending February 28, 2014, as 5,800 (1,500 + 1,350 + 1,400 + 1,550) divided by 4, or 1,450.

(iv) On January 6, 2014, Policy C covers 12,500 lives, on April 4, 2014, 12,250 lives, on July 7, 2014, 12,000 lives, and on October 3, 2014, 11,250 lives. Insurance Company B treats the average number of lives covered under Policy C for the policy year ending December 31, 2014, as 47,750 (12,500 + 12,250 + 12,000 + 11,250) divided by 4, or 12,000.

(v) To calculate the section 4375 fee under paragraph (c)(1) of this section for calendar year 2014, Insurance Company B must first determine the applicable dollar amount for each policy under paragraph (c)(4) of this section and multiply that amount by the number of average lives covered for that policy. Insurance Company B then adds the total fees for all three policies to determine the total fee under section 4375 that it must pay for calendar year 2014.

(v) *Member months method*—(A) *Calculation method*. An issuer may determine the average number of lives covered under all policies in effect for a calendar year based on the member months (an amount that equals the sum of the totals of lives covered on pre-specified days in each month of the reporting period) reported on the National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit filed for that calendar year. Under this method, the average number of lives covered under the policies in effect for the calendar year equals the member months divided by 12.

(B) *Example*. The following example illustrates the principles of paragraphs (c)(1) and (c)(2)(v)(A) of this section:

Example. Insurance Company C chooses to determine the average number of lives covered for all years to which the section 4375 fee applies using the member months method of paragraph (c)(2)(v)(A) of this section. Insurance Company C reports 12,000,000 as its member months on the NAIC Supplemental Health Care Exhibit filed for calendar year 2013. Under the member months method, Insurance Company C calculates the average number of lives covered for all its specified health insurance policies in force during calendar year 2013 by dividing 12,000,000 (member months) by 12 (number of months in the reporting period), which equals 1,000,000. To determine the section 4375 fee it must pay for calendar year 2013, Insurance Company C multiplies 1,000,000 by the applicable dollar amount that is in effect at the end of the calendar year under paragraph (c)(4) of this section.

(vi) *State form method*—(A) *Calculation method*. An issuer that is not required to file NAIC annual financial statements may determine the number of lives covered under all policies in effect for the calendar year using a form that is filed with the issuer's state of domicile and a method similar to that described in paragraph (c)(2)(v) of this section, if the form

reports the number of lives covered in the same manner as member months are reported on the NAIC Supplemental Health Care Exhibit.

(B) *Example*. The following example illustrates the principles of paragraphs (c)(1) and (c)(2)(vi)(A) of this section:

Example. Insurance Company D is not required to file the NAIC Supplemental Health Care Exhibit, but files a form with its state of domicile. Insurance Company D chooses to determine the average number of lives covered for all years to which the section 4375 fee applies using the state form method of paragraph (c)(2)(vi)(A) of this section. The state form reports the number of lives covered in the same manner as member months is reported on the NAIC Supplemental Health Care Exhibit. For calendar year 2013, Insurance Company D reports 12,000,000 as its equivalent member months on the state form. Under the state form method, Insurance Company D calculates the average number of lives covered for all of its specified health insurance policies in force during calendar year 2013 by dividing 12,000,000 (equivalent member months) by 12 (number of months in the reporting period), which equals 1,000,000. To determine the section 4375 fee it must pay for calendar year 2013, Insurance Company D multiplies 1,000,000 by the applicable dollar amount that is in effect at the end of the calendar year under paragraph (c)(4) of this section.

(3) *Special rules for the first year and the last year the fee is in effect*—(i) *Calculation of the average number of lives covered under the policy for the first year the fee is in effect*. For issuers that determine the average number of lives covered using data reported on the 2012 NAIC Supplemental Health Care Exhibit or a permitted state form that covers the 2012 calendar year, the average number of lives covered under all policies in effect for the 2012 calendar year equals the average number of lives covered for that year (as determined under paragraph (c)(2)(v) or (vi) of this section) multiplied by 1/4. The resulting number is deemed to be the average number of lives covered for policies with policy years ending on or after October 1, 2012, and before January 1, 2013. For policy years beginning before May 14, 2012, and ending on or after October 1, 2012, issuers that determine the average number of lives covered using the actual count method under paragraph (c)(2)(iii) of this section may calculate the average number of lives covered using data from the period beginning May 14, 2012, through the end of the policy year. For policy years beginning before May 14, 2012, and ending on or after October 1, 2012, issuers that determine the average number of lives

covered using the snapshot method under paragraph (c)(2)(iv) of this section may calculate the average number of lives covered using dates from the quarters remaining in the policy year starting on or after May 14, 2012. If an abbreviated year is used, the issuer will divide the number of lives covered by the number of days from May 14, 2012, through the end of the policy year (for the actual count method) or the number of days on which a count was made (for the snapshot method).

(ii) *Calculation of the average number of lives covered under the policy for the last year the fee is in effect*. For issuers that determine the average number of lives covered using data reported on the 2019 NAIC Supplemental Health Care Exhibit or a permitted state form that covers the 2019 calendar year, the average number of lives covered for all policies in effect during the 2019 calendar year equals the average number of lives covered for that year (as determined under paragraph (c)(2)(v) or (vi) of this section) multiplied by 3/4. The resulting number is deemed to be the average number of lives covered for policies with policy years ending on or after January 1, 2019, and before October 1, 2019.

(iii) *Examples*. The following examples illustrate the principles of paragraph (c)(3) of this section:

Example 1. Insurance Company E issues Group Health Insurance Policy C, which has a policy year that ends on November 30, 2012. Insurance Company E determines the average number of lives covered under a policy by using the actual count method. Under that method, for that policy year, Insurance Company E calculates the sum of lives covered under Policy C for each day between May 14, 2012, and November 30, 2012, as 10,000. The average number of lives covered under Policy C for that policy year is 10,000 divided by the number of days from May 14, 2012, through November 30, 2012. Alternatively, Insurance Company E could have counted the number of lives covered for the entire policy year and divided the sum by 365.

Example 2. Insurance Company F reports 12,000,000 as its member months on its NAIC Supplemental Health Care Exhibit filed for calendar year 2012. Under the member months method, Insurance Company F calculates the average number of lives covered for 2012 by dividing 12,000,000 (member months) by 12 (number of months in the reporting period), and then multiplying the result (1,000,000) by 1/4, which equals 250,000. Accordingly, the average number of lives covered for policies with policy years ending on or after October 1, 2012, and before January 1, 2013, is 250,000.

(4) *Applicable dollar amount*. For policy years ending on or after October 1,

2012, and before October 1, 2013, the applicable dollar amount is \$1. For policy years ending on or after October 1, 2013, and before October 1, 2014, the applicable dollar amount is \$2. For any policy year ending in any Federal fiscal year beginning on or after October 1, 2014, the applicable dollar amount is the sum of—

(i) The applicable dollar amount for the policy year ending in the previous Federal fiscal year; plus

(ii) The amount equal to the product of—

(A) The applicable dollar amount for the policy year ending in the previous Federal fiscal year; and

(B) The percentage increase in the projected *per capita* amount of the National Health Expenditures most recently released by the Department of Health and Human Services before the beginning of the Federal fiscal year.

(d) *Effective/Applicability date.* This section applies for policies with policy years ending on or after October 1, 2012, and before October 1, 2019.

§46.4376-1 Fee on sponsors of self-insured health plans.

(a) *In general—(1) General rule.* A plan sponsor of an applicable self-insured health plan is liable for a fee imposed by section 4376 for plans with plan years ending on or after October 1, 2012, and before October 1, 2019. Paragraph (b) of this section provides the definitions that apply for purposes of section 4376 and this section. Paragraph (c) of this section provides the requirements for calculating the fee imposed by section 4376. Paragraph (d) of this section provides the applicability date. For rules relating to filing the required return and paying the fee, see §§40.6011(a)-1 and 40.6071(a)-1.

(2) [Reserved]

(b) *Definitions.* The following definitions apply for purposes of section 4376 and this section. See §46.4377-1 for additional definitions.

(1) *Applicable self-insured health plan—(i) In general.* Except as provided in paragraph (b)(1)(ii) of this section and §46.4377-1, *applicable self-insured health plan* means a plan that provides for accident and health coverage (within the meaning of §46.4377-1(a)) if any portion of the coverage is provided other than

through an insurance policy and the plan is established or maintained—

(A) By one or more employers for the benefit of their employees or former employees;

(B) By one or more employee organizations for the benefit of their members or former members;

(C) Jointly by one or more employers and one or more employee organizations for the benefit of employees or former employees;

(D) By a voluntary employees' beneficiary association, as described in section 501(c)(9);

(E) By an organization described in section 501(c)(6); or

(F) By a multiple employer welfare arrangement (as defined in section 3(40) of the Employee Retirement Income Security Act of 1974 (ERISA)), a rural electric cooperative (as defined in section 3(40)(B)(iv) of ERISA), or a rural cooperative association (as defined in section 3(40)(B)(v) of ERISA).

(ii) *Exceptions.* The term *applicable self-insured health plan* does not include any of the following:

(A) A plan that provides benefits substantially all of which are excepted benefits, as defined in section 9832(c). For example, a health flexible spending arrangement (health FSA) (as described in section 106(c)(2)) that satisfies the requirements to be treated as an excepted benefit under section 9832(c) and §54.9831-1(c)(3)(v) of this chapter is not an applicable self-insured health plan. A health FSA that is not treated as an excepted benefit under section 9832(c) and §54.9831-1(c)(3)(v) is an applicable self-insured health plan.

(B) An employee assistance program, disease management program, or wellness program if the program does not provide significant benefits in the nature of medical care or treatment.

(C) A plan that, as demonstrated by the facts and circumstances surrounding the adoption and operation of the plan, was designed specifically to cover primarily employees who are working and residing outside the United States (as defined in §46.4377-1(a)(3)).

(iii) *Multiple self-insured arrangements established or maintained by the same plan sponsor.* For purposes of section 4376, two or more arrangements established or maintained by the same

plan sponsor that provide for accident and health coverage (within the meaning of §46.4377-1(a)) other than through an insurance policy and that have the same plan year may be treated as a single applicable self-insured health plan for purposes of calculating the fee imposed by section 4376. For example, if a plan sponsor establishes or maintains a self-insured arrangement providing major medical benefits, and a separate self-insured arrangement with the same plan year providing prescription drug benefits, the two arrangements may be treated as one applicable self-insured health plan so that the same life covered under each arrangement would count as only one covered life under the plan for purposes of calculating the fee. Similarly, if a plan sponsor provides a Health Reimbursement Arrangement (HRA) and another applicable self-insured health plan that provides major medical coverage, the HRA and the major medical plan may be treated as one applicable self-insured health plan if the HRA and the self-insured plan have the same plan year.

(iv) *Examples.* The following examples illustrate the principle of this paragraph (b)(1):

Example 1. (i) Plan Sponsor D sponsors and maintains three separate plans to provide certain benefits to its employees — Plan 501, Plan 502, and Plan 503.

(ii) Plan 501 is a calendar year plan that provides accident and health benefits, other than through insurance (that is, on a self-insured basis), to employees of Plan Sponsor D. Plan 502 is a calendar year HRA that can be used to pay for qualified accident and medical expenses for employees of Plan Sponsor D and their eligible dependents. Plan 503 provides dental and vision benefits for employees of Plan Sponsor D and eligible dependents, other than through insurance (that is, on a self-insured basis).

(iii) Because Plan 501 and Plan 502 provide accident and health coverage (within the meaning of §46.4377-1(a)) and are maintained by Plan Sponsor D for the benefit of its employees, Plans 501 and 502 are applicable self-insured health plans that are subject to the fee imposed by section 4376. Because dental and vision benefits are excepted benefits, as defined in section 9832(c), Plan 503 is not an applicable self-insured health plan subject to the section 4376 fee. Under the special rule set forth in §46.4376-2(b)(1)(iii), Plan Sponsor D may treat Plans 501 and 502 (both self-insured plans with a calendar year plan year) as a single plan for purposes of calculating the fee imposed by section 4376.

Example 2. Same facts as *Example 1*, except Plan 503 is not a Plan that provides dental and vision benefits, but rather a plan that provides accident and health coverage solely to employees who are working and residing outside the United States and does not pro-

vide any benefits to employees who are not working and residing outside the United States. Plan 503 is designed specifically to provide coverage to employees working and residing outside the United States because it limits coverage to these employees. Therefore, in accordance with the exception described in §46.4376-1(b)(1)(ii)(C), Plan 503 is not an applicable self-insured health plan.

(2) *Plan sponsor*—(i) *In general*. The term *plan sponsor* means—

(A) The employer, in the case of an applicable self-insured health plan established or maintained by a single employer;

(B) The employee organization, in the case of an applicable self-insured health plan established or maintained by an employee organization;

(C) The joint board of trustees, in the case of a multiemployer plan (as defined in section 414(f));

(D) The committee, in the case of a multiple employer welfare arrangement (as defined in section 3(40) of ERISA);

(E) The cooperative or association that establishes or maintains an applicable self-insured health plan established or maintained by a rural electric cooperative (as defined in section 3(40)(B)(iv) of ERISA) or rural cooperative association (as defined in section 3(40)(B)(v) of ERISA);

(F) The trustee, in the case of an applicable self-insured health plan established or maintained by a voluntary employees' beneficiary association (meaning that the voluntary employees' beneficiary association is not merely serving as a funding vehicle for a plan that is established or maintained by an employer or other person); or

(G) In the case of an applicable self-insured health plan the plan sponsor of which is not described in paragraphs (b)(2)(i)(A) through (F) of this section, the person identified by the terms of the document under which the plan is operated as the plan sponsor, or the person designated by the terms of the document under which the plan is operated as the plan sponsor for section 4376 purposes, provided that designation is made in writing, and that person has consented to the designation in writing, by no later than the date by which the return paying the fee under section 4376 for that plan year is required to be filed, after which date that designation for that plan year may not be changed or revoked, and provided further that a person may be designated as the plan sponsor only if the person is one of the persons establishing or maintaining the plan (for example, one of the employers

that establishes or maintains the plan with one or more other employers or employee organizations).

(H) In the case of an applicable self-insured health plan the sponsor of which is not described in paragraphs (b)(2)(i)(A) through (F) of this section, and for which no identification or designation of a plan sponsor has been made pursuant to paragraph (b)(2)(i)(G) of this section, each employer that establishes or maintains the plan (with respect to employees of that employer), each employee organization that establishes or maintains the plan (with respect to members of that employee organization), and each board of trustees, cooperative, or association that establishes or maintains the plan, meaning that each plan sponsor must file a separate Form 720, "Quarterly Federal Excise Tax Return," reflecting its separate liability under section 4376.

(ii) *Examples*. The following examples illustrate the principles of paragraph (b)(2) of this section:

Example 1. (i) Corporation XYZ is a holding company with no employees that owns all the issued and outstanding shares of Employer X, Employer Y, and Employer Z. Employer X, Employer Y, and Employer Z have established the XYZ Group Health Plan to provide accident and health coverage, provided other than through an insurance policy, for the benefit of their employees. The XYZ Group Health Plan has a calendar year plan year. In addition, there is no plan sponsor identified or designated in the plan document.

(ii) Because the XYZ Group Health Plan provides accident and health coverage other than through an insurance policy, and is established by one or more employers for the benefit of their employees, the XYZ Group Health Plan is an applicable self-insured health plan under section 4376(c)(2)(A) and paragraph (b)(1)(i)(A) of this section. Because a plan sponsor is not identified or designated in the governing plan document, the plan sponsor, for purposes of section 4376, is determined under paragraph (b)(2)(i)(H) of this section as each employer that establishes or maintains the plan (Employer X, Employer Y, and Employer Z), each with respect to its employees covered under the plan. Accordingly, Employer X, Employer Y, and Employer Z each must file a Form 720 reflecting their separate liabilities under section 4376, calculated based on lives covered that are employees of that employer (or spouses, dependents, or other beneficiaries of employees of that employer) and the applicable dollar amount in effect for the plan year.

Example 2. The same facts as *Example 1*, except that the governing plan document designates Employer X as the plan sponsor of the XYZ Group Health Plan for purposes of the fee under section 4376 and Employer X consents to this designation no later than the due date for paying the fee under section 4376. Accordingly, the plan sponsor for pur-

poses of section 4376 is determined under paragraph (b)(2)(i)(G) of this section as Employer X. Employer X must file a Form 720 reflecting liabilities under section 4376, calculated based upon lives covered that are employees of Employer X, Employer Y, or Employer Z, or spouses, dependents, or other beneficiaries of employees of those employers and the applicable dollar amount in effect for the plan year.

(c) *Calculation of fee*—(1) *In general*. The amount of the fee for a plan year is equal to the product of the average number of lives covered under the plan for the plan year (determined in accordance with paragraph (c)(2) of this section) and the applicable dollar amount (determined in accordance with paragraph (c)(3) of this section).

(2) *Determination of the average number of lives covered under the plan*—(i) *In general*. To determine the average number of lives covered under an applicable self-insured health plan during a plan year, a plan sponsor must use one of the following methods—

(A) The actual count method (described in paragraph (c)(2)(iii) of this section);

(B) The snapshot method (described in paragraph (c)(2)(iv) of this section); or

(C) The Form 5500 method (described in paragraph (c)(2)(v) of this section).

(ii) *Consistency within plan year*. A plan sponsor must use the same method of calculating the average number of lives covered under the plan consistently for the duration of the plan year. However, a plan sponsor may use a different method from one plan year to the next.

(iii) *Actual count method*—(A) *In general*. A plan sponsor may determine the average number of lives covered under a plan for a plan year by adding the totals of lives covered for each day of the plan year and dividing that total by the number of days in the plan year.

(B) *Example*. The following example illustrates the principles of paragraphs (c)(1) and (c)(2)(iii)(A) of this section:

Example. Employer A is the plan sponsor of the Employer A Self-Insured Health Plan, which has a calendar year plan year. Employer A calculates the sum of lives covered under the plan for each day of the plan year ending December 31, 2013 as 3,285,000. The average number of lives covered under the plan for the plan year ending December 31, 2013, is 3,285,000 divided by 365, or 9,000. To calculate the section 4376 fee for the plan under paragraph (c)(1) of this section for the plan year ending December 31, 2013, Employer A must determine the applicable dollar amount under paragraph (c)(3) of this section and multiply that amount by 9,000.

(iv) *Snapshot method*—(A) *In general.* A plan sponsor may determine the average number of lives covered under an applicable self-insured health plan for a plan year by adding the totals of lives covered on a date during the first, second, or third month of each quarter of the plan year (or more dates in each quarter if an equal number of dates is used in each quarter), and dividing that total by the number of dates on which a count was made. For purposes of this paragraph (c)(2)(iv), each date used for the second, third and fourth quarter must be within three days of the date in that quarter that corresponds to the date used for the first quarter, and all dates used must fall within the same plan year. If a plan sponsor uses multiple dates for the first quarter, the plan sponsor must use dates in the second, third, and fourth quarters that correspond to each of the dates used for the first quarter or are within three days of such corresponding dates, and all dates used must fall within the same plan year. The 30th and 31st day of a month are treated as the last day of the month for purposes of determining the corresponding date for any month that has fewer than 31 days (for example, if either March 30 or March 31 is used for a calendar year plan, June 30 is the corresponding date for the second quarter). For purposes of this paragraph (c)(2)(iv), the number of lives covered on a designated date may be determined using either the snapshot factor method described in paragraph (c)(2)(iv)(B) of this section or the snapshot count method described in paragraph (c)(2)(iv)(C) of this section.

(B) *Snapshot factor method.* Under the snapshot factor method, the number of lives covered on a date is equal to the sum of—

(i) The number of participants with self-only coverage on that date; plus

(ii) The number of participants with coverage other than self-only coverage on the date multiplied by 2.35.

(C) *Snapshot count method.* Under the snapshot count method, the number of lives covered on a date equals the actual number of lives covered on the designated date.

(D) *Examples.* The following examples illustrate the principles of paragraphs (c)(1) and (c)(2)(iv) of this section:

Example 1. (i) Employer B is the plan sponsor of the Employer B Self-Insured Health Plan, which has a calendar year plan year. Employer B uses the snap-

shot method to determine the average number of lives covered under the plan and uses the snapshot count method to determine the number of lives covered on a day in the first month of each calendar quarter of the plan year.

(ii) On January 4, 2013, the Employer B Self-Insured Health Plan covers 2,000 lives, on April 5, 2013, 2,100 lives, on July 5, 2013, 2,050 lives, and on October 4, 2013, 2,050 lives. Under the snapshot method, Employer B must determine the average number of lives covered under the Employer B Self-Insured Health Plan for the plan year ending December 31, 2013, as $8,200 (2,000 + 2,100 + 2,050 + 2,050)$ divided by 4, or 2,050. To calculate the section 4376 fee under paragraph (c)(1) of this section for the plan year ending December 31, 2013, Employer B must determine the applicable dollar amount under paragraph (c)(3) of this section and multiply that amount by 2,050.

Example 2. (i) Same facts as *Example 1*, except that for the 2014 plan year Employer B determines the number of lives covered that are not covered by self-only coverage using the snapshot factor method (that is, based on the number of participants with coverage other than self-only coverage multiplied by 2.35 (the factor set forth in (c)(2)(iv) of this section)).

(ii) On January 10, 2014, Employer B Self-Insured Health Plan provides self-only coverage to 600 employees and other than self-only coverage to 800 employees. On April 11, 2014, Employer B Self-Insured Health Plan provides self-only coverage to 608 employees and other than self-only coverage to 800 employees. On July 11, 2014 and October 10, 2014, Employer B Self-Insured Health Plan provides self-only coverage to 610 employees and other than self-only coverage to 809 employees.

(iii) Under the snapshot factor method, Employer B must determine the average number of lives covered under the Employer B Self-Insured Health Plan for the plan year ending December 31, 2014 as $9,988 [(600+(800 \times 2.35)) + (608 + (800 \times 2.35)) + (610 + (809 \times 2.35)) + (610 + (809 \times 2.35))]$ divided by 4, or 2,497. To calculate the section 4376 fee under paragraph (c)(1) of this section for the plan year ending December 31, 2014, Employer B must determine the applicable dollar amount under paragraph (c)(3) of this section and multiply that amount by 2,497.

(v) *Form 5500 method*—(A) *Calculation method.* A plan sponsor may determine the average number of lives covered under a plan for a plan year based on the number of participants reported on the Form 5500, “*Annual Return/Report of Employee Benefit Plan*,” or the Form 5500-SF, “*Short Form Annual Return/Report of Small Employee Benefit Plan*,” that is filed for the applicable self-insured health plan for that plan year, provided that the Form 5500 or Form 5500-SF is filed no later than the due date for the fee imposed by section 4376 for that plan year. For purposes of this paragraph (c)(2)(v), the average number of lives covered under the plan for the plan year for a plan offering only self-only coverage equals the sum of the total par-

ticipants covered at the beginning and the end of the plan year, as reported on the Form 5500 or Form 5500-SF for the applicable self-insured health plan, divided by 2. For purposes of this paragraph (c)(2)(v), the average number of lives covered under the plan for the plan year for a plan offering self-only coverage and coverage other than self-only coverage equals the sum of total participants covered at the beginning and the end of the plan year, as reported on the Form 5500 or Form 5500-SF filed for the applicable self-insured health plan.

(B) *Examples.* The following examples illustrate the principles of paragraphs (c)(1) and (c)(2)(v)(A) of this section:

Example 1. Employer C is the plan sponsor of the Employer C Self-Insured Health Plan, which has a calendar year plan year ending on December 31, 2013. Employer C is required to file a Form 5500 for the plan for the 2013 plan year by July 31, 2014. However, on July 30, 2014, Employer C obtains an automatic 2-1/2 month extension for filing the 2013 Form 5500. Employer C files the 2013 Form 5500 on September 30, 2014 (that is, before the October 15 extended due date). Employer C is not eligible to use the Form 5500 method to determine the average number of lives covered under Plan C for the plan year ending on December 31, 2013, because the 2013 Form 5500 was not filed by the original due date (that is, by July 31, 2014) for the return that reports liability for the fee imposed by section 4376 for the 2013 plan year.

Example 2. Same facts as *Example 1*, except that the Employer C Self-Insured Health Plan has a fiscal year plan year ending on July 31, 2013, and offers only self-only coverage. Employer C files a Form 5500 for the Employer C Self-Insured Health Plan for the plan year ending July 31, 2013 (the 2012 Form 5500), on the extended due date for filing the 2012 Form 5500 (May 15, 2014). Employer C is eligible to use the Form 5500 method to determine the average number of lives covered under Plan C for the plan year ending on July 31, 2013, because the 2012 Form 5500 had been filed by the due date for the return that reports liability for the fee imposed by section 4376 for that plan year (July 31, 2014).

Example 3. Same facts as *Example 2*, provided further that the Employer C Self-Insured Health Plan 2012 Form 5500 reports 4,000 plan participants on the first day of the plan year and 4,200 plan participants on the last day of the 2012 plan year. For purposes of calculating the fee under section 4376 using the Form 5500 method, Employer C must treat the number of lives covered for the plan year ending July 31, 2013, as equal to the sum of 4,000 and 4,200 or 8,200, divided by 2, or 4,100. To calculate the section 4376 fee under paragraph (c)(1) of this section for the plan year ending July 31, 2013, Employer C must determine the applicable dollar amount under paragraph (c)(3) of this section and multiply that amount by 4,100.

Example 4. Same facts as *Example 3*, except that the Employer C Self-Insured Health plan offers self-only coverage and family coverage. For purposes of calculating the fee under section 4376 us-

ing the Form 5500 method, Employer C must treat the number of lives covered for the plan year ending July 31, 2013, as equal to the sum of 4,000 and 4,200, or 8,200. To calculate the section 4376 fee under paragraph (c)(1) of this section for the plan year ending July 31, 2013, Employer C must determine the applicable dollar amount under paragraph (c)(3) of this section and multiply that amount by 8,200.

(vi) *Special rule for health FSAs and HRAs.* For purposes of this section, if a plan sponsor does not establish or maintain an applicable self-insured health plan other than a health flexible spending arrangement (health FSA) (as described in section 106(c)(2)) or a health reimbursement arrangement (as described in Notice 2002-45, 2002-2 C.B. 93) (HRA), the plan sponsor may treat each participant's health FSA or HRA as covering a single life (and therefore the plan sponsor is not required to include as lives covered any spouse, dependent, or other beneficiary of the individual participant in the health FSA or HRA, as applicable). If a health FSA or HRA that is an applicable self-insured health plan has the same plan sponsor and plan year as another applicable self-insured health plan other than a health FSA or HRA, the two arrangements may be treated as a single plan under paragraph (b)(1)(iii) of this section. However, the special counting rule in this paragraph applies only for purposes of the health FSA or HRA and, therefore, applies only for purposes of the participants in the health FSA or HRA that do not participate in the other applicable self-insured health plan. The participants in the health FSA or HRA that participate in the other applicable self-insured health plan will be counted in accordance with the method applied for counting lives covered under that other plan as described in paragraph (b)(2)(i) of this section. See §601.601(d)(2) of this chapter.

