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Research Brief

TO: Representative Bob Lynn

FROM: Patricia Young, Manager

DATE: December 27, 2013

RE: Federal Excise Tax on Certain Medical Devices under the Affordable Care Act
LRS Report 14.133

You asked several questions about the federal excise tax on medical devices. Specifically, you wished to know how "medical devices" are defined under the Affordable Care Act; whether the tax applies to the sale of commonly used items such as eyeglasses and hearing aids; whether it applies to imported as well as domestically produced devices; and whether it applies to the sale price or to net profits. You also wished to know if the excise tax has been the subject of repeal efforts, and if so, the arguments for and against such repeal.

Legislation commonly known as the Affordable Care Act (ACA) is comprised of the Patient Protection and Affordable Care Act (P.L. 111-148) in conjunction with the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152). Section 1405 of P.L. 111-152 added to the Internal Revenue Code a new section (4191) that imposes an excise tax equal to 2.3 percent of the sale price of any *taxable medical device* sold in the U.S. by a manufacturer, producer, or importer.

The term *taxable medical device* is any device defined under section 201 (h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) that is intended for humans.[1] The section describes devices that are sold to hospitals and medical professionals and that require clinical expertise, such as pacemakers, stents, defibrillators, artificial joints, and CAT scan and MRI machines. While the general definition of taxable medical device is by reference, Section 1405 nevertheless makes explicit that certain items are not subject to the tax. Eyeglasses, contact lenses, and hearing aids are specifically exempted, along with

> any other medical device determined . . . to be of a type which is generally purchased by the general public at retail for individual use [known as the retail exemption].[2]

The tax has been a subject of ongoing debate, with several past attempts at repeal. Opponents of the tax, including some members of both parties in Congress, have expressed concern that uncertainty and confusion over compliance will harm the medical technology industry. Reports from the industry itself argue that the tax is discriminatory, will chill innovation, and will cause the loss of many thousands of jobs. Supporters refute these charges and point out that the $30 billion in revenue that the tax is expected to produce through 2022 is a critical part of the health care reform financing package which is supported by new levies on many sectors. They further argue that the influx of new business in combination with IRS rules that allow businesses to deduct excise taxes that are "ordinary and necessary expenses," will offset the financial impact to the industry.[3]

Arguments for both camps are presented in the attached document by the Kaiser Foundation, "What's at Stake if Congress Repeals the Medical Device Tax." We hope this is helpful. If you have questions or need additional information, please let us know.

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[1] We include as Attachment A the two pages comprising Section 1405 of P.L. 111-152; the pertinent page of the Internal Revenue Code (26 USC 4191); and section 201(h) of the Federal Food, Drug, and Cosmetic Act, codified at 21 USC 321(h).

[2] Regulations subsequently promulgated specify that the determination of whether a device is of a type that qualifies for the retail exemption are to be 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." Attachment B contains the final regulations associated with taxable medical devices, 26 CFR 48.4191-2.

[3] FactCheck.org, a project of the Annenberg Public Policy Center, cites Moody's Investor Services as estimating that IRS deductions will bring the net tax effect to about 1.5 percent. Eugene Kiely, "Boehner and the Medical Device Tax," The Wire, October 9, 2013.

Attachment A

Section 1405 of Public Law 111-152;
Pertinent parts of 26 USC 4191; and
21 USC 321 (h)

SEC. 1404. BRAND NAME PHARMACEUTICALS.

(a) IN GENERAL.—Section 9008 of the Patient Protection and Affordable Care Act is amended— *Ante,* p. 859.

(1) in subsection (a)(1), by striking "2009" and inserting "2010";

(2) in subsection (b)—

(A) by striking "$2,300,000,000" in paragraph (1) and inserting "the applicable amount"; and

(B) by adding at the end the following new paragraph:

"(4) APPLICABLE AMOUNT.—For purposes of paragraph (1), the applicable amount shall be determined in accordance with the following table:

"Calendar year	Applicable amount
2011	$2,500,000,000
2012	$2,800,000,000
2013	$2,800,000,000
2014	$3,000,000,000
2015	$3,000,000,000
2016	$3,000,000,000
2017	$4,000,000,000
2018	$4,100,000,000
2019 and thereafter	$2,800,000,000.";

(3) in subsection (d), by adding at the end the following new paragraph:

"(3) JOINT AND SEVERAL LIABILITY.—If more than one person is liable for payment of the fee under subsection (a) with respect to a single covered entity by reason of the application of paragraph (2), all such persons shall be jointly and severally liable for payment of such fee."; and

(4) by striking subsection (j) and inserting the following new subsection:

"(j) EFFECTIVE DATE.—This section shall apply to calendar years beginning after December 31, 2010.".

