



[4830-01-p]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 48

[REG-113770-10]

RIN 1545-BJ44

Taxable Medical Devices

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Proposed Rulemaking and Notice of Public Hearing.

SUMMARY: This document contains proposed regulations that provide guidance on the excise tax imposed on the sale of certain medical devices under section 4191 of the Internal Revenue Code, enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act. The proposed regulations affect manufacturers, importers, and producers of taxable medical devices. This document also provides a notice of public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by **[INSERT DATE 90 DAYS AFTER PUBLICATION OF THIS DOCUMENT IN THE FEDERAL REGISTER]**. Outlines of topics to be discussed at the public hearing scheduled for May 16, 2012, at 10 a.m., must be received by **[INSERT DATE 90 DAYS AFTER PUBLICATION OF THIS DOCUMENT IN THE FEDERAL REGISTER]**.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-113770-10), Room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044.

Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-113770-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-113770-10). The public hearing will be held on May 16, 2012, in the IRS Auditorium, beginning at 10 a.m., at the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Natalie Payne or Stephanie Bland, at (202) 622-3130; concerning submission of comments, the public hearing, and/or to be placed on the building access list to attend the public hearing, contact Oluwafunmilayo Taylor at (202) 622-7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Statutory Provisions

This document contains proposed regulations that provide guidance on the excise tax imposed on the sale of certain medical devices under section 4191 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).

Section 4191 imposes an excise tax on the sale of certain medical devices by the manufacturer, producer, or importer of the device in an amount equal to 2.3 percent of

the sale price. Section 4191 applies to sales of taxable medical devices after December 31, 2012.

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. Section 201(h) of the FFDCA provides generally that the term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or intended to affect the structure or any function of the body, and that does not achieve its primary intended purposes through chemical action within or on the body and that is not dependent upon being metabolized for the achievement of its primary intended purposes.

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.

In addition, the ACA amended section 4221(a) to limit tax-free sales of taxable medical devices to sales (i) for use by the purchaser for further manufacture, or for resale by the purchaser to a second purchaser for use by such second purchaser in further manufacture, and (ii) for export, or for resale by the purchaser to a second

purchaser for export. The ACA makes a corresponding amendment to section 6416(b)(2) with regard to claims for refund.

Manufacturers Excise Tax Rules Generally

The ACA added section 4191 to chapter 32, subtitle D of the Code, which relates to taxes imposed upon the sales of taxable articles by manufacturers, producers, and importers (commonly referred to as “manufacturers excise taxes”). Therefore, the existing rules governing chapter 32 apply to section 4191. The substantive regulations relating to manufacturers excise taxes are contained in part 48 (Manufacturers and Retailers Excise Tax Regulations) of Title 26 of the Code of Federal Regulations (CFR). The procedural regulations governing manufacturers excise taxes are contained in part 40 (Excise Tax Procedural Regulations) of 26 CFR.

The manufacturers excise tax rules are discussed in Part VII under “Explanation of Provisions,” in this preamble. For additional information on the manufacturers excise tax rules generally, see chapter 5 of IRS Publication 510, “Excise Taxes,” available at <http://www.irs.gov/publications/p510/ch05.html>.

Notice 2010-89

On December 27, 2010, the IRS published Notice 2010-89 (2010-52 IRB 908) to request comments on the implementation and administration of the new tax under section 4191. The IRS and the Treasury Department received numerous comments in response to the notice and considered all comments in the drafting of the proposed regulations. The comments are discussed in more detail in this preamble. The IRS and the Treasury Department also consulted with the Food and Drug Administration (FDA)

and the Centers for Medicare and Medicaid Services (CMS) in developing these regulations.

Explanation of Provisions

I. Definition of “Taxable Medical Device”

Section 4191(b)(1) links the definition of “taxable medical device” to the definition of “device” in section 201(h) of the FFDCA. The FDA generally administers the provisions of the FFDCA, including section 201(h) and other provisions relating to medical devices.

The FDA generally requires owners or operators of places of business (also called establishments) that are located in the United States, or in foreign countries that export devices to the United States, and that manufacture, prepare, propagate, compound, assemble, process, repackage, or relabel medical devices intended for human use to register their establishments and list their devices upon first entering into operation, and to update this information on an annual basis with the FDA. See sections 510(a)–(d), (i), and (j) of the FFDCA, 21 CFR 807.20, and 21 CFR 807.21.

Various commentators observed that the statutory definition of “taxable medical device” leaves uncertainty as to which devices are included in the definition. The proposed regulations address this concern by providing 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 FDA under section 510(j) of the FFDCA and 21 CFR Part 807, pursuant to FDA requirements. The FDA listing requirements are longstanding. Further, device manufacturers must comply with these

requirements as part of the FDA's device regulation process. Therefore, device manufacturers can be expected to know which devices fall within the definition.