(vii) *Special rule for lives covered solely by the fully-insured options under an applicable self-insured health plan—(A) In general.* If an applicable self-insured health plan provides accident and health coverage through fully-insured options and self-insured options, the plan sponsor is permitted to disregard the lives that are covered solely under the fully-insured options in determining the lives covered taken into account for the actual count method (described in paragraph (c)(2)(iii) of this section), the snapshot

method (described in paragraph (c)(2)(iv) of this section), and the Form 5500 method (described in paragraph (c)(2)(v) of this section).

(B) *Example.* The following example illustrates the principles of paragraph (c)(2)(vii) of this section:

Example. (i) Employer C is the plan sponsor of the Employer C Health Plan (Plan P). The Plan offers self-only or family health and accident coverage under fully-insured or self-insured options. On June 28, 2015, Employer C files a Form 5500 for Plan P for the plan year ending December 31, 2014 indicating: (1) a total of 4,000 plan participants on the first day of the 2014 plan year; and (2) a total of 4,200 plan participants on the last day of the plan year. Employer C determines that there were 3,000 plan participants (and their families, as applicable) covered under the fully-insured option offered under the plan on the first day of the 2014 plan year, and 2,900 plan participants (and their families, as applicable) covered under the fully-insured option on the last day of the 2014 plan year. Employer C uses the Form 5500 method to calculate the number of lives covered for the 2014 plan year.

(ii) Pursuant to paragraph (c)(2)(vii) of this section, Employer C determines the number of lives covered for the 2014 plan year as: the sum of 1,000 (4,000 total participants on the first day of the plan year - 3,000 participants covered by the specified health insurance policy on the first day of the plan year) and 1,300 (4,200 total participants - 2,900 participants covered by the specified health insurance policy on the first day of the plan year), or 2,300. To calculate the section 4376 fee under paragraph (c)(1) of this section for the 2014 plan year, Employer C must determine the applicable dollar amount under paragraph (c)(3) of this section and multiply that amount by 2,300.

(viii) *Special rule for the first year the fee is in effect.* Notwithstanding paragraph (c)(2)(i) of this section, for a plan year beginning before July 11, 2012, and ending on or after October 1, 2012, a plan sponsor may determine the average number of lives covered under the plan for the plan year using any reasonable method.

(3) *Applicable dollar amount.* For a plan year ending on or after October 1, 2012, and before October 1, 2013, the applicable dollar amount is \$1. For a plan year ending on or after October 1, 2013, and before October 1, 2014, the applicable dollar amount is \$2. For any plan year ending in any Federal fiscal year beginning on or after October 1, 2014, the applicable dollar amount is equal to the sum of—

(i) The applicable dollar amount for the plan year ending in the previous Federal fiscal year; plus

(ii) The amount equal to the product of—

(A) The applicable dollar amount for the plan year ending in the previous Federal fiscal year; and

(B) The percentage increase in the projected *per capita* amount of the National Health Expenditures most recently released by the Department of Health and Human Services before the beginning of the Federal fiscal year.

(4) *Examples.* The following examples illustrate the principle of paragraph (c)(3) of this section.

Example 1. (Calendar year plan). (i) Plan Sponsor C maintains Plan X which has a calendar year plan year; the plan continues in operation for the entire calendar years 2012 through 2019. Plan X is an applicable self-insured health plan, within the meaning of §46.4376-1(b)(1), and Plan Sponsor C is liable for the fee imposed by section 4376, determined in accordance with these regulations, beginning with the 2012 plan year — the plan year beginning January 1, 2012, and ending December 31, 2012 — and ending with the 2018 plan year — the plan year beginning January 1, 2018, and ending December 31, 2018. In accordance with §40.6071(a)-1(c) of this chapter:

(ii) The first Form 720 that must be filed to report and pay the fee imposed by section 4376 for Plan X covers the 2012 plan year (January 1, 2012, through December 31, 2012) and must be filed no later than July 31, 2013, and the fee reported on this form must be calculated by multiplying the average number lives by \$1 (the applicable dollar amount in effect for plans with plan years beginning on or after October 1, 2012, and before October 1, 2013); and

(ii) The last Form 720 that must be filed to report and pay the fee imposed by section 4376 for Plan X covers the 2018 plan year (January 1, 2018, through December 31, 2018) and must be filed no later than July 31, 2019, and the fee reported on this form must be calculated using the applicable dollar amount in effect for plan years ending on or after October 1, 2018, and before October 1, 2019.

Example 2. (Fiscal year plan). (i) Plan Sponsor B maintains Plan W, which has a fiscal year plan year ending on July 31; the plan continues in operation for the entire fiscal year plan years from August 1, 2012, through July 31, 2019. Plan W is an applicable self-insured health plan, within the meaning of §46.4376-1(b)(1), and Plan Sponsor B is liable for the fee imposed by section 4376, determined in accordance with these regulations, beginning with the 2012 plan year — the plan year beginning on August 1, 2012, and ending on July 31, 2013 — and ending with the 2018 plan year — plan year beginning on August 1, 2018, and ending July 31, 2019. In accordance with §40.6071(a)-1(c) of this chapter:

(ii) The first Form 720 that must be filed to report and pay the fee imposed by section 4376 for Plan X covers the 2012 plan year (August 1, 2012, through July 31, 2013) and must be filed no later than July 31, 2014, and the fee reported on this form must be calculated by multiplying the average number lives by \$1 (the applicable dollar amount in effect for plans with plan years beginning on or after October 1, 2012, and before October 1, 2013); and

(iii) The last Form 720 that must be filed to report and pay the fee imposed by section 4376 for Plan X covers the 2018 plan year (August 1, 2018, through July 31, 2019) and must be filed no later than July 31, 2020, and the fee must be calculated using the applicable dollar amount in effect for plan years ending on or after October 1, 2018, and before October 1, 2019.

(d) *Effective/Applicability date.* This section applies for plan years that end on or after October 1, 2012, and before October 1, 2019.

§46.4377-1 Definitions and special rules.

(a) *Definitions.* The following definitions apply for purposes of sections 4375 and 4376 and §§46.4375-1 and 46.4376-1.

(1) *Accident and health coverage.* The term *accident and health coverage* means any coverage that, if provided by an insurance policy, would cause such policy to be a specified health insurance policy (as defined in section 4375(c) and §46.4375-1(b)(1)). Accident and health coverage also includes coverage for an active employee, a former employee, or a qualifying beneficiary that is continuation coverage required under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) or similar continuation coverage under other federal law or under state law.

(2) *Individual residing in the United States*—(i) The term *individual residing in the United States* means an individual with a place of abode in the United States.

(ii) *Determination of place of abode.* For purposes of paragraph (a)(2) of this section, an issuer or a plan sponsor may rely on the most recent address on file with the issuer or plan sponsor and may treat the primary insured and the primary insured's spouse, dependents, or other beneficiaries covered by the policy as having the same place of abode. For this purpose, the primary insured is the individual covered by the policy whose eligibility for coverage was not due to that individual's status as the spouse, dependent, or other beneficiary of another covered individual.

(3) *United States.* The term *United States* includes American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands, and any other possession of the United States.

(4) *Federal fiscal year.* The term *Federal fiscal year* means the year beginning on October 1 and ending on the following September 30.

(b) *Treatment of exempt governmental programs*—(1) *In general.* The fees imposed by sections 4375 and 4376 do not apply to any covered life under an exempt governmental program as defined in paragraph (b)(2) of this section.

(2) *Exempt governmental program.* For purposes of this section, *exempt governmental program* means any—

(i) Insurance program established under title XVIII of the Social Security Act;

(ii) Medical assistance program established by title XIX or XXI of the Social Security Act;

(iii) Program established by Federal law for providing medical care (other than through insurance policies) to individuals (or their spouses and dependents) by reason of such individuals being (or having been) members of the Armed Forces of the United States; and

(iv) Program established by Federal law for providing medical care (other than through insurance policies) to members of Indian tribes (as defined in section 4(d) of the Indian Health Care Improvement Act).

(c) *Effective/Applicability date.* This section applies to all policy and plan years that end on or after October 1, 2012, and before October 1, 2019.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 12. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 13. In §602.101, paragraph (b) is amended by adding the following entries in numerical order to the table to read as follows:

§602.101 OMB Control numbers.

* * * * *
(b) * * * *

CFR part or section where Identified and described	Current OMB control No.
* * * * *	
46.4375-1	1545-2238
46.4376-1	1545-2238
* * * * *	

Steven T. Miller,
Deputy Commissioner for Services and Enforcement.

Approved November 28, 2012.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).

(Filed by the Office of the Federal Register on November 30, 2012, 2:00 p.m., and published in the issue of the Federal Register for December 5, 2012, 77 F.R. 72268)

Section 6011.—General Requirement of Return, Statement, or List

A Notice of Proposed Rulemaking (NRPM) provides that an individual must report any tax imposed by section 3101(b)(2) on Form 1040. Section 3101(b)(2) was enacted by section 9015 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111-148 (124 Stat. 119 (2010)), and amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029

(2010)) (collectively, the “Affordable Care Act”). See REG-130074-11, page 790.

Section 6205.—Special Rules Applicable to Certain Employment Taxes

A Notice of Proposed Rulemaking (NRPM) provides that adjustments of underpayments of the tax imposed by section 3101(b)(2) may be made only if the error is ascertained in the same year the wages or compensation was paid, unless the underpayment is attributable to an administrative error, section 3509 applies to determine the amount of underpayment, or

the adjustment is reported on a Form 2504 or Form 2504-WC. Section 3101(b)(2) was enacted by section 9015 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111-148 (124 Stat. 119 (2010)), and amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively, the "Affordable Care Act"). See REG-130074-11, page 790.

Section 6402.—Authority to Make Credits or Refunds

A Notice of Proposed Rulemaking (NPRM) provides that employers may claim refund of an overpayment of the tax imposed by section 3101(b)(2) only if the employer did not deduct or withhold the overpayment from the employee's wages or compensation. Section 3101(b)(2) was enacted by section 9015 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111-148 (124 Stat. 119 (2010)), and amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively, the "Affordable Care Act"). See REG-130074-11, page 790.

A Notice of Proposed Rulemaking (NPRM) provides that individuals may claim a refund or credit of an overpayment of the tax imposed by section 3101(b)(2) by taking the overpayment into account in claiming a credit against, or refund of, tax on an individual tax return. See REG-130074-11, page 790.

Section 6413.—Special Rules Applicable to Certain Employment Taxes

A Notice of Proposed Rulemaking (NPRM) provides that an adjustment of an overpayment of the tax imposed by section 3101(b)(2) may be made only if the employer ascertains the error in the same year the wages or compensation was paid and repays or reimburses the employee the amount of the overcollection prior to the end of the calendar year. Section 3101(b)(2) was enacted by section 9015 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111-148 (124 Stat. 119 (2010)), and amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively, the "Affordable Care Act"). See REG-130074-11, page 790.

Section 6621.—Determination of Rate of Interest

26 CFR 301.6621-1: Interest rate.

Interest rates; underpayment and overpayments. The rates for interest determined under section 6621 of the Code for the calendar quarter beginning January 1, 2013, will be 3 percent for overpayments (2 percent in the case of a corporation), 3 percent for the underpayments, and 5 percent for large corporate underpayments. The rate of interest paid on the portion of a corporate overpayment exceeding \$10,000 will be 0.5 percent.

Rev. Rul. 2012-32

Section 6621 of the Internal Revenue Code establishes the interest rates on overpayments and underpayments of tax. Under section 6621(a)(1), the overpayment rate is the sum of the federal short-term rate plus 3 percentage points (2 percentage points in the case of a corporation), except the rate for the portion of a corporate overpayment of tax exceeding \$10,000 for a taxable period is the sum of the federal short-term rate plus 0.5 of a percentage point. Under section 6621(a)(2), the underpayment rate is the sum of the federal short-term rate plus 3 percentage points.

Section 6621(c) provides that for purposes of interest payable under section 6601 on any large corporate underpayment, the underpayment rate under section 6621(a)(2) is determined by substituting "5 percentage points" for "3 percentage points." See section 6621(c) and section 301.6621-3 of the Regulations on Procedure and Administration for the definition of a large corporate underpayment and for the rules for determining the applicable date. Section 6621(c) and section 301.6621-3 are generally effective for periods after December 31, 1990.

Section 6621(b)(1) provides that the Secretary will determine the federal short-term rate for the first month in each calendar quarter. Section 6621(b)(2)(A) provides that the federal short-term rate determined under section 6621(b)(1) for any month applies during the first calendar quarter beginning after that month. Section 6621(b)(2)(B) provides that in determining the addition to tax under section 6654 for failure to pay estimated tax for any taxable year, the federal short-term

rate that applies during the third month following the taxable year also applies during the first 15 days of the fourth month following the taxable year. Section 6621(b)(3) provides that the federal short-term rate for any month is the federal short-term rate determined during that month by the Secretary in accordance with section 1274(d), rounded to the nearest full percent (or, if a multiple of 1/2 of 1 percent, the rate is increased to the next highest full percent).

Notice 88-59, 1988-1 C.B. 546, announced that, in determining the quarterly interest rates to be used for overpayments and underpayments of tax under section 6621, the Internal Revenue Service will use the federal short-term rate based on daily compounding because that rate is most consistent with section 6621 which, pursuant to section 6622, is subject to daily compounding.

The federal short-term rate determined in accordance with section 1274(d) during October 2012 is the rate published in Revenue Ruling 2012-30, 2012-45 I.R.B. 534, to take effect beginning November 1, 2012. The federal short-term rate, rounded to the nearest full percent, based on daily compounding determined during the month of October 2012 is 0 percent. Accordingly, an overpayment rate of 3 percent (2 percent in the case of a corporation) and an underpayment rate of 3 percent are established for the calendar quarter beginning January 1, 2013. The overpayment rate for the portion of a corporate overpayment exceeding \$10,000 for the calendar quarter beginning January 1, 2013, is 0.5 percent. The underpayment rate for large corporate underpayments for the calendar quarter beginning January 1, 2013, is 5 percent. These rates apply to amounts bearing interest during that calendar quarter.

The 3 percent rate also applies to estimated tax underpayments for the first calendar quarter in 2013.

Interest factors for daily compound interest for annual rates of 0.5 percent are published in Appendix A of this Revenue Ruling. Interest factors for daily compound interest for annual rates of 2 percent, 3 percent and 5 percent are published in Tables 9, 11, and 15 of Rev. Proc. 95-17, 1995-1 C.B. 563, 565, and 569.

Annual interest rates to be compounded daily pursuant to section 6622 that apply

for prior periods are set forth in the tables accompanying this revenue ruling.

DRAFTING INFORMATION

The principal author of this revenue ruling is Deborah Colbert-James of the Office of Associate Chief Counsel (Procedure &

Administration). For further information regarding this revenue ruling, contact Ms. Gulas at (202) 622-4570 (not a toll-free call).

APPENDIX A

365 Day Year					
0.5% Compound Rate 184 Days					
Days	Factor	Days	Factor	Days	Factor
1	0.000013699	63	0.000863380	125	0.001713784
2	0.000027397	64	0.000877091	126	0.001727506
3	0.000041096	65	0.000890801	127	0.001741228
4	0.000054796	66	0.000904512	128	0.001754951
5	0.000068495	67	0.000918223	129	0.001768673
6	0.000082195	68	0.000931934	130	0.001782396
7	0.000095894	69	0.000945646	131	0.001796119
8	0.000109594	70	0.000959357	132	0.001809843
9	0.000123294	71	0.000973069	133	0.001823566
10	0.000136995	72	0.000986781	134	0.001837290
11	0.000150695	73	0.001000493	135	0.001851013
12	0.000164396	74	0.001014206	136	0.001864737
13	0.000178097	75	0.001027918	137	0.001878462
14	0.000191798	76	0.001041631	138	0.001892186
15	0.000205499	77	0.001055344	139	0.001905910
16	0.000219201	78	0.001069057	140	0.001919635
17	0.000232902	79	0.001082770	141	0.001933360
18	0.000246604	80	0.001096484	142	0.001947085
19	0.000260306	81	0.001110197	143	0.001960811
20	0.000274008	82	0.001123911	144	0.001974536
21	0.000287711	83	0.001137625	145	0.001988262
22	0.000301413	84	0.001151339	146	0.002001988
23	0.000315116	85	0.001165054	147	0.002015714
24	0.000328819	86	0.001178768	148	0.002029440
25	0.000342522	87	0.001192483	149	0.002043166
26	0.000356225	88	0.001206198	150	0.002056893
27	0.000369929	89	0.001219913	151	0.002070620
28	0.000383633	90	0.001233629	152	0.002084347
29	0.000397336	91	0.001247344	153	0.002098074
30	0.000411041	92	0.001261060	154	0.002111801
31	0.000424745	93	0.001274776	155	0.002125529
32	0.000438449	94	0.001288492	156	0.002139257
33	0.000452154	95	0.001302208	157	0.002152985
34	0.000465859	96	0.001315925	158	0.002166713
35	0.000479564	97	0.001329641	159	0.002180441
36	0.000493269	98	0.001343358	160	0.002194169
37	0.000506974	99	0.001357075	161	0.002207898
38	0.000520680	100	0.001370792	162	0.002221627
39	0.000534386	101	0.001384510	163	0.002235356
40	0.000548092	102	0.001398227	164	0.002249085
41	0.000561798	103	0.001411945	165	0.002262815
42	0.000575504	104	0.001425663	166	0.002276544
43	0.000589211	105	0.001439381	167	0.002290274
44	0.000602917	106	0.001453100	168	0.002304004
45	0.000616624	107	0.001466818	169	0.002317734
46	0.000630331	108	0.001480537	170	0.002331465
47	0.000644039	109	0.001494256	171	0.002345195
48	0.000657746	110	0.001507975	172	0.002358926
49	0.000671454	111	0.001521694	173	0.002372657
50	0.000685161	112	0.001535414	174	0.002386388
51	0.000698869	113	0.001549133	175	0.002400120

365 Day Year

0.5% Compound Rate 184 Days

Days	Factor	Days	Factor	Days	Factor
52	0.000712578	114	0.001562853	176	0.002413851
53	0.000726286	115	0.001576573	177	0.002427583
54	0.000739995	116	0.001590293	178	0.002441315
55	0.000753703	117	0.001604014	179	0.002455047
56	0.000767412	118	0.001617734	180	0.002468779
57	0.000781121	119	0.001631455	181	0.002482511
58	0.000794831	120	0.001645176	182	0.002496244
59	0.000808540	121	0.001658897	183	0.002509977
60	0.000822250	122	0.001672619	184	0.002523710
61	0.000835960	123	0.001686340		
62	0.000849670	124	0.001700062		

366 Day Year

0.5% Compound Rate 184 Days

Days	Factor	Days	Factor	Days	Factor
1	0.000013661	63	0.000861020	125	0.001709097
2	0.000027323	64	0.000874693	126	0.001722782
3	0.000040984	65	0.000888366	127	0.001736467
4	0.000054646	66	0.000902040	128	0.001750152
5	0.000068308	67	0.000915713	129	0.001763837
6	0.000081970	68	0.000929387	130	0.001777522
7	0.000095632	69	0.000943061	131	0.001791208
8	0.000109295	70	0.000956735	132	0.001804893
9	0.000122958	71	0.000970409	133	0.001818579
10	0.000136620	72	0.000984084	134	0.001832265
11	0.000150283	73	0.000997758	135	0.001845951
12	0.000163947	74	0.001011433	136	0.001859638
13	0.000177610	75	0.001025108	137	0.001873324
14	0.000191274	76	0.001038783	138	0.001887011
15	0.000204938	77	0.001052459	139	0.001900698
16	0.000218602	78	0.001066134	140	0.001914385
17	0.000232266	79	0.001079810	141	0.001928073
18	0.000245930	80	0.001093486	142	0.001941760
19	0.000259595	81	0.001107162	143	0.001955448
20	0.000273260	82	0.001120839	144	0.001969136
21	0.000286924	83	0.001134515	145	0.001982824
22	0.000300590	84	0.001148192	146	0.001996512
23	0.000314255	85	0.001161869	147	0.002010201
24	0.000327920	86	0.001175546	148	0.002023889
25	0.000341586	87	0.001189223	149	0.002037578
26	0.000355252	88	0.001202900	150	0.002051267
27	0.000368918	89	0.001216578	151	0.002064957
28	0.000382584	90	0.001230256	152	0.002078646
29	0.000396251	91	0.001243934	153	0.002092336
30	0.000409917	92	0.001257612	154	0.002106025
31	0.000423584	93	0.001271291	155	0.002119715
32	0.000437251	94	0.001284969	156	0.002133405
33	0.000450918	95	0.001298648	157	0.002147096
34	0.000464586	96	0.001312327	158	0.002160786
35	0.000478253	97	0.001326006	159	0.002174477
36	0.000491921	98	0.001339685	160	0.002188168
37	0.000505589	99	0.001353365	161	0.002201859
38	0.000519257	100	0.001367044	162	0.002215550
39	0.000532925	101	0.001380724	163	0.002229242
40	0.000546594	102	0.001394404	164	0.002242933

366 Day Year

0.5% Compound Rate 184 Days

Days	Factor	Days	Factor	Days	Factor
41	0.000560262	103	0.001408085	165	0.002256625
42	0.000573931	104	0.001421765	166	0.002270317
43	0.000587600	105	0.001435446	167	0.002284010
44	0.000601269	106	0.001449127	168	0.002297702
45	0.000614939	107	0.001462808	169	0.002311395
46	0.000628608	108	0.001476489	170	0.002325087
47	0.000642278	109	0.001490170	171	0.002338780
48	0.000655948	110	0.001503852	172	0.002352473
49	0.000669618	111	0.001517533	173	0.002366167
50	0.000683289	112	0.001531215	174	0.002379860
51	0.000696959	113	0.001544897	175	0.002393554
52	0.000710630	114	0.001558580	176	0.002407248
53	0.000724301	115	0.001572262	177	0.002420942
54	0.000737972	116	0.001585945	178	0.002434636
55	0.000751643	117	0.001599628	179	0.002448331
56	0.000765315	118	0.001613311	180	0.002462025
57	0.000778986	119	0.001626994	181	0.002475720
58	0.000792658	120	0.001640678	182	0.002489415
59	0.000806330	121	0.001654361	183	0.002503110
60	0.000820003	122	0.001668045	184	0.002516806
61	0.000833675	123	0.001681729		
62	0.000847348	124	0.001695413		

TABLE OF INTEREST RATES

PERIODS BEFORE JUL. 1, 1975 — PERIODS ENDING DEC. 31, 1986

OVERPAYMENTS AND UNDERPAYMENTS

PERIOD	RATE	In 1995-1 C.B. DAILY RATE TABLE
Before Jul. 1, 1975	6%	Table 2, pg. 557
Jul. 1, 1975—Jan. 31, 1976	9%	Table 4, pg. 559
Feb. 1, 1976—Jan. 31, 1978	7%	Table 3, pg. 558
Feb. 1, 1978—Jan. 31, 1980	6%	Table 2, pg. 557
Feb. 1, 1980—Jan. 31, 1982	12%	Table 5, pg. 560
Feb. 1, 1982—Dec. 31, 1982	20%	Table 6, pg. 560
Jan. 1, 1983—Jun. 30, 1983	16%	Table 37, pg. 591
Jul. 1, 1983—Dec. 31, 1983	11%	Table 27, pg. 581
Jan. 1, 1984—Jun. 30, 1984	11%	Table 75, pg. 629
Jul. 1, 1984—Dec. 31, 1984	11%	Table 75, pg. 629
Jan. 1, 1985—Jun. 30, 1985	13%	Table 31, pg. 585
Jul. 1, 1985—Dec. 31, 1985	11%	Table 27, pg. 581
Jan. 1, 1986—Jun. 30, 1986	10%	Table 25, pg. 579
Jul. 1, 1986—Dec. 31, 1986	9%	Table 23, pg. 577

TABLE OF INTEREST RATES

FROM JAN. 1, 1987 — DEC. 31, 1998

	OVERPAYMENTS			UNDERPAYMENTS		
	1995-1 C.B.			1995-1 C.B.		
	RATE	TABLE	PG	RATE	TABLE	PG
Jan. 1, 1987—Mar. 31, 1987	8%	21	575	9%	23	577
Apr. 1, 1987—Jun. 30, 1987	8%	21	575	9%	23	577

TABLE OF INTEREST RATES
FROM JAN. 1, 1987 — DEC. 31, 1998

	OVERPAYMENTS			UNDERPAYMENTS		
	1995-1 C.B.			1995-1 C.B.		
	RATE	TABLE	PG	RATE	TABLE	PG
Jul. 1, 1987—Sep. 30, 1987	8%	21	575	9%	23	577
Oct. 1, 1987—Dec. 31, 1987	9%	23	577	10%	25	579
Jan. 1, 1988—Mar. 31, 1988	10%	73	627	11%	75	629
Apr. 1, 1988—Jun. 30, 1988	9%	71	625	10%	73	627
Jul. 1, 1988—Sep. 30, 1988	9%	71	625	10%	73	627
Oct. 1, 1988—Dec. 31, 1988	10%	73	627	11%	75	629
Jan. 1, 1989—Mar. 31, 1989	10%	25	579	11%	27	581
Apr. 1, 1989—Jun. 30, 1989	11%	27	581	12%	29	583
Jul. 1, 1989—Sep. 30, 1989	11%	27	581	12%	29	583
Oct. 1, 1989—Dec. 31, 1989	10%	25	579	11%	27	581
Jan. 1, 1990—Mar. 31, 1990	10%	25	579	11%	27	581
Apr. 1, 1990—Jun. 30, 1990	10%	25	579	11%	27	581
Jul. 1, 1990—Sep. 30, 1990	10%	25	579	11%	27	581
Oct. 1, 1990—Dec. 31, 1990	10%	25	579	11%	27	581
Jan. 1, 1991—Mar. 31, 1991	10%	25	579	11%	27	581
Apr. 1, 1991—Jun. 30, 1991	9%	23	577	10%	25	579
Jul. 1, 1991—Sep. 30, 1991	9%	23	577	10%	25	579
Oct. 1, 1991—Dec. 31, 1991	9%	23	577	10%	25	579
Jan. 1, 1992—Mar. 31, 1992	8%	69	623	9%	71	625
Apr. 1, 1992—Jun. 30, 1992	7%	67	621	8%	69	623
Jul. 1, 1992—Sep. 30, 1992	7%	67	621	8%	69	623
Oct. 1, 1992—Dec. 31, 1992	6%	65	619	7%	67	621
Jan. 1, 1993—Mar. 31, 1993	6%	17	571	7%	19	573
Apr. 1, 1993—Jun. 30, 1993	6%	17	571	7%	19	573
Jul. 1, 1993—Sep. 30, 1993	6%	17	571	7%	19	573
Oct. 1, 1993—Dec. 31, 1993	6%	17	571	7%	19	573
Jan. 1, 1994—Mar. 31, 1994	6%	17	571	7%	19	573
Apr. 1, 1994—Jun. 30, 1994	6%	17	571	7%	19	573
Jul. 1, 1994—Sep. 30, 1994	7%	19	573	8%	21	575
Oct. 1, 1994—Dec. 31, 1994	8%	21	575	9%	23	577
Jan. 1, 1995—Mar. 31, 1995	8%	21	575	9%	23	577
Apr. 1, 1995—Jun. 30, 1995	9%	23	577	10%	25	579
Jul. 1, 1995—Sep. 30, 1995	8%	21	575	9%	23	577
Oct. 1, 1995—Dec. 31, 1995	8%	21	575	9%	23	577
Jan. 1, 1996—Mar. 31, 1996	8%	69	623	9%	71	625
Apr. 1, 1996—Jun. 30, 1996	7%	67	621	8%	69	623
Jul. 1, 1996—Sep. 30, 1996	8%	69	623	9%	71	625
Oct. 1, 1996—Dec. 31, 1996	8%	69	623	9%	71	625
Jan. 1, 1997—Mar. 31, 1997	8%	21	575	9%	23	577
Apr. 1, 1997—Jun. 30, 1997	8%	21	575	9%	23	577
Jul. 1, 1997—Sep. 30, 1997	8%	21	575	9%	23	577
Oct. 1, 1997—Dec. 31, 1997	8%	21	575	9%	23	577
Jan. 1, 1998—Mar. 31, 1998	8%	21	575	9%	23	577
Apr. 1, 1998—Jun. 30, 1998	7%	19	573	8%	21	575
Jul. 1, 1998—Sep. 30, 1998	7%	19	573	8%	21	575
Oct. 1, 1998—Dec. 31, 1998	7%	19	573	8%	21	575

