

The Medical Device Excise Tax: A Legal Overview

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Summary

On December 7, 2012, the Department of the Treasury and the Internal Revenue Service issued final regulations explaining the scope of the medical device excise tax created by the Health Care and Education Reconciliation Act of 2010 (HCERA), which modified the Patient Protection and Affordable Care Act of 2010. The new regulations were issued less than a month before the 2.3% excise tax took effect on January 1, 2013. This report provides a brief overview of the recently enacted Treasury regulations, analyzes the legal implications of the regulations, and answers frequently asked questions about the medical device tax.

The Treasury regulations on the medical device excise tax explain both who is subject to the excise tax and the scope of the statutory exemptions provided for the tax. Specifically, the regulations incorporate by reference the general definitions for a "manufacturer, producer, or importer" outlined in the Internal Revenue Code, meaning that the excise tax will be directly paid by manufacturers, as opposed to consumers or others that use a given medical device.

Furthermore, the regulations attempt to clarify the limits to the medical device excise tax. Beyond the statutory exemptions created for eyeglasses, contact lenses, and hearing aids, the law created a "retail exemption" to the excise tax, excluding from the tax medical devices that are "generally purchased by the general public at retail for individual use." The Treasury regulations attempt to simultaneously provide certainty to potential taxpayers as to which devices are subject to the retail exemption, while allowing the government the flexibility to properly apply the retail exemption to the variety of devices that could be exposed to the excise tax. The regulations provide a flexible two-prong test to determine whether a device should fall within the retail exemption, applying the exemption when the device is (1) regularly available for purchase by non-professional consumers and (2) not primarily intended for use by medical professionals. The regulations provide several factors to consider when applying the two-prong test. To provide some certainty to the scope of the retail exemption, the regulations also included several "safe harbor" provisions, explicitly acknowledging that certain devices, such as "over-the-counter" devices, fall within the retail exemption.

The new Treasury regulations on the medical device excise tax, while providing some certainty with respect to what devices will be exempt from the tax, generally favor a more flexible approach to defining the scope of the central exemption to the tax. As a consequence, uncertainty remains as to which medical devices will be subject to the tax. Indeed, Treasury, in releasing the medical device excise tax regulations, notes that further clarification on various issues implicated by the tax is still needed. As such, the regulations constitute only the first step in defining the limits of the medical device excise tax.

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Introduction

As part of recent health care reform efforts, Congress, in the Affordable Care Act,[1] imposed a 2.3% excise tax on the sale of certain medical devices by device manufacturers, producers, or importers.[2] The excise tax is effective on sales of devices made after December 31, 2012.[3] The implementation of the medical device tax has prompted some Members of Congress to seek a delay of the enforcement of the tax out of a concern that the "uncertainty and confusion" regarding compliance with the medical device excise tax will harm the medical technology industry.[4] Others in Congress have sought an outright repeal of the tax.[5] While December 31, 2012, passed without Congress changing or repealing the medical device excise tax, congressional interest remains.[6] On December 7, 2012, the Department of the Treasury (Treasury) issued its final regulations that provide guidance on both who must pay the excise tax and the scope of products encompassed by the excise tax.[7] This report provides a brief overview of the regulations, discusses the extent to which the rules have clarified the excise tax imposed on the sale of medical devices, and answers frequently asked questions about the medical device tax.[8]

On Whom Is the Medical Device Excise Tax Imposed?

Pursuant to §4191(a) of the Internal Revenue Code (IRC), a "manufacturer, producer, or importer" making the sale of a taxable medical device is liable for a tax of 2.3% of the price[9] for

[1] The medical device excise tax was included in an amended version of the Affordable Care Act. *See* Health Care and Education Reconciliation Act of 2010, P.L. 111-152, Title I, Subtitle E, §1405(a)(1), 124 Stat. 1029, (2010) (amending the Patient Protection and Affordable Care Act of 2010, P.L. 111-148).

[2] *See* I.R.C. §4191(a). The medical device excise tax is only one of several provisions created under the HCERA or Patient Protection and Affordable Care Act to raise revenues to pay for expanded health insurance coverage. *See* CRS Report R41128, *Health-Related Revenue Provisions in the Patient Protection and Affordable Care Act (ACA)*, by Janemarie Mulvey.