The FDA has promulgated classification regulations for approximately 1,700 different generic types of devices. Each classification regulation includes one or more product codes that describe a subcategory of the device type described in the regulation. Currently, manufacturers may, in certain circumstances, list multiple different devices that fall within the same product code under a single listing. Therefore, all devices that are listed under a single product code listing in conjunction with the FDA's device listing requirement are "taxable medical devices" unless they fall within an exemption under section 4191(b)(2).

The proposed regulations also 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.

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).

The FDA has grouped each of the 1,700 classification regulations into 16 medical specialties (21 CFR, Parts 862-892). Each of these generic types of devices is assigned to one (or sometimes more than one) of three regulatory classes based on the

level of control necessary to assure the safety and effectiveness of the device. The three classes of FDA devices are Class I (general controls), Class II (special controls), and Class III (pre-market approval). A number of device types that predate the enactment of the Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1976 remain unclassified.

With regard to the retail exemption, section 4191 makes no reference to the three regulatory classes. Further, the Joint Committee on Taxation's Technical Explanation of the ACA makes clear that the FDA regulatory classes do not, by themselves, determine whether a device falls within the retail exemption. Specifically, the Technical Explanation states, "The exemption for such items is not limited by device class as defined in section 513 of the Federal Food, Drug, and Cosmetic Act." Rather, the Technical Explanation notes that the exemption could cover "Class I items such as certain bandages and tipped applicators, Class II items such as certain pregnancy test kits and diabetes testing supplies, and Class III items such as certain denture adhesives and snake bite kits." The Technical Explanation also emphasizes that "items would only be exempt if they are generally designed and sold for individual use." Joint Committee on Taxation, General Explanation of Tax Legislation Enacted in the 111th Congress (JCS-2-11), March 2011, at 366.

The proposed regulations provide a facts and circumstances approach to evaluating whether a taxable 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 set of non-exclusive factors for use in evaluating whether a taxable medical device is of a type that is generally purchased by the general public at retail for individual use. The proposed regulations also include a safe harbor provision.

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).

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. Those 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 parts or subparts of 21 CFR; and (v) whether the device qualifies as durable medical equipment, prosthetics, orthotics, and supplies (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. With regard to the regulatory classifications incorporated into the fourth factor described in this preamble, the IRS and the Treasury Department have determined, based on all the facts and circumstances, that the overwhelming majority of product codes that fall within these regulatory categories do not include devices that are of a type generally purchased by the general public at retail for individual use.

Whether a device is of a type generally purchased by the general public at retail for individual use is determined based on all relevant facts and circumstances. Thus, there may be relevant facts and circumstances in addition to the factors specifically identified in the proposed regulations.

To provide greater certainty, the proposed regulations also include a safe harbor provision that identifies certain categories of taxable 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; (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>; and (iv) certain devices that qualify as DMEPOS for which payment is available on a purchase basis under Medicare Part B payment rules in accordance with the fee schedule published by CMS.

The IRS and the Treasury Department recognize the challenges involved in applying a facts and circumstances test to the wide array of devices that are potentially subject to the medical device excise tax, including for smaller manufacturers or importers for which the application of the retail exemption may determine whether they are subject to the tax at all. The IRS and the Treasury Department intend through the rulemaking process to continue their efforts to find ways to make the test easier to apply to particular cases and to provide certainty with respect to a substantial majority of devices. To that end, comments are requested on additional factors, examples, or safe harbors that could be added to provide greater certainty for a larger number of devices. Comments are particularly requested on how to provide greater clarity with respect to taxable medical devices that are sold primarily or exclusively through specialty medical retailers that sell medical devices and related materials. Comments are also requested on whether the packaging and labeling of a taxable medical device, the terms and conditions of the manufacturer's warranty with respect to a device, and substantial sales of a device over the internet would be meaningful factors for use in establishing whether a device qualifies for the retail exception, and if so, how any such factor should be described and applied. Comments are also requested on other types of DMEPOS that

should be considered for safe harbor treatment and how those items can be consistently and specifically identified. For example, “inexpensive equipment,” as defined in 42 CFR 414.220(a)(1), appears to describe items that may meet the retail exception under an application of the facts and circumstances test. However, comments are requested on how devices that fall under the definition would be identified given that the CMS fee schedule categorizes “inexpensive equipment” together with other medical devices that appear not to fall within the retail exception.