TABLE OF INTEREST RATES
 FROM JANUARY 1, 1999 — PRESENT
 NONCORPORATE OVERPAYMENTS AND UNDERPAYMENTS

	RATE	1995-1 C.B. TABLE	PG
Jan. 1, 1999—Mar. 31, 1999	7%	19	573
Apr. 1, 1999—Jun. 30, 1999	8%	21	575
Jul. 1, 1999—Sep. 30, 1999	8%	21	575
Oct. 1, 1999—Dec. 31, 1999	8%	21	575
Jan. 1, 2000—Mar. 31, 2000	8%	69	623
Apr. 1, 2000—Jun. 30, 2000	9%	71	625
Jul. 1, 2000—Sep. 30, 2000	9%	71	625
Oct. 1, 2000—Dec. 31, 2000	9%	71	625
Jan. 1, 2001—Mar. 31, 2001	9%	23	577
Apr. 1, 2001—Jun. 30, 2001	8%	21	575
Jul. 1, 2001—Sep. 30, 2001	7%	19	573
Oct. 1, 2001—Dec. 31, 2001	7%	19	573
Jan. 1, 2002—Mar. 31, 2002	6%	17	571
Apr. 1, 2002—Jun. 30, 2002	6%	17	571
Jul. 1, 2002—Sep. 30, 2002	6%	17	571
Oct. 1, 2002—Dec. 31, 2002	6%	17	571
Jan. 1, 2003—Mar. 31, 2003	5%	15	569
Apr. 1, 2003—Jun. 30, 2003	5%	15	569
Jul. 1, 2003—Sep. 30, 2003	5%	15	569
Oct. 1, 2003—Dec. 31, 2003	4%	13	567
Jan. 1, 2004—Mar. 31, 2004	4%	61	615
Apr. 1, 2004—Jun. 30, 2004	5%	63	617
Jul. 1, 2004—Sep. 30, 2004	4%	61	615
Oct. 1, 2004—Dec. 31, 2004	5%	63	617
Jan. 1, 2005—Mar. 31, 2005	5%	15	569
Apr. 1, 2005—Jun. 30, 2005	6%	17	571
Jul. 1, 2005—Sep. 30, 2005	6%	17	571
Oct. 1, 2005—Dec. 31, 2005	7%	19	573
Jan. 1, 2006—Mar. 31, 2006	7%	19	573
Apr. 1, 2006—Jun. 30, 2006	7%	19	573
Jul. 1, 2006—Sep. 30, 2006	8%	21	575
Oct. 1, 2006—Dec. 31, 2006	8%	21	575
Jan. 1, 2007—Mar. 31, 2007	8%	21	575
Apr. 1, 2007—Jun. 30, 2007	8%	21	575
Jul. 1, 2007—Sep. 30, 2007	8%	21	575
Oct. 1, 2007—Dec. 31, 2007	8%	21	575
Jan. 1, 2008—Mar. 31, 2008	7%	67	621
Apr. 1, 2008—Jun. 30, 2008	6%	65	619
Jul. 1, 2008—Sep. 30, 2008	5%	63	617
Oct. 1, 2008—Dec. 31, 2008	6%	65	619
Jan. 1, 2009—Mar. 31, 2009	5%	15	569
Apr. 1, 2009—Jun. 30, 2009	4%	13	567
Jul. 1, 2009—Sep. 30, 2009	4%	13	567
Oct. 1, 2009—Dec. 31, 2009	4%	13	567
Jan. 1, 2010—Mar. 31, 2010	4%	13	567
Apr. 1, 2010—Jun. 30, 2010	4%	13	567
Jul. 1, 2010—Sep. 30, 2010	4%	13	567
Oct. 1, 2010—Dec. 31, 2010	4%	13	567
Jan. 1, 2011—Mar. 31, 2011	3%	11	565
Apr. 1, 2011—Jun. 30, 2011	4%	13	567
Jul. 1, 2011—Sep. 30, 2011	4%	13	567
Oct. 1, 2011—Dec. 31, 2011	3%	11	565
Jan. 1, 2012—Mar. 31, 2012	3%	59	613
Apr. 1, 2012—Jun. 30, 2012	3%	59	613

TABLE OF INTEREST RATES
FROM JANUARY 1, 1999 — PRESENT
NONCORPORATE OVERPAYMENTS AND UNDERPAYMENTS

	RATE	1995-1 C.B. TABLE	PG
Jul. 1, 2012—Sep. 30, 2012	3%	59	613
Oct. 1, 2012—Dec. 31, 2012	3%	59	613
Jan. 1, 2012—Mar. 31, 2013	3%	11	565

TABLE OF INTEREST RATES
FROM JANUARY 1, 1999 — PRESENT
CORPORATE OVERPAYMENTS AND UNDERPAYMENTS

	OVERPAYMENTS			UNDERPAYMENTS		
	1995-1 C.B.			1995-1 C.B.		
	RATE	TABLE	PG	RATE	TABLE	PG
Jan. 1, 1999—Mar. 31, 1999	6%	17	571	7%	19	573
Apr. 1, 1999—Jun. 30, 1999	7%	19	573	8%	21	575
Jul. 1, 1999—Sep. 30, 1999	7%	19	573	8%	21	575
Oct. 1, 1999—Dec. 31, 1999	7%	19	573	8%	21	575
Jan. 1, 2000—Mar. 31, 2000	7%	67	621	8%	69	623
Apr. 1, 2000—Jun. 30, 2000	8%	69	623	9%	71	625
Jul. 1, 2000—Sep. 30, 2000	8%	69	623	9%	71	625
Oct. 1, 2000—Dec. 31, 2000	8%	69	623	9%	71	625
Jan. 1, 2001—Mar. 31, 2001	8%	21	575	9%	23	577
Apr. 1, 2001—Jun. 30, 2001	7%	19	573	8%	21	575
Jul. 1, 2001—Sep. 30, 2001	6%	17	571	7%	19	573
Oct. 1, 2001—Dec. 31, 2001	6%	17	571	7%	19	573
Jan. 1, 2002—Mar. 31, 2002	5%	15	569	6%	17	571
Apr. 1, 2002—Jun. 30, 2002	5%	15	569	6%	17	571
Jul. 1, 2002—Sep. 30, 2002	5%	15	569	6%	17	571
Oct. 1, 2002—Dec. 31, 2002	5%	15	569	6%	17	571
Jan. 1, 2003—Mar. 31, 2003	4%	13	567	5%	15	569
Apr. 1, 2003—Jun. 30, 2003	4%	13	567	5%	15	569
Jul. 1, 2003—Sep. 30, 2003	4%	13	567	5%	15	569
Oct. 1, 2003—Dec. 31, 2003	3%	11	565	4%	13	567
Jan. 1, 2004—Mar. 31, 2004	3%	59	613	4%	61	615
Apr. 1, 2004—Jun. 30, 2004	4%	61	615	5%	63	617
Jul. 1, 2004—Sep. 30, 2004	3%	59	613	4%	61	615
Oct. 1, 2004—Dec. 31, 2004	4%	61	615	5%	63	617
Jan. 1, 2005—Mar. 31, 2005	4%	13	567	5%	15	569
Apr. 1, 2005—Jun. 30, 2005	5%	15	569	6%	17	571
Jul. 1, 2005—Sep. 30, 2005	5%	15	569	6%	17	571
Oct. 1, 2005—Dec. 31, 2005	6%	17	571	7%	19	573
Jan. 1, 2006—Mar. 31, 2006	6%	17	571	7%	19	573
Apr. 1, 2006—Jun. 30, 2006	6%	17	571	7%	19	573
Jul. 1, 2006—Sep. 30, 2006	7%	19	573	8%	21	575
Oct. 1, 2006—Dec. 31, 2006	7%	19	573	8%	21	575
Jan. 1, 2007—Mar. 31, 2007	7%	19	573	8%	21	575
Apr. 1, 2007—Jun. 30, 2007	7%	19	573	8%	21	575
Jul. 1, 2007—Sep. 30, 2007	7%	19	573	8%	21	575
Oct. 1, 2007—Dec. 31, 2007	7%	19	573	8%	21	575
Jan. 1, 2008—Mar. 31, 2008	6%	65	619	7%	67	621
Apr. 1, 2008—Jun. 30, 2008	5%	63	617	6%	65	619
Jul. 1, 2008—Sep. 30, 2008	4%	61	615	5%	63	617
Oct. 1, 2008—Dec. 31, 2008	5%	63	617	6%	65	619
Jan. 1, 2009—Mar. 31, 2009	4%	13	567	5%	15	569

TABLE OF INTEREST RATES
FROM JANUARY 1, 1999 — PRESENT
CORPORATE OVERPAYMENTS AND UNDERPAYMENTS

	OVERPAYMENTS			UNDERPAYMENTS		
	1995-1 C.B.			1995-1 C.B.		
	RATE	TABLE	PG	RATE	TABLE	PG
Apr. 1, 2009—Jun. 30, 2009	3%	11	565	4%	13	567
Jul. 1, 2009—Sep. 30, 2009	3%	11	565	4%	13	567
Oct. 1, 2009—Dec. 31, 2009	3%	11	565	4%	13	567
Jan. 1, 2010—Mar. 31, 2010	3%	11	565	4%	13	567
Apr. 1, 2010—Jun. 30, 2010	3%	11	565	4%	13	567
Jul. 1, 2010—Sep. 30, 2010	3%	11	565	4%	13	567
Oct. 1, 2010—Dec. 31, 2010	3%	11	565	4%	13	567
Jan. 1, 2011—Mar. 31, 2011	2%	9	563	3%	11	565
Apr. 1, 2011—Jun. 30, 2011	3%	11	565	4%	13	567
Jul. 1, 2011—Sep. 30, 2011	3%	11	565	4%	13	567
Oct. 1, 2011—Dec. 31, 2011	2%	9	563	3%	11	565
Jan. 1, 2012—Mar. 31, 2012	2%	57	611	3%	59	613
Apr. 1, 2012—Jun. 30, 2012	2%	57	611	3%	59	613
Jul. 1, 2012—Sep. 30, 2012	2%	57	611	3%	59	613
Oct. 1, 2012—Dec. 31, 2012	2%	57	611	3%	59	613
Jan. 1, 2013—Mar. 31, 2013	2%	9	563	3%	11	565

TABLE OF INTEREST RATES FOR
LARGE CORPORATE UNDERPAYMENTS
FROM JANUARY 1, 1991 — PRESENT

	RATE	1995-1 C.B.	PG
		TABLE	
Jan. 1, 1991—Mar. 31, 1991	13%	31	585
Apr. 1, 1991—Jun. 30, 1991	12%	29	583
Jul. 1, 1991—Sep. 30, 1991	12%	29	583
Oct. 1, 1991—Dec. 31, 1991	12%	29	583
Jan. 1, 1992—Mar. 31, 1992	11%	75	629
Apr. 1, 1992—Jun. 30, 1992	10%	73	627
Jul. 1, 1992—Sep. 30, 1992	10%	73	627
Oct. 1, 1992—Dec. 31, 1992	9%	71	625
Jan. 1, 1993—Mar. 31, 1993	9%	23	577
Apr. 1, 1993—Jun. 30, 1993	9%	23	577
Jul. 1, 1993—Sep. 30, 1993	9%	23	577
Oct. 1, 1993—Dec. 31, 1993	9%	23	577
Jan. 1, 1994—Mar. 31, 1994	9%	23	577
Apr. 1, 1994—Jun. 30, 1994	9%	23	577
Jul. 1, 1994—Sep. 30, 1994	10%	25	579
Oct. 1, 1994—Dec. 31, 1994	11%	27	581
Jan. 1, 1995—Mar. 31, 1995	11%	27	581
Apr. 1, 1995—Jun. 30, 1995	12%	29	583
Jul. 1, 1995—Sep. 30, 1995	11%	27	581
Oct. 1, 1995—Dec. 31, 1995	11%	27	581
Jan. 1, 1996—Mar. 31, 1996	11%	75	629
Apr. 1, 1996—Jun. 30, 1996	10%	73	627
Jul. 1, 1996—Sep. 30, 1996	11%	75	629
Oct. 1, 1996—Dec. 31, 1996	11%	75	629
Jan. 1, 1997—Mar. 31, 1997	11%	27	581
Apr. 1, 1997—Jun. 30, 1997	11%	27	581
Jul. 1, 1997—Sep. 30, 1997	11%	27	581
Oct. 1, 1997—Dec. 31, 1997	11%	27	581
Jan. 1, 1998—Mar. 31, 1998	11%	27	581

TABLE OF INTEREST RATES FOR
LARGE CORPORATE UNDERPAYMENTS
FROM JANUARY 1, 1991 — PRESENT

	RATE	1995-1 C.B. TABLE	PG
Apr. 1, 1998—Jun. 30, 1998	10%	25	579
Jul. 1, 1998—Sep. 30, 1998	10%	25	579
Oct. 1, 1998—Dec. 31, 1998	10%	25	579
Jan. 1, 1999—Mar. 31, 1999	9%	23	577
Apr. 1, 1999—Jun. 30, 1999	10%	25	579
Jul. 1, 1999—Sep. 30, 1999	10%	25	579
Oct. 1, 1999—Dec. 31, 1999	10%	25	579
Jan. 1, 2000—Mar. 31, 2000	10%	73	627
Apr. 1, 2000—Jun. 30, 2000	11%	75	629
Jul. 1, 2000—Sep. 30, 2000	11%	75	629
Oct. 1, 2000—Dec. 31, 2000	11%	75	629
Jan. 1, 2001—Mar. 31, 2001	11%	27	581
Apr. 1, 2001—Jun. 30, 2001	10%	25	579
Jul. 1, 2001—Sep. 30, 2001	9%	23	577
Oct. 1, 2001—Dec. 31, 2001	9%	23	577
Jan. 1, 2002—Mar. 31, 2002	8%	21	575
Apr. 1, 2002—Jun. 30, 2002	8%	21	575
Jul. 1, 2002—Sep. 30, 2002	8%	21	575
Oct. 1, 2002—Dec. 31, 2002	8%	21	575
Jan. 1, 2003—Mar. 31, 2003	7%	19	573
Apr. 1, 2003—Jun. 30, 2003	7%	19	573
Jul. 1, 2003—Sep. 30, 2003	7%	19	573
Oct. 1, 2003—Dec. 31, 2003	6%	17	571
Jan. 1, 2004—Mar. 31, 2004	6%	65	619
Apr. 1, 2004—Jun. 30, 2004	7%	67	621
Jul. 1, 2004—Sep. 30, 2004	6%	65	619
Oct. 1, 2004—Dec. 31, 2004	7%	67	621
Jan. 1, 2005—Mar. 31, 2005	7%	19	573
Apr. 1, 2005—Jun. 30, 2005	8%	21	575
Jul. 1, 2005—Sep. 30, 2005	8%	21	575
Oct. 1, 2005—Dec. 31, 2005	9%	23	577
Jan. 1, 2006—Mar. 31, 2006	9%	23	577
Apr. 1, 2006—Jun. 30, 2006	9%	23	577
Jul. 1, 2006—Sep. 30, 2006	10%	25	579
Oct. 1, 2006—Dec. 31, 2006	10%	25	579
Jan. 1, 2007—Mar. 31, 2007	10%	25	579
Apr. 1, 2007—Jun. 30, 2007	10%	25	579
Jul. 1, 2007—Sep. 30, 2007	10%	25	579
Oct. 1, 2007—Dec. 31, 2007	10%	25	579
Jan. 1, 2008—Mar. 31, 2008	9%	71	625
Apr. 1, 2008—Jun. 30, 2008	8%	69	623
Jul. 1, 2008—Sep. 30, 2008	7%	67	621
Oct. 1, 2008—Dec. 31, 2008	8%	69	623
Jan. 1, 2009—Mar. 31, 2009	7%	19	573
Apr. 1, 2009—Jun. 30, 2009	6%	17	571
Jul. 1, 2009—Sep. 30, 2009	6%	17	571
Oct. 1, 2009—Dec. 31, 2009	6%	17	571
Jan. 1, 2010—Mar. 31, 2010	6%	17	571
Apr. 1, 2010—Jun. 30, 2010	6%	17	571
Jul. 1, 2010—Sep. 30, 2010	6%	17	571
Oct. 1, 2010—Dec. 31, 2010	6%	17	571
Jan. 1, 2011—Mar. 31, 2011	5%	15	569
Apr. 1, 2011—Jun. 30, 2011	6%	17	571
Jul. 1, 2011—Sep. 30, 2011	6%	17	571
Oct. 1, 2011—Dec. 31, 2011	5%	15	569
Jan. 1, 2012—Mar. 31, 2012	5%	63	617

TABLE OF INTEREST RATES FOR
LARGE CORPORATE UNDERPAYMENTS
FROM JANUARY 1, 1991 — PRESENT

	RATE	1995-1 C.B. TABLE	PG
Apr. 1, 2012—Jun. 30, 2012	5%	63	617
Jul. 1, 2012—Sep. 30, 2012	5%	63	617
Oct. 1, 2012—Dec. 31, 2012	5%	63	617
Jan. 1, 2013—Mar. 31, 2013	5%	15	569

TABLE OF INTEREST RATES FOR CORPORATE
OVERPAYMENTS EXCEEDING \$10,000
FROM JANUARY 1, 1995 — PRESENT

	RATE	1995-1 C.B. TABLE	PG
Jan. 1, 1995—Mar. 31, 1995	6.5%	18	572
Apr. 1, 1995—Jun. 30, 1995	7.5%	20	574
Jul. 1, 1995—Sep. 30, 1995	6.5%	18	572
Oct. 1, 1995—Dec. 31, 1995	6.5%	18	572
Jan. 1, 1996—Mar. 31, 1996	6.5%	66	620
Apr. 1, 1996—Jun. 30, 1996	5.5%	64	618
Jul. 1, 1996—Sep. 30, 1996	6.5%	66	620
Oct. 1, 1996—Dec. 31, 1996	6.5%	66	620
Jan. 1, 1997—Mar. 31, 1997	6.5%	18	572
Apr. 1, 1997—Jun. 30, 1997	6.5%	18	572
Jul. 1, 1997—Sep. 30, 1997	6.5%	18	572
Oct. 1, 1997—Dec. 31, 1997	6.5%	18	572
Jan. 1, 1998—Mar. 31, 1998	6.5%	18	572
Apr. 1, 1998—Jun. 30, 1998	5.5%	16	570
Jul. 1, 1998—Sep. 30, 1998	5.5%	16	570
Oct. 1, 1998—Dec. 31, 1998	5.5%	16	570
Jan. 1, 1999—Mar. 31, 1999	4.5%	14	568
Apr. 1, 1999—Jun. 30, 1999	5.5%	16	570
Jul. 1, 1999—Sep. 30, 1999	5.5%	16	570
Oct. 1, 1999—Dec. 31, 1999	5.5%	16	570
Jan. 1, 2000—Mar. 31, 2000	5.5%	64	618
Apr. 1, 2000—Jun. 30, 2000	6.5%	66	620
Jul. 1, 2000—Sep. 30, 2000	6.5%	66	620
Oct. 1, 2000—Dec. 31, 2000	6.5%	66	620
Jan. 1, 2001—Mar. 31, 2001	6.5%	18	572
Apr. 1, 2001—Jun. 30, 2001	5.5%	16	570
Jul. 1, 2001—Sep. 30, 2001	4.5%	14	568
Oct. 1, 2001—Dec. 31, 2001	4.5%	14	568
Jan. 1, 2002—Mar. 31, 2002	3.5%	12	566
Apr. 1, 2002—Jun. 30, 2002	3.5%	12	566
Jul. 1, 2002—Sep. 30, 2002	3.5%	12	566
Oct. 1, 2002—Dec. 31, 2002	3.5%	12	566
Jan. 1, 2003—Mar. 31, 2003	2.5%	10	564
Apr. 1, 2003—Jun. 30, 2003	2.5%	10	564
Jul. 1, 2003—Sep. 30, 2003	2.5%	10	564
Oct. 1, 2003—Dec. 31, 2003	1.5%	8	562
Jan. 1, 2004—Mar. 31, 2004	1.5%	56	610
Apr. 1, 2004—Jun. 30, 2004	2.5%	58	612
Jul. 1, 2004—Sep. 30, 2004	1.5%	56	610
Oct. 1, 2004—Dec. 31, 2004	2.5%	58	612
Jan. 1, 2005—Mar. 31, 2005	2.5%	10	564
Apr. 1, 2005—Jun. 30, 2005	3.5%	12	566

TABLE OF INTEREST RATES FOR CORPORATE
OVERPAYMENTS EXCEEDING \$10,000
FROM JANUARY 1, 1995 — PRESENT

	RATE	1995-1 C.B. TABLE	PG
Jul. 1, 2005—Sep. 30, 2005	3.5%	12	566
Oct. 1, 2005—Dec. 31, 2005	4.5%	14	568
Jan. 1, 2006—Mar. 31, 2006	4.5%	14	568
Apr. 1, 2006—Jun. 30, 2006	4.5%	14	568
Jul. 1, 2006—Sep. 30, 2006	5.5%	16	570
Oct. 1, 2006—Dec. 31, 2006	5.5%	16	570
Jan. 1, 2007—Mar. 31, 2007	5.5%	16	570
Apr. 1, 2007—Jun. 30, 2007	5.5%	16	570
Jul. 1, 2007—Sep. 30, 2007	5.5%	16	570
Oct. 1, 2007—Dec. 31, 2007	5.5%	16	570
Jan. 1, 2008—Mar. 31, 2008	4.5%	62	616
Apr. 1, 2008—Jun. 30, 2008	3.5%	60	614
Jul. 1, 2008—Sep. 30, 2008	2.5%	58	612
Oct. 1, 2008—Dec. 31, 2008	3.5%	60	614
Jan. 1, 2009—Mar. 31, 2009	2.5%	10	564
Apr. 1, 2009—Jun. 30, 2009	1.5%	8	562
Jul. 1, 2009—Sep. 30, 2009	1.5%	8	562
Oct. 1, 2009—Dec. 31, 2009	1.5%	8	562
Jan. 1, 2010—Mar. 31, 2010	1.5%	8	562
Apr. 1, 2010—Jun. 30, 2010	1.5%	8	562
Jul. 1, 2010—Sep. 30, 2010	1.5%	8	562
Oct. 1, 2010—Dec. 31, 2010	1.5%	8	562
Jan. 1, 2011—Mar. 31, 2011	0.5%*		
Apr. 1, 2011—Jun. 30, 2011	1.5%	8	562
Jul. 1, 2011—Sep. 30, 2011	1.5%	8	562
Oct. 1, 2011—Dec. 31, 2011	0.5%*		
Jan. 1, 2012—Mar. 31, 2012	0.5%*		
Apr. 1, 2012—Jun. 30, 2012	0.5%*		
Jul. 1, 2012—Sep. 30, 2012	0.5%*		
Oct. 1, 2012—Dec. 31, 2012	0.5%*		
Jan. 1, 2013—Mar. 31, 2013	0.5%*		

Part III. Administrative, Procedural, and Miscellaneous

Qualified Plug-in Electric Drive Motor Vehicle Credit; Update of Notice 2009–89

Notice 2012–54

SECTION 1. PURPOSE

This notice modifies Notice 2009–89, 2009–48 I.R.B. 714, by providing a new address to which a vehicle manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) must send vehicle certifications and quarterly reports under Notice 2009–89.

SECTION 2. BACKGROUND

Section 30D of the Internal Revenue Code originally was enacted in the Energy Improvement and Extension Act of 2008, Pub. L. 110–343, 122 Stat. 3765. The American Recovery and Reinvestment Act of 2009, Pub. L. 111–5, 123 Stat. 115, amended § 30D in certain material respects, effective for vehicles acquired after December 31, 2009. Section 30D, as amended, provides for a credit for certain new qualified plug-in electric drive motor vehicles, equal to the sum of: (1) \$2,500, (2) \$417 for at least 5 kilowatt hours of traction battery capacity, and (3) \$417 for each kilowatt hour of traction battery capacity in excess of 5 kilowatt hours. Section 30D(b)(1) limits the amount of the credit allowed for a vehicle to \$7,500. The credit begins to phase out for a manufacturer's vehicles beginning in the second calendar quarter after the calendar quarter in which at least 200,000 of the manufacturer's qualifying vehicles have been sold for use in the United States (determined on a cumulative basis for sales after December 31, 2008).

On November 13, 2009, the Internal Revenue Service ("Service") published Notice 2009–89, which provides guidance regarding the credit under § 30D for qualified plug-in electric drive motor vehicles acquired after December 31, 2009. Notice 2009–89 sets forth procedures for a vehicle manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) to certify to the Service both:

(1) That a motor vehicle of a particular make, model, and model year meets

certain requirements that must be satisfied to claim the new qualified plug-in electric drive motor vehicle credit under § 30D; and

(2) The amount of the credit allowable with respect to that motor vehicle.

In addition, Notice 2009–89 sets forth procedures for a manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) that has received an acknowledgment of its certification from the Service to submit to the Service a report of the number of qualified plug-in electric drive motor vehicles sold by the manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) to consumers or retail dealers during the calendar quarter.

Section 6.03 of Notice 2009–89 provides the address to which a vehicle manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) must send certifications and quarterly reports under Notice 2009–89.