[3] *See supra* footnote 1, §1405(c). For medical devices financed through an installment sale or a long-term lease, the regulations do not provide any relief for payments made for a device after December 31, 2012, unless that agreement was entered into prior to March 30, 2010, the date the ACA was enacted. *See* Treas. Reg. §48.4191-1(f) (citing Treas. Reg. §48.4216(c)-1(e)).

[4] *See* Letter to the Honorable Harry Reid from 18 Current and Future Members of the Senate, (December 4, 2012) http://www.franken.senate.gov/?p=hot_topic&id=2248.

[5] A bill repealing the medical device excise tax passed the House of Representatives in the 112th Congress. *See* Health Care Cost Reduction Act of 2012, H.R. 436 (2012). Other similar bills have been presented in the 113th Congress. *See* Protect Medical Innovation Act of 2013, H.R. 523 (2013); *see also* Medical Device Tax Elimination Act, H.R. 1295 (2013); Medical Device Access and Innovation Protection Act, S. 232 (2013); A joint resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rule submitted by the Internal Revenue Service of the Department of the Treasury relating to taxable medical devices, S.J.Res. 8 (2013).

[6] *See, e.g.,* Melissa Attias and Emily Ethridge, *Medicare Board, Device Tax Lead House GOP Target List*, Roll Call, January 22, 2013, http://www.cq.com/doc/news-4208077?wr=eFF6UlQqRXM3azJhbDBGWEpQWjBIUQ.

[7] *See* "Taxable Medical Devices," 77 Fed. Reg. 72,924 (December 7, 2012).

[8] This report does not discuss the general Treasury regulations for manufacturer excise taxes unless those regulations uniquely impact the medical device excise tax.

[9] For explanation of the definition of the "price" of an article taxed under Chapter 32 of the Internal Revenue Code, *see* I.R.C. §4216(a).

which the device was sold.[10] Treasury, in the newly released regulations on the medical device excise tax, states that the "existing chapter 32 rules," including the definitions for "manufacturer," "producer," and "importer," apply with respect to the medical device excise tax.[11] In turn, the general chapter 32 rules define the term "manufacturer" as "any person who produces a taxable article ... by processing, manipulating, or changing the form of an article or by combining or assembling two or more articles."[12] Moreover, the general definition for a manufacturer necessarily includes the terms "producer" and "importer."[13] While courts have interpreted the term "manufacturer" within the general chapter 32 rules to encompass a range of activities where a person physically changes a taxable article,[14] the medical device excise tax, by definition, is not directly levied upon a consumer of a medical device.

What Is a "Taxable Medical Device"?

The medical device excise tax created by the ACA is imposed on the sale of "taxable medical device[s]."[15] The statute defines that term by incorporating the definition of "medical device" from the Federal Food, Drug and Cosmetic Act (FFDCA), as that term pertains to a device "intended for humans."[16] Courts have recognized that Congress defined the term "medical device" in the FFDCA "very broadly,"[17] as the Food and Drug Administration (FDA) regulates a range of devices from tongue depressors[18] to artificial hearts.[19] As such, the Health Care and Education Reconciliation Act of 2010 (HCERA) casts a wide net with the term "taxable medical device."[20] In line with the broad scope of the term "taxable medical device," the December 7,

[10] *See* I.R.C. §4191(a).

[11] *See* 77 Fed. Reg. at 72930. Notably, the general exemptions for excise taxes provided to manufacturers who sell an article to a state or local government or to a nonprofit educational organization do not apply to the medical device excise tax. *See* I.R.C. §4221(a).

[12] *See* Treas. Reg. §48.0-2(4)(i). The general definitions for a manufacturer, producer, and importer are incorporated by reference into the regulations clarifying the medical device excise tax. *See* Treas. Reg. §48.4191-1(c). The Internal Revenue Code does not subject a manufacturer to an excise tax if the sale of the article is for use by the purchaser for further manufacturing. *See* I.R.C. §4221(a)(1).

[13] *Id.* Treasury regulations also explain that the term "importer," while typically entailing the person who brings an "article into the United States from a source outside the United States," can also include the beneficial owner of an item if, for example, a customs broker is engaged by an entity to bring a particular item into the country. *Id.* In contrast, the Internal Revenue Code exempts a manufacturer from being subject to an excise tax when the sale of the article is for export. *See* I.R.C. §4221(a)(2).

[14] *See Ruan Financial Corp. v. United States*, 765 F. Supp. 987-88 (S.D. Iowa 1990), *aff'd* 976 F.2d 452 (8th Cir. 1992).

