Medical Device Excise Tax - IRC 4191

Frequently Asked Questions

Q1. What is the medical device excise tax?
A1. Section 4191 of the Internal Revenue Code imposes an excise tax on the sale of certain medical devices by the manufacturer or importer of the device.

Q2. When does the tax go into effect?
A2. The tax applies to sales of taxable medical devices after December 31, 2012.

Q3. How much is the tax?
A3. The tax is 2.3 percent of the sale price of the taxable medical device. See Chapter 5 of IRS Publication 510, Excise Taxes, and Notice 2012-77 for additional information on the determination of sale price.

Q4. Who is responsible for reporting and paying the medical device excise tax?
A4. Generally, the manufacturer or importer of a taxable medical device is responsible for filing Form 720, Quarterly Federal Excise Tax Return, and paying the tax to the IRS.

Q5. Will individual consumers be subject to any reporting or recordkeeping requirements?
A5. Generally, no action is required by individual consumers. Because the tax is imposed upon the sale of a taxable medical device by the manufacturer or importer, the manufacturer or importer is responsible for reporting and paying the tax.

Q6. Who is the manufacturer for purposes of the medical device excise tax?
A6. Generally, with regard to the medical device excise tax, the manufacturer is the person who produces a taxable medical device from scrap, salvage or junk material, or from new or raw material, by processing, manipulating or changing the form of a device or by combining or assembling two or more devices.

Q7. Who is the importer for purposes of the medical device excise tax?
A7. Generally, with regard to the medical device excise tax, the importer of a taxable medical device is the person who brings the device into the United States from a source outside the United States, or withdraws the device from a customs-bonded warehouse for sale or use in the United States.

Q8. What is the tax treatment of convenience kits?
A8. Notice 2012-77 provides interim guidance on the tax treatment of convenience kits. Under the interim guidance, a taxable medical device that goes into a domestically-produced convenience kit will be subject to tax upon its sale by the manufacturer or importer, but the sale of the convenience kit by the kit producer will not be subject to tax. Special rules apply to imported kits.

For purposes of the notice, a convenience kit is a set of two or more devices within the meaning of § 201(h) of the Federal Food, Drug, and Cosmetic Act that is enclosed in a single package, such as a bag, tray, or box, for the convenience of a health care professional or the end user.

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Frequently Asked Questions

Q9. What form will be used to report the medical device excise tax?
A9. The medical device excise tax is a manufacturers excise tax. Like other manufacturers excise taxes, the medical device excise tax is reported on Form 720. See Chapters 11 and 12 of IRS Publication 510 for additional information on filing, deposits, and payments.

Q10. When is the Form 720 due?
A10. Form 720 is filed quarterly. The first return to report the medical device excise tax will be due on April 30, 2013, for the quarterly period including January, February, and March 2013. Quarterly return due dates are as follows:

For the months:	Due by:
Jan., Feb., Mar.	April 30
Apr., May, Jun.	July 31
Jul., Aug., Sep.	Oct. 31
Oct., Nov., Dec.	Jan. 31

Q11. Are tax deposits required for the medical device excise tax?
A11. Yes. Semi-monthly deposits will generally be required if tax liability exceeds $2,500 for the quarter. The first deposit of the medical device excise tax, covering the first 15 days of January 2013, will be due on January 29, 2013. Notice 2012-77 provides transition relief from deposit penalties during the first three calendar quarters of 2013. For details on deposit requirements, see the Instructions to Form 720 and Chapter 12 of IRS Publication 510.

Q12. Should an entity that is disregarded for income tax purposes file Form 720 in the disregarded entity's name or the owner's name?
A12. An entity that is disregarded as an entity separate from its owner for income tax purposes is treated as a separate entity for excise tax purposes. Therefore, the entity, and not the disregarded entity's owner, is responsible for filing Form 720 and paying of the tax.

Q13. Has the IRS issued guidance on the medical device excise tax?
A13. Yes. The IRS and the Treasury Department issued final regulations on December 5, 2012. The IRS and the Treasury Department issued Notice 2012-77 on December 5, 2012, to provide interim guidance on certain issues related to the medical device excise tax.