26 USC 4001 note prec.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect as if included in section 9008 of the Patient Protection and Affordable Care Act.

SEC. 1405. EXCISE TAX ON MEDICAL DEVICE MANUFACTURERS.

(a) IN GENERAL.—Chapter 32 of the Internal Revenue Code of 1986 is amended—

(1) by inserting after subchapter D the following new subchapter:

"Subchapter E—Medical Devices

26 USC 4191.

"Sec. 4191. Medical devices.

"SEC. 4191. MEDICAL DEVICES.

"(a) IN GENERAL.—There is hereby imposed on the sale of any taxable medical device by the manufacturer, producer, or importer a tax equal to 2.3 percent of the price for which so sold.

"(b) TAXABLE MEDICAL DEVICE.—For purposes of this section—

Definition.

"(1) IN GENERAL.—The term 'taxable medical device' means any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans.

"(2) EXEMPTIONS.—Such term shall not include—

"(A) eyeglasses,
"(B) contact lenses,
"(C) hearing aids, and
"(D) any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.", and

(2) by inserting after the item relating to subchapter D in the table of subchapters for such chapter the following new item:

"SUBCHAPTER E. MEDICAL DEVICES".

(b) CERTAIN EXEMPTIONS NOT TO APPLY.—

(1) Section 4221(a) of the Internal Revenue Code of 1986 is amended by adding at the end the following new sentence: "In the case of the tax imposed by section 4191, paragraphs (3), (4), (5), and (6) shall not apply.". 26 USC 4221.

(2) Section 6416(b)(2) of such Code is amended by adding at the end the following: "In the case of the tax imposed by section 4191, subparagraphs (B), (C), (D), and (E) shall not apply.". 26 USC 6416.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after December 31, 2012. 26 USC 4191 note.

(d) REPEAL OF SECTION 9009 OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT.—Section 9009 of the Patient Protection and Affordable Care Act, as amended by section 10904 of such Act, is repealed effective as of the date of enactment of that Act. Effective date.

Ante, p. 862, 1016.

SEC. 1406. HEALTH INSURANCE PROVIDERS.

(a) IN GENERAL.—Section 9010 of the Patient Protection and Affordable Care Act, as amended by section 10905 of such Act, is amended— *Ante,* p. 865, 1017.

(1) in subsection (a)(1), by striking "2010" and inserting "2013";

(2) in subsection (b)(2)—

(A) by striking "For purposes of paragraph (1), the net premiums" and inserting "For purposes of paragraph (1)—

"(A) IN GENERAL.—The net premiums"; and

(B) by adding at the end the following subparagraph:

"(B) PARTIAL EXCLUSION FOR CERTAIN EXEMPT ACTIVITIES.—After the application of subparagraph (A), only 50 percent of the remaining net premiums written with respect to health insurance for any United States health risk that are attributable to the activities (other than activities of an unrelated trade or business as defined in section 513 of the Internal Revenue Code of 1986) of any covered entity qualifying under paragraph (3), (4), (26), or (29) of section 501(c) of such Code and exempt from tax under section 501(a) of such Code shall be taken into account.";

(3) in subsection (c)—

(A) by inserting "during the calendar year in which the fee under this section is due" in paragraph (1) after "risk";

(B) in paragraph (2), by striking subparagraphs (C), (D), and (E) and inserting the following new subparagraphs:

"(C) any entity—

United States Code Annotated
Title 26. Internal Revenue Code (Refs & Annos)
Subtitle D. Miscellaneous Excise Taxes (Refs & Annos)
Chapter 32. Manufacturers Excise Taxes (Refs & Annos)
Subchapter E. Medical Devices

26 U.S.C.A. § 4191

§ 4191. Medical devices

Currentness

(a) In general.--There is hereby imposed on the sale of any taxable medical device by the manufacturer, producer, or importer a tax equal to 2.3 percent of the price for which so sold.

(b) Taxable medical device.--For purposes of this section--

(1) In general.--The term "taxable medical device" means any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans.