[15] I.R.C. §4191(a).

[16] *Id.* at (b)(1) (citing 21 U.S.C. §321(h)).

[17] *See Committee of Dental Amalgam Mfrs. & Distribs. v. Stratton*, 92 F.3d 807, 810 (9th Cir. 1996); *see also United States v. McGuff,* 781 F. Supp. 654, 655 (C.D. Cal. 1991).

[18] 21 C.F.R. §880.6230.

[19] 21 C.F.R. Part 870, subpart D.

[20] Specifically, the Food, Drug, and Cosmetics Act defines a medical device as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component, parts or accessory which is" either (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, 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." *See* 21 U.S.C. §321(h).

2012, Treasury Regulations explain that a "taxable medical device" is a device that has been registered with the Food and Drug Administration pursuant to Section 510(j) of the FFDCA[21] and 21 C.F.R. Part 807.[22] Importantly, Treasury resisted efforts by commenters to narrow the scope of the general term "taxable medical device," by limiting, for example, the term to devices that could exclusively be used by humans or could only be used for a medical purpose, preferring instead to maintain a broad reading of what devices are subject to the excise tax.[23] As a result, devices like infusion pumps, which can be used on both humans and animals, [24] and latex gloves,[25] which can be used for both medical and non-medical purposes, fall within the broad definition of a "taxable medical device."

Medical Devices Exempted from the Excise Tax

In an effort to limit the ambit of the excise tax imposed on medical device manufacturers, Congress explicitly excluded three types of devices from the term "taxable medical device" in IRC §4191(a).[26] Specifically, Congress exempted eyeglasses, contact lenses, and hearing aids from the excise tax.[27] Moreover, the statute empowers the Secretary of the Treasury under the "retail exemption" to exempt "any other medical device" which is determined to be of a "type which is generally purchased by the general public at retail for individual use" from the 2.3% excise tax.[28]

The Retail Exemption

The regulations issued by Treasury on December 7, 2012, provide a broad framework as to which medical devices fall within the "retail exemption" to the excise tax under IRC §4191(b)(2)(d). Specifically, the new Treasury regulations provide a two-prong test to resolve whether a device should fall within the residual exception to the excise tax.[29] First, the device in question should be "regularly available for purchase and use by individual consumers who are not medical professionals." Second, the device's design should "demonstrate[] that it is not primarily intended

[21] 21 U.S.C. §360(j).

[22] For a general explanation of the medical device regulatory framework, *see* CRS Report R42130, *FDA Regulation of Medical Devices*, by Judith A. Johnson. Devices used exclusively in veterinary medicine are not listed under Section 510(j) of the FFDCA and 21 CFR Part 807, and, therefore, Treasury's regulations are exclusive to devices that are intended, at least in part, for use on humans.

[23] 77 Fed. Reg. at 72,925-26. However, medical kits created by a hospital or medical institution are exempt from the excise tax, as the creations of such kits are necessarily excluded from the FDA's registration and listing requirements. *See* 21 C.F.R. §807.65(f).

[24] *See* Food and Drug Administration, *How FDA Regulates Veterinary Devices*, (January 20, 2012), http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm047117.htm.

[25] 21 C.F.R. §880.6250.

[26] I.R.C. §4191(b)(2).

[27] *Id.* §4191(b)(2)(A)-(C).

[28] *Id.* §4191(b)(2)(D); *see also* Joint Committee on Taxation, *General Explanation of Tax Legislation Enacted in the 111th Congress*, committee print, prepared by Staff of the Joint Committee on Taxation, 111th Cong., March 2011, JCS-2-11, p. 366 ("The Secretary may determine that a specific medical device is exempt under the provision if the device is generally sold at retail establishments (including over the internet) to individuals for their personal use.")