SECTION 3. MODIFICATION TO NOTICE 2009–89

This notice modifies Section 6.03 of Notice 2009–89 to read as follows:

.03 *Address for Filing.* Certifications and quarterly reports under section 5 of this notice must be sent to:

Internal Revenue Service
Industry Director, LB&I, Retailers,
Food, Transportation & Healthcare
1901 West Butterfield Road
Suite 310 M/S 1902 WSB
Downers Grove, IL 60515

SECTION 4. EFFECTIVE DATE

This notice is effective for certifications and quarterly reports submitted under Notice 2009–89 after October 1, 2012.

SECTION 5. EFFECT ON OTHER DOCUMENTS

Notice 2009–89 is modified as provided in this notice. Except as explicitly provided, this notice does not otherwise affect the guidance provided in Notice 2009–89.

SECTION 6. DRAFTING INFORMATION

The principal author of this notice is Patrick S. Kirwan of the Office of Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice, contact Mr. Kirwan at (202) 622–3110 (not a toll-free call).

Information Reporting for Discharges of Indebtedness

Notice 2012–65

PURPOSE

This notice invites public comments regarding guidance to be provided to governmental and financial entities (applicable entities) described in Internal Revenue Code section 6050P(c), who discharge indebtedness and may be required to furnish Form 1099–C information returns pursuant to section 6050P and Treas. Reg. § 1.6050P. Section 6050P(b) provides that an applicable entity must issue an information return if \$600 or more of indebtedness is discharged. The corresponding Treasury regulation, Treas. Reg. § 1.6050P–1(b)(2), lists eight identifiable events that trigger a reporting obligation, including the expiration of a non-payment testing period that results when a creditor does not receive payment or engage in *bona fide* collection activity for specified periods of time.

The Department of the Treasury (Treasury) and the Internal Revenue Service (Service) are aware that taxpayers who receive a Form 1099–C due to expiration of the non-payment testing period described in Treas. Reg. § 1.6050P–1(b)(2)(i)(H) and (iv) may be confused regarding whether to include the amount reported on the Form 1099–C as income. This notice requests comments to help Treasury and the Service determine whether the non-payment testing period rule should be modified or eliminated.

BACKGROUND

Section 6050P provides that an applicable entity must issue an information return if it discharges \$600 or more of

indebtedness. The term applicable entity includes governmental entities and financial entities including “any organization a significant trade or business of which is the lending of money.” I.R.C. § 6050P(c)(2)(D). Treasury Regulation § 1.6050P-2 sets forth the test for whether the lending of money is a significant trade or business and contains safe harbors and examples.

Under the regulation, indebtedness is deemed discharged solely for purposes of the section 6050P reporting obligation only upon the occurrence of an identifiable event, whether or not an actual discharge has occurred on or before the date on which the identifiable event has occurred. Treas. Reg. § 1.6050P-1(b)(1). The section 6050P regulations contain eight identifiable events that trigger a reporting obligation for a discharge of indebtedness by an applicable entity. Treas. Reg. § 1.6050P-1(b)(2)(i)(A)-(H). Seven of the eight identifiable events listed in the Treasury regulation are specific occurrences that result from an actual discharge of indebtedness, such as certain judicial proceedings, an agreement between the debtor and creditor, or the creditor’s decision or defined policy to discontinue collection activity. Treas. Reg. § 1.6050P-1(b)(2)(i)(A)-(G). The eighth identifiable event, expiration of a non-payment testing period, does not necessarily result from an actual discharge of indebtedness. Treas. Reg. § 1.6050P-1(b)(2)(i)(H) and (iv).

Treas. Reg. § 1.6050P-1(b)(2)(iv) describes the non-payment testing period as a 36-month period during which time the creditor has not received any payment on the indebtedness. If the testing period expires without payment by the debtor, a rebuttable presumption arises that an identifiable event has occurred, and the creditor should issue a Form 1099-C. The presumption may be rebutted by the creditor, and the creditor is not required to issue a Form 1099-C, if the creditor, or a third party on its behalf, engaged in significant *bona fide* collection activity at any time during the 12-month period ending at the close of the calendar year. Treas. Reg. § 1.6050P-1(b)(2)(iv). The presumption also may be rebutted by the credi-

tor if the facts and circumstances existing as of January 31 of the calendar year following the expiration of the non-payment testing period indicate that the indebtedness has not been discharged. Treas. Reg. § 1.6050P-1(b)(2)(iv).

Treasury and the Service added the non-payment testing period to the final regulations in 1996 in response to concerns of creditors that the temporary and proposed regulations were unclear regarding the effect of continuing collection activity. The temporary and proposed regulations had contained a facts and circumstances test for determining when an identifiable event has occurred. Creditors raised concerns that this did not present a sufficiently clear rule for determining when reporting was required and proposed (among other things) that the final regulations require reporting after a fixed time period during which there had been no collection efforts. In response to these comments, the final regulation added the 36-month non-payment testing period as an additional identifiable event.

Creditors who issue a Form 1099-C upon expiration of a 36-month non-payment testing period are not necessarily signaling that a debt has actually been cancelled. The actual discharge of indebtedness, for purposes of determining when taxable income is incurred, may be prior to or after the identifiable event. In some circumstances, moreover, there may never be an actual discharge of indebtedness. As a consequence, the receipt of a Form 1099-C upon expiration of a non-payment testing period can cause confusion for taxpayers regarding whether and when to include any income attributable to an actual discharge of indebtedness. To address this confusion, Treasury and the IRS are considering clarification, revision, or removal of the non-payment testing period as an identifiable event.

REQUESTS FOR PUBLIC COMMENT

Treasury and the Service are requesting comments from all affected persons and entities and are particularly interested in any comments regarding:

- Whether Treas. Reg. § 1.6050P-1(b)(2)(i) should be

amended to remove the non-payment testing period as an identifiable event;

- Whether the removal of the non-payment testing period would increase or decrease the burden on creditors and taxpayers;
- If the non-payment testing period is removed, whether additional rules are necessary to address continuing collection activity; and
- If the non-payment testing period is retained, how it should be modified to improve its usefulness and alleviate confusion.

The information collected will assist Treasury and the IRS in determining whether additional guidance is necessary. Written comments should be sent to: CC:PA:LPD:PR (Notice 2012-65), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, D.C. 20044. Alternatively, comments may be hand delivered between the hours of 8:00 a.m. and 4:00 p.m. Monday to Friday to CC:PA:LPD:PR (Notice 2012-65), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, D.C. Comments may also be transmitted electronically via the following e-mail address: Notice.Comments@irs.counsel.treas.gov. Please include “Notice 2012-65” in the subject line of any electronic communications.

All comments will be available for public inspection and copying and must be received by February 11, 2013.

DRAFTING INFORMATION

The principal author of this notice is Ronald J. Goldstein, formerly of the Office of Associate Chief Counsel (Procedure & Administration). For further information regarding this notice, contact Janet Engel Kidd of the Office of Associate Chief Counsel (Procedure & Administration) at (202) 622-4940 (not a toll-free call).

2012 Cumulative List of Changes in Plan Qualification Requirements

Notice 2012-76

I. PURPOSE

This notice contains the 2012 Cumulative List of Changes in Plan Qualification Requirements (2012 Cumulative List) described in section 4 of Rev. Proc. 2007-44, 2007-2 C.B. 54. The 2012 Cumulative List is to be used by plan sponsors and practitioners submitting determination letter applications for plans during the period beginning February 1, 2013 and ending January 31, 2014.

Plans using this Cumulative List will primarily be single employer individually designed defined contribution plans and single employer individually designed defined benefit plans that are in Cycle C, and § 414(d) governmental plans (including governmental multiemployer or governmental multiple employer plans) that choose to file during Cycle C. Generally an individually designed plan is in Cycle C if the last digit of the employer identification number of the plan sponsor is 3 or 8. In addition, the 2012 Cumulative List will be used by sponsors of defined benefit pre-approved plans (that is, defined benefit plans that are master and prototype (M&P) or volume submitter (VS) plans) for the second submission under the remedial amendment cycle described in Rev. Proc. 2007-44.

The list of changes in section IV of this notice does not extend the deadline by which a plan must be amended to comply with any statutory, regulatory, or guidance changes. The general deadline for timely adoption of an interim or discretionary amendment can be found in section 5.05 of Rev. Proc. 2007-44.

II. BACKGROUND

Rev. Proc. 2007-44 sets forth procedures for issuing opinion, advisory, and determination letters and describes the five-year remedial amendment cycle for individually designed plans and the six-year remedial amendment cycle for

pre-approved plans. In addition, section 5.05 of Rev. Proc. 2007-44 provides the deadline for timely adoption of an interim amendment or discretionary amendment.

Under section 4 of Rev. Proc. 2007-44, the Internal Revenue Service announced its intention to annually publish a Cumulative List to identify statutory, regulatory, and guidance changes that must be taken into account in submissions by plan sponsors to the Service requesting opinion, advisory, and determination letters whose submission period begins on February 1st following issuance of the Cumulative List.

In Notice 2011-97, 2011-52 I.R.B. 923, the Service published the 2011 Cumulative List of Changes in Plan Qualification Requirements (2011 Cumulative List).¹

Rev. Proc. 2012-50, 2012-50 I.R.B. 708, provides that the sponsor of an individually designed governmental plan may elect Cycle E (instead of Cycle C) as the plan's second remedial amendment cycle. The election is made by filing a determination letter application for the plan during the one-year submission period for the second Cycle E (February 1, 2015 through January 31, 2016).

III. APPLICATION OF 2012 CUMULATIVE LIST

This notice is being issued in conjunction with the determination letter program for individually designed plans eligible for Cycle C. In accordance with Rev. Proc. 2007-44, the Service will start accepting determination letter applications for Cycle C individually designed plans beginning on February 1, 2013. The 12-month submission period for Cycle C plans will end on January 31, 2014. In addition, the Service will start accepting opinion and advisory letter applications for defined benefit pre-approved plans beginning on February 1, 2013. The 12-month submission period for non-mass submitter sponsors and practitioners, word-for-word identical adopters, and M&P minor modifier placeholder applications will end on January 31, 2014. The 9-month submission period for mass submitters will end on October 31, 2013, as provided in section 18.02(2) of Rev. Proc. 2007-44.

The 2012 Cumulative List, set forth in section IV of this notice, informs plan sponsors of issues the Service has specifically identified for review in determining whether a plan filing in Cycle C has been properly updated. Specifically, the 2012 Cumulative List reflects law changes under the Pension Protection Act of 2006 (PPA '06), Pub. L. 109-280; the U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act, 2007, Pub. L. 110-28; the Heroes Earnings Assistance and Relief Tax Act of 2008 (HEART Act), Pub. L. 110-245; the Worker, Retiree, and Employer Recovery Act of 2008 (WRERA), Pub. L. 110-458; the Small Business Jobs Act of 2010 (SBJA), Pub. L. 111-240; the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (PRA 2010), Pub. L. No. 111-192; and the Moving Ahead for Progress in the 21st Century Act (MAP-21), Pub. L. 112-141.

Except as provided below, the Service will not consider in its review of any determination letter application for the submission period that begins February 1, 2013, any:

1. guidance issued after October 1, 2012;
2. statutes enacted after October 1, 2012;
3. qualification requirements first effective in 2014 or later; or
4. statutory provisions that are first effective in 2013, for which there is no guidance identified in this notice.

However, in order to be qualified, a plan must comply with all relevant qualification requirements, not just those on the 2012 Cumulative List.

The Service's review of a determination letter application filed in the Cycle C submission period will not consider the 2010 final hybrid plan regulations (other than with respect to § 411(a)(13)(A)) unless the plan has been amended to satisfy those regulations. For this purpose, the Service will only consider those provisions of the regulations that are effective for plan years beginning on or after January 1, 2011.

The 2012 Cumulative List includes the following guidance issued after October 1, 2012:

¹ For previous cumulative lists, see Notice 2010-90, 2010-52 I.R.B. 909; Notice 2009-98, 2009-52 I.R.B. 974; Notice 2008-108, 2008-2 C.B. 1275; Notice 2007-94, 2007-2 C.B. 1179; Notice 2007-3, 2007-1 C.B. 255; Notice 2005-101, 2005-2 C.B. 1219; and Notice 2004-84, 2004-2 C.B. 1030, for the 2010, 2009, 2008, 2007, 2006, 2005, and 2004 Cumulative Lists, respectively.

Final Regulations under section 411(d)(6) which provide an additional limited exception to the anti-cutback rules to permit a plan sponsor that is a debtor in a bankruptcy proceeding to amend its single-employer defined benefit plan to eliminate a single-sum distribution option (or other optional form of benefit providing for accelerated payments) under the plan if certain specified conditions are satisfied (77 Fed Reg. 66915).

Notice 2012-70, 2012-51 I.R.B. 712, which extends the deadline previously set forth in Notice 2011-96, 2011-52 I.R.B. 915, to amend a defined benefit plan to satisfy the requirements of § 436 and provides associated relief from the requirements of § 411(d)(6).

With respect to matters addressed by proposed regulations identified in the footnotes of section IV of this notice, the Service's review of the plan will be based on a reasonable interpretation of the statute, existing final regulations, or other published guidance. For this purpose, compliance with proposed regulations will be treated as meeting that standard. However, a determination letter cannot be relied on with respect to whether the plan complies with the proposed regulations.

Terminating plans must include all law changes in effect at the time of termination. See section 8 of Rev. Proc. 2007-44 regarding plan termination.

IV. 2012 CUMULATIVE LIST OF CHANGES IN PLAN QUALIFICATION REQUIREMENTS

The following list consists of statutory provisions and associated guidance which reflect changes to plan qualification requirements. Miscellaneous guidance is also provided. The Service has identified below plan qualification requirements that differ from those that were on the 2011 or earlier Cumulative Lists as "(New)."

Items from the 2007 Cumulative List that apply solely to defined contribution plans have been deleted from the 2012 Cumulative List. Thus, the 2012 Cumulative List contains those plan qualification requirements listed in the 2007 Cumulative List that are applicable to defined benefit pre-approved plans, the plan qualification requirements in the 2008, 2009, 2010, and 2011 Cumulative Lists, as well as additional 2012 plan qualification require-

ments. The deletions have been made to enhance the utility of the cumulative list, by removing items that would have been previously reviewed in the case of a plan that was submitted during the initial Cycle C submission period (February 1, 2008 – January 31, 2009). However, if a plan has not been previously reviewed for items on earlier cumulative lists, the items from the earlier cumulative lists must be taken into account.

1. 401(a):

- Notice 2007-69, 2007-2 C.B. 468, provides temporary relief for certain pension plans under which the definition of normal retirement age may be required to be changed to comply with the regulations, but only until the first day of the first plan year that begins after June 30, 2008. (2007 C.L.)
- Notice 2008-98, 2008-2 C.B. 1080, provides that the Service and Treasury intend to amend the normal retirement age regulations to change the effective date for governmental plans to plan years beginning on or after January 1, 2011. (2009 C. L.)
- Notice 2009-86, 2009-46 I.R.B. 629, provides that the Service and Treasury intend to amend the normal retirement age regulations to change the effective date for governmental plans to plan years beginning on or after January 1, 2013. (2010 C. L.)
- Rev. Rul. 2008-40, 2008-2 C.B. 166, provides that the transfer of amounts from a trust under a plan qualified under § 401(a) to a non-qualified foreign trust is treated as a distribution from the transferor plan and that transfer of assets and liabilities from a qualified plan to a plan that satisfies § 1165 of the Puerto Rico Code is also treated as a distribution from the transferor plan. (2008 C. L.)
- Rev. Rul. 2008-45, 2008-2 C.B. 403, provides that the exclusive benefit rule of § 401(a) is violated if the sponsorship of a qualified retirement plan is transferred from an employer to an unrelated taxpayer and the transfer is not

in connection with a transfer of business assets or operations from the employer to the unrelated taxpayer. (2008 C. L.)

- Rev. Rul. 2011-1, 2011-2 I.R.B. 251, revises the generally applicable rules for group trusts and, if certain requirements are met, permits the participation in group trusts of custodial accounts under § 403(b)(7), retirement income accounts under § 403(b)(9), and governmental retiree benefit plans under § 401(a)(24). This revenue ruling also modifies the transition relief provided in Rev. Rul. 2008-40. (2011 C. L.)
- Notice 2012-6, 2012-3 I.R.B. 293, extends and expands the transition relief provided under Rev. Rul. 2011-1 for certain group trusts, certain retirement trusts that qualify under the Puerto Rico Internal Revenue Code that participate in group trusts, and certain qualified retirement plans that benefit Puerto Rico residents. The notice also provides additional time for governmental retiree benefit plans described in § 401(a)(24) to be amended to satisfy the applicable requirements of Rev. Rul. 2011-1. (New)
- Notice 2012-29, 2012-18 I.R.B. 872, provides that the Service and Treasury intend to modify the normal retirement age regulations to clarify that governmental plans that do not provide for in-service distributions before age 62 do not need to have a definition of normal retirement age and to modify the age-50 safe harbor rule for qualified public safety employees. The notice also provides that the Service and Treasury intend to amend the normal retirement age regulations to extend the effective date for governmental plans to annuity starting dates that occur in plan years beginning on or after the later of (1) January 1, 2015 or (2) the close of the first regular legislative session of the legislative body with the authority to amend the plan that begins on or after the date that is 3 months after

- the final regulations are published in the **Federal Register**. (New)
2. *401(a)(5)*: PPA '06 § 861(a)(1) amended § 401(a)(5)(G) with respect to governmental plans. (2008 C. L.)
 3. *401(a)(9)*:
 - Pursuant to PPA '06 § 823, final regulations under § 401(a)(9) were published on September 8, 2009 (74 Fed. Reg. 45993), which permit a governmental plan to comply with the required minimum distribution rules of § 401(a)(9) by using a reasonable and good faith interpretation of the statute. (2009 C. L.)
 - Section 201(a) of WRERA added § 401(a)(9)(H) which provides a suspension of the required minimum distribution rules for 2009 applicable to defined contribution plans. (2010 C. L.)
 - Notice 2009–82, 2009–41 I.R.B. 491, provides guidance relating to the suspension of the required minimum distribution rules for 2009 applicable to defined contribution plans. (2010 C. L.)
 4. *401(a)(22)*:
 - Notice 2011–19, 2011–11 I.R.B. 550, provides that the terms readily tradable on an established securities market and readily tradable on an established market mean employer securities that are readily tradable on an established securities market within the meaning of § 1.401(a)(35)–1(f)(5) for purposes of § 401(a)(22). Notice 2011–19 is effective for plan years that begin on or after January 1, 2012, except for certain plans that have a delayed effective date. (2011 C. L.)
 5. *401(a)(26)*: PPA '06 § 861(a)(1) amended § 401(a)(26)(G) with respect to governmental plans. (2008 C. L.)
 6. *401(a)(28)(C)*:
 - Notice 2011–19, 2011–11 I.R.B. 550, provides that the terms readily tradable on an established securities market and readily tradable on an established market mean employer securities that are readily tradable on an established securities market within the meaning of § 1.401(a)(35)–1(f)(5) for purposes of § 401(a)(28)(C). Notice 2011–19 is effective for plan years that begin on or after January 1, 2012, except for certain plans that have a delayed effective date. (2011 C. L.)
 7. *401(a)(35)*: PPA '06 § 901(a)(1) added § 401(a)(35) requiring that defined contribution plans provide employees with the freedom to divest publicly traded employer securities. (2008 C. L.)
 - Notice 2006–107, 2006–2 C.B. 1114. (2008 C. L.)
 - Notice 2008–7, 2008–1 C.B. 276, extends certain transitional guidance and transitional relief provided to certain defined contribution plans holding publicly traded employer securities under Notice 2006–107. (2008 C. L.)
 - WRERA § 109(a) amended the definition of one-participant retirement plan under § 401(a)(35)(E)(iv). (2009 C. L.)
 - Notice 2009–97, 2009–52 I.R.B. 972, extends the deadline to amend for § 401(a)(35) to the last day of the first plan year that begins on or after January 1, 2010. (2010 C. L.)
 - Final regulations under § 401(a)(35) were published on May 19, 2010 (75 Fed. Reg. 27927). (2010 C. L.)
 8. *401(a)(36)*: PPA '06 § 905(b) added § 401(a)(36) regarding distributions to a participant who has attained age 62 and who has not separated from employment at the time of the distribution. (2008 C. L.)
 9. *401(a)(37)*: HEART Act § 104(a) added § 401(a)(37) with respect to benefits payable on the death of a plan participant while performing qualified military service. (2010 C. L.)
 - Notice 2010–15, 2010–6 I.R.B. 390, provides guidance regarding HEART Act § 104(a). (2010 C. L.)
 10. *401(k) & 401(m)*²
 - PPA '06 § 826 modified the rules relating to distributions from a § 401(k) plan on account of a participant's hardship to permit the plan to treat a participant's beneficiary under the plan the same as the participant's spouse or dependent. (2008 C. L.)
 - Notice 2007–7, 2007–1 C.B. 395, provides guidance regarding PPA '06 § 826. (2008 C. L.)
 - Announcement 2007–59, 2007–1 C.B. 1448, provides that a plan will not fail to satisfy the requirements of a § 401(k) safe harbor plan because of a mid-year change to implement the PPA '06 § 826 hardship withdrawals. (2008 C. L.)
 - PPA '06 § 827 added § 401(k)(2)(B)(i)(V) which permits reservists called to active duty after September 11, 2001 and before 2008 to take in-service distributions from a § 401(k) plan. (2008 C. L.)
 - Section 107(a) of the HEART Act extends the applicability of the qualified reservist distribution to individuals ordered or called to active duty after December 31, 2007. (2009 C. L.)
 - Notice 2010–15, 2010–6 I.R.B. 390, provides guidance regarding HEART Act § 107. (2010 C. L.)
 - PPA '06 § 861(a)(2) amended § 401(k)(3)(G) with respect to governmental plans. (2008 C. L.)
 - PPA '06 § 902(e)(3) eliminated the gap period income rule for excess contributions in § 401(k)(8)(A)(i). (2008 C. L.)

² Proposed amendments to the regulations under § 401(k) and § 401(m) were published on May 18, 2009 (74 Fed. Reg. 23134) and may be relied upon until final regulations are issued.

- PPA '06 § 902 added § 401(k)(13) with respect to qualified automatic contribution arrangements. (2008 C. L.)
 - Final regulations under § 401(k) with respect to qualified automatic contribution arrangements were published on February 24, 2009 (74 Fed. Reg. 8200). (2009 C. L.)
 - Rev. Rul. 2009–30, 2009–39 I.R.B. 391, provides information with respect to automatic contribution increases under automatic contribution arrangements. (2009 C. L.)
 - Notice 2009–65, 2009–39 I.R.B. 413, provides sample amendments that plan sponsors can use to add automatic contribution features to their plans. (2009 C. L.)
 - PPA '06 § 902(e)(3) eliminated the gap period income rule for excess aggregate contributions in § 401(m)(6)(A). (2008 C. L.)
 - PPA '06 § 902 added § 401(m)(12) with respect to qualified automatic contribution arrangements. (2008 C. L.)
 - Final regulations under § 401(m) with respect to qualified automatic contribution arrangements were published on February 24, 2009 (74 Fed. Reg. 8200). (2009 C. L.)
11. *402(c)(2)(A)*: PPA '06 § 822(a) amended § 402(c)(2)(A) to permit nontaxable distributions from a qualified plan to be directly rolled over tax-free to either another qualified plan or a § 403(b) plan if the separate accounting requirements are met. (2008 C. L.)
12. *402(c)(11)*: PPA '06 § 829(a)(1) added § 402(c)(11) to allow non-spouse beneficiaries to directly roll over distributions from a qualified plan to an individual retirement plan. (2008 C. L.)
- Notice 2007–7, 2007–1 C.B. 395, provides guidance regarding § 402(c)(11). (2008 C. L.)
 - WRERA § 108(f) requires that plans provide for non-spouse beneficiary rollovers under § 402(c)(11), effective for plan years beginning after December 31, 2009. (2009 C. L.)
13. *402(f)*: PPA '06 § 1102(a) provides that notice required to be provided under § 402(f) may be provided as much as 180 days before the annuity starting date.³ (2008 C. L.)
- Notice 2007–7, 2007–1 C.B. 395, provides guidance regarding PPA '06 § 1102. (2008 C. L.)
 - Notice 2009–68, 2009–39 I.R.B. 423, provides two safe harbor explanations that may be provided to recipients of eligible rollover distributions from an employer to satisfy § 402(f). (2009 C. L.)
 - WRERA § 108(f)(2) amended § 402(f)(2)(A) with respect to the definition of eligible rollover distribution. (2009 C. L.)
14. *402(g)(2)*: WRERA § 109(b)(3) amended § 402(g)(2)(A)(ii) to eliminate the distribution of gap period earnings with excess deferrals. (2009 C. L.)
15. *402A*: SBJA § 2112 added § 402A(c)(4) which permits rollovers from a plan account other than a designated Roth account to the plan's designated Roth account. (2010 C. L.)
- Notice 2010–84, 2010–51 I.R.B. 872, provides guidance regarding § 402A(c)(4). (2010 C. L.)
16. *408A(e)*: PPA '06 § 824 added § 408A(e) which permits rollovers to Roth IRAs from accounts that are not designated Roth accounts that are part of qualified plans, § 403(b) plans, and § 457 plans. (2008 C. L.)
- Notice 2008–30, 2008–1 C.B. 638, provides guidance regarding § 408A(e). (2008 C. L.)
17. *409*:
- Notice 2011–19, 2011–11 I.R.B. 550, provides that the terms readily tradable on an established securities market and readily tradable on an established market mean employer securities that are readily tradable on an established securities market within the meaning of § 1.401(a)(35)–1(f)(5) for purposes of § 409(h)(1)(B) and § 409(l). Notice 2011–19 is effective for plan years that begin on or after January 1, 2012, except for certain plans that have a delayed effective date. (2011 C. L.)
18. *411(a)*: PPA '06 § 904 amended § 411(a) to provide for faster vesting of employer nonelective contributions. (2008 C. L.)
- Notice 2007–7, 2007–1 C.B. 395, provides guidance regarding § 411(a), as amended by § 904 of PPA '06. (2008 C. L.)
 - Rev. Rul. 2012–4, 2012–8 I.R.B. 386, describes whether a qualified defined benefit pension plan that accepts a direct rollover of an eligible rollover distribution from a qualified defined contribution plan maintained by the same employer satisfies §§ 411 and 415 in a case in which the defined benefit plan provides an annuity resulting from the direct rollover. (New).
19. *411(a)(11)*: PPA '06 § 1102(a) provides that notice required to be provided under § 411(a)(11) may be provided as much as 180 days before the annuity starting date. Section 1102(b) of PPA '06 requires that the notice under § 411(a)(11) also include a description of the consequences of failing to defer receipt of a distribution.⁴ (2008 C. L.)
- Notice 2007–7, 2007–1 C.B. 395, provides guidance regarding PPA '06 § 1102. (2008 C. L.)
20. *411(a)(13)*: PPA '06 § 701(b)(2) added § 411(a)(13) with respect to

³ Proposed regulations under § 402(f) were published on October 9, 2008 (73 Fed. Reg. 59575) and may be relied upon until final regulations are issued.