Q14. What is a taxable medical device?
A14. In general, a taxable medical device is a device that is listed as a device with the Food and Drug Administration under section 510(j) of the Federal Food, Drug, and

Cosmetic Act and 21 CFR part 807, unless the device falls within an exemption from the tax, such as the retail exemption.

Q15. Are there any exemptions to the medical device excise tax?
A15. Yes. There are specific statutory exemptions for eyeglasses, contact lenses, and hearing aids. There is also an exemption for other devices that are of a type that are generally purchased by the general public at retail for individual use (the retail exemption).

Q16. How does a manufacturer determine if a particular type of device qualifies for the retail exemption?
A16. The regulations provide a facts and circumstances approach to determine whether a type of device meets the retail exemption. The regulations enumerate several factors that are relevant, but there may be relevant factors in addition to those enumerated in the regulations. The determination is based on the overall balance of factors relevant to a particular type of device. No one factor is determinative. See § 48.4191-2(b)(2) of the regulations for more information about the retail exemption. The regulations also provide a safe harbor for certain devices that will be considered to be of a type that falls within the retail exemption. See Q&A 18.

Q17. Do the regulations illustrate how the retail exemption facts and circumstances test should be applied?
A17. Yes. The regulations include examples that apply the facts and circumstances test to several types of medical devices. Based on the totality of the circumstances presented in the examples, the examples conclude that non-sterile absorbent tipped applicators, adhesive bandages, snake bite suction kits, denture adhesives, mechanical and powered wheelchairs, portable oxygen concentrators, and therapeutic AC powered adjustable home use beds are devices that fall within the retail exemption. Based on the totality of the circumstances presented in the examples, the examples also conclude that mobile x-ray systems, nonabsorbable silk sutures, and nuclear magnetic resonance imaging systems are not devices that fall within the retail exemption.

Q18. Is there a retail exemption safe harbor?
A18. Yes. The regulations identify certain categories of devices that qualify for the retail exemption so that manufacturers and importers do not have to apply the facts and circumstances test. Those categories are set forth in a safe harbor provision in § 48.4191-2(b)(2)(iii) of the regulations.

Q19. Are there any circumstances under which a taxable medical device can be sold tax-free?
A19. Yes. A manufacturer or importer of a taxable medical device may, in certain circumstances, sell a taxable medical device tax-free for use by the purchaser for further manufacture (or for resale by the purchaser to a second purchaser for further manufacture), or for export (or for resale for export). To make a tax-free sale for further manufacture or export, both parties to the sale must be registered with the IRS. Form 637, Application for Registration for Certain Excise Tax Activities, is used for the registration process. For more information on the Form 637 registration process, see the 637 Registration Program at IRS.gov.

Q20. I'm not familiar with manufacturers excise taxes. Where can I learn more?
A20. For more information about manufacturers excise taxes in general, see Chapter 5 of IRS Publication 510.

Part III - Administrative, Procedural, and Miscellaneous

Interim Guidance and Request for Comments; Medical Device Excise Tax; Manufacturers Excise Taxes; Constructive Sale Price; Deposit Penalties

Notice 2012-77

Section 1. PURPOSE

This notice provides interim guidance relating to the excise tax on medical devices imposed by § 4191 (the "medical device excise tax") of the Internal Revenue Code (the "Code"). Specifically, this notice provides interim guidance for determining price under § 4216(b). This notice also provides interim guidance relating to donated taxable medical devices, the licensing of taxable medical devices, and the tax treatment of medical convenience kits. In addition, this notice provides transition relief to medical device manufacturers from the failure to deposit penalties imposed by § 6656. Finally, this notice requests comments from taxpayers about the rules described in this notice.