[29] Treas. Reg. §48.4191-2(b)(2).

for use" in a medical institution, office, or by a medical professional.[30] Neither prong is dispositive to the determination, as the regulations caution that an analysis of whether a device fits within the retail exemption is dependent on "all" "relevant facts and circumstances."[31]

To guide the analysis of whether a particular device meets the relevant requirements for the retail exemption, the new Treasury regulations provide a host of factors to examine.[32] Factors implicating the question of whether a device is regularly available for purchase by individual consumers include (1) the ability of end consumers to purchase the device in person through a drug store or other retailer that primarily sells a particular device; (2) the need of a consumer to seek help from a medical professional to use the device safely and effectively; and (3) whether the device has been classified by the Food and Drug Administration as a "physical medicine device" for human use.[33] To illustrate, with respect to adhesive bandages,[34] an application of the multi-factor test would conclude that the device is regularly available for purchase by individual consumers. Specifically, while adhesive bandages are not a "physical medicine device," the product can be readily purchased at various retail stores and can be properly used without formal training from a medical professional.[35]

Treasury also issued a list of factors to aid the determination of whether a device is designed primarily for use in a medical institution or office or by a medical professional.[36] Relevant factors include (1) whether the device must be implanted, inserted, operated, or administered by a medical professional; (2) the cost of obtaining and using the device; (3) how the device has been classified by the FDA;[37] and (4) whether the device is one for which payment is available "exclusively on a rental basis" and is an item requiring "frequent and substantial servicing" as those terms are defined under Medicare Part B payment rules.[38] Returning to the example of adhesive bandages, the multi-factor test counsels that the product is not primarily intended for use in a medical institution, office, or by a medical professional. Specifically, using adhesive bandages does not require the aid of a medical professional, and bandages are inexpensive to obtain and use.[39] Moreover, adhesive bandages are not classified as a complex medical device or a device needing frequent and substantial servicing.[40] Coupled with the earlier conclusion that adhesive bandages are regularly available for purchase by individual consumers, the totality of

[30] *Id.*

[31] *Id*.

[32] *Id.*

[33] For more detail on the factors implicating whether a device can be considered regularly available for purchase and use by individual consumers, *see* Treas. Reg. §48.4191-2(b)(2)(i)(A)-(C). With respect to devices classified by the FDA as a "physical medicine device," such devices are listed under subpart D of 21 CFR part 890, and include devices such as canes, *see* 21 C.F.R. §890.3075, crutches, *id.* §890.3150, and wheelchairs, *id.* §§890.3850 - 890.3860.

[34] *See* Treas. Reg. §48.4191-2(b)(2)(iv)(Example 2).

[35] *Id.*

[36] *See* Treas. Reg. §48.4191-2(b)(2)(ii)(A)-(E).

[37] The regulations specifically cite as a factor a devices' classification as a Class III device, the medical devices subject to the most intensive pre-market screening by the FDA, *see* CRS Report R42130, *FDA Regulation of Medical Devices*, by Judith A. Johnson, to be relevant in determining whether a device should be subject to the retail exemption. *See* Treas. Reg. §48.4191-2(b)(2)(ii)(C). In addition, the new Treasury regulations explain that the FDA's classification of a device under one of fifteen various categories of medical devices in the Code of Federal Regulations is an additional factor to examine when determining whether to apply the retail exemption. *Id.* §48.4191-2(b)(2)(ii)(D).

[38] *See* Treas. Reg. §48.4191-2(b)(2)(ii)(D) (citing 42 C.F.R. part 210).

[39] *See* Treas. Reg. §48.4191-2(b)(2)(iv)(Example 2).

[40] *Id.*

the circumstances indicates that "adhesive bandages are devices that are of a type that" should fall within the retail exemption to the medical device excise tax.[41]

Notably, Treasury explained in issuing the medical device excise tax regulations that two potential factors—the packaging or labeling of a medical device and the nature of documents submitted to the FDA in obtaining approval of a device—are irrelevant in assessing whether a device should fall within the retail exemption to the excise tax.[42] As a consequence, a medical device manufacturer cannot hope to escape the excise tax, for example, by labeling that its product is "intended for retail use only."

The Retail Exemption's Safe Harbor Provisions

In contrast to the malleable multi-factor test that outlines the limits to the retail exemption, the December 7, 2012, Treasury regulations also include a list of "safe harbor" devices that necessarily fall within the retail exemption.[43] The purpose of the safe harbor provisions is to "provide greater certainty" with respect to which devices are subject to the retail exemption.[44] The safe harbor includes medical devices, like pregnancy test kits, that are described as "over-the-counter" (OTC) devices in the FDA's online database for *in vitro* diagnostic tests, the FDA's classification regulations, or the FDA's device registration and listing database.[45] In addition, the safe harbor includes certain devices that qualify as "durable medical equipment, prosthetics, orthotics, and supplies" for which payment is available on a purchase basis under Medicare part B payment rules,[46] such as therapeutic shoes.[47]

Examples of How the Retail Exemption Is Applied

The Treasury regulations conclude by providing 15 different examples of how the retail exemption to the medical device excise tax would be applied in practice.[48] The examples range from the aforementioned "adhesive bandages"[49] to "blood glucose monitors"[50] to "magnetic resonance systems."[51] Examples of devices that Treasury concludes "based on the totality of the facts and circumstances" fall within the retail exemption include "absorbent tipped applicators,"[52] "adhesive bandages,"[53] "snake bite suction kits,"[54] "denture adhesives,"[55] "mechanical and

[41] *Id.*

[42] 77 Fed. Reg. at 72,929.

