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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 48

[TD 9604]

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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 **[INSERT DATE OF PUBLICATION OF THIS DOCUMENT IN THE FEDERAL REGISTER]**.

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) (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 FDCA 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 FDCA. Section 201(h) of the FDCA 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 FDCA 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 FDCA 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 FFDCFA that are intended for use directly on patients or directly in patient care from other devices defined in section 201(h) of the FFDCFA 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 FFDCFA 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 FFDCFA 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 FFDCFA 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 FFDCFA. 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 FFDCFA 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/cfrl/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)(1). 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)(1) 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 FDCA 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 CB 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.

Uses

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 CB 331) and Rev. Rul. 72-563 (1972-1 CB 568).

With regard to evaluation and testing products, Rev. Rul. 76-119 (1976-1 CB 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.

Rebates

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 FFDCFA 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 FFDCFA 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 CB 179), Rev. Rul. 83-149 (1983-2 CB 186), Rev. Rul. 68-40 (1968-1 CB 452), Rev. Rul. 64-202 (1964-2 CB 431), and Rev. Rul. 58-586 (1958-2 CB 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 CB 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 FFDCFA 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 expire. 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 subchapter S 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 FDCA 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 FDCA 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.

List of Subjects in 26 CFR Part 48

Excise taxes, Reporting and recordkeeping requirements.

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

Sec.

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 FDCA 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 (DMEPOS) 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/cfrl/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 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 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 paragraph (e) 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).