The IRS and the Treasury Department received numerous comments suggesting that it is not feasible to base the retail exception on quantitative data that compares the relative number of sales of a certain taxable medical device at retail to the number of sales of the device to doctors’ offices, hospitals, and other medical and health care providers and institutions. Several commentators stated that for a given device, numerical data on the proportion of sales to retail purchasers and to non-retail purchasers is often not available to the manufacturers and importers of the device, even with respect to the devices that they manufacture or import. Further, the commentators noted that even if the data is available, a rule that looks to industry-wide data regarding the percentage of retail and non-retail sales of a device would require an ongoing, resource-intensive effort to collect industry-wide sales information, and would not provide certainty to stakeholders because the data may change from year to year. In light of these difficulties, the proposed regulations do not adopt a market data approach to the retail exception.

One commentator suggested that the IRS and the Treasury Department provide a retail exception safe harbor based on a manufacturer’s or importer’s proportion of

sales of a particular device at retail, compared to that manufacturer's or importer's overall sales of the device. Under this suggestion, if the retail sales of a particular device by a manufacturer or importer met or exceeded a certain ratio or percentage, as compared to overall sales by the manufacturer or importer of that device, then all sales of the device would be exempt from tax. The proposed regulations do not adopt this approach to the retail exception because the suggested safe harbor could result in inconsistent treatment of different manufacturers of the same device. The language of section 4191 applies the retail exception to types of devices, not to manufacturers and importers based on the nature of their distributions or sales.

Some commentators suggested that if the manufacturer or importer is able to determine that a particular taxable medical device is sold to consumers at retail, no tax should be imposed on any sale of that device, even if the device is not of a type that is generally purchased by the general public at retail for individual use. Such an approach would be contrary to the language of the statute. Therefore, the proposed regulations do not adopt this approach.

III. Veterinary Devices

The definition of "device" in section 201(h) of the FFDCA includes devices used in veterinary medicine. However, the definition of "taxable medical device" under section 4191 limits taxable medical devices to devices described in section 201(h) of the FFDCA that are "intended for humans." The proposed regulations further limit the definition of "taxable medical device" to devices that are listed with the FDA. Under existing FDA regulations, a device intended for use exclusively in veterinary medicine must be labeled as such and is not subject to several pre-market and post-market

provisions of the FFDCA, including the listing requirement. Therefore, under the proposed regulations, devices intended for use exclusively in veterinary medicine are not “taxable medical devices.”

A commentator has noted, however, that many medical devices used in veterinary practices are also used in human medicine. The commentator suggested that if the manufacturer can demonstrate that a device is sold for use in veterinary medicine, the excise tax should not be imposed on that sale. The proposed regulations do not adopt this suggestion because the statutory language does not limit the definition of “taxable medical device” to devices intended exclusively for humans. Therefore, a device that is intended for humans but that is also intended for use or used in veterinary medicine is a “taxable medical device” if it is listed as a device with the FDA pursuant to FDA requirements, and does not fall within an exemption under section 4191(b)(2), such as the retail exemption.

IV. Dual Use Devices

Devices That Have Medical and Non-Medical Uses

Many commentators expressed concern over the potential taxation of devices that have both medical and non-medical uses, such as latex gloves, and requested that the excise tax not be imposed on the sale of devices for non-medical uses.

Section 4191 imposes a tax upon the sale of a taxable medical device by the manufacturer, unless the sale is for export or further manufacture. In most instances, the manufacturer does not sell directly to the end user of the device. Therefore, the manufacturer does not typically know the identity of the end user at the time of sale. Further, commentators suggest that manufacturers would have difficulty tracking their

products through the supply chain and determining the ultimate destination of their products once they are sold to a distributor. Commentators also stated that, in some cases, after the manufacturer sells a device to a distributor, the distributor may package and label the device for sale for non-medical uses.

Under the proposed regulations, the definition of “taxable medical device” is tied to the FDA’s listing requirements for devices. Therefore, a device that is listed with the FDA pursuant to FDA requirements is a “taxable medical device,” unless it falls within an exemption under section 4191(b)(2), such as the retail exemption.

“Research Use Only” Devices

Several commentators stated that they manufacture devices that are used in clinical medicine to diagnose disease in humans, as well as in industrial laboratory work and laboratory research. Those commentators further stated that when sold for non-medical purposes, such devices are labeled “Research Use Only.” The comments suggest that, although the devices labeled “Research Use Only” are physically suitable for clinical use, FDA regulations prohibit the use of devices with this label in a clinical setting for human medical purposes. The commentators requested that sales of devices that are labeled “Research Use Only” be exempt from the medical device excise tax because of the intended use of such devices.