[43] *See* Treas. Reg. §48.4191-2(b)(iii).

[44] *Id.* at 72927.

[45] *See* Treas. Reg. §48.4191-2(b)(2)(iii)(A)-(C).

[46] *Id.* §48.4191-2(b)(2)(iii)(D).

[47] *Id.* §48.4191-2(b)(2)(iii)(D)(4).

[48] *Id.* §48.4191-2(b)(2)(iv).

[49] *Id.* (Example 2).

[50] *Id.* (Example 7).

[51] *Id.* (Example 13).

[52] *Id.* (Example 1).

[53] *Id.* (Example 2).

[54] *Id.* (Example 3).

[55] *Id.* (Example 4).

powered wheelchairs,"[56] "portable oxygen concentrators,"[57] and "therapeutic AC powered adjustable home use beds."[58] Treasury also concludes that "pregnancy test kits,"[59] "blood glucose monitors, test strips, and lancets,"[60] "prosthetic legs and certain prosthetic leg components,"[61] and "urinary ileostomy bags"[62] fall within the regulations' safe harbor provisions. In contrast, Treasury, in its examples, finds that the following devices, based on the totality of the circumstances, are not exempt from the medical device excise tax: "mobile x-ray systems,"[63] "nonabsorbable silk sutures,"[64] "nuclear magnetic resonance imaging systems,"[65] and "powered floatation therapy beds."[66]

The Future of the Medical Device Tax

Whether the new Treasury regulations provide the needed clarity to alleviate the "uncertainty and confusion" that some Members of Congress have feared that the new tax would engender within the medical technology industry remains to be seen.[67] To be sure, the medical device tax regulations, with their safe harbor provisions, clarify that generally devices recognized as over-the-counter devices will not be the subject of the tax, providing an easy to understand exemption to manufacturers, importers, and producers of such products.[68] However, the safe harbor provisions are narrow, and the regulations open-ended two-part test defining the limits of the retail exemption, while providing flexibility as to the scope of the exemption, naturally creates ambiguity with respect to which products are exposed to the excise tax, save those specifically exempted under the regulations. Moreover, the limits of the retail exemption, which are based, in part, on regulations that were not crafted with the retail exemption in mind, could prove to be either over or under inclusive of Congress's original intent in enacting the medical device excise tax.[69] Treasury, in the release of the final regulations, identified several issues raised by the medical device tax regulations that warranted the agency issuing separate clarifying guidance, including the treatment, for purposes of the medical device excise tax, of licensing software [70] and "kits."[71] Given the wide variety of items that are categorized as medical devices,[72] some may see

[56] *Id.* (Example 9).

[57] *Id.* (Example 10).

[58] *Id.* (Example 14).

[59] *Id.* (Example 6).

[60] *Id.* (Example 7).

[61] *Id.* (Example 8).

[62] *Id.* (Example 11).

[63] *Id.* (Example 5).

[64] *Id.* (Example 12).

[65] *Id.* (Example 13).

[66] *Id.* (Example 15).

[67] *See supra* footnote 4.

[68] *See* Treas. Reg. § 48.4191-2(b)(2)(iii)(A)-(C).

[69] Several of the factors used to determine the scope of the retail exemption are FDA regulations relating to safety controls on the release of medical devices or Medicare Part B payment rules. *See, e.g.,* Treas. Reg. §§48.4191-2(i)(C), (ii)(C)-(E).

[70] 77 Fed. Reg. at 72931.

[71] *Id.* at 72932.