(2) Exemptions.--Such term shall not include--

(A) eyeglasses,

(B) contact lenses,

(C) hearing aids, and

(D) any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.

CREDIT(S)

(Added Pub.L. 111-152, Title I, § 1405(a)(1), Mar. 30, 2010, 124 Stat. 1064.)

26 U.S.C.A. § 4191, 26 USCA § 4191
Current through P.L. 113-57 (excluding P.L. 113-54 and 113-56) approved 12-9-13

End of Document

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter II. Definitions (Refs & Annos)

21 U.S.C.A. § 321

§ 321. Definitions; generally

Effective: June 22, 2009
Currentness

For the purposes of this chapter--

(a)(1) The term “State”, except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term “Territory” means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term “interstate commerce” means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term “Department” means Department of Health and Human Services.

(d) The term “Secretary” means the Secretary of Health and Human Services.

(e) The term “person” includes individual, partnership, corporation, and association.

(f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term “drug” means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is

made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

Attachment B

26 CFR 48.4194-2

Code of Federal Regulations
Title 26. Internal Revenue
Chapter I. Internal Revenue Service, Department of the Treasury
Subchapter D. Miscellaneous Excise Taxes
Part 48. Manufacturers and Retailers Excise Taxes (Refs & Annos)
Subpart L. Taxable Medical Devices (Refs & Annos)

26 C.F.R. § 48.4191–2, Treas. Reg. § 48.4191–2

§ 48.4191–2 Taxable medical device.

Effective: March 13, 2013
Currentness

(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 (Immunology and Microbiology Devices), 21 CFR part 868 (Anesthesiology Devices), 21 CFR part 870 (Cardiovascular Devices), 21 CFR part 874 (Ear, Nose, and Throat Devices), 21 CFR part 876 (Gastroenterology--Urology Devices), 21 CFR part 878 (General and Plastic Surgery Devices), 21 CFR part 882 (Neurological Devices), 21 CFR part 886 (Ophthalmic Devices), 21 CFR part 888 (Orthopedic Devices), or 21 CFR part 892 (Radiology Devices);

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) Supplies necessary for the effective use of durable medical equipment (DME), as described in section 110.3 of chapter 15 of the Medicare Benefit Policy Manual (Centers for Medicare and Medicaid Studies Publication 100–02).

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

Example 1. X manufactures non-sterile absorbent tipped applicators. X sells the applicators to distributors Y and Z, which, in turn, sell the applicators to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of non-sterile absorbent tipped applicators to list the applicators as

a device with the FDA. The applicators are classified by the FDA under 21 CFR part 880 (General Hospital and Personal Use Devices) and product code KXF.

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

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

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

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

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

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

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

Example 3. X manufactures snake bite suction kits. X sells the snake bite suction kits to distributors Y and Z, which, in turn, sell the kits to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of snake bite suction kits to list the kits as a device with the FDA. The FDA classifies

the snake bit suction kits under 21 CFR part 880 (General Hospital and Personal Use Devices) and product code KYP.

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

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

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

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

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

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

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

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

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

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

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

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

The pregnancy test kits are included in the FDA's online IVD Home Use Lab Tests (Over-the–Counter Tests) database. Therefore, the over the counter pregnancy test kits fall within the safe harbor set forth in paragraph (b)(2)(iii)(A) of this section. Further, the FDA product code name for LCX is "Kit, Test, Pregnancy, HCG, Over The Counter." Therefore, the pregnancy test kits also fall within the safe harbor set forth in paragraph (b)(2)(iii)(C) of this section. Accordingly, the pregnancy test kits are devices that are of a type 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)(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 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)(iii)(D)(5) 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 makes prosthetic legs. The FDA requires manufacturers of knee shin systems and prosthetic legs to list the items as devices with the FDA. The FDA classifies prosthetic leg components, including knee shin systems, as external limb prosthetic components under Subpart D of 21 CFR part 890.3420 and product code ISH. The FDA classifies prosthetic legs as an external assembled lower limb prosthesis under 21 CFR part 890.3500 and product code ISW/KFX. In addition, the Centers for Medicare and Medicaid Services have assigned the knee shin systems Healthcare Procedure Coding System code L5810.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Individual consumers who are not medical professionals may be able to regularly purchase the NMRI systems over the Internet. However, individual consumers cannot use the NMRI systems safely and effectively for their intended medical purpose without training from a medical professional. Although the NMRI systems are not Class III devices and are not "items requiring frequent and substantial servicing" as defined in 42 CFR 414.222, they need to be operated by a medical professional, and are of a type classified by the FDA under 21 CFR part 892 (Radiology Devices). Further, the cost to acquire, maintain, and/or use the NMRI systems requires a large initial investment and/or ongoing expenditure that is not affordable for the average consumer.