The proposed regulations define “taxable medical device” as any device that is listed as a device with the FDA pursuant to FDA requirements. Under 21 CFR 807.65(f) of the FDA regulations, persons that “manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution” are exempt from the FDA’s registration and

listing requirements. See section 510(g) of the FFDCA. Accordingly, a device that is sold for use in research that is not listed because it satisfies the requirements of 21 CFR 807.65(f) is not a “taxable medical device” under the proposed regulations. In contrast, a device that is sold for use in research that is listed with the FDA pursuant to FDA requirements, such as a device not solely used in research or one that is introduced into commercial distribution, is a “taxable medical device” under the proposed regulations, unless it falls within an exemption under section 4191(b)(2), such as the retail exemption.

V. Devices Approved by the FDA for Limited Use – Investigational Devices

Several commentators requested an exemption for devices that are subject to an Investigational Device Exemption (IDE). The FDA permits the distribution of certain devices that the FDA has not yet approved for marketing under an IDE. See 21 CFR Part 812 for the FDA’s regulatory provisions regarding the IDE. Devices under an IDE are exempt from the FDA’s listing requirements. Accordingly, a device subject to an IDE is not a “taxable medical device” under the proposed regulations.

VI. Dental Instruments and Equipment

A commentator requested that the proposed regulations provide a blanket exclusion for dental instruments and equipment. The proposed regulations do not adopt this suggestion. There is no statutory basis for treating dental devices differently from other taxable medical devices. Many dental instruments and equipment items are subject to the FDA’s listing requirement. Accordingly, those devices that are listed as devices with the FDA pursuant to FDA requirements are “taxable medical devices”

under the proposed regulations, unless they fall within an exemption under section 4191(b)(2), such as the retail exemption.

VII. Manufacturers Excise Tax Rules Generally; Application to Taxable Medical Devices

The ACA added section 4191 to chapter 32; therefore, the existing rules governing chapter 32 apply to the medical device excise tax. Those rules are longstanding. They are contained in statutory and regulatory provisions, and have been developed further through revenue rulings, other published guidance, and case law.

Several commentators requested clarification on the existing manufacturers excise tax rules. This section provides an overview of the rules and addresses some of the manufacturers excise tax issues raised by commentators.

Liability for Tax; Definition of “Manufacturer” and “Importer”

In general, the manufacturer or importer of a taxable article is liable for the tax upon the sale of the article. Under chapter 32, the lease or use of a taxable article by the manufacturer is generally treated as a sale.

The term “manufacturer” means any person who produces a taxable article from scrap, salvage, or junk material, or from new or raw material, by processing, manipulating, or changing the form of an article or by combining or assembling two or more articles. A manufacturer that sells a taxable article in knockdown (that is, unassembled) condition is considered the manufacturer and is liable for tax on the sale of the article. For chapter 32 purposes, the term “manufacturer” also includes an “importer.” The importer of a taxable article is any person who brings the article into the United States from a source outside the United States, or withdraws an article from a

customs bonded warehouse for sale or use in the United States. See §48.0-2(a)(4) for the definitions of the terms “manufacturer” and “importer.”

If more than one person is involved in the manufacture or importation of an item, such as a contract manufacturing arrangement, the determination of which person is the manufacturer or the importer is based on the facts and circumstances of the arrangement. The substance rather than the form of the transaction is determinative. See Rev. Rul. 58-134 (1958-1 CB 395), Rev. Rul. 60-42 (1960-1 CB 474), and Polaroid v. U.S., 235 F2d. 276 (1st Cir. 1956), for rules regarding the determination of which party is the manufacturer for chapter 32 purposes. See Rev. Rul. 68-197 (1968-1 CB 455) and Rev. Rul. 82-40 (1982-1 CB 175) for rules regarding the determination of which party is the importer for chapter 32 purposes.

Some commentators suggested that, in determining who is liable for the tax, the IRS and the Treasury Department should apply either the section 954 contract manufacturing rules or the FDA’s registration and listing rules under 21 CFR Part 807. The proposed regulations do not adopt these suggestions. As noted above, the existing chapter 32 framework includes definitions of “manufacturer” and “importer.” Section 4191 does not provide alternate definitions for those terms. Accordingly, the definitions of “manufacturer” and “importer” under chapter 32 apply to section 4191.

Taxable event

Generally, the manufacturers excise tax attaches when the title to the taxable article passes from the manufacturer to a purchaser. When title passes is dependent upon the intention of the parties as gathered from the contract of sale and the attendant circumstances. In the case of a sale on credit, the tax attaches whether or not the

purchase price is actually paid. In the case of conditional or installment sales of a taxable article, the tax attaches to each partial payment. See §48.0-2(b) for the general rules regarding the attachment of tax.