[72] *See supra* note footnote 22.

a need for further clarification with respect to other medical devices, including potentially expanding the safe harbor provisions. As a result, the December 7, 2012, regulations could be only the first step in clarifying the application of a tax that the Treasury Department acknowledges "may present certain implementation challenges."[73]

Moreover, looming over all the questions about the implementation and enforcement of the medical device tax is whether Congress will repeal the tax.[74] On March 21, 2013, the Senate voted 79-20 on an amendment to the Senate's 2014 budget to repeal the medical device excise tax.[75] Nonetheless, in 2012 the White House threatened to veto a repeal of the medical device tax,[76] and in the wake of recent debates over the federal budget, the majority leader of the Senate expressed doubts with respect to the likelihood of an outright repeal of the tax.[77] In short, the future of the medical device tax is at best uncertain.

Frequently Asked Questions About the Medical Device Excise Tax

What is the text of the law that imposes the medical device tax?

The excise tax on medical devices has been codified in the United States Code in section 4191 of Internal Revenue Code. That section reads:

> (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.[78]

[73] 77 Fed. Reg. at 72933.

[74] *See supra* footnote 5.

[75] *See* "To promote innovation, preserve high-paying jobs, and encourage economic growth for manufacturers of lifesaving medical devices and cutting edge medical therapies," S.Amdt. 297 to S.Con.Res. 8 (2013).

[76] *See* Office of Management and Budget, "Statement of Administration Policy," June 6, 2012, http://www.whitehouse.gov/sites/default/files/omb/legislative/sap/112/saphr436r_20120606.pdf ("If the President were presented with H.R. 436, his senior advisors would recommend that he veto the bill.").

[77] *See* Honorable Harry Reid, "Reid Statement on Latest Republican Attempt to Force a Government Shutdown," September 30, 2013, http://www.reid.senate.gov/reid_statement_on_latest_republican_attempt_to_force_a_government_shutdown.cfm ("To be absolutely clear, the Senate will reject both the one-year delay of the Affordable Care Act and the repeal of the medical device tax.")

[78] I.R.C. §4191.

What is the taxable amount?

The tax is 2.3 percent of the price for which a manufacturer, producer, or importer sold the taxable medical device.[79]

What is the effective date for the medical device tax?

The medical device tax applies to sales made after December 31, 2012.[80]

Can the tax be imposed on a contract to purchase a medical device that was agreed to prior to January 1, 2013?

The regulations provide some transition relief with respect to certain long-term contracts. Specifically, payments made on or after January 1, 2013 for contracts entered into before March 30, 2010 are not subject to the medical device excise tax unless the contract was materially modified on or after March 30, 2010.[81]

Where do the funds that are collected go as a result of the medical device excise tax?

The funds from the medical device tax go into the general treasury. The law that created the medical device excise tax, HCERA, did not contain any language regarding the disposition of the funds collected from the tax.[82] Without any specific overriding language governing with respect to the disposition of the funds, the Miscellaneous Receipts Statute would control.[83] That statute provides that generally "an official or agent of the Government receiving money for the Government from any source shall deposit the money in the Treasury as soon as practicable without deduction for any charge or claim."[84] As such, without any other authorization, the Internal Revenue Service, upon collecting the medical device tax, must deposit all funds received in the general fund of the Treasury as a miscellaneous receipt.[85]

Is there a complete list of taxable medical devices?

The medical device tax is imposed on manufacturers, producers, or importers of a medical device that is intended for humans.[86] The Treasury's regulations interpret such medical devices as those

[79] I.R.C. §4191(a).

[80] *See* Health Care and Education Reconciliation Act of 2010, P.L. 111-152, Title I, Subtitle E, § 1405(d) ("EFFECTIVE DATE. – The amendments made by this section shall apply to sales after December 31, 2012).

[81] *See* Treas. Reg. §48.4191-1(f).

[82] *See* Health Care and Education Reconciliation Act of 2010, P.L. 111-152, Title I, Subtitle E, § 1405(b)

[83] *See* 31 U.S.C. § 3302(b).

[84] *Id.*

[85] *See* Securities and Exchange Commission—Reduction of Obligation of Appropriated Funds Due to Sublease (7/19/96) Comp. Gen. Dec. No. B-265727.

[86] *See* I.R.C. § 4191(b).

that are listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807.[87] This list is quite broad and open-ended,[88] and, as such, the tax applies generally to all devices intended for humans subject to certain exemptions and exclusions, such as the retail exemption.

Is there a complete list of medical devices that are not subject to the tax?