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

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

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

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

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

Example 15. X manufactures powered flotation therapy beds. X sells the beds to distributors Y and Z, which, in turn, sell the beds to medical institutions and offices, and medical professionals. The FDA requires manufacturers of powered flotation therapy beds to list the items as devices with the FDA. The FDA classifies the powered flotation therapy beds under 21 CFR part 890 (Physical Medicine Devices) and product code IOQ.

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

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

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

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

Credits

[T.D. 9604, 77 FR 72934, Dec. 7, 2012; 78 FR 15878, March 13, 2013]

SOURCE: T.D. 9604, 77 FR 72934, Dec. 7, 2012, unless otherwise noted.

AUTHORITY: 26 U.S.C. 7805, unless otherwise noted.; Section 48.4052–1 also issued under 26 U.S.C. 4052(g).; Section 48.4064–1(b)(3) also issued under 26 U.S.C. 4064(b)(1)(C)(iii).; Section 48.4064–1(d)(3)(iii) also issued under 26 U.S.C. 4064(d)(1).; Section 48.4064–1(d)(5) also issued under 26 U.S.C. 4064(d)(2).; Section 48.4081–4 also issued under 26 U.S.C. 4083(a)(2).; Section 48.4081–6 also issued under 26 U.S.C. 4081(c);; Section 48.4081–7 also issued under 26 U.S.C. 4081(e).; Section 48.4082–1 also issued under 26 U.S.C. 4082.; Section 48.4082–1T also issued under 26 U.S.C. 4082(a).; Section 48.4082–2 also issued under 26 U.S.C. 4082.; Section 48.4082–5 also issued under 26 U.S.C. 4082.; Section 48.4082–6 also issued under 26 U.S.C. 4082(d).; Section 48.4082–7 also issued under 26 U.S.C. 4082(d).; Section 48.4101–1 also issued under 26 U.S.C. 4101(a).; Section 48.4101–2 also issued under 26 U.S.C. 6071(a).; 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).; Section 48.4221–3(e) also issued under 26 U.S.C. 4221(a).; Section 48.6416(b)(2)–2(b) also issued under 26 U.S.C. 6416(b).; Section 48.6427–8 also issued under 26 U.S.C. 6427(m).; Section 48.6427–9 also issued under 26 U.S.C. 6427(m).; Section 48.6427–10 also issued under 26 U.S.C. 6427(m).; Section 48.6427–11 also issued under 26 U.S.C. 6427(m).

Current through December 12, 2013; 78 FR 75895.

End of Document

Attachment C

"What's at Stake if Congress Repeals the Medical Device Tax," *Kaiser Health News*, October 11, 2013

KHN
KAISER HEALTH NEWS

FAQ: What's At Stake If Congress Repeals The Medical Device Tax

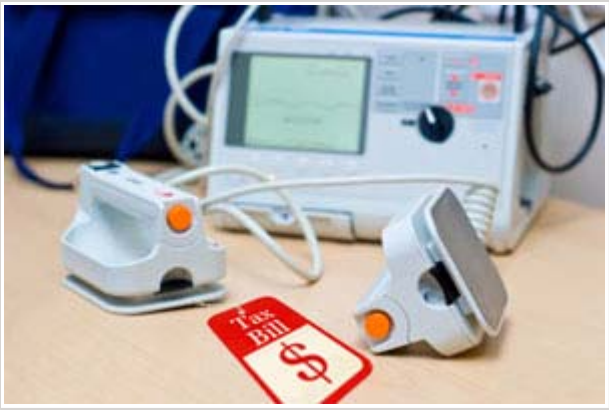
TOPICS: HEALTH REFORM, POLITICS, HEALTH COSTS

By MARY AGNES CAREY

KHN Staff Writer

OCT 11, 2013

As Republicans and Democrats have battled over reopening the federal government and raising the federal debt ceiling, one idea that keeps coming up is a repeal of the 2010 health law's tax on medical devices.