Section 4218 imposes tax on certain uses of an article by the article's manufacturer. The tax attaches at the time the use begins. Under §48.4218-1(b), generally, 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. However, if a manufacturer uses a taxable article in the testing of another article of its own manufacture, the use of the taxable article by the manufacturer is not a taxable use. See Rev. Rul. 76-119 (1976-1 CB 345). Section 48.4218-5 provides rules on how to calculate the price on which the tax is imposed in cases of the taxable use of an article by the manufacturer.

Several commentators requested guidance on whether taxable medical devices that are used as demonstration products are subject to the medical device excise tax. The provision or use of a taxable medical device as a demonstration product may constitute a taxable sale or use, depending on the facts and circumstances of the arrangement. For example, Rev. Rul. 72-563 (1972-2 CB 568) holds that a manufacturer has sold an article when it provides the article "free of charge" to another person for promotional purposes. In addition, Rev. Rul. 60-290 (1960-2 CB 331) holds that the use of a taxable article by its manufacturer for demonstration purposes is a taxable use for purposes of section 4218.

Leases

Under section 4217(a), the lease of a taxable article by the manufacturer is considered a sale. If, at the time of making the lease, the manufacturer is in the business of selling the same type and model of article in arm's length transactions, the tax attaches to each lease payment until the cumulative total of the tax payments equals the total tax. If, however, at the time of making the lease, the manufacturer is not engaged in the business of selling the same type and model of article in arm's length transactions, the tax attaches to each lease payment if the article is leased by the manufacturer. See section 4216(c), section 4217(b), §48.4216(c)-1, and §48.4217-2 for the rules regarding the attachment and payment of tax in the context of leases.

Under §48.4217-1, the term "lease" means a contract or agreement, written or verbal, that gives the lessee an exclusive, continuous right to the possession or use of a particular article for a period of time. The term includes any renewal or extension of a lease, or any subsequent lease of the article.

Sale price

The tax imposed under section 4191 is based on the price for which a taxable medical device is sold. Under section 48.4216(a)-1(a), the price for which a taxable article is sold includes the total consideration paid for the device, whether that consideration is in the form of money, services, or other things.

The taxable sale price of a taxable article also includes, among other things, any charge for coverings or containers (regardless of their nature), and any charge incident to placing the article in a condition to be packed and ready for shipment. However, the taxable sale price excludes (i) the manufacturers excise tax, whether or not it is stated

as a separate charge; (ii) the actual cost of transportation, delivery, insurance, installation, and other expenses incurred by the manufacturer or importer in placing the article in the hands of the purchaser pursuant to a bona fide sale (the costs of transportation of goods to a warehouse before their bona fide sale are not excludable); (iii) discounts, rebates, and similar allowances actually granted to the purchaser; (iv) local advertising charges; and (v) charges for warranty paid at the purchaser's option. See section 4216(a) and §48.4216(a)-1 for the rules regarding the charges included in sale price. See sections 4216(a) and (e), §48.4216(a)-2, §48.4216(e)-1, §48.4216(e)-2, and §48.4216(e)-3 for the rules regarding exclusions from sale price.

The basic sale price rules assume that the manufacturer sells the taxable article in an arm's length transaction (that is, in a transaction between two unrelated parties) to a wholesale distributor that then sells the taxable article to a retailer that resells to consumers. However, if a manufacturer sells a taxable article other than to a wholesale distributor or at less than a fair market arm's length price, the taxable sale price is determined on a constructive sale price rather than the actual sale price. The constructive sale price rules are set forth in section 4216(b), in §48.4216(b)-1, §48.4216(b)-2, §48.4216(b)-3, and §48.4216(b)-4 of the regulations, and in numerous revenue rulings.

If a purchaser of a taxable article returns the article to the manufacturer under a warranty as to its quality or service and the manufacturer replaces the article with a new taxable article free of charge or at a reduced price, the tax on the new article is computed on the actual amount, if any, paid to the manufacturer for the new article. See §48.4216(a)-3(b) for the rules regarding replacements under warranty.

Several commentators requested clarification on how the sale price rules work in the context of taxable medical devices, particularly with regard to “bonus” goods and rebates. These commentators indicated that rebates are a common practice in the medical device industry. Under existing manufacturers tax rules, if a manufacturer sells taxable articles at the regular price and includes some of the same articles as a bonus, the tax imposed under section 4191 applies to the total price charged for the entire order. With regard to rebates, §48.4216(a)-3(c) provides that the tax must be based on the original price of the taxable article, unless the rebate has been made prior to the close of the period for which the tax is returned. However, if a manufacturer subsequently allows a rebate for taxable articles on which tax has been paid, the manufacturer is entitled to a credit or refund for that portion of the tax that is proportionate to the part of the price that is rebated. See Rev. Rul. 68-659 (1968-2 CB 511) and Rev. Rul. 69-73 (1969-1 CB 284) for applications of the rules regarding bonus goods, free goods, and rebates. See §48.4216(a)-3(c) for rules regarding readjustments in sale price for discounts, rebates, and bonuses.