The statute imposing the medical device tax lists three specific devices that are not subject to the tax: eyeglasses, contact lenses, and hearing aids.[89] The statute also exempts "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."[90] Treasury regulations have provided examples of devices that would generally fall into the open-ended retail exemption.[91] Examples that Treasury has provided with respect to devices that are exempt from the tax are: absorbent tipped applicators, adhesive bandages, snake bite suction kits, denture adhesives, pregnancy test kits, blood glucose monitors, test strips, and lancets, prosthetic legs, endoskeletal shin systems, mechanical and powered wheelchairs, portable oxygen concentrators, urinary ileostomy bags, and powered adjustable home use beds.[92] In addition, the FDA has provided a list of certain "safe harbor" items that fall within the retail exemption.[93] Nonetheless, because of the malleable nature of the retail exemption, there is no complete list of medical devices that are not subject to the excise tax.

Are there reporting requirements for entities that have to pay the tax?

Just as with other excise taxes, in order to report the tax liability to the government and pay the tax, those that are required to pay the medical device tax generally must file a quarterly return with the Internal Revenue Service using form 720.[94] In addition, section 40.6302(c)-1(a) of the Excise Tax Procedural Regulations generally requires entities that are liable for excise taxes to make semimonthly deposits of tax during the period in which the tax liability is incurred.[95] Generally under section 6656 of the Internal Revenue Code, failure to deposit the requisite tax subjects delinquent taxpayers to certain penalties.[96] However, the Internal Revenue Service has waived such penalties for the first three quarters of 2013.[97]

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[87] *See* Treas. Reg. §48.4191-2(a).

[88] *See supra* "What is a 'Taxable Medical Device'"

[89] *See* I.R.C. §4191(b).

[90] *Id.*

[91] *See* Treas. Reg. § 48.4191-2 (examples).

[92] *Id.*

[93] *See supra* "The Retail Exemption's Safe Harbor Provisions"

[94] *See* Treas. Reg. § 40.6011(a)-1.

[95] *See* Treas. Reg. § 40.6302(c)-1(a). Entities with tax liability of $2,500 or less need not file the semimonthly deposit. *Id.* § 40.6302(c)-1(f).

[96] *See* I.R.C. § 6656.

[97] *See* Internal Revenue Service, "Interim Guidance and Request for Comments; Medical Device Excise Tax; Manufacturers Excise Taxes; Constructive Sale Price; Deposit Penalties," Notice 2012-77, Section 6, http://www.irs.gov/pub/irs-drop/n-12-77.pdf ("In consideration of the short time frame between the effective date of the (continued...)

Will the medical device tax appear on a line item on a consumer receipt?

The medical device tax does not regulate what can or cannot appear on a consumer receipt for a medical device. Nonetheless, because of the retail exemption to the medical device tax, it would be unlikely for the medical device tax to be imposed on a good that is sold to the general public at retail.[98] In recent months, customers of the sporting goods chain Cabela's have circulated images of a receipt indicating that the company was imposing an additional charge on customer receipts for a "medical excise tax."[99] The charge imposed by Cabela's was reportedly the result of a software glitch and was not the product of any mandate imposed by HCERA's imposition of the medical device excise tax.[100]

Did HCERA, in addition to imposing a medical device tax, also impose excise taxes on other items, such as sporting equipment?

E-mails have been circulated suggesting that HCERA also imposed excise taxes on hunting and fishing equipment, gas guzzler automobiles, vaccines, tires, and coal.[101] HCERA imposed two main excise taxes, the medical device excise tax[102] and, beginning in 2018, a forty percent excise tax on the value of health insurance benefits exceeding a certain threshold.[103] These excise taxes were added to the list of excise taxes that already existed under subtitle D of the Internal Revenue Code.[104] The origins of several of the excise taxes that have been confused for originating in HCERA are summarized in **Table 1**.

Table 1. The Origins of Select Excise Taxes

Subject of the Excise Tax	Originating Act
Sporting equipment	Excise Tax Reduction Act of 1965 – section 205
Gas guzzler automobiles	Energy Tax Act of 1978 – section 201
Vaccines	Vaccine Compensation Amendments of 1987 – Sec. 9201

(...continued)

tax and the due date of the first deposit, and in the interest of sound tax administration, the IRS and the Treasury Department have decided to provide temporary relief from the § 6656 penalty for the first three calendar quarters of 2013.").

[98] *See* I.R.C. § 4191(b).

[99] *See, e.g.* PoliFact, "A hidden provision in Obamacare taxes sporting goods as medical devices," June 12, 2013, www.politifact.com/ohio/statements/2013/jun/14/chain-email/chain-email-claims-health-care-law-contains-hidden/.