Section 2. BACKGROUND

Section 4191, enacted by section 1405 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)), in conjunction with the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), imposes an excise tax on the sale of certain medical devices. The excise tax imposed by § 4191 is 2.3% of the price for which the taxable medical device is sold. The medical device excise tax is codified in chapter 32, subtitle D of the Code ("chapter 32"), which pertains to excise taxes imposed on the sale or use of taxable articles by manufacturers, producers, and importers (commonly referred to as "manufacturers excise taxes"). See § 48.0-2(a)(4)(i) of the Manufacturers and Retailers Excise Tax Regulations (the "regulations") (which defines the term "manufacturer" to include a "producer" and an "importer"). As a result, the existing chapter 32 rules, including the regulations issued thereunder, apply to the medical device excise tax.

On December 7, 2012, the Internal Revenue Service (IRS) and the Treasury Department issued TD 9604, containing final regulations under § 4191. The final regulations do not address certain issues that the IRS and the Treasury Department continue to study. These issues include the determination of price under § 4216(b); the

tax treatment of medical software licenses; the taxability of donated medical devices; and the taxability of medical convenience kits.

The IRS and the Treasury Department may issue additional published guidance on these issues in the future. The IRS and the Treasury Department recognize, however, that manufacturers need rules on these issues that will apply on an interim basis. Sections 3 through 5 of this notice prescribe those interim rules.

In addition, several comments on the proposed regulations requested transition relief from the deposit penalty under § 6656. In response to those comments, this notice waives penalties under § 6656 for the first three calendar quarters of 2013. Section 6 of this notice delineates the scope of this deposit penalty relief.

Unless otherwise stated, existing definitions provided in chapter 32, and the regulations issued thereunder, apply to this notice.

Section 3. CONSTRUCTIVE SALE PRICE

(a) *Overview of Constructive Sale Price*. Section 4216 provides rules for determining "price" for purposes of chapter 32. Those rules treat the price for which a manufacturer sells a taxable article to an independent wholesale distributor, subject to certain adjustments, as the applicable price for purposes of imposing the tax. In general, when a manufacturer sells a taxable article to a purchaser other than an independent wholesale distributor, § 4216(b) and the regulations thereunder prescribe rules for constructing a sale price that approximates the price an independent wholesale distributor would pay to the manufacturer for an identical article. In such situations, tax is imposed on the constructive sale price as determined under § 4216(b).

The IRS and the Treasury Department recognize that the medical device industry encompasses a diverse group of manufacturers that produce a broad range of articles. The IRS and the Treasury Department also recognize that many manufacturers in the medical device industry do not sell to independent wholesale distributors, and they may employ more than one distribution chain according to industry practice related to a particular article. Further, the IRS and the Treasury Department recognize that current published guidance relating to the constructive sale price rules does not address some of the types of distribution chains regularly employed in the medical device industry. In addition, Rev. Rul. 80-273, 1980-2 C.B. 315, which provides a mechanism for computing the constructive sale price where the articles are sold at retail by manufacturers who do not sell like articles to wholesale distributors, does not by its terms apply to § 4191.

(b) *Interim Rules*. This section provides interim rules for how taxpayers may apply the constructive sale price rules to certain model distribution chains employed by some manufacturers in the medical device industry. The IRS and the Treasury

Department identified the distribution chains addressed in these interim rules through written comments on the proposed regulations on taxable medical devices and informal taxpayer inquiries.

If a taxpayer uses one of the distribution chains described in this section, the taxpayer may apply the rules provided in this section to determine its medical device excise tax liability. A taxpayer does not need to make any additional or special filing, or notation on any filing, to apply these rules. If a taxpayer does not apply the rules provided in this notice, and does not use the actual sale price of the article to calculate its medical device excise tax liability, then the taxpayer bears the burden of demonstrating that it used the fair market price of the article to calculate its tax liability. This approach is consistent with the general rule under which a manufacturer may rebut the constructive sale price if the manufacturer demonstrates that it sold the article at a fair market price. Rev. Rul. 89-47, 1989-1 C.B. 295. Taxpayers may apply the rules provided in this section until the IRS and the Treasury Department issue further guidance.

For purposes of these rules, a "related party" means that one of the parties is controlled (in law or fact) by the other, or there is common control of the parties (regardless of whether such control is actually exercised to influence the sale price). See § 48.4216(b)-2(e)(1). Further, for purposes of these rules, a "reseller" means a sales company, a leasing company, a distributor, or a retailer. Finally, the application of constructive sale price rules to calculate the tax base does not shift the liability for excise tax from the manufacturer to any other person.