Sales by persons other than the manufacturer

If title to, or ownership of, a taxable article passes from the manufacturer to a transferee by operation of law (such as through an inheritance or as part of the sale of a business) or as a result of any transaction not taxable under chapter 32, tax attaches to the sale of the article by the transferee to the same extent and in the same manner as if the transferee were the manufacturer of the article. See section 4219 and §48.4219-1 for the rules regarding transfers of title to taxable articles by operation of law.

Tax-free sales for further manufacture and export

Under section 4221(a), the tax imposed by section 4191 does not apply to the sale of taxable medical devices for use by the purchaser for further manufacture (or for resale by the purchaser to a second purchaser for further manufacture) or for export (or for resale for export).

Under §48.4221-2(b), an article is sold for use in further manufacture if the article is sold for use by the purchaser as material in the production of, or as a component part of, another article taxable under chapter 32. Section 48.4221-2 sets forth rules governing tax-free sales of articles to be used or resold for further manufacture.

Under §48.0-2(a)(10), an article is exported if the article is severed from the mass of things belonging within the United States with the intention of uniting it with the mass of things belonging within some foreign country or within a possession of the United States. Section 48.4221-3 sets forth rules regarding tax-free sales of articles for export.

To make a tax-free sale for further manufacture or export, the manufacturer, the first purchaser, and in some cases the second purchaser must be registered by the IRS. A manufacturer or purchaser applies for registration by filing a Form 637, "Application for Registration (For Certain Excise Tax Activities)," in accordance with the instructions on the form. See §48.4222(a)-1 for the registration requirements for tax-free sales. Foreign purchasers of articles sold or resold for export are exempt from the registration requirement. See §48.4222(b)-1(b).

Generally, the purchaser of a taxable article must provide the purchaser's registration number to the manufacturer and certify the exempt purpose for which the

article will be used. The information must be in writing and may be noted on the purchase order or other document furnished by the purchaser to the manufacturer in connection with the sale. See §48.4221-1(c).

A credit or refund of the manufacturers excise tax may be available if a tax-paid article is exported or used for an exempt purpose, such as further manufacture. See 6416 and the corresponding regulations for the conditions to allowance of a claim for credit or refund of tax and for the documentation required to support a claim for credit or refund.

Procedural rules

Part 40 of 26 CFR contains the procedural rules applicable to manufacturers excise taxes with regard to returns, deposits, and payments.

Subtitle F of the Code contains the procedural rules applicable to “internal revenue taxes” (including manufacturers excise taxes) with regard to assessment, collection, penalties, overpayments, refunds, and statutes of limitations.

VIII. Other Issues Raised in Comments on Notice 2010-89

Kits

Several commentators requested clarification on the taxation of kits, often referred to as “convenience kits.” In general, a convenience kit is two or more different medical devices, or a combination of medical devices and other items, packaged together for the convenience of the user.

According to commentators, a number of different types of businesses, including device manufacturers and distributors, engage in the practice of creating such convenience kits. A manufacturer may assemble a kit containing a combination of

items that it manufactures and items that it purchases from other manufacturers, importers, or distributors. A kit may also be assembled by a distributor that purchases the items contained in the kit from one or more manufacturers or importers. Some kits are designed to be used by medical or health care professionals for the performance of a particular medical procedure. Other kits are available to the general public at retail, such as first aid kits and home pregnancy test kits.

Several commentators expressed concern over the potential for double taxation when one or more taxable medical devices are included in a kit. Some commentators suggested that tax should not be imposed on both the taxable medical devices used as components of the kit and the kit itself. Other commentators recommended imposing tax on the taxable medical devices included in the kit, but not on the assembled kit. Other commentators suggested that the assembly of a kit does not constitute manufacture because the items included in the kit are not transformed.

Under the proposed regulations, a kit is a “taxable medical device” if the kit is listed as a device with the FDA pursuant to FDA requirements. The proposed regulations define “kit” as a set of two or more articles packaged in a single bag, tray, or box for the convenience of the end user.

Moreover, the existing manufacturers excise tax rules apply to kits in determining who is liable for the tax and which sale is subject to tax. Under these existing rules, if a manufacturer sells a taxable medical device to a distributor that uses the device to produce a kit that is a distinct taxable medical device, the distributor’s assembly of the kit constitutes further manufacture because the distributor has created a new taxable article. The proposed regulations clarify 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 by the person who assembles the kit.