⁴ Proposed regulations under § 411(a)(11) were published on October 9, 2008 (73 Fed. Reg. 59575). Until final regulations are issued, a plan will be treated as complying with § 411(a)(11) if (1) the plan complies with either the proposed regulations or Q&A–32 and Q&A–33 in Notice 2007–7 or (2) the plan administrator makes a reasonable attempt to comply with § 411(a)(11).

special vesting rules for applicable defined benefit plans, such as cash balance plans. (2008 C. L.)

- Notice 2007–6, 2007–1 C.B. 272, provides guidance regarding cash balance plans and other hybrid defined benefit plans. (2008 C. L.)
- WRERA § 107(b)(2) amended § 411(a)(13)(A). (2009 C. L.)
- Notice 2009–97, 2009–52 I.R.B. 972, extends the deadline for amending cash balance and other applicable defined benefit plans, within the meaning of § 411(a)(13)(C), to meet the requirements of § 411(a)(13) (other than § 411(a)(13)(A)) to the last day of the first plan year that begins on or after January 1, 2010. (2010 C. L.)
- Final Regulations under § 411(a)(13) were published on October 19, 2010 (75 Fed. Reg. 64123).⁵ (2010 C. L.)
- Notice 2010–77, 2010–51 I.R.B. 851, extends the deadline for amending cash balance and other applicable defined benefit plans, within the meaning of § 411(a)(13)(C), to meet the requirements of § 411(a)(13) (other than § 411(a)(13)(A)) to the last day of the first plan year that begins on or after January 1, 2011. (2010 C. L.)
- Notice 2011–85, 2011–44 I.R.B. 605, extends the deadline for adopting an interim or discretionary amendment under § 411(a)(13) (other than § 411(a)(13)(A)). (2011 C. L.)
- Notice 2012–61, 2012–42 I.R.B. 479, provides that certain provisions in the 2010 final hybrid plan regulations will not be effective for plan years beginning before January 1, 2014. (New)

21. *411(b)(1)*:⁶

- Rev. Rul. 2008–7, 2008–1 C.B. 419, addresses (1) the application

of the backloading provisions of § 411(b)(1)(A), (B), and (C) to defined benefit cash balance plans and (2) the use of a “greater of” formula in the instance of a conversion of a defined benefit pension plan to a cash balance plan, including limited § 7805(b) relief. (2008 C. L.)

22. *411(b)(5)*: PPA '06 § 701(b)(1) added § 411(b)(5) with respect to applicable defined benefit plans, such as cash balance plans, and special rules relating to age. (2008 C. L.)

- Notice 2007–6, 2007–1 C.B. 272, provides guidance regarding cash balance plans and other hybrid defined benefit plans. (2008 C. L.)
- WRERA § 107(b)(1) amended § 411(b)(5). (2009 C. L.)
- Notice 2009–97, 2009–52 I.R.B. 972, extends the deadline for amending cash balance and other applicable defined benefit plans, within the meaning of § 411(a)(13)(C), to meet the requirements of § 411(b)(5) to the last day of the first plan year that begins on or after January 1, 2010. (2010 C. L.)
- Final Regulations under § 411(b)(5) were published on October 19, 2010 (75 Fed. Reg. 64123).⁷ (2010 C. L.)
- Notice 2010–77, 2010–51 I.R.B. 851, extends the deadline for amending cash balance and other applicable defined benefit plans, within the meaning of § 411(a)(13)(C), to meet the requirements of § 411(b)(5) to the last day of the first plan year that begins on or after January 1, 2011. (2010 C. L.)
- Notice 2011–85, 2011–44 I.R.B. 605, announces that the Treasury Department and the Service intend to amend the 2010 final hybrid plan regulations to postpone the effective/applicability date of § 1.411(b)(5)–1(d)(1)(iii),

(d)(1)(vi), and (d)(6)(i) to plan years that begin on or after a date to be specified in those regulations that is not earlier than January 1, 2013. This notice also extends the deadline for adopting an interim or discretionary amendment under § 411(b)(5). (2011 C. L.)

- Notice 2012–61, 2012–42 I.R.B. 479, provides that certain provisions in the 2010 final hybrid plan regulations will not be effective for plan years beginning before January 1, 2014. (New)

23. *411(d)(6)*:

- Final Regulations under § 411(d)(6), which provide an additional limited exception to the anti-cutback rules to a plan sponsor who is a debtor in a bankruptcy proceeding, were published on November 8, 2012 (77 Fed Reg. 66915). (New)

24. *414(d)*: PPA '06 § 906(a)(1) added language to the definition of governmental plan in § 414(d) with respect to Indian tribal governments. (2008 C. L.)

- Notice 2007–67, 2007–2 C.B. 467, extends the transition relief for plans subject to PPA '06 § 906 that was originally provided in Notice 2006–89, 2006–2 C.B. 772. (2008 C. L.)

25. *414(f)(6)*: PPA '06 § 1106(b) added § 414(f)(6) with respect to a multiemployer status election. Section 6611(a)(2) and (b)(2) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 amends § 414(f)(6). (2008 C. L.)

26. *414(u)*:

- HEART Act § 104(b) amended § 414(u) by adding § 414(u)(9) regarding how a plan may provide benefit accruals for a person who dies or becomes disabled while

⁵ Proposed regulations under § 411(a)(13) were published on October 19, 2010 (75 Fed. Reg. 64197) and may be relied upon until final regulations are issued.

⁶ Proposed regulations under § 411(b)(1) were published on October 19, 2010 (75 Fed. Reg. 64197) with respect to a variable interest crediting rate that potentially can be negative in any given year. Proposed regulations under § 411(b)(1) were published on June 18, 2008 (73 Fed. Reg. 34665) with respect to the application of the accrual rule where plan benefits are determined on the basis of the greater of two or more separate formulas.

⁷ Proposed regulations under § 411(b)(5) also were published on October 19, 2010 (75 Fed. Reg. 64197) and may be relied upon until final regulations are issued.

performing qualified military service. (2010 C. L.)

- Notice 2010–15, 2010–6 I.R.B. 390, provides guidance regarding HEART Act § 104(b). (2010 C. L.)
- Section 105(b)(1) of the HEART Act added § 414(u)(12) with respect to the treatment of differential wage payments during the period a person, while on active duty, is performing service in the uniformed services. (2010 C. L.)
- Notice 2010–15, 2010–6 I.R.B. 390, provides guidance regarding HEART Act § 105(b)(1). (2010 C. L.)

27. *414(w)*: PPA '06 § 902(d)(1) added § 414(w) with respect to eligible automatic contribution arrangements. (2008 C. L.)

- WRERA § 109(b)(4), (5), and (6) amended § 414(w)(3), (5), and (6), respectively. (2009 C. L.)
- Final regulations under § 414(w) with respect to eligible automatic contribution arrangements were published on February 24, 2009 (74 Fed. Reg. 8200). (2009 C. L.)
- Rev. Rul. 2009–30, 2009–39 I.R.B. 391, provides information with respect to automatic contribution increases under automatic contribution arrangements. (2009 C. L.)
- Notice 2009–65, 2009–39 I.R.B. 413, provides sample amendments that plan sponsors can use to add automatic contribution features to their plans. (2009 C. L.)

28. *414(x)*: PPA '06 § 903(a) added § 414(x) with respect to special rules for eligible combined plans that consist of a defined benefit plan and a qualified cash or deferred arrangement. (2010 C. L.)

29. *415*:

- WRERA § 103(a) changed the deadline to adopt PFEA amendments from the end of the 2008 plan year to the end of the 2009 plan year. (2009 C. L.)

- PPA '06 § 303 amended § 415(b)(2)(E)(ii) regarding the interest rate assumption for applying benefit limitations to lump sum distributions. (2008 C. L.)
- PPA '06 § 832(a) amended § 415(b)(3) to eliminate the active participant restriction from the “average compensation for high 3 years” definition. (2008 C. L.)
- PPA '06 § 906(b)(1)(A) and (B) modified §§ 415(b)(2)(H) and 415(b)(10), respectively, regarding Indian tribal governments. (2008 C. L.)
- PPA '06 § 867(a) amended § 415(b)(11) to remove the 100% of compensation limitation for a church plan participant if the participant has never been a highly compensated employee of the church. (2008 C. L.)
- WRERA § 103(b)(2)(B)(i) amended § 415(b)(2)(E)(v) to change the mortality table to the applicable mortality table within the meaning of § 417(e)(3)(B). (2009 C. L.)
- Rev. Rul. 2012–4, 2012–8 I.R.B. 386, describes whether a qualified defined benefit pension plan that accepts a direct rollover of an eligible rollover distribution from a qualified defined contribution plan maintained by the same employer satisfies §§ 411 and 415 in a case in which the defined benefit plan provides an annuity resulting from the direct rollover. (New)

30. *416*:

- PPA '06 § 902(c) amended § 416(g)(4)(H) to include a plan that consists solely of a cash or deferred arrangement described in § 401(k)(13) and matching contributions with respect to which the requirements of § 401(m)(12) are met in the list of plans that are not top heavy. (2008 C. L.)

31. *417*:

- PPA '06 § 1102(a) provides that notice required to be provided under § 417 may be provided as

much as 180 days before the annuity starting date.⁸ (2008 C. L.)

- Notice 2007–7, 2007–1 C.B. 395, provides guidance regarding PPA '06 § 1102. (2008 C. L.)
- PPA '06 § 302(b) amended the applicable interest rate and mortality table to be used for determining the present value of lump sum distributions in § 417(e)(3). (2008 C. L.)
- Rev. Rul. 2007–67, 2007–2 C.B. 1047, addresses the mortality tables required by § 417(e)(3). (2008 C. L.)
- Notice 2008–30, 2008–1 C.B. 638, provides guidance regarding PPA '06 § 302. (2008 C. L.)
- WRERA § 103(b)(2)(A) amended § 417(e)(3)(D)(i) by striking “clause (ii)” and inserting “subparagraph (C)”. (2009 C. L.)
- PPA '06 § 1004(a) added the qualified optional survivor annuity benefit to § 417. (2008 C. L.)
- Notice 2008–30, 2008–1 C.B. 638, provides guidance regarding PPA '06 § 1004. (2008 C. L.)
- Rev. Rul. 2012–3, 2012–6 I.R.B. 383, describes how the qualified joint and survivor annuity (“QJSA”) and the qualified preretirement survivor annuity (“QPSA”) rules, described in §§ 401(a)(11) and 417, apply when a deferred annuity contract is purchased under a profit sharing plan. (New)

32. *420*:

- Section 6613 of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq, Accountability Appropriations Act, 2007, amends § 420(c)(3)(A) regarding minimum cost requirements for transfers of excess pension assets to retiree health accounts. (2007 C.L.)
- PPA '06 § 114(d)(1) modified the definition of the term “excess pension assets” in § 420(e)(2).

⁸ Proposed regulations under § 417 were published on October 9, 2008 (73 Fed. Reg. 59575) and may be relied upon until final regulations are issued.

Section 6612(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, amends § 420(e)(2)(B). (2007 C.L.)

- Sections 40241 and 40242 of MAP-21 amend § 420 to extend the provisions relating to transfers of excess pension assets to retiree health accounts and to expand those provisions to allow transfers to retiree group term life insurance accounts. (New)

33. 431(b)(8):

- PRA 2010 § 211(a)(2) added § 431(b)(8), which provides two special funding rules available to multiemployer plans. (2011 C.L.)
 - Notice 2010-83, 2010-51 I.R.B. 862, provides guidance with respect to the special funding rules under § 431(b)(8). (2011 C.L.)

34. 432: PPA '06 § 212(a) added § 432 which requires that a funding improvement plan or a rehabilitation plan be adopted for multiemployer plans in endangered or critical status and provides for certain benefit reductions.⁹ (2008 C. L.)

- WRERA § 204 provides a temporary delay of designation of multiemployer plans in endangered or critical status. (2009 C. L.)
 - Notice 2009-31, 2009-16 I.R.B. 856, as modified by Notice 2009-42, 2009-20 I.R.B. 1011, provides election and notice procedures for multiemployer plans under WRERA § 204. (2009 C. L.)
 - Rev. Proc. 2009-43, 2009-40 I.R.B. 460, provides procedures with respect to the revocation of elections by multiemployer plans to freeze funded status under WRERA § 204. (2009 C. L.)
- WRERA § 205 provides a temporary extension of the funding improvement or rehabilitation peri-

ods for multiemployer plans in endangered or critical status for 2008 or 2009. (2009 C. L.)

- Notice 2009-31, 2009-16 I.R.B. 856, as modified by Notice 2009-42, 2009-20 I.R.B. 1011, provides election and notice procedures for multiemployer plans under WRERA § 205. (2009 C. L.)

35. 436:

- §1.436-1 provides guidance on the application of § 436, which provides a series of limitations on the accrual and payment of benefits under underfunded single employer defined benefit plans. (New)
- Notice 2011-3, 2011-2 I.R.B. 263, provides guidance on the special rules relating to the relaxation of § 436 rules that were included in the funding relief for single employer defined benefit pension plans under PRA 2010. (New)
- Notice 2011-96, 2011-52 I.R.B. 915, provides a sample plan amendment that plan sponsors may adopt to satisfy § 436 regarding limitations on the accrual and payment of benefits. The notice also extends both the deadline to amend a plan to satisfy § 436 and the period during which such an amendment is eligible for relief from the anti-cutback requirements of § 411(d)(6). (New)
- Notice 2012-70, 2012-51 I.R.B. 712. This notice extends the deadline, as set forth in Notice 2011-96, 2011-52 I.R.B. 915, to amend a defined benefit plan to satisfy the requirements of § 436 and provides associated relief from the requirements of § 411(d)(6). (New)

36. *Miscellaneous:*

- Notice 2008-21, 2008-1 C.B. 431, provides transitional guidance for 2008 under § 436 for small plans with end-of-year valuation dates. (2008 C. L.)

- Notice 2008-73, 2008-2 C.B. 717, expands transition relief of Notice 2008-21. (2008 C. L.)
- Rev. Rul. 2009-31, 2009-39 I.R.B. 395, provides guidance with respect to annual paid time off contributions. (2009 C. L.)
- Rev. Rul. 2009-32, 2009-39 I.R.B. 398, provides guidance with respect to paid time off contributions at termination of employment. (2009 C. L.)

The following guidance contains sample or model amendments: Notice 2009-65, 2009-39 I.R.B. 413 (automatic contribution features); Notice 2009-82, 2009-41 I.R.B. 491 (suspension of the minimum distribution requirement for 2009); Rev. Rul. 2011-1, 2011-2 I.R.B. 251 (group trusts); and Notice 2011-96, 2011-52 I.R.B. 915 (limitations on the accrual and payment of benefits under underfunded single employer defined benefit plans).

DRAFTING INFORMATION

The principal author of this notice is Kathleen Herrmann of the Employee Plans, Tax Exempt and Government Entities Division. For further information regarding this notice, please contact the Employee Plans taxpayer assistance answering service at 1-877-829-5500 (a toll-free number) or e-mail Ms. Herrmann at RetirementPlanQuestions@irs.gov.

Interim Guidance and Request for Comments; Medical Device Excise Tax; Manufacturers Excise Taxes; Constructive Sale Price; Deposit Penalties

Notice 2012-77

Section 1. PURPOSE

This notice provides interim guidance relating to the excise tax on medical devices imposed by § 4191 (the "medical device excise tax") of the Internal Revenue Code (the "Code"). Specifically, this notice provides interim guidance for determining price under § 4216(b). This no-

⁹ Proposed regulations under § 432 were published on March 18, 2008 (73 Fed. Reg. 14417) and may be relied upon until final regulations are issued.

tice also provides interim guidance relating to donated taxable medical devices, the licensing of taxable medical devices, and the tax treatment of medical convenience kits. In addition, this notice provides transition relief to medical device manufacturers from the failure to deposit penalties imposed by § 6656. Finally, this notice requests comments from taxpayers about the rules described in this notice.

Section 2. BACKGROUND

Section 4191, enacted by section 1405 of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)), in conjunction with the Patient Protection and Affordable Care Act, Public Law 111–148 (124 Stat. 119 (2010)), imposes an excise tax on the sale of certain medical devices. The excise tax imposed by § 4191 is 2.3% of the price for which the taxable medical device is sold. The medical device excise tax is codified in chapter 32, subtitle D of the Code (“chapter 32”), which pertains to excise taxes imposed on the sale or use of taxable articles by manufacturers, producers, and importers (commonly referred to as “manufacturers excise taxes”). See § 48.0–2(a)(4)(i) of the Manufacturers and Retailers Excise Tax Regulations (the “regulations”) (which defines the term “manufacturer” to include a “producer” and an “importer”). As a result, the existing chapter 32 rules, including the regulations issued thereunder, apply to the medical device excise tax.

On December 7, 2012, the Internal Revenue Service (IRS) and the Treasury Department issued T.D. 9604, 2012–52 I.R.B. 730 (77 FR 72924), containing final regulations under § 4191. The final regulations do not address certain issues that the IRS and the Treasury Department continue to study. These issues include the determination of price under § 4216(b); the tax treatment of medical software licenses; the taxability of donated medical devices; and the taxability of medical convenience kits.

The IRS and the Treasury Department may issue additional published guidance on these issues in the future. The IRS and the Treasury Department recognize, however, that manufacturers need rules on these issues that will apply on an interim basis. Sections 3 through 5 of this notice prescribe those interim rules.

In addition, several comments on the proposed regulations requested transition relief from the deposit penalty under § 6656. In response to those comments, this notice waives penalties under § 6656 for the first three calendar quarters of 2013. Section 6 of this notice delineates the scope of this deposit penalty relief.

Unless otherwise stated, existing definitions provided in chapter 32, and the regulations issued thereunder, apply to this notice.

Section 3. CONSTRUCTIVE SALE PRICE

(a) *Overview of Constructive Sale Price.* Section 4216 provides rules for determining “price” for purposes of chapter 32. Those rules treat the price for which a manufacturer sells a taxable article to an independent wholesale distributor, subject to certain adjustments, as the applicable price for purposes of imposing the tax. In general, when a manufacturer sells a taxable article to a purchaser other than an independent wholesale distributor, § 4216(b) and the regulations thereunder prescribe rules for constructing a sale price that approximates the price an independent wholesale distributor would pay to the manufacturer for an identical article. In such situations, tax is imposed on the constructive sale price as determined under § 4216(b).

The IRS and the Treasury Department recognize that the medical device industry encompasses a diverse group of manufacturers that produce a broad range of articles. The IRS and the Treasury Department also recognize that many manufacturers in the medical device industry do not sell to independent wholesale distributors, and they may employ more than one distribution chain according to industry practice related to a particular article. Further, the IRS and the Treasury Department recognize that current published guidance relating to the constructive sale price rules does not address some of the types of distribution chains regularly employed in the medical device industry. In addition, Rev. Rul. 80–273, 1980–2 C.B. 315, which provides a mechanism for computing the constructive sale price where the articles are sold at retail by manufacturers who do not sell like articles to wholesale distributors, does not by its terms apply to § 4191.

(b) *Interim Rules.* This section provides interim rules for how taxpayers may apply the constructive sale price rules to certain model distribution chains employed by some manufacturers in the medical device industry. The IRS and the Treasury Department identified the distribution chains addressed in these interim rules through written comments on the proposed regulations on taxable medical devices and informal taxpayer inquiries.

If a taxpayer uses one of the distribution chains described in this section, the taxpayer may apply the rules provided in this section to determine its medical device excise tax liability. A taxpayer does not need to make any additional or special filing, or notation on any filing, to apply these rules. If a taxpayer does not apply the rules provided in this notice, and does not use the actual sale price of the article to calculate its medical device excise tax liability, then the taxpayer bears the burden of demonstrating that it used the fair market price of the article to calculate its tax liability. This approach is consistent with the general rule under which a manufacturer may rebut the constructive sale price if the manufacturer demonstrates that it sold the article at a fair market price. Rev. Rul. 89–47, 1989–1 C.B. 295. Taxpayers may apply the rules provided in this section until the IRS and the Treasury Department issue further guidance.

For purposes of these rules, a “related party” means that one of the parties is controlled (in law or fact) by the other, or there is common control of the parties (regardless of whether such control is actually exercised to influence the sale price). See § 48.4216(b)–2(e)(1). Further, for purposes of these rules, a “reseller” means a sales company, a leasing company, a distributor, or a retailer. Finally, the application of constructive sale price rules to calculate the tax base does not shift the liability for excise tax from the manufacturer to any other person.

The interim rules are as follows:

(1) *Sales at retail; no regular sales to independent wholesale distributors.*

(A) *Description.* In this distribution chain, the manufacturer sells taxable articles directly to unrelated end-users. The manufacturer does not regularly sell its taxable articles to independent wholesale distributors.

(B) *Interim Rule.* Until the IRS and the Treasury Department issue further guidance, the constructive sale price for this distribution chain, determined pursuant to § 4216(b)(1)(A), is 75% of the actual selling price after taking into account the adjustments provided by § 4216(a). No further adjustments under § 4216 are allowed. See Rev. Rul. 80-273, 1980-2 C.B. 315.

(2) *Sales to unrelated retailers; no regular sales to independent wholesale distributors.*

(A) *Description.* In this distribution chain, the manufacturer sells taxable articles to unrelated retailers. The manufacturer does not regularly sell its taxable articles to independent wholesale distributors.

(B) *Interim Rule.* Until the IRS and the Treasury Department issue further guidance, the constructive sale price for this distribution chain is 90% of the lowest price for which the articles are sold to unrelated retailers. This computation is made without adjustment for any exclusion (except for the tax imposed on such article) or readjustment under § 4216(a) and (e) and § 6416(b)(1). See Rev. Rul. 82-211, 1982-2 C.B. 296.

(3) *Sales to related retailer; no regular sales to independent wholesale distributors.*

(A) *Description.* In this distribution chain, the manufacturer sells taxable articles to a related retailer. The related retailer sells the articles at retail to unrelated end-users. The manufacturer and related retailer do not regularly sell the articles to independent wholesale distributors.

(B) *Interim Rule.* Until the IRS and the Treasury Department issue further guidance, the constructive sale price for this distribution chain, determined pursuant to § 4216(b)(1)(C), is 75% of the product of 95% and the actual selling price (that is, the price at which the article is sold to a person that is not a member of the group of companies that are related to the manufacturer). The 5% discount is an allowance for the exclusions from the selling price otherwise allowed under § 4216(a). See Rev. Rul. 82-211. The additional 25% discount adjusts the selling price to approximate the selling price to an independent wholesale distributor. See Rev. Rul. 80-273. No further adjustments under § 4216 are allowed.

(4) *Sales to related reseller that leases and sells at retail.*

(A) *Description.* In this distribution chain, the manufacturer sells taxable articles to a related reseller. The related reseller sells the articles at retail to unrelated end-users, and also leases articles to unrelated end-users.

(B) *Interim Rule.* Until the IRS and the Treasury Department issue further guidance, the constructive sale price for this distribution chain, determined pursuant to § 4216(b)(1)(C), is 75% of the product of 95% and the actual selling price (that is, the price at which the article is sold to a person that is not a member of the group of companies that are related to the manufacturer). The 5% discount is an allowance for the exclusions from the selling price otherwise allowed under § 4216(a). See Rev. Rul. 82-211. The additional 25% discount adjusts the selling price to approximate the selling price to an independent wholesale distributor. See Rev. Rul. 80-273. No further adjustments under § 4216 are allowed.

(5) *Sales to related reseller that only leases at retail; no regular sales to independent wholesale distributors.*

(A) *Description.* In this distribution chain, the manufacturer sells taxable articles to a related reseller. The related reseller leases the articles to unrelated end-users, but does not sell articles at retail. The manufacturer and related reseller do not regularly sell the articles to independent wholesale distributors.

(B) *Interim Rule.* Until the IRS and the Treasury Department issue further guidance, the price for this distribution chain is the actual selling price to the related reseller, provided that the selling price to the related reseller reasonably approximates the fair market price of the article within the meaning of § 4216.

(c) *Applicability to other taxes imposed by chapter 32 of the Code.* Until the IRS and the Treasury Department issue further guidance, all manufacturers subject to the taxes imposed by chapter 32 of the Code may apply the rules provided in this section to determine the constructive sale price of taxable articles under chapter 32 to the extent that any statute or other published guidance do not already provide rules addressing a particular fact pattern or situation.

Section 4: SPECIAL CHAPTER 32 RULES APPLICABLE TO THE MEDICAL DEVICE EXCISE TAX

(a) *Sale to Hospital or Doctor's Office Treated as Sale at Retail for Purposes of Determining Price*

(1) *Overview.* Section 48.4216(b)-1(c)(1) of the regulations defines "sale at retail" as the sale of an article to a purchaser who intends to use the article, or to lease it to another person, rather than resell it. Section 48.4216(b)-1(c)(2) defines "retailer" as a person engaged in the business of selling articles at retail. Therefore, a sale to a retailer is a sale of an article to a person engaged in the business of selling articles at retail. Medical institutions and offices, such as hospitals and doctor's offices, purchase taxable articles that are used to treat patients. Sometimes an article is completely consumed on the premises of a medical institution or office and other times the articles leave the medical institution or office with the patient. Under the definitions described above, it is unclear whether a sale of an article to a medical institution or office is a sale at retail or a sale to a retailer.

(2) *Interim Rule.* Until the IRS and the Treasury Department issue further guidance, the IRS will treat the sale of a taxable article to a medical institution or office as a "sale at retail."

(b) *Licenses*

(1) *Overview.* In response to the proposed regulations, one commenter requested clarification on whether the licensing of software that is a taxable medical device is a taxable event for purposes of § 4191. That commenter requested that the IRS and the Treasury department treat the licensing of software as a lease.

Under existing chapter 32 rules, the manufacturers excise tax generally attaches upon the sale or use of a taxable article by the manufacturer. See § 48.0-2(b). Section 4217(a) provides that the lease of a taxable article by the manufacturer is considered a sale. Neither the existing chapter 32 rules nor the final regulations address the issue of whether the licensing of a taxable article, such as software that is a taxable medical device, is a taxable event.

(2) *Interim Rule.* Until the IRS and the Treasury Department issue further

guidance, the IRS will treat a license of a taxable medical device as a lease of that taxable medical device as of the date both parties entered into the license agreement. Accordingly, the rules under §§ 4216(c) and 4217, and §§ 48.4216(c)-1(a), 48.4216(c)-1(e), 48.4217-1, and 48.4217-2 apply.

(c) *Excise Tax Treatment of Donations of Taxable Medical Devices to Organizations Described in § 170(c)*

(1) *Overview.* The existing chapter 32 rules do not specifically address whether a donation of a taxable article constitutes a taxable use under § 4218. The IRS and the Treasury Department will continue to study this issue.

