DESCRIPTION OF H.R. 436, THE "PROTECT MEDICAL INNOVATION ACT OF 2011"

Scheduled for Markup
By the
HOUSE COMMITTEE ON WAYS AND MEANS
on May 31, 2012

Prepared by the Staff
of the
JOINT COMMITTEE ON TAXATION

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INTRODUCTION

The House Committee on Ways and Means has scheduled a markup on May 31, 2012, of H.R. 436, the "Protect Medical Innovation Act of 2011," a bill to amend the Internal Revenue Code of 1986 to repeal the medical device excise tax.[1] This document,[2] prepared by the staff of the Joint Committee on Taxation, describes the provisions of the bill.

[1] Unless otherwise stated, all section references are to the Internal Revenue Code of 1986, as amended.

[2] This document may be cited as follows: Joint Committee on Taxation, *Description of H.R. 436, the "Protect Medical Innovation Act of 2011"* (JCX-45-12), May 29, 2012. This document can also be found on the internet at www.jct.gov.

A. Repeal of Medical Device Excise Tax

Present Law

Effective for sales after December 31, 2012, a tax equal to 2.3 percent of the sale price is imposed on the sale of any taxable medical device by the manufacturer, producer, or importer of such device.[3] A taxable medical device is any device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act,[4] intended for humans. Proposed regulations further define a medical device as one that is listed by the Food and Drug Administration ("FDA") under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, pursuant to FDA requirements.[5]

The excise tax does not apply to eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use ("retail exemption"). Proposed regulations provide guidance on the types of devices that are exempt under the retail exemption. A device is exempt under these provisions if: (1) it is regularly available for purchase and use by individual consumers who are not medical professionals; and (2) 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.[6] Additionally, the proposed regulations provide certain safe harbors for devices eligible for the retail exemption.[7]

The medical device excise tax is generally subject to the rules applicable to other manufacturers excise taxes. These rules include certain general manufacturers excise tax exemptions including the exemption for sales for use by the purchaser for further manufacture (or for resale to a second purchaser in further manufacture) or for export (or for resale to a

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[3] Sec. 4191.

[4] 21 U.S.C. sec. 321. Section 201(h) defines device as 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.

[5] Prop. Treas. Reg. sec. 48.4191-2(a). The proposed regulations also include devices that should have been listed as a device with the FDA as of the date the FDA notifies the manufacturer or importer that corrective action with respect to listing is required.

[6] Prop. Treas. Reg. sec. 48.4191-2(b)(2).

[7] Prop. Treas. Reg. sec. 48.4191-2(b)(2)(iii). The safe harbor includes devices that are described as over-the-counter devices in relevant FDA classification headings as well as certain FDA device classifications listed in the proposed regulations.

second purchaser for export).[8] If a medical device is sold free of tax for resale to a second purchaser for further manufacture or for export, the exemption does not apply unless, within the six-month period beginning on the date of sale by the manufacturer, the manufacturer receives proof that the medical device has been exported or resold for use in further manufacturing.[9] In general, the exemption does not apply unless the manufacturer, the first purchaser, and the second purchaser are registered with the Secretary of the Treasury. Foreign purchasers of articles sold or resold for export are exempt from the registration requirement.

Proposed regulations provide guidance related to the sale of medical devices for use in kits. Under the proposed regulations, the kit itself is a taxable medical device if the kit is listed as a device with the FDA pursuant to FDA requirements.[10] The process of producing or assembling a kit that is a taxable device constitutes further manufacture under the proposed regulations.

The lease of a medical device is generally considered to be a sale of such device.[11] Special rules apply for the imposition of tax to each lease payment. The use of a medical device subject to tax by manufacturers, producers, or importers of such device, is treated as a sale for the purpose of imposition of excise taxes.[12]

There are also rules for determining the price of a medical device on which the excise tax is imposed.[13] These rules provide for (1) the inclusion of containers, packaging, and certain transportation charges in the price, (2) determining a constructive sales price if a medical device is sold for less than the fair market price, and (3) determining the tax due in the case of partial payments or installment sales.

Description of Proposal

The proposal repeals the medical device excise tax.

Effective Date

The proposal is effective on the date of enactment.

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[8] Sec. 4221(a). Other general manufacturers excise tax exemptions (*i.e.*, the exemption for sales to vessels or aircraft, to a State or local government, to a nonprofit educational organization, or to a qualified blood collector organization) do not apply to the medical device excise tax.

[9] Sec. 4221(b).

[10] Prop. Treas. Reg. sec. 48.4221-2(b)(3).

[11] Sec. 4217(a).

[12] Sec. 4218.

[13] Sec. 4216.

B. Revenue Effect of the Proposal

The following presents the estimated Federal fiscal year budget effects of the proposal.

Fiscal Years [Millions of Dollars]												
Item	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2013-17**	**2013-22**
Repeal the 2.3 percent excise tax on medical devices…….	-1,742	-2,562	-2,668	-2,771	-2,889	-3,012	-3,143	-3,280	-3,428	-3,582	-12,631	-29,076

NOTE: Details may not add to totals due to rounding.