In some circumstances, the manufacturer may make a tax-free sale of a taxable medical device to the distributor for use in the production or assembly of a kit; tax will attach, however, upon the sale of the kit by the distributor. If the manufacturer sells a taxable medical device to the distributor for use in the production or assembly of a kit at a tax-included price, the distributor may be eligible to claim a credit or refund for the overpayment of tax pursuant to section 6416(b)(3). The rules regarding tax-free sales for further manufacture and the credit and refund provisions of section 6416(b)(3) provide a mechanism for avoiding double taxation when a taxable medical device is included in a kit that is also a taxable medical device. See §48.4221-2(b) for the circumstances under which a taxable article is sold for use in further manufacture. See section 4221 and §48.4221-1, §48.4221-2, §48.4222(a)-1, and §48.4223-1 for the rules regarding tax-free sales for further manufacture.

Generally, under §48.4216(a)-1(e), if a taxable and nontaxable article are sold by the manufacturer as a unit, the tax attaches to that portion of the unit that is properly allocable to the taxable article. In the case of a kit that is a separate taxable medical device, the taxable and nontaxable articles used in the kit's production or assembly have lost their identity as separate articles. Accordingly, the proposed regulations clarify that the provisions of §48.4216(a)-1(e) do not apply to the sale of kits that are separate taxable medical devices. The proposed regulations further clarify that under such circumstances, the entire sale price of the kit is subject to tax under section 4191.

Associated Devices and Components of Devices

Several commentators requested clarification on the tax treatment of an associated or secondary device that is sold with a primary device, such as a monitor that is sold as part of an x-ray system. Commentators also requested information on the tax treatment of components of a device.

Under the proposed regulations, the definition of “taxable medical device” is tied to the FDA’s listing requirements for devices. Therefore, associated devices or components that are listed as devices with the FDA pursuant to FDA requirements are “taxable medical devices” for purposes of section 4191, unless they fall within an exemption under section 4191(b)(2), such as the retail exemption. However, if a manufacturer uses an associated device or component in creating a new device that must be listed with the FDA, then the rules under section 4221 and the corresponding regulations regarding further manufacture apply.

Combination products

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. See 21 CFR 3.2(e). The IRS and the Treasury Department received a comment regarding combination products consisting of a device component and a drug component, such as prefilled syringes and inhalers. The commentator suggested that the sale of a combination product should not be subject to the medical device tax if its drug component is taken into account in computing the branded prescription drug (BPD) fee enacted under section 9008 of the ACA. The commentator suggested that the combination product be subject to either the BPD fee or the medical device tax, but not both, based on the FDA’s determination of a

combination product's primary mode of action.

The ACA enacted both the medical device excise tax and the BPD fee, but provided no coordination between the provisions. Under the proposed regulations, the definition of "taxable medical device" is tied to the FDA's listing requirements for devices. In general, the annual BPD fee is allocated among covered entities engaged in the business of manufacturing or importing branded prescription drugs with aggregate branded prescription drug sales of over \$5 million to specified government programs. See section 9008 of the ACA and 26 CFR Part 51. For this purpose, each branded prescription drug is identified based on its National Drug Code (NDC). 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. The IRS and the Treasury Department request comments on the extent to which combination products may be subject to the medical device excise tax and taken into account in computing the BPD fee, and the mechanisms by which any such impact could be avoided.

Contracts for medical software and IT systems

A commentator requested transition relief for sales contracts for medical software and IT systems. According to the commentator, sellers of software and IT systems frequently provide medical devices, such as medical device data systems, under long-term, multi-year contracts. Under these contracts, the manufacturer often delivers software and IT systems in stages, with partial payments due at various times during the contract term. The commentator requested that contracts, leases, and other

agreements entered into before January 1, 2013, not be subject to the medical device excise tax, even if payments on the contract are received after December 31, 2012.

The proposed regulations apply the existing manufacturers excise tax rules for sales contracts. Under section 4216 and §48.4216(c)-1(b), generally, when a taxable article is sold under an installment payment contract with title reserved in the seller, or under another arrangement that creates a security interest and under which payments are to be made in installments, tax is computed and paid on each payment made by the purchaser. The tax payable with each payment is a percentage of each payment based on the rate of the tax, if any, in effect on the date the payment is due.

The proposed regulations do not adopt the request for transition relief. The statute was enacted on March 30, 2010, with an effective date of January 1, 2013. The statute did not provide an exception or special rule for sales pursuant to contracts in existence prior to the effective date of the tax. The proposed regulations track the statute.