(2) *Interim Rules.* Until the IRS and the Treasury Department issue further guidance, taxpayers may rely on the following rules relating to the donation of medical devices:

(A) *Non-taxable use.* The donation of a taxable medical device by the manufacturer of the device to an *eligible donee* will not constitute a taxable use as defined in § 4218 of the Code. However, if at the time of donation, the manufacturer has reason to believe that the donation is not being made to an *eligible donee* or that the article donated will be resold by the *eligible donee*, the manufacturer is not relieved from the liability for the tax imposed by § 4191.

(B) *Eligible donee.* For purposes of this safe harbor, an *eligible donee* is an entity described in § 170(c) of the Code.

(C) *Subsequent sales of donated articles.* The rules of § 4219 (related to the application of tax in case of sales by other than the manufacturer) apply to an *eligible donee* that receives a donated taxable medical device and subsequently sells the taxable medical device.

Section 5. CONVENIENCE KITS

(a) *Overview.* Under § 4191, a “taxable medical device” is a device defined in § 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) that is intended for humans. Under § 48.4191-2(a) of the regulations, a device defined in section 201(h) of the FFDCA that is intended for humans means a device that is listed as a device with the Food and Drug Administration (FDA) under section 510(j) of the FFDCA and 21 CFR Part 807, pursuant to FDA requirements. Finished taxable

medical devices are sometimes packaged together into kits for the convenience of a healthcare provider in the performance of a medical procedure. Convenience kits that are listed with the FDA under section 510(j) of the FFDCA and 21 CFR Part 807 are “taxable medical devices” under the regulations unless they fall within an exemption under § 4191(b) or § 48.4191-2(b) of the regulations.

The IRS and the Treasury Department have received numerous written and informal comments suggesting that the sale of convenience kits by the kit producer should not be subject to tax under § 4191. The IRS and the Treasury Department are studying the taxability of convenience kits and intend to issue additional guidance in the future.

(b) *Definition of a “Convenience Kit.”* For purposes of this notice, a “convenience kit” is a set of two or more devices within the meaning of section 201(h) of the FFDCA that is enclosed in a single package, such as a bag, tray, or box, for the convenience of a health care professional or the end user. A convenience kit may contain a combination of devices within the meaning of section 201(h) of the FFDCA and other articles.

(c) *Interim Rule for Domestically-Produced Convenience Kits.* Until the IRS and the Treasury Department issue further guidance, no tax will be imposed upon the sale of a domestically-produced convenience kit that is a “taxable medical device” under § 4191 of the Code and § 48.4191-2(b) of the regulations. During this interim period, the sale of a taxable medical device that goes into a domestically-produced convenience kit will be subject to tax upon its sale by the manufacturer or importer, pursuant to the normal rules of § 4191 and the regulations thereunder; however, the sale of the convenience kit by the kit producer will not be subject to tax.

(d) *Interim Rule for Imported Convenience Kits.* Until the IRS and the Treasury Department issue further guidance, tax is imposed under § 4191 on the sale by an importer of a convenience kit that is a taxable medical device under § 4191 of the Code and § 48.4191-2(b), but only on that portion of the importer’s sale price of the convenience kit that is properly allocable to the individual taxable medical devices included in the convenience kit.

(1) *Allocation.* When an importer sells a convenience kit that is a taxable medical device, and also sells all of the individual taxable medical devices and nontaxable articles that are included in the convenience kit, the taxable portion of the sale price of such convenience kit may be determined by applying to the importer’s sale price of the convenience kit the ratio that the importer’s separate sale price of the taxable medical devices in the convenience kit bears to the sum of the sale prices of both the taxable medical devices and nontaxable articles in the convenience kit.

When an importer sells a convenience kit that is a taxable medical device, but does not sell all of the individual taxable medical devices and nontaxable articles that are included in the convenience kit, the taxable portion of the sale price of such convenience kit may be determined by applying to the importer’s sale price of the convenience kit the ratio that the cost to the importer of the taxable medical devices in the convenience kit bears to the sum of the cost to the importer of both the taxable medical devices and nontaxable articles in the convenience kit. The importer may determine the cost of the taxable medical devices and the nontaxable articles in the convenience kit by any reasonable method. Thus, if the cost of the taxable medical devices represents half of the total cost to the importer of the convenience kit, the tax applies to half of the price charged by the importer upon the sale of the convenience kit.

(2) *Alternative to Allocation.* In lieu of allocation, the importer of a convenience kit that is a taxable medical device may pay tax on the entire price for which the importer sells the convenience kit.

Section 6: DEPOSIT PENALTY RELIEF

(a) *Overview.* Section 6302 of the Code authorizes the IRS to establish the mode and time for collecting certain taxes, including the taxes imposed by chapter 32. Section 40.6302(c)-1(a) of the Excise Tax Procedural Regulations requires manufacturers that are liable for excise taxes to make semimonthly deposits of tax during the period in which the tax liability is incurred.

The deposit for a tax imposed by chapter 32 for each semimonthly period must not be less than 95% of the amount of net tax liability incurred during the semi-

monthly period unless the safe harbor in § 40.6302(c)-1(b)(2)(ii) applies. Under the safe harbor, any person that filed a Form 720, *Quarterly Federal Excise Tax Return*, reporting a tax imposed by chapter 32 for the second preceding calendar quarter is considered to have met the semi-monthly deposit requirement for the current quarter if: (i) the deposit for each semi-monthly period in the current calendar quarter is not less than 1/6 of the net tax liability reported for the look back quarter; (ii) each deposit is made on time; (iii) the amount of any underpayment is paid by the due date of the return; and (iv) the person's liability does not include any tax that was not imposed during the look back quarter. Section 40.6302(c)-1(b)(2)(v) provides that if a person fails to make deposits as required, the IRS may withdraw the person's right to use the safe harbor rules of § 40.6302(c)-1(b)(2)(ii).

Section 6656 imposes a penalty in the case of any failure by any person to make timely deposits as required by § 6302. A taxpayer may avoid penalties under § 6656 for failure to make deposits of taxes if the taxpayer makes an affirmative showing that such failure is due to reasonable cause and not due to willful neglect. *See* § 6656 and the corresponding regulations.

The IRS and the Treasury Department recognize that many medical device manufacturers will still be preparing their systems to comply with the medical device excise tax when the tax goes into effect on January 1, 2013, including the requirement to make semi-monthly deposits. The first deposit of the medical device excise tax, covering the first 15 days of January, is due by January 29, 2013. In consideration of the short time frame between the effective date of the tax and the due date of the first deposit, and in the interest of sound tax administration, the IRS and the Treasury Department have decided to provide temporary relief from the § 6656 penalty for the first three calendar quarters of 2013. The normal rules under § 6656 and the corresponding regulations will apply with respect to deposits due during the fourth calendar quarter of 2013 and thereafter.

In addition to the temporary penalty relief, the normal safe harbor rules of § 40.6302(c)-1(b)(2)(ii) apply. Beginning in the third quarter of 2013, medical device manufacturers may use the safe harbor rules of § 40.6302(c)-1(b)(2)(ii)

for semi-monthly deposits due during that quarter. For purposes of the safe harbor, the first calendar quarter of 2013 is the look back quarter for deposits due during the third calendar quarter.

(b) *Interim Rule.* During the first three calendar quarters of 2013, the IRS will not impose the penalty provided in § 6656 on a taxpayer that is liable for the medical device excise tax that fails to make timely deposits of the medical device excise tax as required by §§ 40.6302(c)-1 and 40.6302(c)-2 (relating to special deposits required in September), provided that the taxpayer demonstrates a good faith attempt to comply with requirements of §§ 40.6302(c)-1 and 40.6302(c)-2 and that the failure was not due to willful neglect.

Thereafter, a taxpayer may avoid penalties if it makes an affirmative showing that the failure to deposit is due to reasonable cause and not due to willful neglect. In addition, during the third and fourth calendar quarters of 2013, the IRS will not exercise its authority under § 40.6302(c)-1(b)(2)(v) to withdraw the taxpayer's right to use the deposit safe harbor rules of § 40.6302(c)-1(b)(2)(ii).

Section 7. REQUEST FOR COMMENTS

The IRS and the Treasury Department invite comments on the interim rules set forth in this notice. In particular, the IRS and the Treasury Department request comments on whether there are distribution chains not described in section 3 of this notice that are commonly employed by the medical device industry. In addition, the IRS and the Treasury Department recognize that different segments of the industry use different distribution chains for different devices and that determination of the price at which a manufacturer would sell its devices to an independent wholesale distributor may vary across those segments. The IRS and the Treasury Department request comments on how the constructive sale price rules might address this segmentation, including comments on what is a reasonable percentage of the applicable sale price for determining the constructive sale price for each segment or product. After reviewing the comments submitted in response to this request and other information collected by the IRS, the IRS and the Treasury Department will

determine an appropriate percentage allowance for the industry as a whole or, alternatively, for particular segments of the industry. The IRS and the Treasury Department will announce any such adjustments in published guidance. Further, the IRS and the Treasury Department request comments regarding alternative methods for determining price for the distribution chain described in paragraph (b)(5) of section 3 of this notice (sales to related resellers that lease, but do not sell, taxable medical devices).

The deadline for submission of comments is March 29, 2013. All materials submitted will be available for public inspection and copying. Written comments should be submitted to: Internal Revenue Service, CC:PA:LPD:PR (Notice 2012-77), Room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (Notice 2012-77), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC. Comments may be transmitted electronically via the following e-mail address: Notice.Comments@irs.counsel.treas.gov. Please include "Notice 2012-77" in the subject line of any electronic communications.

Section 8. EFFECTIVE DATE

This notice is effective on and after January 1, 2013.

Section 9. DRAFTING INFORMATION

The principal author of this notice is Michael H. Beker of the Office of the Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice, please contact Mr. Beker at (202) 622-3130 (not a toll-free number).

Update for Weighted Average Interest Rates, Yield Curves, and Segment Rates

Notice 2012-78

This notice provides guidance as to the corporate bond weighted average interest

rate and the permissible range of interest rates specified under § 412(b)(5)(B)(ii)(II) of the Internal Revenue Code as in effect for plan years beginning before 2008. It also provides guidance on the corporate bond monthly yield curve (and the corresponding spot segment rates), and the 24-month average segment rates under § 430(h)(2). In addition, this notice provides guidance as to the interest rate on 30-year Treasury securities under § 417(e)(3)(A)(ii)(II) as in effect for plan years beginning before 2008, the 30-year Treasury weighted average rate under § 431(c)(6)(E)(ii)(I), and the minimum present value segment rates under § 417(e)(3)(D) as in effect for plan years beginning after 2007. These rates reflect certain changes implemented by the Moving Ahead for Progress in the 21st Century Act, Public Law 112-141 (MAP-21). MAP-21 provides that for

purposes of § 430(h)(2), the segment rates are limited by the applicable maximum percentage or the applicable minimum percentage based on the average of segment rates over a 25 year period.

CORPORATE BOND WEIGHTED AVERAGE INTEREST RATE

Sections 412(b)(5)(B)(ii) and 412(l)(7)(C)(i) provide that the interest rates used to calculate current liability and to determine the required contribution under § 412(l) for plan years beginning in 2004 through 2007 must be within a permissible range based on the weighted average of the rates of interest on amounts invested conservatively in long term investment grade corporate bonds during the 4-year period ending on the last day before the beginning of the plan year.

Notice 2004-34, 2004-1 C.B. 848, provides guidelines for determining the cor-

porate bond weighted average interest rate and the resulting permissible range of interest rates used to calculate current liability. That notice establishes that the corporate bond weighted average is based on the monthly composite corporate bond rate derived from designated corporate bond indices. The methodology for determining the monthly composite corporate bond rate as set forth in Notice 2004-34 continues to apply in determining that rate. See Notice 2006-75, 2006-2 C.B. 366.

The composite corporate bond rate for November 2012 is 3.91 percent. Pursuant to Notice 2004-34, the Service has determined this rate as the average of the monthly yields for the included corporate bond indices for that month.

The following corporate bond weighted average interest rate was determined for plan years beginning in the month shown below.

For Plan Years Beginning in		Corporate Bond Weighted Average	Permissible Range	
<i>Month</i>	<i>Year</i>		90%	100%
December	2012	5.07	4.56	5.07

YIELD CURVE AND SEGMENT RATES

Generally, except for certain plans under sections 104 and 105 of the Pension Protection Act of 2006, § 430 of the Code specifies the minimum funding requirements that apply to single employer plans pursuant to § 412. Section 430(h)(2) specifies the interest rates that must be used to determine a plan's target normal cost and funding target. Under this provision, present value is generally determined using three 24-month average interest rates ("segment rates"), each of

which applies to cash flows during specified periods. To the extent provided under § 430(h)(2)(C)(iv), these segment rates are adjusted by the applicable percentage of the 25-year average segment rates for the period ending September 30 of the year preceding the calendar year in which the plan year begins. However, an election may be made under § 430(h)(2)(D)(ii) to use the monthly yield curve in place of the segment rates.

Notice 2007-81, 2007-44 I.R.B. 899, provides guidelines for determining the monthly corporate bond yield curve, and the 24-month average corporate bond seg-

ment rates used to compute the target normal cost and the funding target. Pursuant to Notice 2007-81, the monthly corporate bond yield curve derived from November 2012 data is in Table I at the end of this notice. The spot first, second, and third segment rates for the month of November 2012 are, respectively, 0.97, 3.50, and 4.60. The three 24-month average corporate bond segment rates applicable for December 2012, without adjustment by the applicable percentage of the 25-year average segment rates, are as follows:

24-Month Segment Rates Without Adjustment by 25-Year Average Segment Rates		
First Segment	Second Segment	Third Segment
1.66	4.47	5.52

For plan years beginning in 2012, the 24-month average segment rates determined under § 430(h)(2)(C)(iv) must be not less than 90% nor greater than 110% of the 25-year average segment rates. Pur-

suant to Notice 2012-55, 2012-36 I.R.B. 332, the first, second, and third 25-year segment rates applicable for plan years beginning in 2012 are 6.15, 7.61, and 8.35, respectively. Therefore, for plan

years beginning in 2012, the three adjusted 24-month average corporate bond segment rates applicable for December 2012, taking into account the applicable percentage

of the 25-year average segment rates, are as follows:

Adjusted 24-Month Average Segment Rates,
Using Applicable Percentage of 25-Year Average Segment Rates

Applicable Month	For Plan Years Beginning in	First Segment	Second Segment	Third Segment
December 2012	2012	5.54	6.85	7.52

The 25-year average segment rates for the period ending September 30, 2012 have not been determined yet. The Service will issue additional guidance on the December 2012 adjusted 24-month average segment rates applicable for plan years beginning in 2013 when those 25-year average segment rates are determined.

**30-YEAR TREASURY SECURITIES
INTEREST RATES**

Section 417(e)(3)(A)(ii)(II) (prior to amendment by PPA) defines the applicable interest rate, which must be used for purposes of determining the minimum present value of a participant's benefit under § 417(e)(1) and (2), as the annual rate of interest on 30-year Treasury securities for the month before the date of distribution or such other time as the Secretary may by regulations prescribe.

Section 1.417(e)-1(d)(3) of the Income Tax Regulations provides that the applicable interest rate for a month is the annual rate of interest on 30-year Treasury securities as specified by the Commissioner for that month in revenue rulings, notices or other guidance published in the Internal Revenue Bulletin.

The rate of interest on 30-year Treasury securities for November 2012 is 2.80 percent. The Service has determined this rate as the average of the yield on the 30-year Treasury bond maturing in August 2042 determined each day through November 7, 2012, and the yield on the 30-year Treasury bond maturing in November 2042 determined each day for the balance of the month.

Generally for plan years beginning after 2007, § 431 specifies the minimum funding requirements that apply to

multiemployer plans pursuant to § 412. Section 431(c)(6)(B) specifies a minimum amount for the full-funding limitation described in section 431(c)(6)(A), based on the plan's current liability. Section 431(c)(6)(E)(ii)(I) provides that the interest rate used to calculate current liability for this purpose must be no more than 5 percent above and no more than 10 percent below the weighted average of the rates of interest on 30-year Treasury securities during the four-year period ending on the last day before the beginning of the plan year. Notice 88-73, 1988-2 C.B. 383, provides guidelines for determining the weighted average interest rate. The following rates were determined for plan years beginning in the month shown below.

For Plan Years Beginning in		30-Year Treasury Weighted Average	Permissible Range	
<i>Month</i>	<i>Year</i>		90%	to 105%
December	2012	3.63	3.26	3.81

**MINIMUM PRESENT VALUE
SEGMENT RATES**

In general, the applicable interest rates under § 417(e)(3)(D) are segment rates computed without regard to a 24-month average. For plan years beginning in

2008 through 2011, the applicable interest rates are the monthly spot segment rates blended with the applicable rate under § 417(e)(3)(A)(ii)(II) as in effect for plan years beginning in 2007. Notice 2007-81 provides guidelines for determining the minimum present value segment rates.

Pursuant to that notice, the minimum present value transitional segment rates determined for November 2012, taking into account the November 2012 30-year Treasury rate of 2.80 stated above, are as follows:

For Plan Years Beginning in	First Segment	Second Segment	Third Segment
2011	1.34	3.36	4.24
2012	0.97	3.50	4.60
2013	0.97	3.50	4.60

DRAFTING INFORMATION

The principal author of this notice is Tony Montanaro of the Employee Plans,

Tax Exempt and Government Entities Division. Mr. Montanaro may be e-mailed at *RetirementPlanQuestions@irs.gov*.

Table I

Monthly Yield Curve for November 2012
 Derived from November 2012 Data

<i>Maturity</i>	<i>Yield</i>								
0.5	0.32	20.5	4.35	40.5	4.63	60.5	4.73	80.5	4.79
1.0	0.52	21.0	4.36	41.0	4.63	61.0	4.74	81.0	4.79
1.5	0.70	21.5	4.38	41.5	4.64	61.5	4.74	81.5	4.79
2.0	0.84	22.0	4.39	42.0	4.64	62.0	4.74	82.0	4.79
2.5	0.95	22.5	4.40	42.5	4.64	62.5	4.74	82.5	4.79
3.0	1.05	23.0	4.40	43.0	4.65	63.0	4.74	83.0	4.79
3.5	1.14	23.5	4.41	43.5	4.65	63.5	4.74	83.5	4.79
4.0	1.25	24.0	4.42	44.0	4.65	64.0	4.75	84.0	4.79
4.5	1.37	24.5	4.43	44.5	4.66	64.5	4.75	84.5	4.79
5.0	1.51	25.0	4.44	45.0	4.66	65.0	4.75	85.0	4.80
5.5	1.67	25.5	4.45	45.5	4.66	65.5	4.75	85.5	4.80
6.0	1.84	26.0	4.46	46.0	4.67	66.0	4.75	86.0	4.80
6.5	2.02	26.5	4.46	46.5	4.67	66.5	4.75	86.5	4.80
7.0	2.20	27.0	4.47	47.0	4.67	67.0	4.75	87.0	4.80
7.5	2.39	27.5	4.48	47.5	4.68	67.5	4.76	87.5	4.80
8.0	2.57	28.0	4.49	48.0	4.68	68.0	4.76	88.0	4.80
8.5	2.75	28.5	4.50	48.5	4.68	68.5	4.76	88.5	4.80
9.0	2.91	29.0	4.50	49.0	4.68	69.0	4.76	89.0	4.80
9.5	3.07	29.5	4.51	49.5	4.69	69.5	4.76	89.5	4.80
10.0	3.21	30.0	4.52	50.0	4.69	70.0	4.76	90.0	4.80
10.5	3.35	30.5	4.53	50.5	4.69	70.5	4.76	90.5	4.80
11.0	3.47	31.0	4.53	51.0	4.69	71.0	4.77	91.0	4.81
11.5	3.58	31.5	4.54	51.5	4.70	71.5	4.77	91.5	4.81
12.0	3.69	32.0	4.54	52.0	4.70	72.0	4.77	92.0	4.81
12.5	3.78	32.5	4.55	52.5	4.70	72.5	4.77	92.5	4.81
13.0	3.86	33.0	4.56	53.0	4.70	73.0	4.77	93.0	4.81
13.5	3.93	33.5	4.56	53.5	4.71	73.5	4.77	93.5	4.81
14.0	3.99	34.0	4.57	54.0	4.71	74.0	4.77	94.0	4.81
14.5	4.04	34.5	4.57	54.5	4.71	74.5	4.77	94.5	4.81
15.0	4.09	35.0	4.58	55.0	4.71	75.0	4.77	95.0	4.81
15.5	4.13	35.5	4.58	55.5	4.71	75.5	4.78	95.5	4.81
16.0	4.17	36.0	4.59	56.0	4.72	76.0	4.78	96.0	4.81
16.5	4.20	36.5	4.59	56.5	4.72	76.5	4.78	96.5	4.81
17.0	4.23	37.0	4.60	57.0	4.72	77.0	4.78	97.0	4.81
17.5	4.25	37.5	4.60	57.5	4.72	77.5	4.78	97.5	4.81
18.0	4.27	38.0	4.61	58.0	4.72	78.0	4.78	98.0	4.82
18.5	4.29	38.5	4.61	58.5	4.73	78.5	4.78	98.5	4.82
19.0	4.31	39.0	4.62	59.0	4.73	79.0	4.78	99.0	4.82
19.5	4.33	39.5	4.62	59.5	4.73	79.5	4.78	99.5	4.82
20.0	4.34	40.0	4.63	60.0	4.73	80.0	4.79	100.0	4.82

Part IV. Items of General Interest

Notice of Proposed Rulemaking and Notice of Public Hearing

Rules Relating to Additional Medicare Tax

REG-130074-11

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to Additional Hospital Insurance Tax on income above threshold amounts (“Additional Medicare Tax”), as added by the Affordable Care Act. Specifically, these proposed regulations provide guidance for employers and individuals relating to the implementation of Additional Medicare Tax. This document also contains proposed regulations relating to the requirement to file a return reporting Additional Medicare Tax, the employer process for making adjustments of underpayments and overpayments of Additional Medicare Tax, and the employer and employee processes for filing a claim for refund for an overpayment of Additional Medicare Tax. This document also provides notice of a public hearing on these proposed rules.

DATES: Written or electronic comments must be received by March 5, 2013. Requests to speak (with outlines of topics to be discussed) at the public hearing scheduled for April 4, 2013, must be received by February 28, 2013.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-130074-11), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-130074-11), 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-130074-11). The

public hearing will be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Andrew K. Holubeck or Ligeia M. Donis at (202) 622-6040; concerning submission of comments, the hearing, and/or to be placed on the building access list to attend the hearing, please contact Oluwafunmilayo (Funmi) Taylor at Oluwafunmilayo.P.Taylor@irscounsel.treas.gov or (202) 622-7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these proposed regulations was previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-2097. Comments on the collection of information should be sent to the **Office of Management and Budget**, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the **Internal Revenue Service**, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:M:S, Washington, DC 20224. Comments on the collection of information should be received by February 4, 2013. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations is in §§31.6011(a)-1, 31.6011(a)-2, 31.6205-1, 31.6402(a)-2, 31.6413(a)-1, and 31.6413(a)-2. This

information is required by the IRS to verify compliance with return requirements under section 6011, employment tax adjustments under sections 6205 and 6413, and claims for refund of overpayments under section 6402. This information will be used to determine whether the amount of tax has been reported and calculated correctly. The likely respondents are employers and individuals.

Estimated total annual reporting and/or recordkeeping burden: 1,900,000 hours.

Estimated average annual burden per respondent: 1 hour.

Estimated number of respondents: 1,900,000.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

These proposed regulations are issued in connection with the Additional Hospital Insurance Tax on income above threshold amounts (“Additional Medicare Tax”), as added by section 9015 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111-148 (124 Stat. 119 (2010)), and as amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively, the “Affordable Care Act”). The proposed regulations include amendments to §1.1401-1 of the Income Tax Regulations, and §§31.3101-2, 31.3102-1, 31.3102-4, 31.3202-1, 31.6011(a)-1, 31.6011(a)-2, 31.6205-1, 31.6402(a)-2, 31.6413(a)-1, and 31.6413(a)-2 of the Employment Tax Regulations. The proposed regulations provide guidance for employers and individuals relating to the implementation of Additional Medicare Tax, including the requirement to withhold Additional Medicare Tax on certain wages and

compensation, the requirement to file a return reporting Additional Medicare Tax, the employer process for adjusting underpayments and overpayments of Additional Medicare Tax, and the employer and employee processes for filing a claim for refund of Additional Medicare Tax.

For purposes of these proposed regulations, the term *employment taxes* means the Federal Insurance Contributions Act (FICA) tax imposed on employers and employees, the Railroad Retirement Tax Act (RRTA) tax imposed on employers and employees, and federal income tax withholding (ITW).

Federal Insurance Contributions Act and Railroad Retirement Tax Act Taxes

Tax under the FICA is composed of Old-Age, Survivors, and Disability Insurance (OASDI) tax, also referred to as social security tax, and Hospital Insurance (HI) tax, also referred to as Medicare tax. The Medicare portion of FICA tax is imposed separately on the employer, under section 3111(b), and the employee, under section 3101(b), in an amount equal to a percentage of wages. Under section 3102, the employer is required to collect the employee portion of FICA tax by deducting the amount of the tax from wages, as and when paid, and is liable for payment of the tax required to be collected. Until collected, the employee also is liable for the employee portion of the tax. See §31.3102-1(d).

Under the RRTA, railroad employment is subject to a separate and distinct system of taxes from those imposed under the FICA. The RRTA serves as the functional equivalent of FICA for railroad employers, employees, and employee representatives (a group unique to the railroad industry). Tax under the RRTA is divided into tiers and each tier finances different benefits. Tier 1 RRTA tax provides equivalent social security and Medicare benefits. Section 3201(a) imposes Tier 1 RRTA tax on employees and section 3211(a) imposes Tier 1 RRTA tax on employee representatives, in an amount equal to the applicable percentage of compensation. For employees, the applicable percentage under section 3201(a) is the sum of the rates of tax under section 3101(a) and (b). For employee representatives, the applicable per-

centage under section 3211(a) is the sum of the rates of tax under sections 3101(a) and (b) and 3111(a) and (b).

Under section 3202, the employer is required to collect the employee portions of RRTA tax by deducting the amount of the taxes from compensation as and when paid, and is liable for payment of the taxes required to be collected. Until collected, the employee also is liable for the employee portion of the tax. See §31.3202-1(e).

The Affordable Care Act added section 3101(b)(2). Section 3101(b)(2) increases the employee portion of Medicare tax for wages received in any taxable year beginning after December 31, 2012, by an additional 0.9 percent of FICA wages which are in excess of certain threshold amounts. Additional Medicare Tax differs from Medicare tax in that Additional Medicare Tax is not imposed until wages exceed a threshold amount, and the threshold amount for application of the tax is based on the filing status of the individual. Under section 3101(b)(2), the threshold amount is \$250,000 in the case of a joint return, \$125,000 in the case of a married taxpayer filing a separate return, and \$200,000 in any other case. Additional Medicare Tax also differs from Medicare Tax in that there is no employer portion to correspond to the amount owed by the employee.