While the idea has drawn support from members of both parties, experts say it's still a heavy lift for the repeal's proponents. For starters, repealing the tax would create about a $30 billion revenue hole over the next decade. And supporters of the law fear that making such a change could start a stampede of demands for similar rollbacks from insurers and health care providers, who are also subject to new taxes and fees to help finance the health law.

With that in mind, here are some frequently asked questions about the tax.

Q: What is the medical device tax?

A: Since the beginning of this year, medical device manufacturers and importers have paid a 2.3 percent tax on the sale of any taxable medical device. The tax applies to devices like artificial hips or pacemakers, not to devices sold over-the-the counter, like eyeglasses or contact lenses.

Q: Why did Congress put the tax into the health law?

A: The law created a package of new taxes and fees to finance the cost of the health law's subsidies to help purchase coverage on the online marketplaces, or exchanges, and the law's Medicaid expansion.

In addition to the tax on medical devices, an annual fee for health insurers is expected to raise more than $100 billion over 10 years, while a fee for brand name drugs will bring in another $34 billion. In 2018, the law also will impose a 40 percent excise tax on the portion of most employer-sponsored health coverage (excluding dental and vision) that exceeds $10,200 a year and $27,500 for families. That has been dubbed a "Cadillac" tax because it hits the most generous plans.

Q: Why do proponents of the repeal suggest the medical device manufacturers should get a break over those other industries?

A: Medical device makers say the tax will cost 43,000 jobs over the next decade and will increase health care costs. In a September letter to lawmakers, device manufacturers said if the tax were not repealed, "it will continue to force affected companies to cut manufacturing operations, research and development, and employment levels to recoup the lost earnings due to the tax."

The device makers also assert that, unlike other health industry groups that are being taxed through the health law, they will not see increased sales because of the millions of people who will be getting insurance through the overhaul. "Unlike other industries that may benefit from expanded coverage, the majority of device-intensive medical procedures are performed on patients that are older and already have private insurance or Medicare coverage. Where states have dramatically extended health coverage, such as in Massachusetts where they added 400,000 new covered lives, there is no evidence of a device 'windfall,'" the group's letter to Congress stated.

The left-leaning Center for Budget and Policy Priorities has challenged industry assertions that the tax will lead medical device manufacturers to shift operations overseas and that it will reduce industry innovation. Since the tax applies to imported and as well as domestically produced devices, sales of medical devices in the U.S. will be subject to the tax whether they are produced here or abroad, the center's analysis notes. Innovation in the medical device industry has slowed for reasons unrelated to the tax, the center said, noting that the health law may spur medical-device innovation by promoting more cost-effective ways to deliver care.

Q: Who else is pushing for a repeal?

A: Republicans and Democrats in both chambers – in particular those who hail from states with many device manufactures, such as Minnesota, Massachusetts and New York -- have sought to repeal the medical device tax. Most recently, Sen. Susan Collins, R-Maine, has pushed for a repeal as part of larger legislation to lift the debt ceiling and reopen the government.

The Republican-controlled House has twice passed legislation to scrap the tax, including a recent measure that would have also delayed implementation of the health law by a year. In the Senate, 33 Democrats and Maine Independent Angus King voted earlier this year to repeal the tax, although the vote was a symbolic one, taken as part of a non-binding budget resolution.

Q. Who opposes the repeal?

The White House in the past has said the president would not support such a measure, although it has not commented about the issue in the current negotiations. In a statement issued last year about a congressional effort to get rid of the tax, the White House said, "The medical device industry, like others, will benefit from an additional 30 million potential consumers who will gain health coverage under the Affordable Care Act starting in 2014. This excise tax is one of several designed so that industries that gain from the coverage expansion will help offset the cost of that expansion."

Senate Majority Leader Harry Reid, D-Nev., has said that the Senate will reject any attempts by Republicans to delay implementation of the law or to repeal the medical device tax as part of reopening the government or lifting the federal debt ceiling. But it is unclear if he would still oppose the effort if it was part of a major bipartisan compromise on the health law and budget issues.

Meanwhile, other health care providers are watching closely. In a recent blog post, Chip Kahn, president and chief executive officer of the Federation of American Hospitals, an association of for-profit institutions, wrote that if Congress reopens the heath law "to reconsider the contributions of any one health care sector that benefits from ACA's coverage expansion, it should simultaneously address the changed circumstances of hospitals and provide similar relief."