Availability of IRS Documents

The IRS notice 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 notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory 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, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the Treasury Department request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 16, 2012, at 10 a.m., in the IRS Auditorium, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the FOR FURTHER INFORMATION CONTACT section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit electronic or written comments by

[INSERT DATE 90 DAYS AFTER PUBLICATION OF THIS DOCUMENT IN THE

FEDERAL REGISTER] and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by **[INSERT DATE 90 DAYS AFTER PUBLICATION OF THIS DOCUMENT IN THE FEDERAL REGISTER]**.

A period of 10 minutes will be allotted to each person for making comments. An agenda showing the schedule of speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Natalie Payne, 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.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 48 is proposed to be 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) 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, that is intended for humans. For purposes of this section, a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act 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 Federal Food, Drug, and Cosmetic Act 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) In general. The term taxable medical device does not include eyeglasses, contact lenses, hearing aids, and any other device of a type that is generally purchased by the general public at retail for individual use (the retail exception).

(2) 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 listed in paragraphs (b)(2)(i) and (ii) of this section. 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 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 suggest that a device is of a type that is regularly available for purchase and use by individual consumers who are not medical professionals:

(A) Consumers who are not medical professionals can purchase the device through retail businesses that also sell items other than medical devices, such as drug stores, supermarkets, and similar vendors.

(B) 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.

(C) 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 suggest that the device is designed primarily for use in a medical institution or office or by a medical professional:

(A) The device generally must be implanted, inserted, operated, or otherwise administered by a medical professional.

(B) 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.

(C) The device is a Class III device under the FDA system of classification.

(D) 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).

(E) 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 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).

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 to retail establishments. The FDA requires manufacturers and importers 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 exception 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 and other similar establishments, 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 that tend to show they are regularly available for purchase and use by individual consumers and none of the 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 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 to retail establishments. The FDA requires manufacturers and importers 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 exception 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 and other similar establishments, 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 bandages have multiple factors that tend to show they are regularly available for purchase and use by individual consumers and none of the 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 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 to retail establishments. The FDA requires manufacturers and importers 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, and other similar establishments, 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 that tend to show they are regularly available for purchase and use by individual consumers and none of the 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 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 establishments. The FDA requires manufacturers and importers 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, and other similar establishments, 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 that tend to show they are regularly available for purchase and use by individual consumers and none of the 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 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, and medical professionals. The FDA requires manufacturers and importers 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 cannot regularly purchase the mobile x-ray systems at drug stores, supermarkets, and other similar establishments, and 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, require a large investment and/or ongoing expenditure, and are of a type classified by the FDA under 21 CFR Part 892 (Radiology Devices). Thus, the x-ray systems do not meet any of the factors that tend to show that they are regularly available for purchase and use by

individual consumers. However, the x-ray systems do meet several of the 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 to retail establishments. The FDA requires manufacturers and importers 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 to retail establishments. The FDA requires manufacturers and importers 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 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.

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

Par. 4. 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. 5. Section 48.4221-2 is amended by adding headings to paragraphs (b)(1) and (b)(2) and adding paragraph (b)(3).

The additions read as follows:

(b) * * *

(1) In general. * * *

(2) Material in the manufacture or production of another article. * * *

(3) Kits--(i) The process of producing or assembling a kit that is a taxable medical device (as defined in §48.4191-2) constitutes further manufacture. Under such circumstances, the taxable and nontaxable articles used in the production or assembly of the kit lose their identity as separate articles once they are incorporated into the kit because the kit is a new taxable article. Accordingly, the provisions of §48.4216(a)-1(e) do not apply upon the sale of a kit that is a taxable medical device, and the entire sale price of the kit is subject to tax under section 4191.

(ii) For purposes of this section, the term kit means a set of two or more articles that is enclosed in a single package, such as a bag, tray, or box, for the convenience of

a medical or health care professional or the end user. A kit may contain a combination of one or more taxable medical devices and other articles.

(iii) The following example illustrates the rule of this paragraph (b)(3).

Example. X is a manufacturer of scalpels. X is registered with the IRS as a manufacturer of taxable medical devices in accordance with §48.4222(a)-1. Y is a distributor of taxable medical devices. Y is registered with the IRS as a manufacturer of taxable medical devices and as a buyer of taxable medical devices for use in further manufacture in accordance with §48.4222(a)-1. Y purchases scalpels from X for inclusion in surgical kits that Y produces. Both the scalpels and the kits are “taxable medical devices” as defined in §48.4191-2. Accordingly, X may sell the scalpels to Y tax free, provided Y furnishes its registration number to X and certifies in writing that the scalpels will be used in further manufacture.

(iv) This paragraph (b)(3) applies to sales of taxable medical devices on and after January 1, 2013.

* * * * *

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).

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Steven T. Miller

Deputy Commissioner for Services and Enforcement.