The interim rules are as follows:

(1) *Sales at retail; no regular sales to independent wholesale distributors.*

(A) Description. In this distribution chain, the manufacturer sells taxable articles directly to unrelated end-users. The manufacturer does not regularly sell its taxable articles to independent wholesale distributors.

(B) Interim Rule. Until the IRS and the Treasury Department issue further guidance, the constructive sale price for this distribution chain, determined pursuant to § 4216(b)(1)(A), is 75% of the actual selling price after taking into account the adjustments provided by § 4216(a). No further adjustments under § 4216 are allowed. See Rev. Rul. 80-273, 1980-2 C.B. 315.

(2) *Sales to unrelated retailers; no regular sales to independent wholesale distributors.*

(A) Description. In this distribution chain, the manufacturer sells taxable articles to unrelated retailers. The manufacturer does not regularly sell its taxable articles to independent wholesale distributors.

(B) Interim Rule. Until the IRS and the Treasury Department issue further guidance, the constructive sale price for this distribution chain is 90% of the lowest price for which the articles are sold to unrelated retailers. This computation is made without adjustment for any exclusion (except for the tax imposed on such article) or readjustment under § 6416(b)(1)(a) and (e). See Rev. Rul. 82-211, 1982-2 C.B. 296.

(3) *Sales to related retailer; no regular sales to independent wholesale distributors.*

(A) Description. In this distribution chain, the manufacturer sells taxable articles to a related retailer. The related retailer sells the articles at retail to unrelated end-users. The manufacturer and related retailer do not regularly sell the articles to independent wholesale distributors.

(B) Interim Rule. Until the IRS and the Treasury Department issue further guidance, the constructive sale price for this distribution chain, determined pursuant to § 4216(b)(1)(C), is 75% of the product of 95% and the actual selling price (that is, the price at which the article is sold to a person that is not a member of the group of companies that are related to the manufacturer). The 5% discount is an allowance for the exclusions from the selling price otherwise allowed under § 4216(a). See Rev. Rul. 82-211. The additional 25% discount adjusts the selling price to approximate the selling price to an independent wholesale distributor. See Rev. Rul. 80-273. No further adjustments under § 4216 are allowed.

(4) *Sales to related reseller that leases and sells at retail.*

(A) Description. In this distribution chain, the manufacturer sells taxable articles to a related reseller. The related reseller sells the articles at retail to unrelated end-users, and also leases articles to unrelated end-users.

(B) Interim Rule. Until the IRS and the Treasury Department issue further guidance, the constructive sale price for this distribution chain, determined pursuant to § 4216(b)(1)(C), is 75% of the product of 95% and the actual selling price (that is, the price at which the article is sold to a person that is not a member of the group of companies that are related to the manufacturer). The 5% discount is an allowance for the exclusions from the selling price otherwise allowed under § 4216(a). See Rev. Rul. 82-211. The additional 25% discount adjusts the selling price to approximate the selling

price to an independent wholesale distributor. See Rev. Rul. 80-273. No further adjustments under § 4216 are allowed.

(5) *Sales to related reseller that only leases at retail; no regular sales to independent wholesale distributors.*

(A) Description. In this distribution chain, the manufacturer sells taxable articles to a related reseller. The related reseller leases the articles to unrelated end-users, but does not sell articles at retail. The manufacturer and related reseller do not regularly sell the articles to independent wholesale distributors.

(B) Interim Rule. Until the IRS and the Treasury Department issue further guidance, the price for this distribution chain is the actual selling price to the related reseller, provided that the selling price to the related reseller reasonably approximates the fair market price of the article within the meaning of § 4216.

(c) *Applicability to other taxes imposed by chapter 32 of the Code*. Until the IRS and the Treasury Department issue further guidance, all manufacturers subject to the taxes imposed by chapter 32 of the Code may apply the rules provided in this section to determine the constructive sale price of taxable articles under Chapter 32 to the extent that any statute or other published guidance do not already provide rules addressing a particular fact pattern or situation.

