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.

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

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


§ 48.4191–2 Taxable medical device.

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

(2) Devices that should have been listed with the FDA. If a device is not listed as a device with the FDA but the FDA determines that the device should have been listed as a device, the device will be deemed to be listed as a device with the FDA as of the date the FDA notifies the manufacturer or importer in writing that corrective action with respect to listing is required.

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

(2) Retail exemption. The term taxable medical device does not include any device of a type that is generally purchased by the general public at retail for individual use (the retail exemption). A device will be considered to be of a type that is 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 (Immunochemistry 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 (Ophthalmological and Enteral Nutritional 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/cfR1/cfR1.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 414.236(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).
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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 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. 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.

Example 2. X manufactures adhesive bandages. X sells 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 retail 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. Therefore, the 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.

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. Therefore, the 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.
storm, as well as medical professionals. Based on the totality of the facts and circumstances, the smoke detection systems 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)(A) of this section. Therefore, the over the counter 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

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 not 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 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.
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 that are 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)(ii) 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)(ii)(A) of this section.

In addition, the lancets are supplies necessary for the effective use of DME as described in section 110.3 of chapter 15 of the Medicare Policy Benefit Manual. Therefore, the lancets fall within the safe harbor set forth in paragraph (b)(2)(ii)(D) of this section.

Accordingly, the blood glucose monitors, test strips, and lancets are devices that are of a type that are 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 manufactures 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 ISW. The FDA classifies prosthetic legs as an external assembly lower limb prosthesis under 21 CFR part 890.3540 and product code 1SW/KFX. In addition, the Centers for Medicare and Medicaid Services have assigned the knee shin systems Healthcare Procedure Coding System code L5810.

The FDA classifies prosthetic legs under Subpart D of 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)(ii)(C) 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 that are 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 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)(i) 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)(i) of this section, they do not need to be implanted, inserted, or otherwise administered by a medical professional.

**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 21 CFR 414.222, 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)(ii)(i) of this section. Accordingly, the urinary ileostomy bags are devices that are of a type that are 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)(ii) 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, they need to be implanted, inserted, or otherwise 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 that they are not 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 14. 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)(i) 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) of this section, the NMRI systems have, at most, one factor that tends to show that they are not 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 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 retail businesses. 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.

Thus, the 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.


Subpart M—Special Provisions Applicable to Manufacturers Taxes

§ 48.4216(a)—1 Charges to be included in sale price.

(a) In general. The “price” for which an article is sold includes the total consideration paid for the article, whether that consideration is in the form of money, services, or other things. See §48.0–2 (a) (5). However, for purposes of the taxes imposed under Chapter 32 certain collateral charges made in connection with the sale of a taxable article must be included in the taxable sale price, whereas others may be excluded. Any charge which is required by a manufacturer, producer, or importer to be paid as a condition of its sale of a taxable article and which is not attributable to an expense falling within one of the exclusions provided in section 4216 or the regulations thereunder is includible in the taxable sale price. It is immaterial for this purpose that the charge may be paid to a person other than the manufacturer, producer, or importer, or that it may be separately billed to the purchaser as a charge earmarked for expenses incurred or to be incurred in his behalf, such as charges for demonstration or display of the article, for sales promotion programs, or otherwise. With respect to the rules relating to exclusion (in the case of sales after December 31, 1960) of charges for local advertising of a manufacturer’s products, see section 4216(e) and §48.4216(e)—1. In the case of sales on credit, a carrying, finance, or service charge is excludable from the sale price if it is reasonably related to the costs of carrying the deferred portion of the sale price (such as interest on the deferred portion of the sale price, expenses of bookkeeping necessary to keep the records of such sales, and expenses of correspondence and other communication in connection with collection).

(b) Tools and dies. Separate charges for tools and dies used in the manufacture or production of a taxable article are to be included, in whole or in part, in the sale price on which the tax is based. It is immaterial whether the charges for such items are billed in a lump sum or are amortized or allocated to each of the taxable articles. If, at the termination of a contract to manufacture taxable articles, the tools and dies used in production pass to the purchaser, only the amount of depreciation of the tools and dies incurred in production, computed on a “production output” basis, should be included in the sale price. If the purchaser furnishes the tools and dies, the amount of the cost thereof, to the extent that such cost has been depreciated in the production of the taxable articles (computed on a “production output” basis), shall be included in determining the sale price of the articles for purposes of computing the tax. This paragraph applies to sales by manufacturers after May 5, 1974.

(c) Charges for warranty. A charge for a warranty of an article which the manufacturer, producer, or importer requires the purchaser to pay in order