Additional Medicare Tax applies to RRTA compensation paid to railroad employees and employee representatives. See reference to section 3101(b) in sections 3201(a) and 3211(a). Accordingly, Tier 1 RRTA tax imposed under sections 3201(a) and 3211(a) will be increased for compensation received in any taxable year beginning after December 31, 2012, by an additional 0.9 percent of RRTA compensation which is in excess of certain threshold amounts as enumerated in section 3101(b)(2). The threshold amount for Additional Medicare Tax applies separately to the FICA and the RRTA. Accordingly, an individual will not combine FICA wages and RRTA compensation in determining whether Additional Medicare Tax applies under FICA or under RRTA.

The Affordable Care Act added section 3102(f). Section 3102(f)(1) provides that an employer's obligation under section 3102(a) to withhold Additional Medicare Tax applies only to the extent that the

wages the employee receives from the employer are in excess of \$200,000 in a calendar year. Section 3102(f)(1) further provides that in satisfying its obligation to withhold Additional Medicare Tax, the employer may disregard the amount of wages received by the employee's spouse.

Calculating wages for purposes of withholding Additional Medicare Tax is no different than calculating wages for FICA generally. Thus, for example, if an employee has amounts deferred under a nonqualified deferred compensation plan and the nonqualified deferred compensation (NQDC) is taken into account as wages for FICA tax purposes under the special timing rule described in §31.3121(v)(2)-1(a)(2), the NQDC would likewise be taken into account under the special timing rule for purposes of determining an employer's obligation to withhold Additional Medicare Tax.

Similarly, when an employee is concurrently employed by related corporations and one of the corporations disburses wages for services performed for each of the employers and the arrangement otherwise satisfies the common paymaster provisions of section 3121(s), liability for FICA tax with respect to the wages disbursed by the common paymaster is computed as if there was a single employer. In this case, the obligation to withhold Additional Medicare Tax on wages in excess of \$200,000 disbursed by the common paymaster would also be determined as if there was a single employer.

Section 3102(f)(2) specifies that to the extent Additional Medicare Tax is not withheld by the employer, the employee must pay the tax. This is consistent with the general FICA rule in §31.3102-1(d), which provides that the employee is liable for the employee portion of FICA tax until collected by the employer.

Section 3102(f)(3) provides that if an employer fails to withhold Additional Medicare Tax, and the tax is subsequently paid by the employee, the IRS will not collect the tax from the employer. Section 3102(f)(3) specifies, however, that the employer would remain subject to any applicable penalties or additions to tax for failure to withhold Additional Medicare Tax as required. Section 3102(f)(3), reflecting that Additional Medicare Tax is imposed only on employees and is ultimately based on the employee's filing

status, is similar to section 3402(d), which abates the employer's liability for ITW when the employee has paid the income tax.

Self-Employment Contributions Act Taxes

Section 1401 imposes social security and Medicare taxes on the self-employment income of every individual at the same combined employer and employee rates applicable under the FICA.

The Affordable Care Act added section 1401(b)(2). Section 1401(b)(2)(A) increases the Medicare tax on self-employment income for any taxable year beginning after December 31, 2012, by an additional 0.9 percent of self-employment income which is in excess of certain threshold amounts. As with Additional Medicare Tax under the FICA, the threshold amounts for an individual to be subject to Additional Medicare Tax under the Self-Employment Contributions Act (SECA) are determined by the individual's filing status. The threshold amounts enumerated under section 1401(b)(2)(A), are \$250,000 in the case of a joint return, \$125,000 in the case of a married taxpayer filing a separate return, and \$200,000 in any other case.

Section 1401(b)(2)(B) provides for coordination with Additional Medicare Tax under the FICA and specifies that the threshold amounts under section 1401(b)(2)(A) are reduced (but not below zero) by the amount of wages taken into account in determining Additional Medicare Tax under the FICA. Section 1401(b)(2)(B) does not provide for similar coordination with Additional Medicare Tax under the RRTA. Therefore, the amount of RRTA compensation taken into account in determining Additional Medicare Tax under the RRTA will not reduce the threshold amounts under section 1401(b)(2)(A) for determining Additional Medicare Tax under the SECA.

Estimated Taxes

Section 6654 imposes an addition to tax in the case of an individual's underpayment of estimated tax. Generally, the addition to tax imposed under section 6654 will not apply to individuals who have sufficient ITW on wages or who make estimated tax payments throughout the year. Employees may request additional ITW on

wages on Form W-4, "*Withholding Allowance Certificate*," to reduce the need to make estimated tax payments to cover the individual's tax liability.

Under section 6654(m), which was added by the Affordable Care Act, Additional Medicare Tax is treated as a tax subject to estimated tax payment requirements. In the case of employees, Additional Medicare Tax is collected through withholding on FICA wages or RRTA compensation in excess of \$200,000 in a calendar year. In addition, employees may request additional ITW on wages on Form W-4 and use this additional ITW to apply against taxes shown on their return, including any Additional Medicare Tax liability. To the extent not withheld, Additional Medicare Tax must be included when making estimated tax payments.

Interest-Free Adjustments of Employment Taxes

The current regulations under section 6205 set forth the procedures for making interest-free adjustments for underpayments of employment taxes. Generally, under the regulations, if an employer ascertains an underpayment of FICA or RRTA tax, the employer can make an underpayment adjustment, within the period of limitations for assessment, by reporting the additional amount due on an adjusted return for the return period in which the wages or compensation was paid. For underpayments of ITW, subject to limited exceptions for correcting worker misclassification errors or for administrative errors (that is, errors involving the inaccurate reporting of the amount actually withheld) and for audit adjustments, an adjustment may be made only for errors ascertained during the calendar year in which the wages were paid.

The current regulations under section 6413(a) set forth the procedures for making interest-free adjustments for overpayments of employment taxes. Under the regulations, if an employer ascertains within the applicable period of limitations on credit or refund that an overpayment error was made, the employer is generally required to repay or reimburse its employees the amount of overcollected employee FICA tax or employee RRTA tax prior to the expiration of the applicable period of limitations on credit or refund. The

regulations further provide that once an employer repays or reimburses an employee, the employer may report both the employee and employer portions of FICA or RRTA tax as an overpayment on an adjusted return within the period of limitations on credit or refund. The employer must generally certify on the adjusted return that it has repaid or reimbursed its employees.

Similar rules apply for making interest-free adjustments for overpayments of ITW, except that an interest-free adjustment may only be made if the employer ascertains the error and repays or reimburses its employees within the same calendar year that the wages were paid, unless the employer is correcting an administrative error.

Claims for Refund of Employment Taxes

In lieu of making an interest-free adjustment under section 6413(a) for an overpayment, employers may file a claim for refund pursuant to section 6402. Under section 6402(a), the IRS may credit the amount of an overpayment, including any interest, against any tax liability of the person who made the overpayment and shall, subject to certain offsets, refund any balance to such person. A claim for refund under section 6402(a) must be filed within the period of limitations on credit or refund. Section 6414 permits refunds of ITW only to the extent the amount of the ITW overpayment was not actually deducted and withheld from an employee.

The current regulations under section 6402(a) set out the procedures for filing a claim for refund of overpaid FICA and RRTA taxes. The regulations permit an employer to file a claim for refund of an overpayment of FICA or RRTA tax, but generally require the employer to certify as part of the claim process that the employer has repaid or reimbursed the employee's share of the overpayment of FICA or RRTA tax to the employee or has secured the written consent of the employee to allowance of the refund or credit.

Generally, under the current section 6402 regulations, an employee may file a claim for refund of overpaid FICA or RRTA tax as long as the employee has not been repaid or reimbursed by the employer and does not give the employer consent to file a claim on his or her behalf, and the

employee has not taken the overcollection into account in claiming a credit against, or refund of, his or her income tax, in the case of a claim under section 6413(c) for overpaid employee social security tax.

The current regulations under section 6414 set out the procedures for filing a claim for refund of overpaid ITW and provide that an employer may not file a claim for refund of an overpayment of ITW to the extent the amount was deducted or withheld from an employee.

Explanation of Provisions

The proposed regulations provide rules for the withholding, computation, reporting, and payment of Additional Medicare Tax on wages, self-employment income, and RRTA compensation. The proposed regulations also provide rules for when and how employers may make an interest-free adjustment to correct an overpayment or an underpayment of Additional Medicare Tax and how employers and employees may claim refunds for overpayments of Additional Medicare Tax. These procedural rules for interest-free adjustments and claims for refund track the existing rules that apply to ITW rather than the rules that apply to FICA tax. The regulations take this approach because Additional Medicare Tax, like ITW, does not include an employer portion, and the ultimate liability is reconciled on the individual employee's income tax return.

Rates and Computation of Employee FICA Tax

The proposed regulations under section 3101(b) update the rates of tax for the social security and Medicare tax on employees, and add a paragraph describing the rate of Additional Medicare Tax. The proposed regulations also provide an updated example illustrating that the social security and Medicare rates applicable to the calendar year in which wages are received apply to compute the tax liability.

Employer's Obligation to Withhold Additional Medicare Tax

The proposed regulations under sections 3102 and 3202(a) describe the extent to which an employer is required to withhold Additional Medicare Tax. The proposed regulations under section 3102(f)

provide that an employer must withhold Additional Medicare Tax from an employee's wages only to the extent that the employee receives wages from the employer in excess of \$200,000 in a calendar year. In determining whether wages exceed \$200,000, an employer does not take into account the employee's filing status or other wages or compensation which may impact the employee's liability for the tax. An employee may not request that the employer deduct and withhold Additional Medicare Tax on wages of \$200,000 or less. However, an employee who anticipates liability for Additional Medicare Tax may request that the employer deduct and withhold an additional amount of ITW under §31.3402(i)-2 on Form W-4. This additional ITW can apply against taxes shown on Form 1040, "U.S. Individual Tax Return," including any Additional Medicare Tax liability. An employee might request that the employer deduct and withhold an additional amount of ITW on wages that are not in excess of \$200,000 if, for example, the employee is married and files a joint return, and anticipates liability for Additional Medicare Tax because the combined wages of the employee and the employee's spouse will exceed \$250,000. The proposed regulations under sections 3102(f) and 3202(a) include examples illustrating the extent of the employer's obligation to withhold Additional Medicare Tax.

Further, the proposed regulations under section 3102(f) provide that to the extent Additional Medicare Tax is not withheld by the employer, the employee is liable for the tax. The proposed regulations also provide that the IRS will not collect from an employer the amount of Additional Medicare Tax it failed to withhold from wages paid to an employee if the employee subsequently pays the Additional Medicare Tax. However, the proposed regulations also specify that the employer would remain subject to any applicable penalties or additions to tax for failure to withhold Additional Medicare Tax as required.

Although Additional Medicare Tax applies to RRTA compensation, the Affordable Care Act did not add provisions similar to section 3102(f) to the RRTA, nor does the RRTA cross-reference section 3102(f). However, in light of the general similarities between the FICA and the RRTA and the principles discussed

above, and in order to provide guidance to railroad employers regarding their liability to withhold Additional Medicare Tax, the proposed regulations under section 3202(a) incorporate the same rules as provided in section 3102(f). Therefore, the proposed regulations under section 3202(a) provide that railroad employers must withhold Additional Medicare Tax from an employee's compensation only to the extent the employee receives compensation from the employer in excess of \$200,000 in a calendar year. Similar to the FICA rule, an employee may not request that the employer deduct and withhold Additional Medicare Tax on compensation of \$200,000 or less. Instead, an employee who anticipates liability for Additional Medicare Tax may request that the employer deduct and withhold an additional amount of ITW under §31.3402(i)-2 on Form W-4 to apply against taxes shown on Form 1040, including any Additional Medicare Tax liability. The regulations under section 3202 further provide that: (1) to the extent Additional Medicare Tax is not withheld by the employer, the employee is liable for the tax; (2) the IRS will not collect Additional Medicare Tax from an employer who fails to withhold Additional Medicare Tax on compensation paid by the employer, if the tax is subsequently paid by the employee; and (3) the employer will remain subject to any applicable penalties or additions to tax for failure to withhold Additional Medicare Tax as required.

Employee's Obligation to Report and Pay Additional Medicare Tax

The proposed regulations under sections 3102(f) and 3202(a) provide that an employee is liable for Additional Medicare Tax on wages or compensation to the extent that the tax is not withheld by the employee's employer. This is consistent with the general rule in §§31.3102-1(d) and 31.3202-1(e) for FICA and RRTA purposes, respectively, that provides that the employee is liable for the tax until collected by the employer. Under the proposed regulations under section 6011, an individual must report Additional Medicare Tax on Form 1040. An individual will claim credit for any withheld Additional Medicare Tax on Form 1040 and pay any such tax due that was not previously paid

through withholding or estimated tax. For example, if an employee and his or her spouse each had wages of \$200,000 or less, such that their employers did not withhold Additional Medicare Tax from the employee's or the spouse's wages, but the combined wages of the employee and the employee's spouse exceed the threshold for a joint return under section 3101(b)(2) (that is, exceed \$250,000), the proposed regulations indicate that the employee and the employee's spouse are liable to pay Additional Medicare Tax. The proposed regulations under sections 3102(f) and 3202(a) include examples illustrating this principle for FICA wages and RRTA compensation, respectively.

Self-Employed Individual's Obligation to Pay Additional Medicare Tax

The proposed regulations under section 1401(b) describe the extent to which an individual who has self-employment income is liable for Additional Medicare Tax. Specifically, the proposed regulations describe how the applicable threshold amounts under section 1401(b)(2)(A) are reduced (but not below zero) by the amount of FICA wages taken into account in determining Additional Medicare Tax liability. Thus, the proposed regulations under section 1401(b)(2) illustrate the application of the reduced threshold amounts for purposes of determining liability for Additional Medicare Tax attributable to the individual's self-employment income.

The Affordable Care Act did not provide for a reduction in the self-employment income threshold amounts by the amount of any RRTA compensation taken into account in determining liability for Additional Medicare Tax. Accordingly, an individual who receives both RRTA compensation and self-employment income would not reduce the self-employment income threshold amounts under section 1401(b)(2)(A) by the amount of RRTA compensation taken into account in determining Additional Medicare Tax liability.

Interest-Free Adjustments of Additional Medicare Tax

The proposed regulations under sections 6205 provide that adjustments of underpayments of Additional Medicare Tax may be made only if the error is ascertained in the same year the wages or

compensation was paid, unless: (1) the underpayment is attributable to an administrative error, (2) section 3509 applies to determine the amount of the underpayment, due to the employer's failure to treat the individual as an employee, or (3) the adjustment is the result of an IRS examination.

Similarly, the proposed regulations under section 6413 provide that an adjustment of overpaid Additional Medicare Tax may only be made if the employer ascertains the error in the year the wages or compensation was paid and repays or reimburses the employee the amount of the overcollection prior to the end of the calendar year. As in the case of all overpayment adjustments, the requirement to repay or reimburse does not apply to the extent that, after reasonable efforts, the employer cannot locate the employee. However, if an employer has not repaid or reimbursed the amount of the overcollection to the employee, an adjustment cannot be made.

Claims for Refund of Additional Medicare Tax

The proposed regulations under section 6402 provide a process by which employers and employees claim refunds of overpaid Additional Medicare Tax. Under the proposed regulations, employers may claim refunds of overpaid Additional Medicare Tax only if the employer did not deduct or withhold the overpaid Additional Medicare Tax from the employee's wages or compensation.

For employees, the proposed regulations eliminate the requirements that the employee first seek a refund from the employer and provide a statement in support of the employee's claim. Further, the proposed regulations direct the employee to claim the refund or credit of overpaid Additional Medicare Tax by taking the overpayment into account in claiming a credit against, or refund of, tax on an individual tax return (for example, Form 1040) for the year in which the overpayment was made, or for a taxable year for which a tax return has been filed, by filing Form 1040X, "Amended U.S. Individual Income Tax Return." This process is in lieu of filing a claim for refund for overpaid Additional Medicare Tax on Form 843, "Claim for Refund and Request for Abatement."

Employees may only claim a refund of Additional Medicare Tax if they have not received repayment or reimbursement from their employer in the context of an interest-free adjustment.

Proposed Effective/Applicability Dates

These regulations are proposed to be effective the date the final regulations are published in the **Federal Register**. The regulations under the Internal Revenue Code (Code) sections 1401, 3101, 3102, and 3202 are proposed to apply to quarters beginning after the date the final regulations are published in the **Federal Register**. The regulations under Code section 6011 are proposed to apply to taxable years beginning after the date the final regulations are published in the **Federal Register**. The regulations under Code sections 6205, 6402, and 6413 are proposed to apply to adjustments made and claims for refund filed after the date the final regulations are published in the **Federal Register**.

The Treasury Department and IRS intend to finalize these proposed regulations in 2013. Taxpayers may rely on these proposed regulations for tax periods beginning before the date that the final regulations are published in the Federal Register.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

The proposed regulations under section 6011 affect all taxpayers that file individual tax returns and are subject to Additional Medicare Tax. The proposed regulations under sections 6205, 6402, and 6413 affect all taxpayers that file employment tax returns, as well as taxpayers that file claims for refund of employment taxes. Therefore, the IRS has determined that these proposed regulations will have an impact on a substantial number of small entities.

The IRS has determined, however, that the impact on entities affected by the proposed regulations will not be significant.

The proposed regulations require taxpayers who file employment tax returns and who make interest-free adjustments to their employment taxes for either underpayments or overpayments of Additional Medicare Tax or who file claims for refund for an overpayment of Additional Medicare Tax to provide an explanation setting forth the basis for the correction or the claim in detail, designating the return period in which the error was ascertained and the return period being corrected, and setting forth such other information as may be required by the instructions to the form. In addition, for adjustments of overpayments of Additional Medicare Tax, employers must also obtain and retain the written receipt of the employee showing the date and amount of the repayment to the employee or retain evidence of reimbursement. This collection of information is not new to the proposed regulations. The proposed regulations merely apply the existing procedural requirements, with appropriate modifications, to corrections of Additional Medicare Tax. The filing of a claim for refund and the making of an interest-free adjustment pursuant to the proposed regulations are voluntary on the part of taxpayers.

Based on these facts, the IRS hereby certifies that the collection of information contained in these proposed regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the 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 Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The Treasury Department and the IRS specifically request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. All comments that are submitted by the public will be available for public inspection and copying at <http://www.regulations.gov> or upon request. A public hearing has been scheduled for April 4, 2013, beginning at 10 a.m., in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW, Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts.

For information about having your name placed on the building access list to attend the hearing, see the "FOR FURTHER INFORMATION CONTACT" section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit comments and an outline of the topics to be discussed and the time to be devoted to each topic by February 28, 2013.

A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the

deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these proposed regulations are Sydney L. Gernstein, formerly of the Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), Andrew K. Holubeck, and Ligeia M. Donis of the Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and the Treasury Department participated in their development.

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Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 31 are proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:
Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.1401-1 is amended by revising paragraph (b) and adding new paragraphs (d) and (e) to read as follows:

§1.1401-1 Tax on self-employment income.

* * * * *

(b) The rates of tax on self-employment income are as follows (these regulations do not reflect off-Code revisions to the below rates):

(1) For Old-age, Survivors, and Disability Insurance:

<i>Taxable year</i>	<i>Percent</i>
Beginning after December 31, 1983 and before January 1, 1988	11.40
Beginning after December 31, 1987 and before January 1, 1990	12.12
Beginning after December 31, 1989	12.40

(2)(i) For Hospital Insurance:

<i>Taxable year</i>	<i>Percent</i>
Beginning after December 31, 1983 and before January 1, 1985	2.60

Beginning after December 31, 1984 and before January 1, 1986	2.70
Beginning after December 31, 1985	2.90

(ii) For Additional Medicare Tax:

<i>Taxable year</i>	<i>Percent</i>
Beginning after December 31, 2012	0.9

* * * * *

(d) *Special rules regarding Additional Medicare Tax.* (1) *General rule.* An individual is liable for Additional Medicare

Tax to the extent that his or her self-employment income exceeds the following threshold amounts.

<i>Filing Status</i>	<i>Threshold</i>
Married individual filing a joint return	\$250,000
Married individual filing a separate return	\$125,000
Any other case	\$200,000

Note: These threshold amounts are specified under section 1401(b)(2)(A).

(2) *Coordination with Federal Insurance Contributions Act.* (i) *General rule.* Under section 1401(b)(2)(B), the applicable threshold specified under section 1401(b)(2)(A) is reduced (but not below zero) by the amount of wages (as defined in section 3121(a)) taken into account in determining Additional Medicare Tax under section 3101(b)(2) with respect to the taxpayer. This rule does not apply to Railroad Retirement Tax Act (RRTA) compensation (as defined in section 3231(e)).

income threshold to \$70,000 (\$200,000 threshold minus the \$130,000 of wages). C is liable to pay Additional Medicare Tax on \$75,000 of self-employment income (\$145,000 in self-employment income minus the reduced threshold of \$70,000).

(e) *Effective/applicability date.* Paragraphs (b) and (d) of this section apply to quarters beginning after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(ii) *Examples.* The rules provided in paragraph (d)(2)(i) of this section are illustrated by the following examples:

Example 4. E, who is married and files a joint return, has \$140,000 in self-employment income. F, E's spouse, has \$130,000 in wages. F's wages are not in excess of \$200,000 so F's employer did not withhold Additional Medicare Tax. However, the \$130,000 of F's wages reduces E's self-employment income threshold to \$120,000 (\$250,000 threshold minus the \$130,000 of wages). E and F are liable to pay Additional Medicare Tax on \$20,000 of E's self-employment income (\$140,000 in self-employment income minus the reduced threshold of \$120,000).

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT THE SOURCE

Par. 3. The authority citation for part 31 continues to read in part as follows:

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

Par. 4. Revise §31.3101-2 to read as follows:

Example 1. A, a single filer, has \$130,000 in self-employment income and \$0 in wages. A is not liable to pay Additional Medicare Tax.

Example 5. D, who is married and files married filing separately, has \$150,000 in self-employment income and \$200,000 in wages. D's wages are not in excess of \$200,000 so D's employer did not withhold Additional Medicare Tax. However, the \$200,000 of wages reduces the self-employment income threshold to \$0 (\$125,000 threshold minus the \$200,000 of wages). D is liable to pay Additional Medicare Tax on \$75,000 of wages (\$200,000 in wages minus the \$125,000 threshold for a married filing separately return) and on \$150,000 of self-employment income (\$150,000 in self-employment income minus the reduced threshold of \$0).

§31.3101-2 *Rates and computation of employee tax.*

(a) *Old-Age, Survivors, and Disability Insurance.* The rates of employee tax for Old-Age, Survivors, and Disability Insurance (OASDI) with respect to wages received in calendar years after 1983 are as follows (these regulations do not reflect off-Code revisions to the below rates):

<i>Calendar year</i>	<i>Percent</i>
1984, 1985, 1986, or 1987	5.7
1988 or 1989	6.06
1990 and subsequent years	6.2

(b)(1) *Hospital Insurance.* The rates of employee tax for Hospital Insurance (HI)

with respect to wages received in calendar years after 1973 are as follows:

<i>Calendar year</i>	<i>Percent</i>
1974, 1975, 1976, or 1977	0.90
1978	1.00
1979 or 1980	1.05
1981, 1982, 1983, or 1984	1.30
1985	1.35
1986 and subsequent years	1.45

(2) *Additional Medicare Tax.* (i) The rate of Additional Medicare Tax with respect to wages received in taxable years beginning after December 31, 2012, is as follows:

<i>Taxable year</i>	<i>Percent</i>
Beginning after December 31, 2012	0.9

(ii) Individuals are liable for Additional Medicare Tax with respect to wages received in taxable years beginning after December 31, 2012, which are in excess of:

<i>Filing Status</i>	<i>Threshold</i>
Married individual filing a joint return	\$250,000
Married individual filing a separate return	\$125,000
Any other case	\$200,000

(c) *Computation of employee tax.* The employee tax is computed by applying to the wages received by the employee the rates in effect at the time such wages are received.

Example. In 1989, A performed services for X which constituted employment (see §31.3121(b)-2). In 1990, A receives from X \$1,000 as remuneration for such services. The tax is payable at the 6.2 percent OASDI rate and the 1.45 percent HI rate in effect for the calendar year 1990 (the year in which the wages are received) and not at the 6.06 percent OASDI rate and the 1.45 percent HI rate which were in effect for the calendar year 1989 (the year in which the services were performed).

(d) *Effective/applicability date.* Paragraphs (a) (b), and (c) of this section apply to quarters beginning after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 5. Section 31.3102-1 is amended by adding a new sentence at the end of paragraph (a) and a new paragraph (f) to read as follows:

§31.3102-1 Collection of, and liability for, employee tax; in general.

(a) *** For special rules relating to Additional Medicare Tax imposed under section 3101(b)(2), see §31.3102-4.

* * * * *

(f) *Effective/applicability date.* Paragraph (a) of this section applies to quarters beginning after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 6. Section 31.3102-4 is added to read as follows:

§31.3102-4 Special rules regarding Additional Medicare Tax.

(a) *Collection of tax from employee.* An employer is required to collect from each of its employees the tax imposed by section 3101(b)(2) (Additional Medicare Tax) with respect to wages for employment performed for the employer by the employee only to the extent the employer pays wages to the employee in excess of \$200,000 in a calendar year. This rule applies regardless of the employee's filing status or other income. Thus, the employer disregards any amount of wages or Railroad Retirement Tax Act (RRTA) compensation paid to the employee's spouse. The employer also disregards any RRTA compensation paid by the employer to the employee or any wages or RRTA compensation paid to the employee by another employer.

Example. H, who is married and files a joint return, receives \$100,000 in wages from his employer for the calendar year. I, H's spouse, receives

\$300,000 in wages from her employer for the same calendar year. H's wages are not in excess of \$200,000, so H's employer does not withhold Additional Medicare Tax. I's employer is required to collect Additional Medicare Tax only with respect to wages it pays which are in excess of the \$200,000 threshold (that is, \$100,000) for the calendar year.

(b) *Collection of amounts not withheld.* To the extent the employer does not collect Additional Medicare Tax imposed on the employee by section 3101(b)(2), the employee is liable to pay the tax.

Example. J, who is married and files a joint return, receives \$190,000 in wages from his employer for the calendar year. K, J's spouse, receives \$150,000 in wages from her employer for the same calendar year. Neither J's nor K's wages are in excess of \$200,000, so neither J's nor K's employers are required to withhold Additional Medicare Tax. J and K are liable to pay Additional Medicare Tax on \$90,000 (\$340,000 minus the \$250,000 threshold for a joint return).

(c) *Employer's liability for tax.* If the employer deducts less than the correct amount of Additional Medicare Tax, or if it fails to deduct any part of Additional Medicare Tax, it is nevertheless liable for the correct amount of tax that it was required to withhold, until the employee pays the tax. If an employee subsequently pays the tax that the employer failed to deduct, the tax will not be collected from the employer. The employer, however, will remain subject to any applicable

penalties or additions to tax resulting from the failure to withhold as required.