Section 4: SPECIAL CHAPTER 32 RULES APPLICABLE TO THE MEDICAL DEVICE EXCISE TAX

(a) *Sale to Hospital or Doctor's Office Treated as Sale at Retail for Purposes of Determining Price*

(1) *Overview.* Section 48.4216(b)-1(c)(1) of the regulations defines "sale at retail" as the sale of an article to a purchaser who intends to use the article, or to lease it to another person, rather than resell it. Section 48.4216(b)-1(c)(2) defines "retailer" as a person engaged in the business of selling articles at retail. Therefore, a sale to a retailer is a sale of an article to a person engaged in the business of selling articles at retail. Medical institutions and offices, such as hospitals and doctor's offices, purchase taxable articles that are used to treat patients. Sometimes an article is completely consumed on the premises of a medical institution or office and other times the articles leave the medical institution or office with the patient. Under the definitions described above, it is unclear whether a sale of an article to a medical institution or office is a sale at retail or a sale to a retailer.

(2) *Interim Rule*. Until the IRS and the Treasury Department issue further guidance, the IRS will treat the sale of a taxable article to a medical institution or office as a "sale at retail."

(b) *Licenses*

(1) *Overview.* In response to the proposed regulations, one commenter requested clarification on whether the licensing of software that is a taxable medical device is a taxable event for purposes of § 4191. That commenter requested that the IRS and the Treasury department treat the licensing of software as a lease.

Under existing chapter 32 rules, the manufacturers excise tax generally attaches upon the sale or use of a taxable article by the manufacturer. See § 48.0-2(b). Section 4217(a) provides that the lease of a taxable article by the manufacturer is considered a sale. Neither the existing chapter 32 rules nor the final regulations address the issue of whether the licensing of a taxable article, such as software that is a taxable medical device, is a taxable event.

(2) *Interim Rule*. Until the IRS and the Treasury Department issue further guidance, the IRS will treat a license of a taxable medical device as a lease of that taxable medical device as of the date both parties entered into the license agreement. Accordingly, the rules under §§ 4216(c) and 4217, and §§ 48.4216(c)-1(a), 48.4216(c)-1(e), 48.4217-1, and 48.4217-2 apply.

(c) *Excise Tax Treatment of Donations of Taxable Medical Devices to Organizations Described in § 170(c)*

(1) *Overview.* The existing chapter 32 rules do not specifically address whether a donation of a taxable article constitutes a taxable use under § 4218. The IRS and the Treasury Department will continue to study this issue.

(2) *Interim Rules*. Until the IRS and the Treasury Department issue further guidance, taxpayers may rely on the following rules relating to the donation of medical devices:

(A) Non-taxable use. The donation of a taxable medical device by the manufacturer of the device to an *eligible donee* will not constitute a taxable use as defined in § 4218 of the Code. However, if at the time of donation, the manufacturer has reason to believe that the donation is not being made to an *eligible donee* or that the article donated will be resold by the *eligible donee*, the manufacturer is not relieved from the liability for the tax imposed by § 4191.

(B) Eligible donee. For purposes of this safe harbor, an *eligible donee* is an entity described in §170(c) of the Code.

(C) Subsequent sales of donated articles. The rules of § 4219 (related to the application of tax in case of sales by other than the manufacturer) apply to an

eligible donee that receives a donated taxable medical device and subsequently sells the taxable medical device.

Section 5. CONVENIENCE KITS

(a) *Overview*. Under § 4191, a "taxable medical device" is a device defined in § 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) that is intended for humans. Under § 48.4191-2(a) of the regulations, 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. Finished taxable medical devices are sometimes packaged together into kits for the convenience of a healthcare provider in the performance of a medical procedure. Convenience kits that are listed with the FDA under section 510(j) of the FFDCA and 21 CFR Part 807 are “taxable medical devices” under the regulations unless they fall within an exemption under § 4191(b) or § 48.4191-2(b) of the regulations.