[100] *See* "Cabela's blames 'glitch' for Jan. 1 tax error, promises refunds," Omaha World-Herald, January 8, 2013, http://omaha.com/article/20130108/MONEY/701089985/1101.

[101] *See* FactCheck.org, "Cabela's Medical Tax Mistake," September 18, 2013, http://www.factcheck.org/2013/09/cabelas-medical-tax-mistake/.

[102] *See* Health Care and Education Reconciliation Act of 2010, P.L. 111-152, Title I, Subtitle E, § 1405.

[103] *Id.* § 1401.

[104] *See* I.R.C. §§ 4001 *et seq.*

Subject of the Excise Tax	Originating Act
Tires	Highway Revenue Act of 1956 – section 204(a)
Coal	Black Lung Benefits Revenue Act of 1977 - Section 2(a)

Source: Created by CRS

What bills have been introduced to repeal the medical device excise tax?

Table 2 contains a list of major bills and resolutions in the 112th and 113th Congresses to fully repeal the medical device excise tax.

Table 2. Proposals to Repeal the Medical Device Excise Tax

Bill or Resolution Number	Title	Date Introduced	Last Action
H.R. 523 – 113th	Protect Medical Innovation Act of 2013	2/6/13	Referred to House Ways and Means
H.R. 1295—113th	Medical Device Tax Elimination Act	3/20/13	Referred to House Ways and Means
H.J. Res. 59- EAH – 113th	Resolved, That the House agree to the amendment of the Senate to the resolution (H.J. Res. 59) entitled `Joint Resolution making continuing appropriations for fiscal year 2014, and for other purposes.', with the following	9/29/13	In conference
S. 232 – 113th	Medical Device Access and Innovation Protection Act	2/7/13	Referred to Senate Finance
S. J. Res. 8 – 113th	A joint resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rule submitted by the Internal Revenue Service of the Department of the Treasury relating to taxable medical devices.	2/27/13	Referred to Senate Finance
S. Amdt. 297 to S. Con. Res. 8 – 113th	To promote innovation, preserve high-paying jobs, and encourage economic growth for manufacturers of lifesaving medical devices and cutting edge medical therapies,	3/21/13	Agreed to on a 79-20 vote; Held at the desk 4/15/13

Bill or Resolution Number	Title	Date Introduced	Last Action
H.R. 436 – 112th	Health Care Cost Reduction Act of 2012	1/25/11	Passed House, 270-146, Placed on Senate Legislative Calendar 6/12/12
H.R. 488—112th	Save Our Medical Devices Act of 2011	1/26/11	Referred to House Ways and Means
H.R. 734—112th	To amend the Internal Revenue Code of 1986 to repeal the medical device tax, and for other purposes	2/16/11	Referred to House Ways and Means & Appropriations
H.R. 1310—112th	To amend the Internal Revenue Code of 1986 to exempt certain emergency medical devices from the excise tax on medical devices, and for other purposes.	4/1/11	Referred to House Ways and Means
H.R. 4064—112th	Keeping Promises to Taxpayers Act of 2012	2/16/12	Referred to House Ways and Means & Energy and Commerce
H.R. 5906—112th	To amend the Internal Revenue Code of 1986 to repeal the excise tax on medical devices	6/7/12	Referred to House Ways and Means
H.R. 6088—112th	Total Repeal of the Unfair Taxes on Healthcare Act of 2012	7/9/12	Referred to House Subcommittee on Health
H. Res. 679—112th	Providing for consideration of the bill (H.R. 436) to amend the Internal Revenue Code of 1986 to repeal the excise tax on medical devices, and providing for consideration of the bill (H.R. 5882) making appropriations for the Legislative Branch for the fiscal year ending September 30, 2013, and for other purposes.	6/6/12	Agreed to in House, 241-173, 6/7/12
S. 17 –112th	Medical Device Access and Innovation Protection Act	1/25/11	Referred to Senate Finance
S. 262—112th	A bill to repeal the excise tax on medical device manufacturers.	2/3/11	Referred to Senate Finance

Bill or Resolution Number	Title	Date Introduced	Last Action
S.J. Res. 51 –112th	A joint resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rule submitted by the Internal Revenue Service of the Department of the Treasury relating to taxable medical devices.	12/21/12	Referred to Senate Finance

Source: Created by CRS

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