(d) *Effective/applicability date.* This section applies to quarters beginning after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 7. Section 31.3202-1 is amended by adding new paragraphs (g) and (h) to read as follows:

§31.3202-1 Collection of, and liability for, employee tax

* * * * *

(g) *Special rules regarding Additional Medicare Tax.* (1) An employer is required to collect from each of its employees the portion of the tax imposed by section 3201(a) (as calculated under section 3101(b)(2)) (Additional Medicare Tax) with respect to compensation for employment performed for the employer by the employee only to the extent the employer pays compensation to the employee in excess of \$200,000 in a calendar year. This rule applies regardless of the employee's filing status or other income. Thus, the employer disregards any amount of compensation or Federal Insurance Contributions Act (FICA) wages paid to the employee's spouse. The employer also disregards any FICA wages paid by the employer to the employee or any compensation or FICA wages paid to the employee by another employer.

Example. A, who is married and files a joint return, receives \$100,000 in compensation from her employer for the calendar year. B, A's spouse, receives \$300,000 in compensation from his employer for the same calendar year. A's compensation is not in excess of \$200,000, so A's employer does not withhold Additional Medicare Tax. B's employer is required to collect Additional Medicare Tax only with respect to compensation it pays to B that is in excess of the \$200,000 threshold (that is, \$100,000) for the calendar year.

(2) To the extent the employer does not collect Additional Medicare Tax imposed on the employee by section 3201(a) (as calculated under section 3101(b)(2)), the employee is liable to pay the tax.

Example. C, who is married and files a joint return, receives \$190,000 in compensation from her employer for the calendar year. D, C's spouse, receives \$150,000 in compensation from his employer for the same calendar year. Neither C's nor D's compensation is in excess of \$200,000, so neither C's nor D's employers are required to withhold Additional Medicare Tax. C and D are liable to pay Additional Medicare Tax on \$90,000 (\$340,000 minus the \$250,000 threshold for a joint return).

(3) If the employer deducts less than the correct amount of Additional Medicare Tax, or if it fails to deduct any part of Additional Medicare Tax, it is nevertheless liable for the correct amount of tax that it was required to withhold, until the employee pays the tax. If an employee subsequently pays the tax that the employer failed to deduct, the tax will not be collected from the employer. The employer, however, will remain subject to any applicable penalties or additions to tax resulting from the failure to withhold as required.

(h) *Effective/applicability date.* Paragraph (g) of this section applies to quarters beginning after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 8. Section 31.6011(a)-1 is amended by adding new paragraphs (h) and (i) to read as follows:

§31.6011(a)-1 Returns under Federal Insurance Contributions Act.

* * * * *

(h) *Returns by employees in respect of Additional Medicare Tax.* An employee who is paid wages, as defined in sections 3121(a), subject to the tax under section 3101(b)(2) (Additional Medicare Tax), must make a return for the taxable year in respect of such tax. The return shall be made on Form 1040. The form to be used by residents of the U.S. Virgin Islands, Guam, American Samoa, or the Northern Mariana Islands is Form 1040-SS, "U.S. Self-Employment Tax Return (Including Additional Child Tax Credit for Bona Fide Residents of Puerto Rico)." The form to be used by residents of Puerto Rico is either Form 1040-SS or Form 1040-PR, "Planilla para la Declaración de la Contribución Federal sobre el Trabajo por Cuenta Propia (Incluyendo el Crédito Tributario Adicional por Hijos para Residentes Bona Fide de Puerto Rico)."

(i) *Effective/applicability date.* Paragraph (h) of this section applies to taxable years beginning after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 9. Section 31.6011(a)-2 is amended by adding new paragraphs (d) and (e) to read as follows:

§31.6011(a)-2 Returns under Railroad Retirement Tax Act.

* * * * *

(d) *Returns by employees and employee representatives in respect of Additional Medicare Tax.* An employee or employee representative who is paid compensation, as defined in section 3231(e), subject to the tax under sections 3201(a) (as calculated under section 3101(b)(2)) or section 3211(a) (as calculated under section 3101(b)(2)) (Additional Medicare Tax), must make a return for the taxable year in respect of such tax. The return shall be made on Form 1040. The form to be used by residents of the U.S. Virgin Islands, Guam, American Samoa, or the Northern Mariana Islands is Form 1040-SS, "U.S. Self-Employment Tax Return (Including Additional Child Tax Credit for Bona Fide Residents of Puerto Rico)." The form to be used by residents of Puerto Rico is either Form 1040-SS or Form 1040-PR, "Planilla para la Declaración de la Contribución Federal sobre el Trabajo por Cuenta Propia (Incluyendo el Crédito Tributario Adicional por Hijos para Residentes Bona Fide de Puerto Rico)."

(e) *Effective/applicability date.* Paragraph (d) of this section applies to taxable years beginning after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 10. Section 31.6205-1 is amended by:

1. Revising the first sentence in paragraph (b)(2)(i).
2. Adding a new second sentence to paragraphs (b)(2)(ii) and (b)(2)(iii).
3. Adding two new sentences after the sixth sentence in paragraph (b)(3).
4. Adding a new paragraph (b)(4).
5. Revising paragraph (d)(1).
6. Adding a new paragraph (e).

The revisions and additions read as follows:

§31.6205-1 Adjustments of underpayments.

* * * * *

(b) * * * *

(2) * * * (i) If an employer files a return on which FICA tax or RRTA tax is required to be reported, and reports on the return less than the correct amount of em-

ployee or employer FICA or RRTA tax with respect to a payment of wages or compensation, and if the employer ascertains the error after filing the return, the employer shall correct the error through an interest-free adjustment as provided in this section, except as provided in paragraph (b)(4) of this section for Additional Medicare Tax. * * *

(ii) * * * However, if the employer also reported less than the correct amount of Additional Medicare Tax, the employer shall correct the underwithheld and underpaid Additional Medicare Tax in accordance with paragraph (b)(4) of this section. * * *

(iii) * * * However, if the employer also reported less than the correct amount of Additional Medicare Tax, the employer shall correct the underwithheld and underpaid Additional Medicare Tax in accordance with paragraph (b)(4) of this section. * * *

(3) * * * However, an adjustment of Additional Medicare Tax required to be withheld under section 3101(b)(2) or section 3201(a) may only be reported pursuant to this section if the error is ascertained within the same calendar year that the wages were paid to the employee, or if section 3509 applies to determine the amount of the underpayment, or if the adjustment is reported on a Form 2504 or Form 2504-WC. See paragraph (b)(4) of this section. * * *

(4) *Additional Medicare Tax.* If an employer files a return on which FICA tax or RRTA tax is required to be reported, and reports on the return less than the correct amount of Additional Medicare Tax required to be withheld with respect to a payment of wages or compensation, and if the employer ascertains the error after filing the return, the employer shall correct the error through an interest-free adjustment as provided in this section. An adjustment of Additional Medicare Tax may only be reported pursuant to this paragraph (b)(4) if the error is ascertained within the same calendar year that the wages or compensation were paid to the employee, unless the underpayment is attributable to an administrative error (that is, an error involving the inaccurate reporting of the amount actually withheld), section 3509 applies to determine the amount of the underpayment, or the adjustment is reported on a Form 2504 or Form 2504-WC. The

employer shall adjust the underpayment of Additional Medicare Tax by reporting the additional amount due on an adjusted return for the return period in which the wages or compensation were paid, accompanied by a detailed explanation of the amount being reported on the adjusted return and any other information as may be required by this section and by the instructions relating to the adjusted return. The reporting of the underpayment on an adjusted return constitutes an adjustment within the meaning of this section only if the adjusted return is filed within the period of limitations for assessment for the return period being corrected, and by the due date for filing the return for the return period in which the error is ascertained. For purposes of the preceding sentence, the due date for filing the adjusted return is determined by reference to the return being corrected, without regard to the employer's current filing requirements. For example, an employer with a current annual filing requirement who is correcting an error on a previously filed quarterly return must file the adjusted return by the due date for filing a quarterly return for the quarter in which the error is ascertained. The amount of the underpayment adjusted in accordance with this section must be paid to the IRS by the time the adjusted return is filed. If an adjustment is reported pursuant to this section, but the amount of the adjustment is not paid when due, interest accrues from that date (see section 6601).

* * * * *

(d) * * * (1) *Federal Insurance Contributions Tax Act and Railroad Retirement Tax Act.* If an employer collects less than the correct amount of employee FICA or RRTA tax from an employee with respect to a payment of wages or compensation, the employer must collect the amount of the undercollection by deducting the amount from remuneration of the employee, if any, paid after the employer ascertains the error. If an employer collects less than the correct amount of Additional Medicare Tax required to be withheld under section 3101(b)(2) or section 3201(a), the employer must collect the amount of the undercollection on or before the last day of the calendar year by deducting the amount from remuneration of the employee, if any, paid after the employer

ascertains the error. Such deductions may be made even though the remuneration, for any reason, does not constitute wages or compensation. The correct amount of employee tax must be reported and paid, as provided in paragraph (b) of this section, whether or not the undercollection is corrected by a deduction made as prescribed in this paragraph (d)(1), and even if the deduction is made after the return on which the employee tax must be reported is due. If such a deduction is not made, the obligation of the employee to the employer with respect to the undercollection is a matter for settlement between the employee and the employer. If an employer makes an erroneous collection of employee tax from two or more of its employees, a separate settlement must be made with respect to each employee. An overcollection of employee tax from one employee may not be used to offset an undercollection of such tax from another employee. For provisions relating to the employer's liability for the tax, whether or not it collects the tax from the employee, see §§31.3102-1(d), 31.3102-4(c), and 31.3202-1. This paragraph (d)(1) does not apply if section 3509 applies to determine the employer's liability.

* * * * *

(e) *Effective/applicability date.* Paragraphs (b) and (d) of this section apply to adjustments made after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 11. Section 31.6402(a)-2 is amended by:

1. Revising paragraph (a)(1)(i) and the first sentence in paragraph (a)(1)(ii).
2. Re-designating paragraphs (a)(1)(iii), (a)(1)(iv), (a)(1)(v), and (a)(1)(vi), as new paragraphs (a)(1)(iv), (a)(1)(v), (a)(1)(vi), and (a)(1)(vii), respectively.
3. Adding a new paragraph (a)(1)(iii).
4. Revising newly-designated paragraphs (a)(1)(iv) and (a)(1)(v).
5. Revising paragraph (b).
6. Adding a new paragraph (c).

The revisions and additions read as follows:

§31.6402(a)-2 *Credit or refund of tax under Federal Insurance Contributions Act or Railroad Retirement Tax Act.*

(a) * * * (1) * * *

(i) Except as provided in paragraph (a)(1)(iii) of this section, any person may file a claim for credit or refund for an overpayment (except to the extent that the overpayment must be credited pursuant to §31.3503-1) if the person paid to the Internal Revenue Service (IRS) more than the correct amount of employee Federal Insurance Contributions Act (FICA) tax under section 3101 or employer FICA tax under section 3111, employee Railroad Retirement Tax Act (RRTA) tax under section 3201, employee representative RRTA tax under section 3211, or employer RRTA tax under section 3221, or interest, addition to the tax, additional amount, or penalty with respect to any such tax.

(ii) Except as provided in paragraph (a)(1)(iii) of this section, the claim for credit or refund must be made in the manner and subject to the conditions stated in this section. * * *

(iii) *Additional Medicare Tax.* No refund or credit to the employer will be allowed for the amount of any overpayment of Additional Medicare Tax imposed under section 3101(b)(2) or section 3201(a) (as calculated under section 3101(b)(2)), which the employer deducted or withheld from an employee.

(iv) For adjustments without interest of overpayments of FICA or RRTA taxes, including Additional Medicare Tax, see §31.6413(a)-2.

(v) For corrections of FICA and RRTA tax paid under the wrong chapter, see §31.6205-1(b)(2)(ii) and (b)(2)(iii) and §31.3503-1.

* * * * *

(b) *Claim by employee*—(1) *In general.* Except as provided in (b)(3) of this section, if more than the correct amount of employee tax under section 3101 or section 3201 is collected by an employer from an employee and paid to the IRS, the employee may file a claim for refund of the overpayment if—

(i) The employee does not receive repayment or reimbursement in any manner from the employer and does not authorize the employer to file a claim and receive refund or credit,

(ii) The overcollection cannot be corrected under §31.3503-1, and

(iii) In the case of overpaid employee social security tax due to having received wages or compensation from multiple em-

ployers, the employee has not taken the overcollection into account in claiming a credit against, or refund of, his or her income tax, or if so, such claim has been rejected. See §31.6413(c)-1.

(2) *Statements supporting employee's claim.* (i) Except as provided in (b)(3) of this section, each employee who makes a claim under paragraph (b)(1) of this section shall submit with such claim a statement setting forth (a) the extent, if any, to which the employer has repaid or reimbursed the employee in any manner for the overcollection, and (b) the amount, if any, of credit or refund of such overpayment claimed by the employer or authorized by the employee to be claimed by the employer. The employee shall obtain such statement, if possible, from the employer, who should include in such statement the fact that it is made in support of a claim against the United States to be filed by the employee for refund of employee tax paid by such employer to the IRS. If the employer's statement is not submitted with the claim, the employee shall make the statement to the best of his or her knowledge and belief, and shall include therein an explanation of his or her inability to obtain the statement from the employer.

(ii) Except as provided in paragraph (b)(3) of this section, each individual who makes a claim under paragraph (b)(1) of this section also shall submit with such claim a statement setting forth whether the individual has taken the amount of the overcollection into account in claiming a credit against, or refund of, his or her income tax, and the amount, if any, so claimed (see §31.6413(c)-1).

(3) *Additional Medicare Tax.* (i) If more than the correct amount of Additional Medicare Tax under section 3101(b)(2) or section 3201(a) (as calculated under section 3101(b)(2)), is collected by an employer from an employee and paid to the IRS, the employee may file a claim for refund of the overpayment and receive a refund or credit if the overcollection cannot be corrected under §31.3503-1 and if the employee has not received repayment or reimbursement from the employer in the context of an interest-free adjustment. The claim for refund shall be made on Form 1040, "U.S. Individual Income Tax Return," by taking the overcollection into account in claiming a credit against,

or refund of, tax. The form to be used by residents of the U.S. Virgin Islands, Guam, American Samoa, or the Northern Mariana Islands is Form 1040-SS, "U.S. Self-Employment Tax Return (Including Additional Child Tax Credit for Bona Fide Residents of Puerto Rico)." The form to be used by residents of Puerto Rico is either Form 1040-SS or Form 1040-PR, "Planilla para la Declaración de la Contribución Federal sobre el Trabajo por Cuenta Propia (Incluyendo el Crédito Tributario Adicional por Hijos para Residentes Bona Fide de Puerto Rico)." The employee may not authorize the employer to claim the credit or refund for the employee. See §31.6402(a)-2(a)(1)(iii).

(ii) In the case of an overpayment of Additional Medicare Tax under section 3101(b)(2) or section 3201(a) for a taxable year of an individual for which a Form 1040 (or other applicable return in the Form 1040 series) has been filed, a claim for refund shall be made by the individual on Form 1040X, "Amended U.S. Individual Income Tax Return."

(c) *Effective/applicability date.* This section applies to claims for refund filed after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 12. Section 31.6413(a)-1 is amended by:

1. Revising the first sentence in paragraph (a)(2)(i).

2. Re-designating paragraphs (a)(2)(ii), (a)(2)(iii), (a)(2)(iv), (a)(2)(v), (a)(2)(vi), and (a)(2)(vii), as new paragraphs (a)(2)(iii), (a)(2)(iv), (a)(2)(v), (a)(2)(vi), (a)(2)(vii), and (a)(2)(viii), respectively.

3. Adding a new paragraph (a)(2)(ii).

4. Adding a new sentence after the first sentence in newly-designated paragraph (a)(2)(iv).

5. Adding a new sentence after the second sentence in newly-designated paragraph (a)(2)(v).

6. Revising newly-designated paragraph (a)(2)(viii).

7. Adding a new paragraph (c).

The revisions and additions read as follows:

§31.6413(a)-1 Repayment or reimbursement by employer of tax erroneously collected from employee.

(a) * * *

(2) * * * (i) Except as provided in paragraph (a)(2)(ii) of this section, if an employer files a return for a return period on which FICA tax or RRTA tax is reported, collects from an employee and pays to the IRS more than the correct amount of the employee FICA or RRTA tax, and if the employer ascertains the error after filing the return and within the applicable period of limitations on credit or refund, the employer shall repay or reimburse the employee in the amount of the overcollection prior to the expiration of such limitations period. * * *

(ii) If an employer files a return for a return period on which Additional Medicare Tax under section 3101(b)(2) or section 3201(a) is reported, collects from an employee and pays to the IRS more than the correct amount of Additional Medicare Tax required to be withheld from wages or compensation, and if the employer ascertains the error after filing the return but before the end of the calendar year in which the wages were paid, the employer shall repay or reimburse the employee in the amount of the overcollection prior to the end of the calendar year. However, this paragraph does not apply to the extent that, after reasonable efforts, the employer cannot locate the employee.

* * * * *

(iv) * * * However, for purposes of overcollected Additional Medicare Tax under section 3101(b)(2) or section 3201(a), the employer shall reimburse the employee by applying the amount of the overcollection against the employee FICA or RRTA tax which attaches to wages or compensation paid by the employer to the employee in the calendar year in which the overcollection is made. * * *

(v) * * * This paragraph (a)(2)(v) does not apply for purposes of overcollected Additional Medicare Tax under section 3101(b)(2) or section 3201(a) which must be repaid or reimbursed to the employee in the calendar year in which the overcollection is made. * * *

* * * * *

(viii) For corrections of FICA and RRTA tax paid under the wrong chapter, see §31.6205-1(b)(2)(ii) and (b)(2)(iii) and §31.3503-1.

* * * * *

(c) *Effective/applicability date.* Paragraph (a) of this section applies to adjustments made after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Par. 13. Section 31.6413(a)-2 is amended by:

1. Adding a new sentence after the first sentence in paragraph (a)(1).

2. Adding a new sentence after the second sentence in paragraph (b)(2)(i).

3. Adding a new paragraph (e).

The revisions and additions read as follows:

§31.6413(a)-2 Adjustments of overpayments.

(a) * * *

(1) * * * However, this section only applies to overcollected or overpaid Additional Medicare Tax under section 3101(b)(2) or section 3201(a) if the employer has repaid or reimbursed the amount of the overcollection of such tax to the employee in the year in which the overcollection was made. * * *

* * * * *

(b) * * *

(2) * * * (i) * * * However, for purposes of Additional Medicare Tax under section 3101(b)(2) or section 3201(a), if the amount of the overcollection is not repaid or reimbursed to the employee under §31.6413(a)-1(a)(2)(ii), there is no overpayment to be adjusted under this section and the employer may only adjust an overpayment of such tax attributable to an administrative error, that is, an error involving the inaccurate reporting of the amount withheld, pursuant to this section. * * *

* * * * *

(e) *Effective/applicability date.* Paragraphs (a) and (b) of this section apply to adjustments made after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Steven T. Miller,
*Deputy Commissioner for
Services and Enforcement.*

(Filed by the Office of the Federal Register on November 30, 2012, 2:00 p.m., and published in the issue of the Federal Register for December 5, 2012, 77 F.R. 72268)

Deletions From Cumulative List of Organizations Contributions to Which are Deductible Under Section 170 of the Code

Announcement 2012-49

The Internal Revenue Service has revoked its determination that the organizations listed below qualify as organizations described in sections 501(c)(3) and 170(c)(2) of the Internal Revenue Code of 1986.

Generally, the Service will not disallow deductions for contributions made to a listed organization on or before the date of announcement in the Internal Revenue Bulletin that an organization no longer qualifies. However, the Service is not precluded from disallowing a deduction for any contributions made after an organization ceases to qualify under section 170(c)(2) if the organization has not timely filed a suit for declaratory judgment under section 7428 and if the contributor (1) had knowledge of the revocation of the ruling or determination letter, (2) was aware that such revocation was imminent, or (3) was in part responsible for or was aware of the activities or omissions of the organization that brought about this revocation.

If on the other hand a suit for declaratory judgment has been timely filed, contributions from individuals and organizations described in section 170(c)(2) that are otherwise allowable will continue to be deductible. Protection under section 7428(c) would begin on December 27, 2012, and would end on the date the court first determines that the organization is not described in section 170(c)(2) as more particularly set forth in section 7428(c)(1). For individual contributors, the maximum deduction protected is \$1,000, with a husband and wife treated as one contributor. This benefit is not extended to any individual, in whole or in part, for the acts or omissions of the organization that were the basis for revocation.

Amani Foundation
Aurora, CO

Excalibur Foundation
Sparks, NV

**Update to Announcement
2012-25 — Extension of Time
for Businesses to Comply with
Rev. Rul. 2012-18 Regarding
the Proper Treatment of
Service Charges**

Announcement 2012-50

This announcement extends the time for businesses to comply with the rules regarding proper treatment of service charges specified in Q&A 1 of Rev. Rul. 2012-18, 2012-26 I.R.B. 1032. This extension is provided in order to allow businesses not

currently in compliance additional time to modify their business practices and make needed system changes.

In a previously issued interim guidance memorandum (IGM), included as an attachment to Announcement 2012-25, 2012-26 I.R.B. 1054, the Internal Revenue Service (Service) provides administrative guidelines to examiners concerning Rev. Rul. 2012-18. Specifically, the IGM instructs examiners to apply Q&A 1 of Rev. Rul. 2012-18, in limited circumstances, prospectively to amounts paid on or after January 1, 2013. In Announcement 2012-25, the Service sought public comments regarding whether additional time was needed to ensure that systems are compliant. Based on the comments received, the Service has determined that an extension to January 1, 2014, is appro-

priate. An updated IGM will be issued to examiners informing them of the extension of time to January 1, 2014, with the extension to apply in the limited circumstances set forth in the IGM.

EFFECT ON OTHER DOCUMENTS

Announcement 2012-25 is amplified.

DRAFTING INFORMATION

The principal author of this announcement is Linda L. Conway-Hataloski of the Office of Division Counsel/Associate Chief Counsel (Tax Exempt & Government Entities). For questions regarding this announcement, contact Linda L. Conway-Hataloski at 202-622-0047 (not a toll-free call).

Definition of Terms

Revenue rulings and revenue procedures (hereinafter referred to as “rulings”) that have an effect on previous rulings use the following defined terms to describe the effect:

Amplified describes a situation where no change is being made in a prior published position, but the prior position is being extended to apply to a variation of the fact situation set forth therein. Thus, if an earlier ruling held that a principle applied to A, and the new ruling holds that the same principle also applies to B, the earlier ruling is amplified. (Compare with *modified*, below).

Clarified is used in those instances where the language in a prior ruling is being made clear because the language has caused, or may cause, some confusion. It is not used where a position in a prior ruling is being changed.

Distinguished describes a situation where a ruling mentions a previously published ruling and points out an essential difference between them.

Modified is used where the substance of a previously published position is being changed. Thus, if a prior ruling held that a principle applied to A but not to B, and the new ruling holds that it applies to both A

and B, the prior ruling is modified because it corrects a published position. (Compare with *amplified* and *clarified*, above).

Obsoleted describes a previously published ruling that is not considered determinative with respect to future transactions. This term is most commonly used in a ruling that lists previously published rulings that are obsoleted because of changes in laws or regulations. A ruling may also be obsoleted because the substance has been included in regulations subsequently adopted.

Revoked describes situations where the position in the previously published ruling is not correct and the correct position is being stated in a new ruling.

Superseded describes a situation where the new ruling does nothing more than restate the substance and situation of a previously published ruling (or rulings). Thus, the term is used to republish under the 1986 Code and regulations the same position published under the 1939 Code and regulations. The term is also used when it is desired to republish in a single ruling a series of situations, names, etc., that were previously published over a period of time in separate rulings. If the new ruling does more than restate the substance

of a prior ruling, a combination of terms is used. For example, *modified* and *superseded* describes a situation where the substance of a previously published ruling is being changed in part and is continued without change in part and it is desired to restate the valid portion of the previously published ruling in a new ruling that is self contained. In this case, the previously published ruling is first modified and then, as modified, is superseded.

Supplemented is used in situations in which a list, such as a list of the names of countries, is published in a ruling and that list is expanded by adding further names in subsequent rulings. After the original ruling has been supplemented several times, a new ruling may be published that includes the list in the original ruling and the additions, and supersedes all prior rulings in the series.

Suspended is used in rare situations to show that the previous published rulings will not be applied pending some future action such as the issuance of new or amended regulations, the outcome of cases in litigation, or the outcome of a Service study.

Abbreviations

The following abbreviations in current use and formerly used will appear in material published in the Bulletin.

A—Individual.
Acq.—Acquiescence.
B—Individual.
BE—Beneficiary.
BK—Bank.
B.T.A.—Board of Tax Appeals.
C—Individual.
C.B.—Cumulative Bulletin.
CFR—Code of Federal Regulations.
CI—City.
COOP—Cooperative.
Ct.D.—Court Decision.
CY—County.
D—Decedent.
DC—Dummy Corporation.
DE—Donee.
Del. Order—Delegation Order.
DISC—Domestic International Sales Corporation.
DR—Donor.
E—Estate.
EE—Employee.
E.O.—Executive Order.

ER—Employer.
ERISA—Employee Retirement Income Security Act.
EX—Executor.
F—Fiduciary.
FC—Foreign Country.
FICA—Federal Insurance Contributions Act.
FISC—Foreign International Sales Company.
FPH—Foreign Personal Holding Company.
F.R.—Federal Register.
FUTA—Federal Unemployment Tax Act.
FX—Foreign corporation.
G.C.M.—Chief Counsel’s Memorandum.
GE—Grantee.
GP—General Partner.
GR—Grantor.
IC—Insurance Company.
I.R.B.—Internal Revenue Bulletin.
LE—Lessee.
LP—Limited Partner.
LR—Lessor.
M—Minor.
Nonacq.—Nonacquiescence.
O—Organization.
P—Parent Corporation.
PHC—Personal Holding Company.
PO—Possession of the U.S.
PR—Partner.

PRS—Partnership.
PTE—Prohibited Transaction Exemption.
Pub. L.—Public Law.
REIT—Real Estate Investment Trust.
Rev. Proc.—Revenue Procedure.
Rev. Rul.—Revenue Ruling.
S—Subsidiary.
S.P.R.—Statement of Procedural Rules.
Stat.—Statutes at Large.
T—Target Corporation.
T.C.—Tax Court.
T.D.—Treasury Decision.
TFE—Transferee.
TFR—Transferor.
T.I.R.—Technical Information Release.
TP—Taxpayer.
TR—Trust.
TT—Trustee.
U.S.C.—United States Code.
X—Corporation.
Y—Corporation.
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Key to Abbreviations:

Ann	Announcement
CD	Court Decision
DO	Delegation Order
EO	Executive Order
PL	Public Law
PTE	Prohibited Transaction Exemption
RP	Revenue Procedure
RR	Revenue Ruling
SPR	Statement of Procedural Rules
TC	Tax Convention
TD	Treasury Decision
TDO	Treasury Department Order

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