The IRS and the Treasury Department have received numerous written and informal comments suggesting that the sale of convenience kits by the kit producer should not be subject to tax under § 4191. The IRS and the Treasury Department are studying the taxability of convenience kits and intend to issue additional guidance in the future.

(b) *Definition of a “Convenience Kit.”* For purposes of this notice, a "convenience kit" is a set of two or more devices within the meaning of section 201(h) of the FFDCA that is enclosed in a single package, such as a bag, tray, or box, for the convenience of a health care professional or the end user. A convenience kit may contain a combination of devices within the meaning of section 201(h) of the FFDCA and other articles.

(c) *Interim Rule for Domestically-Produced Convenience Kits*. Until the IRS and the Treasury Department issue further guidance, no tax will be imposed upon the sale of a domestically-produced convenience kit that is a "taxable medical device" under § 4191 of the Code and § 48.4191-2(b) of the regulations. During this interim period, the sale of a taxable medical device that goes into a domestically-produced convenience kit will be subject to tax upon its sale by the manufacturer or importer, pursuant to the normal rules of § 4191 and the regulations thereunder; however, the sale of the convenience kit by the kit producer will not be subject to tax.

(d) *Interim Rule for Imported Convenience Kits*. Until the IRS and the Treasury Department issue further guidance, tax is imposed under § 4191 on the sale by an importer of a convenience kit that is a taxable medical device under § 4191 of the Code and § 48.4191-2(b), but only on that portion of the importer’s sale price of the

convenience kit that is properly allocable to the individual taxable medical devices included in the convenience kit.

(1) *Allocation*. When an importer sells a convenience kit that is a taxable medical device, and also sells all of the individual taxable medical devices and nontaxable articles that are included in the convenience kit, the taxable portion of the sale price of such convenience kit may be determined by applying to the importer's sale price of the convenience kit the ratio that the importer's separate sale price of the taxable medical devices in the convenience kit bears to the sum of the sale prices of both the taxable medical devices and nontaxable articles in the convenience kit.

When an importer sells a convenience kit that is a taxable medical device, but does not sell all of the individual taxable medical devices and nontaxable articles that are included in the convenience kit, the taxable portion of the sale price of such convenience kit may be determined by applying to the importer's sale price of the convenience kit the ratio that the cost to the importer of the taxable medical devices in the convenience kit bears to the sum of the cost to the importer of both the taxable medical devices and nontaxable articles in the convenience kit. The importer may determine the cost of the taxable medical devices and the nontaxable articles in the convenience kit by any reasonable method. Thus, if the cost of the taxable medical devices represents half of the total cost to the importer of the convenience kit, the tax applies to half of the price charged by the importer upon the sale of the convenience kit.

(2) *Alternative to Allocation*. In lieu of allocation, the importer of a convenience kit that is a taxable medical device may pay tax on the entire price for which the importer sells the convenience kit.

Section 6: DEPOSIT PENALTY RELIEF

(a) *Overview*. Section 6302 of the Code authorizes the IRS to establish the mode and time for collecting certain taxes, including the taxes imposed by chapter 32. Section 40.6302(c)-1(a) of the Excise Tax Procedural Regulations requires manufacturers that are liable for excise taxes to make semimonthly deposits of tax during the period in which the tax liability is incurred.

The deposit for a tax imposed by chapter 32 for each semimonthly period must not be less than 95% of the amount of net tax liability incurred during the semimonthly period unless the safe harbor in § 40.6302(c)-1(b)(2)(ii) applies. Under the safe harbor, any person that filed a Form 720, Quarterly Federal Excise Tax Return, reporting a tax imposed by chapter 32 for the second preceding calendar quarter is considered to have met the semimonthly deposit requirement for the current quarter if: (i) the deposit for each semimonthly period in the current calendar quarter is not less than 1/6 of the net tax liability reported for the look back quarter: (ii) each deposit is made on time; (iii) the amount of any underpayment is paid by the due date of the return; and (iv) the person's

liability does not include any tax that was not imposed during the look back quarter. Section 40.6302(c)-1(b)(2)(v) provides that if a person fails to make deposits as required, the IRS may withdraw the person's right to use the safe harbor rules of § 40.6302(c)-1(b)(2)(ii).

Section 6656 imposes a penalty in the case of any failure by any person to make timely deposits as required by § 6302. A taxpayer may avoid penalties under § 6656 for failure to make deposits of taxes if the taxpayer makes an affirmative showing that such failure is due to reasonable cause and not due to willful neglect. See § 6656 and the corresponding regulations.

The IRS and the Treasury Department recognize that many medical device manufacturers will still be preparing their systems to comply with the medical device excise tax when the tax goes into effect on January 1, 2013, including the requirement to make semimonthly deposits. The first deposit of the medical device excise tax, covering the first 15 days of January, is due by January 29, 2013. In consideration of the short time frame between the effective date of the 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. The normal rules under § 6656 and the corresponding regulations will apply with respect to deposits due during the fourth calendar quarter of 2013 and thereafter.

In addition to the temporary penalty relief, the normal safe harbor rules of § 40.6302(c)-1(b)(2)(ii) apply. Beginning in the third quarter of 2013, medical device manufacturers may use the safe harbor rules of § 40.6302(c)-1(b)(2)(ii) for semimonthly deposits due during that quarter. For purposes of the safe harbor, the first calendar quarter of 2013 is the look back quarter for deposits due during the third calendar quarter.

(b) *Interim Rule*. During the first three calendar quarters of 2013, the IRS will not impose the penalty provided in § 6656 on a taxpayer that is liable for the medical device excise tax that fails to make timely deposits of the medical device excise tax as required by §§ 40.6302(c)-1 and 40.6302(c)-2 (relating to special deposits required in September), provided that the taxpayer demonstrates a good faith attempt to comply with requirements of §§ 40.6302(c)-1 and 40.6302(c)-2 and that the failure was not due to willful neglect.

Thereafter, a taxpayer may avoid penalties if it makes an affirmative showing that the failure to deposit is due to reasonable cause and not due to willful neglect. In addition, during the third and fourth calendar quarters of 2013, the IRS will not exercise its authority under § 40.6302(c)-1(b)(2)(v) to withdraw the taxpayer's right to use the deposit safe harbor rules of § 40.6302(c)-1(b)(2)(ii).

Section 7. REQUEST FOR COMMENTS

The IRS and the Treasury Department invite comments on the interim rules set forth in this notice. In particular, the IRS and the Treasury Department request comments on whether there are distribution chains not described in section 3 of this notice that are commonly employed by the medical device industry. In addition, the IRS and the Treasury Department recognize that different segments of the industry use different distribution chains for different devices and that determination of the price at which a manufacturer would sell its devices to an independent wholesale distributor may vary across those segments. The IRS and the Treasury Department request comments on how the constructive sale price rules might address this segmentation, including comments on what is a reasonable percentage of the applicable sale price for determining the constructive sale price for each segment or product. After reviewing the comments submitted in response to this request and other information collected by the IRS, the IRS and the Treasury Department will determine an appropriate percentage allowance for the industry as a whole or, alternatively, for particular segments of the industry. The IRS and the Treasury Department will announce any such adjustments in published guidance. Further, the IRS and the Treasury Department request comments regarding alternative methods for determining price for the distribution chain described in paragraph (b)(5) of section 3 of this notice (sales to related resellers that lease, but do not sell, taxable medical devices).

The deadline for submission of comments is March 29, 2013. All materials submitted will be available for public inspection and copying. Written comments should be submitted to: Internal Revenue Service, CC:PA:LPD:PR (Notice 2012-77), Room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (Notice 2012-77), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Comments may be transmitted electronically via the following e-mail address: Notice.Comments@irscounsel.treas.gov. Please include "Notice 2012-77" in the subject line of any electronic communications.

Section 8. EFFECTIVE DATE

This notice is effective on and after January 1, 2013.

Section 9. DRAFTING INFORMATION

The principal author of this notice is Michael H. Beker of the Office of the Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice, please contact Mr. Beker at (202) 622-3130 (not a toll-free number).